Articles

Effect of scaling up women's groups on birth outcomes in three rural districts in Bangladesh: a cluster-randomised controlled trial



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Summary

Background Two recent trials have shown that women's groups can reduce neonatal mortality in poor communities. We assessed the effectiveness of a scaled-up development programme with women's groups to address maternal and neonatal care in three rural districts of Bangladesh.

Methods 18 clusters (with a mean population of 27 953 [SD 5953]) in three districts were randomly assigned to either intervention or control (nine clusters each) by use of stratified randomisation. For each district, cluster names were written on pieces of paper, which were folded and placed in a bottle. The first three cluster names drawn from the bottle were allocated to the intervention group and the remaining three to control. All clusters received health services strengthening and basic training of traditional birth attendants. In intervention clusters, a facilitator convened 18 groups every month to support participatory action and learning for women, and to develop and implement strategies to address maternal and neonatal health problems. Women were eligible to participate if they were aged 15–49 years, residing in the project area, and had given birth during the study period (Feb 1, 2005, to Dec 31, 2007). Neither study investigators nor participants were masked to treatment assignment. In a population of 229 195 people (intervention clusters only), 162 women's groups provided coverage of one group per 1414 population. The primary outcome was neonatal mortality rate (NMR). Analysis was by intention to treat. This trial is registered as an International Standard Randomised Controlled Trial, number ISRCTN54792066.

Findings We monitored outcomes for 36113 births (intervention clusters, n=17514; control clusters, n=18599) in a population of 503163 over 3 years. From 2005 to 2007, there were 570 neonatal deaths in the intervention clusters and 656 in the control clusters. Cluster-level mean NMR (adjusted for stratification and clustering) was 33.9 deaths per 1000 livebirths in the intervention clusters compared with 36.5 per 1000 in the control clusters (risk ratio 0.93, 95% CI 0.80-1.09).

Interpretation For participatory women's groups to have a significant effect on neonatal mortality in rural Bangladesh, detailed attention to programme design and contextual factors, enhanced population coverage, and increased enrolment of newly pregnant women might be needed.

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Introduction

An estimated 3.7 million neonatal deaths occur worldwide every year, 198% of which are in developing countries. In Bangladesh, the neonatal mortality rate (NMR) declined from 63 per 1000 livebirths in 1985–89 to 34 per 1000 in 2002–06. A recent survey showed that around 85% of births occur at home. Since around 45% of deaths in children under 5 years of age in Bangladesh occur in the first month of life, further progress in reducing neonatal mortality is essential to achieve Millennium Development Goal 4 (to reduce child mortality by two-thirds by 2015). This progress would require community-based interventions to improve the supply and demand for maternal and neonatal care.

We tested a low-cost, participatory, community-based approach to improving birth outcomes in rural areas in two cluster-randomised controlled trials: the first in

Makwanpur, Nepal (2001-03),7 and the second in Jharkhand and Orissa, India (2005-08).8 Participatory women's groups reduced neonatal mortality by 30% in Nepal over years 2 and 3 and by 32% in rural India over the 3-year study period. We also assessed a similar approach in a larger population within three rural districts of Bangladesh." We recruited local female peer facilitators who undertook twice as many meetings than did facilitators in the Nepal trial (18 vs nine) and covered a population two to five times larger. We also introduced a key informant system to monitor maternal and neonatal mortality rates with detailed interviews or verbal autopsies for all births, neonatal deaths, and maternal deaths. 10 Our aim was to test the generalisability and scalability of this community-based participatory approach with women's groups. A cluster-randomised design was used in the trial because the women's group

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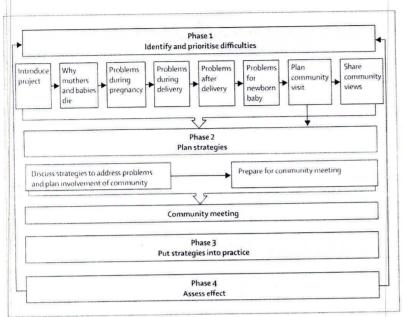


Figure 1: Description of women's group meetings in the community action cycle

intervention was implemented at a community rather than individual level.

Methods

Study design, location, and population

We assessed two interventions in the same study area using a factorial design against a common background of health services strengthening: first, a community-based intervention with participatory women's groups to improve maternal and neonatal health outcomes; second, an intervention that involved training traditional birth attendants in bag-valve-mask resuscitation of neonates with symptoms of birth asphyxia.

Three districts, Bogra, Faridpur, and Moulavibazar, were selected by use of purposive sampling from three different divisions in Bangladesh on the basis of the districts having active Diabetic Association of Bangladesh (BADAS) offices (webappendix p 1). Within these districts, subdistricts (upazilas) and unions (the lowest-level administrative units in rural Bangladesh) were also purposefully sampled by use of recommendations from BADAS representatives, the main criteria being perceived limited access to perinatal health care in those unions, and a feasible travelling distance from BADAS district headquarters.

We approached community leaders and obtained their permission to establish women's groups in the intervention clusters in 2004. 451 community orientation meetings were undertaken with the chairmen and members of union councils and community members. The team also undertook 451 village mapping exercises to identify the location of health facilities and social and religious meeting places.

Women were eligible to participate in the study if they were aged 15–49 years, residing in the project area, and had given birth during the study period (Feb 1, 2005, to Dec 31, 2007). The study population was an open cohort—ie, women could enter the study at any time during the trial period if they had given birth. Data was obtained for all eligible women throughout the study period.

Ethics approval was obtained from the ethics committees of BADAS and the University College London Institute of Child Health. Women who chose to participate in the study during the baseline survey and the period of prospective surveillance gave verbal consent and were free to decline an interview at any time.

Randomisation and masking

Each district constituted one stratum and each union a cluster (see webappendix p 2). 18 unions (six per district) were selected. The total population within these 18 unions was 503 163 people, with union sizes ranging from 15 441 to 35 110. Unions were randomly allocated to either intervention or control groups by district in the presence of four project staff (including the project director and project manager) and two external individuals (Nazmun Nahar, Department of Paediatrics. Dhaka Medical College, Dhaka, and Azad Khan, BADAS, Dhaka). For each district, cluster names were written on pieces of paper, which were folded and placed in a bottle. The first three cluster names drawn from the bottle were allocated to the women's group intervention and the remaining three to control. The project manager drew the papers from the bottle. The allocation sequence was decided upon by the project team before drawing the papers and was based on clusters rather than individuals. Clusters had been pre-identified by the team on the basis of previously mentioned criteria.

The control clusters included three tea garden estates that had substantially worse health and socioeconomic indicators than did the rest of the study area. In these areas, surveillance started late because of entry restrictions. We did not know about the entry difficulties and high mortality rates before the recruitment and allocation of clusters and therefore did not exclude these areas before allocation. Additionally, about 10% of mothers in our study area were temporary residents and mainly came into the cluster areas to give birth, since the tradition is for women to go to their mothers' home just before delivery. These temporary residents were not exposed to the women's group intervention, and often had returned to their marital homes outside the study area before the post-natal interview.

In a second-level randomisation, the randomised clusters were further randomly assigned by the same method to traditional birth attendant intervention or control groups. Of the nine women's group intervention clusters, five became traditional birth attendant intervention clusters and four became controls. The nine women's group control clusters were randomised so that

See Online for webappendix

four received the traditional birth attendant intervention and five became controls. Overall, for this second-level randomisation, there were nine traditional birth attendant intervention groups and nine control clusters (webappendix p 2).

The randomisation process was done before the collection and analysis of baseline data, and none of the staff attending the randomisation process had any previous knowledge of the health and socioeconomic status of the chosen union clusters. Neither the study investigators nor the participants were masked to group allocation.

Women's group intervention

Women's group facilitators visited every tenth household within the intervention clusters and invited married women of reproductive age to join the groups. The groups initially only included women of reproductive age but others joined later because group members requested that mothers-in-law, adolescents, and other women should also attend.

Women's groups were facilitated by a local female peer facilitator who acted as a catalyst for community mobilisation. Every facilitator was responsible for 18 groups. Facilitators received five training sessions that covered participatory modes of communication and maternal and neonatal health issues. The role of the facilitator was to activate and strengthen groups, to support them in identifying and prioritising maternal and neonatal problems, to help to identify possible strategies, and to support the planning, implementation, and monitoring of strategies in the community. Locally recruited supervisors supported facilitators in preparing for meetings and liaising with community leaders. Groups took part in a participatory learning and action cycle consisting of four phases (figure 1 and webappendix p 3). Control and intervention clusters all received health services strengthening and basic training of traditional birth attendants.

Traditional birth attendant intervention

In clusters assigned to the traditional birth attendant intervention, 482 attendants were given basic training in undertaking clean and safe deliveries, providing safe delivery kits, recognising danger signs in mothers and infants, making emergency preparedness plans, accompanying women to facilities, and undertaking mouth-to-mouth resuscitation. They also received additional training in neonatal resuscitation with bagvalve-mask. A pre-test and post-test questionnaire was done for every traditional birth attendant at the start and end of the initial training session and at subsequent training sessions. Control clusters were given basic training but no training in bag-valve-mask resuscitation.

Health service inputs

The project did not have resources to improve service delivery intensively at all levels of government health

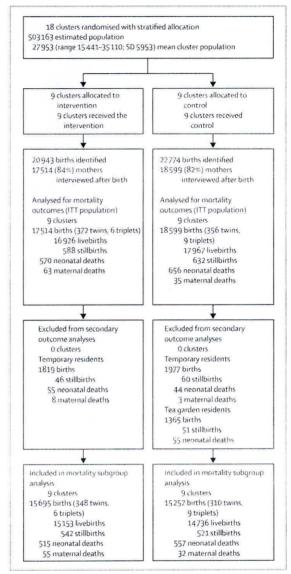


Figure 2: Trial profile ITT=intention to treat

services. Activities undertaken in both intervention and control clusters focused on improving referral systems, links between the community and health services and between different levels of health services, efficient use of available resources, basic and refresher clinical training relating to essential neonatal and maternal care, in addition to information, education, and communication materials. The training was provided to doctors, nurses, and paramedical staff working at district, upazila, and union levels. This training consisted mainly of refreshing knowledge about antenatal, natal, and postnatal care, recognition of danger signs in the mother and newborn baby, essential care of the newborn baby, the five cleans (clean delivery surface, clean perineum,

	Intervention area	Control area
Births		
Total	3162	3227
Livebirths	3054	3069
Stillbirths	42	73
Neonatal deaths	66	85
Neonatal mortality rate (per 1000 livebirths)*	21.6	26-9
Stillbirth rate (per 1000 births)*	13-3	22.6
Socioeconomic characteristics		
Household characteristics		
Own agricultural land	1558 (49%)	1566 (49%)
Own house	3095 (98%)	3110 (96%)
Own one of almyrah (wardrobe), radio or tape recorder, sewing machine, or bicycle	941 (30%)	1429 (44%)
Own none of the appliances on the list	322 (10%)	248 (8%)
Use of sanitary latrine	1007 (32%)	1476 (46%
Access to tubewell† water	3061 (97%)	3072 (95%
Religion		
Islam	2794 (88%)	2621 (81%
Hinduism	368 (12%)	601 (19%
Maternal age (years)		
<20	520 (16%)	417 (13%
20-29	2044 (65%)	1930 (60%
>30	591 (19%)	851 (26%
Maternal education		
None	1589 (50%)	1560 (48%
Primary	1011 (32%)	901 (28%
Secondary or higher	560 (18%)	761 (24%
NGO membership‡	853 (27%)	1046 (32%
Health-care-seeking and home-care practices		
Antenatal care by formal provider at last pregnancy	1148 (36%)	1085 (34%
Four or more antenatal check-ups by formal provider at last pregnancy	211 (7%)	284 (9%)
Health facility visit in case of illness during pregnancy	330 (10%)	406 (13%
Institutional delivery	226 (7%)	302 (9%)
Home delivery	2924 (92%)	2891 (90%
Home delivery attended by trained TBAS	529 (18%)	424 (15%
Home delivery attended by untrained TBAS	1058 (37%)	1245 (43%
Birth attendant washed hands	1959 (67%)	1847 (63%
Blade boiled during delivery\$	1767 (60%)	1733 (60%
Appropriate cord care§	2044 (70%)	1891 (65%
Infant wiped immediately after delivery§	1405 (48%)	1540 (53%
Infant wrapped immediately after delivery§	1640 (56%)	1658 (57%
Infant not bathed in first 24 h§	625 (21%)	777 (27%
Health-care provider seen in first 24 h after delivery	978 (31%)	1434 (449
Infant put to breast within 1 h	1611 (51%)	1672 (52%

Data are number or number (%), 6389 mothers were interviewed, 3213 from intervention unions and 3176 from control unions. NGO=non-governmental organisation. TBA=traditional birth attendant, "Baseline mortality rates were lower than expected when compared with district and national estimates. Unlike the trial data, the baseline mortality estimates were based on retrospective recall rather than prospective identification of thirs and deaths, which might account for under-reporting. TWell made by driving a tube into the earth to a stratum that bears water those membership is defined as belonging to a microcredit or savings organisation. §Home deliveries only.

Tuble 1: Baseline characteristics of mothers and their most recent birth in intervention and control areas

clean hands of attendant, clean blade to cut cord, clean umbilical stump without anything applied to it), safe delivery kits (soap, a blade, gauze, polythene, and a thread), and safer motherhood.

Surveillance

A prospective monitoring system was developed to record all births and their outcomes within the 18 control and intervention clusters during the project. The system was similar to the one implemented in the India trial and consisted of two stages (webappendix p 4).10 First, traditional birth attendants (ie, key informants) in the study area identified all births, irrespective of whether they attended them, and deaths in all women during pregnancy or up to 6 weeks after delivery. Each traditional birth attendant was responsible for about 200 households, and was paid an incentive of 60 Taka (US\$0.87 on June 8, 2009) for each accurate identification. Surveillance monitors met with traditional birth attendants once a month to gather the information. Second, when births were identified, women were interviewed once 6 weeks after delivery. Interviewers verified the births and deaths identified by key informants and completed a questionnaire that covered background characteristics and the antenatal, delivery, and postpartum periods. All eligible women identified were also asked if they could identify any other pregnant women. In the event of a stillbirth or neonatal death, a verbal autopsy was done with the mother. In the event of a maternal death up to 6 weeks after delivery, a verbal autopsy was done with a close friend or relative. Surveillance started in August, 2004, and covered all clusters by January, 2005.

Primary and secondary outcomes

The primary outcome of the women's group study was NMR (deaths in the first 28 days per 1000 livebirths). Secondary outcomes were maternal deaths (death of a pregnant woman or within 42 days of cessation of pregnancy from any cause related to the pregnancy or its management, but not from accidental causes), stillbirths (fetal death after 28 weeks of gestation but before delivery of the baby's head), uptake of antenatal and delivery services, home-care practices during and after delivery, infant morbidity, health-care seeking behaviour (seeking care for any maternal or newborn illness or complication), perinatal mortality, and early and late NMR. We used the International Classification of Diseases version 9 definition of stillbirth because it was appropriate for this setting."

The primary outcome of the traditional birth attendant study was early NMR. This outcome is presented in this report, but a more detailed analysis of the intervention will be reported in a separate publication. Early neonatal deaths refer to deaths within 6 completed days after birth and late neonatal deaths from 7–28 completed days after birth. Miscarriage was defined as cessation of a presumptive pregnancy before 28 weeks of gestation. Perinatal death describes either a stillbirth or an early neonatal death. We obtained background demographic

	Year 1 (2005)		Year 2 (2006)		Year 3 (2007)		Years 1-3 (2005-	-07)	All
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	
Births*	4620 (4706)	4586 (4924)	5495 (6183)	5250 (6426)	5580 (6625)	5421 (7249)	15 695 (17 514)	15257 (18599)	30 952 (36 113)
Livebirths	4457 (4538)	4441 (4770)	5296 (5961)	5062 (6200)	5400 (6427)	5233 (6997)	15153 (16926)	14736 (17967)	29889 (34893)
Stillbirths	163 (168)	145 (154)	199 (222)	188 (226)	180 (198)	188 (252)	542 (588)	521 (632)	1063 (1220)
Neonatal deaths	138 (139)	175 (196)	187 (215)	202 (233)	190 (216)	180 (227)	515 (570)	557 (656)	1072 (1226)
Early (0-6 days)	108 (109)	128 (144)	159 (184)	158 (184)	143 (167)	149 (186)	410 (460)	435 (514)	845 (974)
Late (7-28 days)	30 (30)	47 (52)	28 (31)	44 (49)	47 (49)	31 (41)	105 (110)	122 (142)	227 (252)
Perinatal deaths	271 (277)	273 (298)	358 (406)	346 (410)	323 (365)	337 (438)	952 (1048)	956 (1146)	1908 (2194)
Maternal deaths	14 (14)	11 (11)	23 (28)	9 (11)	18 (21)	12 (13)	55 (63)	32 (35)	87 (98)
Stillbirth rate per 1000 births	35.3 (35.7)	31.6 (31.3)	36-2 (35-9)	35-8 (35-1)	32-2 (29-9)	34.7 (34.8)	34.5 (33.6)	34.1 (33.9)	34-6 (33-8)
NMR per 1000 livebirths	30-9 (30-6)	39-4 (41-1)	35-3 (36-1)	39-9 (37-5)	35-2 (33-6)	34-4 (32-4)	34 (33-7)	37-8 (36-5)	35-9 (35-1)
Early NMR per 1000 livebirths (0–6 days)	24.2 (24.0)	28-9 (26-8)	30 (30-9)	31-2 (29-7)	26-5 (26-4)	28-5 (26-6)	27-0 (27-1)	29.5 (28.6)	28-3 (27.9)
Late NMR per 1000 livebirths (7–28 days)	6-7 (6-1)	10-6 (10-9)	5-3 (5-2)	8-7 (7-9)	8-7 (7-6)	5-9 (5-8)	6-9 (6-7)	8-3 (7-9)	7-6 (7-2)
Perinatal mortality rate per 1000 births	58-6 (58-8)	59-5 (60-5)	65-1 (65-6)	65-9 (63-8)	57-8 (55-0)	62-2 (60-4)	60-6 (59-8)	62-6 (61-6)	62-4 (60-7)
Maternal mortality ratio per 100 000 livebirths	314-1 (308-5)	247-7 (230-6)	434-3 (469-7)	177-8 (177-4)	333-3 (326-7)	229-3 (185-7)	363 (372-2)	217-1 (188-1)	291-1 (280-8

Data in parentheses include temporary and tea garden residents. NMR=neonatal mortality rate: *Includes all births for which interviews were completed from Feb 1, 2005, to Dec 31, 2007.

Table 2: Births, deaths, and crude mortality rates in intervention and control clusters during the trial period (2005-07)

and socioeconomic information to investigate cluster comparability.

Quality control of data

Data were double-entered in an electronic database. Quality checks were undertaken by district-based surveillance supervisors who manually checked information provided by the traditional birth attendants and monitors. The field surveillance manager, data input officer, and data manager undertook manual and systematic data checks. Additionally, we cross-checked a subsample of our data with government records.

Statistical analysis

We undertook a cross-sectional baseline survey for the women's group study from January to March, 2003, in more than 6000 mothers who had delivered a baby within the past year, to obtain data for household and demographic characteristics, in addition to data for pregnancy, delivery, and neonatal outcomes. Details of the sampling method used for this survey have been published elsewhere.9 The baseline survey was undertaken to gather data for neonatal care practices and behaviour, but not to provide precise NMRs in view of its limited sample size. We based our original sample size calculations on the national estimate of neonatal mortality from Bangladesh Demographic and Health Survey data from 2004, which gave a value of 41 deaths per 1000 livebirths for the 1999-2003 period. With an estimated 1600 livebirths per cluster over 3 years, a k value of 0.3, and a baseline NMR of 41 deaths per 1000 livebirths, the study had a power of 56% to detect a

30% reduction in NMR at the 95% significance level. After the end of the trial, we undertook a retrospective calculation to understand whether our inability to detect an effect of the intervention could be caused by a lack of power. From our study data, the harmonic mean of the number of recorded livebirths per cluster over the study period was 1467 (range 1081–2708). The stratum-average intracluster correlation coefficient was 0.00056, corresponding to a between-cluster coefficient (k) of 0.12 with the observed NMR in the control groups of 38 deaths per 1000 livebirths. On the assumption of a baseline NMR of 38 deaths per 1000 livebirths, the study had a power of 88% to detect a reduction in neonatal mortality of 25% at the 95% significance level.

We did not expect the intervention to have adverse effects at cluster or participant level and therefore did not have any stopping rules. A preliminary analysis was undertaken in July, 2008, and findings were presented to an independent data safety monitoring board. The board recommended a final analysis of data for all births in the study area between Feb 1, 2005, and Dec 31, 2007.

Analysis was by intention to treat (ITT) at cluster and participant levels. Temporary and tea garden residents were included in the analysis for mortality outcomes. However, they were excluded from analyses for secondary outcomes since they were unlikely to have been exposed to the intervention.

We compared NMRs, stillbirth rates, and maternal mortality ratios between control and intervention groups by use of stratified cluster-level analysis because of the small number of clusters in each group. These analyses involved calculating risk ratios for each stratum and then

	Intention-to	-treat pop	oulation	Excluding temporary and tea garden residents					
	Intervention cluster	Control cluster	Unadjusted* risk ratio (95% CI)	Intervention cluster	Control cluster	Unadjusted risk ratio* (95% CI)	Adjusted risk ratio (95% CI)		
NMR per 1000 livebirths	33.9	36.5	0-93 (0-80-1-09)	34-2	37.7	0.92 (0.75-1.12)	0.90 (0.73-1.10)		
Early NMR per 1000 livebirths (0-6 days)	27-2	28-8	0-95 (0-78-1-16)	27-1	29.5	0.93 (0.75-1.15)	0-91 (0-72-1-14)		
Late NMR per 1000 livebirths (7-28 days)	6.7	7.7	0.87 (0.59-1.29)	7.0	8.1	0-90 (0-57-1-41)	0.87 (0.54-1.38)		
Stillbirth rate per 1000 births	33-6	34-3	0-97 (0-82-1-15)	34-5	33.8	1 01 (0 82-1-21)	1-00 (0-82-1-21)		
Perinatal mortality rate per 1000 births	59-9	62-2	0-96 (0-87-1-07)	60-7	62.3	0.97 (0.90-1.05)	0-96 (0-88-1-04)		
Maternal mortality ratio per 100 000 livebirths	388-9	189-1	2-02 (1-11-3-68)	375-2	211-4	1-73 (0-98-3-05)	1-74 (0-97-3-13)		

Data are mean rate. NMR=neonatal mortality rate. *Adjusted for stratification and clustering only. †Adjusted for stratification, clustering, maternal age (continuous maternal education (categorical 1–5), and having no household assets.

Table 3: Comparison of mortality rates in intervention and control clusters (2005-07)

an overall weighted mean of these, testing the null hypothesis that the true overall risk ratio is 1 by use of a stratified t test.18 We noted baseline differences in maternal education, maternal age, and household assets between intervention and control clusters: mothers in the intervention clusters were slightly younger, less educated, and had fewer household assets. We adjusted for these covariates by use of the two-stage method described by Hayes and co-workers" for cluster-level analysis. First, a logistic regression model was fitted to the individual-level data, which incorporated the stratum. maternal age, education, and household assets, but excluded any information about trial group. The resulting regression model was used to calculate ratio residuals for each cluster, which were then used in place of clusterlevel observations for a stratified t test described above for unadjusted analysis. Results are presented as risk ratios with 95% CIs.

In the assessment of the traditional birth attendant intervention, only home deliveries were included in the analysis. Analysis was at cluster level and adjusted for stratification as described for the women's group assessment, but in this analysis the strata were clusters in which the women's group intervention was implemented, and clusters in which no women's groups were implemented. We undertook tests to check for interactions between the traditional birth attendant and women's group interventions and did not find any. We therefore analysed the women's group data as if from a single trial with two groups.

This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN54792066.

Role of the funding source

The sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. Representatives from the Big Lottery Fund and Saving Newborn Lives visited the project during the trial implementation. All authors had access to all the data in the study. KA and AC had final responsibility for the decision to submit for publication.

Results

Figure 2 shows the trial profile. The estimated population size was 503 163 people. All nine selected clusters had the intervention. All women's groups had finished their first meeting by September, 2004. The traditional birth attendant intervention started in March. 2005, with all attendants completing their training in May, 2005. We monitored births and deaths in the study area between Feb 1, 2005, and Dec 31, 2007. Interviews were completed for 17514 births in the intervention clusters and for 18599 births in control clusters (including temporary and tea garden residents). These data correspond with 84% of 20943 births registered by key informants in intervention areas and 82% of 22774 births in control areas (figure 2). The main reason for failure to interview was maternal migration.

Table 1 shows baseline characteristics of intervention and control clusters gathered in a retrospective survey. 6389 mothers were interviewed. 3213 from intervention unions and 3176 from control unions. The number of mothers to be interviewed in each union was weighted according to the total union population based on the 1991 Bangladesh census.4 Women who had delivered a baby within the past 12 months were selected for interview by use of random sampling. We noted differences in maternal education, maternal age, and household assets between intervention and control unions, with a greater proportion of mothers in the intervention unions with no education and no household assets. Mothers in intervention unions were also more likely to be younger than mothers in control unions. Further results from this survey are reported elsewhere."

In a total population of 229195 people in the nine clusters, 162 women's groups provided a coverage of one group per 1414 population. In 2007, 2363 (9%) women of reproductive age in the intervention clusters (n=27614) were group members. Almost half the members (1158 women, 49%) were between 25 years and 34 years old with fewer (378 women, 16%) younger members (<24 years old). The groups held meetings once a month and completed a cycle of 20 meetings. The mean

attendance during the first ten meetings was 73% (1735 women) of registered members. Only 477 (3%) of 15695 women who gave birth and were interviewed during the study period reported attending a group.

Unadjusted NMRs per 1000 livebirths were 30.6 in 2005, 36.1 in 2006, and 33.6 in 2007 in the intervention clusters (including all residents), and 41.1, 37.5, and 32.4 in the control clusters, respectively (table 2). The risk ratio for neonatal mortality, taking into account clustering and stratification, for the 3-year period was 0.93 (95% CI 0.80-1.09; table 3). The difference in maternal mortality ratio between intervention and control clusters was based on fairly small numbers of deaths but reached significance when temporary and tea garden residents were included in the analysis (table 3). Although this finding is of concern, 46 of the 55 maternal deaths in the intervention clusters (excluding tea garden or temporary residents) were to women who had neither heard of nor attended groups and there were no maternal deaths in members of women's groups, which suggests that the intervention did not have a direct adverse effect. Additionally, maternal mortality was a secondary outcome of the study and the sample size only gave us power to detect large differences.

In intervention clusters, neonatal mortality increased during year 2 then stabilised in year 3. In control clusters, neonatal mortality decreased over time, although the differences were not significant (figure 3). Stillbirth rates did not differ between intervention and control clusters.

No significant differences were noted in most home-care practices or health-care-seeking behaviours between intervention and control clusters (table 4). However, we did see higher frequencies of delayed bathing and exclusive breastfeeding in the intervention clusters than in the control clusters. The proportion of institutional deliveries was slightly higher in control clusters than in intervention clusters, which might have contributed to the difference noted in maternal mortality.

To further examine the effect of the women's group intervention, we compared birth outcomes and selected home-care and health-care-seeking practices in women's group members and non-group members in the intervention clusters (webappendix pp 5–6). The proportion of women with hygienic delivery practices was higher in group members than in non-group members. Additionally, group members were more likely to avoid bathing in the first 24 h and to undertake exclusive breastfeeding for the first 6 weeks than were non-group members.

Data from our process assessment showed that the three main strategies implemented by women's groups were the creation of emergency funds managed by the groups, the raising of awareness of maternal and newborn health issues during meetings and in the community by use of materials provided by the groups (such as picture cards and flipcharts), and the fostering of effective communication with health-care providers

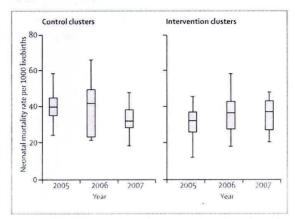


Figure 3: Mean overall neonatal mortality rates in intervention and control clusters by year (2005–07)

Boxes include lower and upper quartiles, the lines within boxes represent the median, and the error lines represent the range.

through meetings with group representatives. These strategies changed over time and varied between groups.

In clusters in which selected traditional birth attendants were trained in bag-valve-mask resuscitation, there were 12519 home births, of which 8618 were attended by any traditional birth attendant and 2792 by a traditional birth attendant trained in bag-valve-mask resuscitation. In the control clusters, there were 13195 home births, of which 9171 were attended by any traditional birth attendant and 2536 by a traditional birth attendant trained in mouth-tomouth resuscitation. Mean early NMRs did not differ significantly between clusters in which traditional birth attendants received training in bag-valve-mask resuscitation (25 · 4 deaths per 1000 livebirths) and control clusters (26.5 deaths per 1000 livebirths). The risk ratio for early neonatal death was 0.95 (95% CI 0.75-1.21). A more detailed assessment of this intervention will be reported in a separate publication. We did not find any interactions between the traditional birth attendant and women's group interventions.

Discussion

Our study shows that participatory women's groups did not significantly reduce neonatal mortality in poor rural populations of Bangladesh. This finding contrasts with the large reductions in mortality reported in other trials undertaken in Nepal and India.78 This trial monitored birth outcomes in a large population and had fewer clusters than did previous trials; however, the intracluster correlation coefficient was small, thus our inability to detect a difference in NMR between intervention and control clusters cannot be attributed to lack of power. Although neonatal mortality was lower in the intervention clusters than in the control clusters over the 3 years of the trial, there was also a decline in neonatal mortality in the control clusters over time. This finding might reflect underlying secular trends in mortality seen in other parts of Bangladesh, and merits further investigation. 15.16

	Intervention cluster	Control cluster	Unadjusted risk ratio* (95% CI)	Adjusted risk ratio† (95% CI)
Births‡				
Any antenatal care	58-7%	64.5%	0.88 (0.72-1.09)	0-91 (0-76-1-09
≥4 ANC visits	13-1%	15.8%	0-74 (0-39-1-39)	0-79 (0-46-1-37
Any iron tablets	53.7%	57.5%	0.95 (0.69-1.30)	0-96 (0-70-1-31
Maternal tetanus-toxoid injection	69-1%	69.4%	0.99 (0.86-1.14)	0-99 (0-86-1-14
Institutional deliveries	14.6%	16.2%	0.91 (0.67-1.24)	0-97 (0-77, 1-24)
Home deliveries	84.3%	82-4%	1-02 (0-96-1-09)	1.01 (0.96-1.06
Attended by formal provider (doctor or nurse)	2.0%	4-3%	0.85 (0.63-1.14)	0.90 (0.72-1.14
Attendant washed hands with soap	68-4%	65-3%	1.05 (0.86-1.29)	1-25 (0-88-1-75
Safe delivery kit used	27.1%	18-4%	1-29 (0-77-2-16)	1-28 (0-71-2-30
Plastic sheet used	46.7%	41-4%	1-11 (0-87-1-43)	1-12 (0-86-1-47
Cord cut with new or boiled blade	92.4%	92.1%	1.01 (0.97-1.04)	1.00 (0.97-1.03
Appropriate cord care	68.1%	67-2%	1.01 (0.80-1.27)	1.00 (0.80-1.26
Livebirths (home deliveries)				
Infant wiped within 30 min	78.1%	72.7%	1.06 (0.85-1.33)	1.06 (0.85-1.32
Infant wrapped within 30 min	75.6%	76.1%	0.98 (0.75-1.28)	0.98 (0.76-1.27
Infant not bathed in first 24 h	70.7%	60-4%	1-14 (0-97-1-33)	1.15 (0.97-1.36
Infants alive at 1 month				
Any of three infant illnesses (cough, fever, diarrhoea)	27-4%	28.6%	0-93 (0-74-1-17)	0.92 (0.73-1.16
Health-care-seeking behaviour in event of infant illness	22-5%	24-3%	0-89 (0-70-1-13)	0-89 (0-71-1-13
Exclusive breastfeeding for first 6 weeks	68-0%	61.5%	1-10 (0-98-1-24)	1-10 (0-98-1-23

Data are %. Percentages based on cluster means. ANC=antenatal clinic. *Adjusted for clustering and stratification only. †Adjusted for clustering, stratification, maternal education, maternal age, and having no household assets. ‡Excludes births to tea garden and temporary residents, includes births between Feb 1, 2005, and Dec 31, 2007.

Table 4: Process indicators in intervention and control clusters

Maternal mortality was higher in intervention clusters than in control clusters during the 3 years of the trial. This difference only reached significance when tea garden and temporary residents were included in the analysis. There are no obvious population, health service, or other contextual factors to explain this finding, and there is no evidence that women's groups discouraged use of health services. Also, there were no deaths in mothers who attended women's groups. We do not wish to over-interpret differences in maternal mortality rates on the basis of low numbers of maternal deaths. The effects of women's group membership on maternal mortality might become evident with meta-analysis of several trials.

Despite the absence of a significant effect of women's groups on neonatal mortality, process data suggested that good perinatal practices in intervention clusters were slightly better than they were in control clusters, such as use of a safe delivery kit, exclusive breastfeeding for the first 6 weeks, and avoidance of early bathing. Nonetheless, none of these findings were significant, and the continuing second phase trial, in which women's group coverage has been increased to one group per 400 population, should clarify questions about any

significant effects of women's groups on maternal mortality or perinatal care practices.

We believe that the lack of effect of the intervention in this setting was caused by three main factors. First, the population coverage of women's groups (one group per 1414 population) was less than a third of the coverage achieved in the India trial (one group per 468 population) and less than half that in the Nepal trial (one group per 756 population). Findings from these three trials suggest that population coverage and the proportion of newly pregnant women enrolled in groups might need threshold levels to have an effect on birth outcomes (perhaps of the order of one group per 450–750 population, and between 30% and 50% of newly pregnant women attending groups, respectively). The enrolment of newly pregnant women is likely to be a key determinant of the effectiveness of women's groups.

Second, we believe that the quality of the intervention might have been affected by several factors related to the size of the study. The total population covered by the project was much larger than that covered in the Nepal or India trials, but facilitators in our study had to coordinate more groups than did those in other trials. The project had difficulties in retaining facilitators and supervisors, which might have led to disruptions in meetings and reduced support for community mobilisation. Facilitators also had an increased workload, since they arranged 18 meetings per month compared with nine per month in the trial in Nepal. Although the support structure and ratio of supervisors to facilitators in this study were similar to those in Nepal and India, in practice coordinators often lived further away from women's group facilitators than did those in other sites, and they were not able to provide refresher training and continuing support to facilitators. Facilitators' use of participatory techniques to stimulate community mobilisation is the hallmark of this intervention and lack of support for facilitators might have damaged the quality of the intervention.

Third, local contextual factors could have had a role: adverse climatic conditions affected the facilitators' ability to travel to meetings and one of the intervention unions in Faridpur was entirely flooded in 2007. Additionally, there are signs that gender-based barriers were strong in some of the intervention unions, and might have prevented some women from joining groups, seeking care, or from implementing strategies if they had joined a group. For example, some women reported facing problems when asking for their husbands' or in-laws' permission to join a group. Other women's groups linked to non-governmental organisations (NGOs) operated in our study area, and women were regularly asked to participate in NGO activities for which they could receive financial incentives. Women might therefore have been deterred from investing time in women's group meetings for which no incentives were offered. Despite these problems, all 162 groups continued to meet after the end of the programme's cycle.

The purposive selection of districts and upazilas, and the stratification of sampling, together with the restricted number of clusters, might have limited the effectiveness of randomisation procedures. The participatory approach assessed in this study contrasts with health-worker-led interventions tested in other recent trials of communitybased newborn care. 17.18 In Bangladesh, the Projahnmo trial compared home care, consisting of multiple community health worker visits to pregnant mothers, with a community mobilisation group and a control group. The results showed no overall significant differences between groups in NMR over the 3 years of the trial, but there was a 34% reduction in NMR in the final 6 months of the trial in the home-care group. However, the community mobilisation approach used in the Projahnmo trial was not participatory and was less intensive than the approaches used in the Nepal, Indian, and Bangladesh Perinatal Care Project trials. In the Projahnmo community-care group, each female community health worker was responsible for a population of 18000 people, which was divided so that each geographical area of about 225 people was visited once every 4 months; the male community health workers visited each area every 10 months. Just as we propose for this trial with women's groups, we do not believe that this level of coverage and intensity is sufficient to bring about behaviour change and reduction in mortality.

Few government programmes have managed to provide multiple prenatal or postnatal home visits to mothers and infants when scaled up.19 By contrast, women's groups, if scaled to an adequate coverage, have the potential to reach the poorest people and bring about substantial health and non-health benefits. Nonetheless, a women's group approach requires adequate human resources support for community mobilisation and appropriate coverage. The threshold coverage or dose effect for the women's group intervention needs to be established for future scale-up programmes. This threshold coverage raises an important new research and policy question: would scaling up the coverage of women's groups in Bangladesh achieve the same effect on mortality as did the intervention in India and Nepal, or is the absence of effect caused by other delivery and social context barriers? We are currently assessing the effect of more intensive scale-up of women's groups in the intervention clusters to increase population coverage and membership of pregnant women to levels similar to those reported in the trial in India. Additionally, we are improving support for facilitators and implementing strategies to counter gender-based barriers, such as the involvement of men and religious leaders. We are closely monitoring contextual factors that might affect the delivery of the intervention through a detailed process assessment. The results of this assessment will establish whether the success of women's groups is dependent on population coverage, or whether specific contextual and delivery factors reduce their effectiveness.

Contributors

All the authors contributed to the design of the study and criticised drafts of the report. KA, SB, and AC were responsible for the conception and overall supervision of the trial. KA and her team managed the project, data collection, data entry, and administration with assistance from BB and SS. SB. ME, and AC were technical advisers to the study. AC, KA, and SB helped design the original trial protocol. SB designed the data collection methods and epidemiological surveillance system. AP, CP, and SB undertook the quantitative analysis. AC, AP, SB, and KA wrote the first draft of the report and were responsible for subsequent collation of inputs and redrafting. KA and AC are guarantors for the report.

Conflicts of interest

We declare that we have no conflicts of interest.

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Effect of a participatory intervention with women's groups on birth outcomes and maternal depression in Jharkhand and Orissa, India: a cluster-randomised controlled trial

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Summar

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Background Community mobilisation through participatory women's groups might improve birth outcomes in poor rural communities. We therefore assessed this approach in a largely tribal and rural population in three districts in eastern India.

Methods From 36 clusters in Jharkhand and Orissa, with an estimated population of 228 186, we assigned 18 clusters to intervention or control using stratified randomisation. Women were eligible to participate if they were aged 15–49 years, residing in the project area, and had given birth during the study. In intervention clusters, a facilitator convened 13 groups every month to support participatory action and learning for women, and facilitated the development and implementation of strategies to address maternal and newborn health problems. The primary outcomes were reductions in neonatal mortality rate (NMR) and maternal depression scores. Analysis was by intention to treat. This trial is registered as an International Standard Randomised Controlled Trial, number ISRCTN21817853.

Findings After baseline surveillance of 4692 births, we monitored outcomes for 19 030 births during 3 years (2005–08). NMRs per 1000 were $55 \cdot 6$, $37 \cdot 1$, and $36 \cdot 3$ during the first, second, and third years, respectively, in intervention clusters, and $53 \cdot 4$, $59 \cdot 6$, and $64 \cdot 3$, respectively, in control clusters. NMR was 32% lower in intervention clusters adjusted for clustering, stratification, and baseline differences (odds ratio $0 \cdot 68$, 95% CI $0 \cdot 59 - 0 \cdot 78$) during the 3 years, and 45% lower in years 2 and 3 ($0 \cdot 55$, $0 \cdot 46 - 0 \cdot 66$). Although we did not note a significant effect on maternal depression overall, reduction in moderate depression was 57% in year 3 ($0 \cdot 43$, $0 \cdot 23 - 0 \cdot 80$).

Interpretation This intervention could be used with or as a potential alternative to health-worker-led interventions, and presents new opportunities for policy makers to improve maternal and newborn health outcomes in poor populations.

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Introduction

Every year, an estimated 3-7 million children worldwide die in the first month of life.^{1,2} Global progress in reduction of maternal and child mortality rates is insufficient—only 16 of 68 countries are on track to achieve Millennium Development Goal 4 (reduction of mortality rate in children <5 years by two-thirds between 1990–2015). India accounts for 20% of maternal deaths worldwide, 21% of all child (<5 years) deaths, and 25% of all neonatal deaths. Urgent efforts are needed to reduce these mortality rates quickly through cost-effective and scalable interventions.

Large improvements were noted in birth outcomes in a poor rural population in Makwanpur, Nepal, after a low-cost, potentially sustainable, and scalable participatory intervention with women's groups. Newborn mortality rates were 30% lower in intervention areas than in control areas (odds ratio 0.70, 95% CI 0.53–0.94). Local female facilitators assisted women's groups every month to consider the causes and underlying problems leading to

maternal and newborn deaths, develop practical strategies with community leaders and men, and implement and assess the outcomes of these strategies. This community-action cycle, adapted from a programme developed in Bolivia, created health and non-health benefits at low cost.*

Maternal depression is an increasing public health concern in low-income countries because of its high prevalence and wide-ranging implications for the health of the mother and infant. Delivery of appropriate interventions to prevent or treat maternal depression through health workers is a major challenge in countries with under-resourced health systems, and community groups assisted by non-health-care workers might have some advantage in helping the poorest women.*

Jharkhand and Orissa are two of the poorest states in eastern India. About 40% of their total combined population lives below the poverty line." The average life expectancy among women in both states is about 60 years, and an estimated 63% are illiterate." Neonatal mortality

rate (NMR) per 1000 livebirths is 49 in Jharkhand and 45 in Orissa, and maternal mortality ratio per 100 000 livebirths is 371 and 358, respectively. These are disproportionately higher than India's national estimates of 39 per 1000 for NMR and 301 per 100 000 for maternal mortality ratio. The second s

More than 20% of Jharkhand and Orissa's population is affiliated with Scheduled Tribes (or Adivasi—ie, indigenous groups), and about 12% with scheduled castes. Despite calls for inclusive development. Adivasi communities remain underserved—their employment rate is roughly half that of non-indigenous people, and nearly a third of Adivasi children in Jharkhand and Orissa do not receive primary education. Indigenous communities also have higher mortality rates and poorer access to health services than do the non-indigenous populations.

We hypothesised that a participatory intervention with women's groups could reduce neonatal mortality by at least 25% in underserved tribal communities of eastern India, and improve home-care practices and health-seeking behaviour of pregnant and postnatal women, and their family members; and that the women's group intervention could reduce maternal depression in the intervention areas by 30%.

Methods

Study location and population

Our study was done in three contiguous districts of Iharkhand and Orissa-Saraikela Kharswan, West Singhbhum, and Keonjhar (figure 1). The proportion of Adivasis within the study clusters was 58-70%. Eligible participants were women aged 15-49 years, residing in the project area, and who had given birth during the study (July 31, 2005, to July 30, 2008). The study population was an open cohort—ie, women could enter the study at any time during the trial period if they had given birth. Women who chose to participate gave their consent (written or left-thumb print) and were free to decline an interview at any time. Women who were identified by interviewers as having symptoms of severe depression were referred to the nearest tertiary mental health centre at Ranchi. Ethical approval was obtained from an independent ethical committee in Jamshedpur, India.

Randomisation

We identified 12 rural clusters per district, with a mean population of 6338 per cluster (range 3605–7467). The estimated population in these 36 clusters was 228186 (on the basis of the 2001 Indian census projections). In 18 clusters, existing women's groups were involved in savings and credit activities (seven in West Singhbhum, three in Saraikela Kharswan, and eight in Keonjhar). In the first district (West Singhbhum), an external observer from a partner non-governmental organisation (Professional Assistance for Development Action) drew folded papers with numbers corresponding to clusters

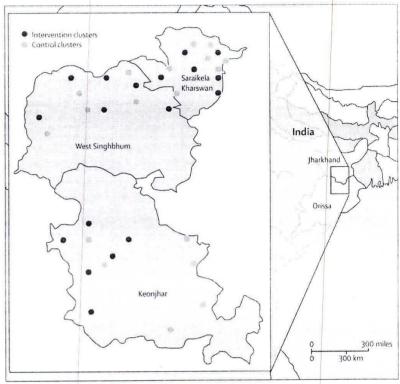


Figure 1: Map of districts and distribution of clusters

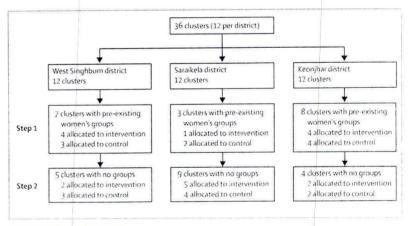


Figure 2: Randomisation process

with existing groups from a basket. The first four clusters were allocated to the intervention group, the rest to the control group. This process was repeated for clusters without women's groups and in the other two districts in the presence of external observers (figure 2). We chose this method because of simplicity and visibility, which were necessary to convince local communities that the process was transparent. Because of the nature of the intervention, neither the intervention team nor the participants were masked to group assignment during the trial.

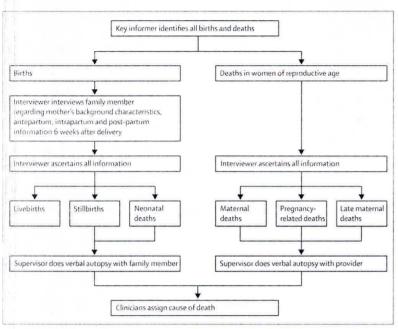


Figure 3: Surveillance system

Panel 1: Definitions

- Miscarriage: cessation of a presumptive pregnancy before 22 weeks of gestation before delivery of the baby's head¹²
- Neonatal death: death of a liveborn infant within 28 completed days of birth
- Early neonatal deaths: deaths arising within 6 completed days
- Late neonatal deaths: deaths arising from 7 to 28 completed days of birth
- · Perinatal death: a stillbirth or an early neonatal death
- Maternal death: death of a woman while pregnant or within 42 days of cessation of pregnancy from any cause related to the pregnancy or its management, but not from accidental causes

In September, 2004, we met with gram sabhas (village councils), headmen, and representatives from panchayats (elected representatives for basic governance) in the three districts. These representatives granted permission to start surveillance of births and deaths, and to work with women's groups.

Surveillance

A surveillance system with key informants was established in the three districts. Figure 3 shows this system, and Barnett and colleagues describe it in detail. One key informant, usually a traditional birth attendant or active village member, was responsible for about 250 households, and reported any births, maternal or newborn deaths, and deaths in women of reproductive

age every month within their allocated area. The key informant met with an interviewer once a month who verified births and interviewed all identified mothers to gather information about their sociodemographic characteristics, pregnancy, delivery, and postnatal period through a structured questionnaire about 6 weeks after delivery. As additional checks for the identification stage, all women identified were asked to locate any others of reproductive age who had recently given birth or died in the study area. Every district had 12 interviewers, one interviewer supervisor, and a district manager. The monitoring manager supervised fieldbased activities in all three districts and data entry at the head office. The intervention and surveillance teams were partitioned—interviewers and facilitators belonged to different villages, their training was done separately. and they had review meetings on separate days.

In the event of a stillbirth or neonatal death (panel 1), the interviewer administered a questionnaire and did a verbal autopsy with the mother and other individuals present at the time of death; the verbal autopsy included free text in which the mother was asked to narrate the details of events leading to the death of the neonate. For deaths among women of reproductive age, the interviewer spoke to family members to ascertain the age of the woman, cause of death, and whether she was pregnant or had recently given birth. In the event of a maternal death, the monitoring supervisors, initially accompanied by a physician, did verbal autopsies with a relative who was present at the time of the death. Supervisors completed a standard questionnaire with free text for elaboration of the sequence of events before the death. Verbal autopsies for maternal deaths were done by a physician (n=11), interviewer supervisor (n=96), or district manager (n=2).

Maternal depression was included as a trial outcome in the second year of the study because of delays in identification of a contextually appropriate scale. We used the Kessler-10 item scale (K10), a questionnaire for the detection of common mental disorders in community settings, that has been used in India and World Mental Health Surveys. A psychiatrist (RL) did three training sessions of 2 days each for groups of 12–15 interviewers that consisted of administration of the K10 questionnaire, aspects of understanding depression and body language, association between physical health and mental health, active listening skills, and confidentiality.

Clusters and coverage of women's groups

In the 18 intervention clusters, we used a participatory action cycle with 172 existing groups and created an additional 72 groups. Coverage of Ekjut groups was one group per 468 population. In year 1, 546 (18%) of 3119 newly pregnant women attended the groups, rising to 1718 (55%) of 3126 in year 3. We recorded 111006 group attendances over 3 years. 74715 (67%) of these were from married women of reproductive age, 15030 (14%) from

adolescent girls, 10452 (9%) from men, and 10809 (10%) from elderly women.

Women's group intervention

Every group met monthly for a total of 20 meetings, and a local woman, selected on the basis of criteria (including speaking the local language and having the ability to travel to meetings) identified by the community, facilitated the meetings. After a 7-day residential training course to review the cycle's contents, and to practice participatory communication techniques. facilitators were given support through fortnightly meetings with district coordinators. Facilitators coordinated an average of 13 meetings every month with as many groups.

Groups took part in a participatory learning and action cycle (figure 4). Community members who were not regular group members were also encouraged to participate in discussions. Information about clean delivery practices and care-seeking behaviour was shared through stories and games, rather than presented as key messages. By discussion of case studies imparted through contextually appropriate stories, group members identified and prioritised maternal and newborn health problems in the community, collectively selected relevant strategies to address these problems, implemented the strategies, and assessed the results. Although some strategies were common, each group was free to implement its own combination of strategies. The intervention team adapted facilitation materials from the study in Makwanpur, Nepal, to guide the meetings.3 Groups used methods such as picture-card games, role play, and story-telling to help discussions about the causes and effects of typical problems in mothers and infants, and devised strategies for prevention, homecare support, and consultations (figure 5).

Health-service inputs

We formed health committees in all intervention and control clusters so that community members would have the opportunity to express their opinions about the design and management of local health services. About ten village representatives within every cluster met once every 2 months and used a structured action cycle to discuss maternal and newborn health entitlement issues. As a result, committee members became more knowledgable about the government health system and assisted with the formation of village health committees as part of the National Rural Health Mission programme.2 In addition to the creation of cluster-level health committees, we provided workshops for appreciative inquiry with frontline government health staff from seven clusters per district in Jharkhand.²² Participants assessed the programme qualitatively at the end of every training session. We expected that any improvement in performance or service quality would be equal in intervention and control clusters.

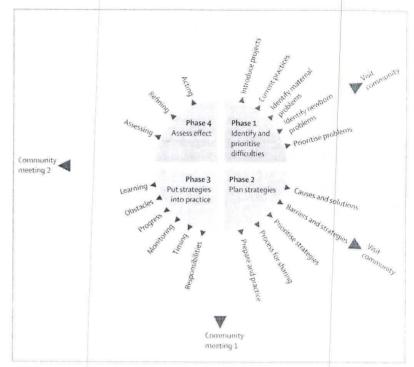


Figure 4: Meetings in women's group cycle

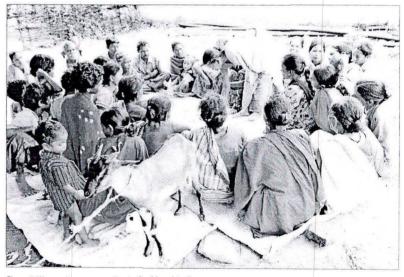


Figure 5: Women's group meeting in Jharkhand, India. Individuals in the photo provided permission (written or thumb print) for publication of image.

Primary and secondary outcomes

The primary outcomes were reductions in NMR and maternal depression scores. Secondary outcomes were stillbirths, maternal and perinatal deaths, uptake of antenatal and delivery services, home-care practices during and after delivery, and health-care-seeking behaviour (seeking care from qualified providers in the

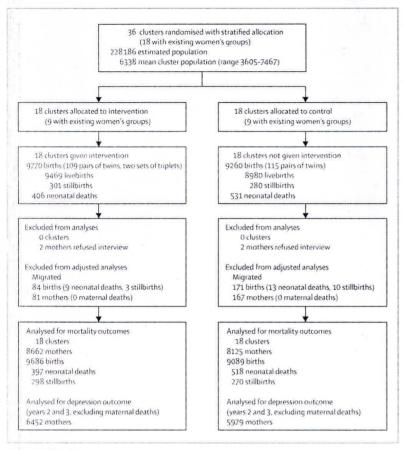


Figure 6: Trial profile

antenatal, delivery, and postnatal period, for checkups and problems).

Quality control of data

Data were double-entered in an electronic database. Surveillance supervisors manually checked information provided by key informants and interviewers. The field surveillance manager, data input officer, and data manager undertook manual and systematic data checks.

Statistical analysis

We did not expect the intervention to have adverse effects at cluster or participant level, and therefore did not have any rules for stopping the intervention. In December, 2007, we presented findings from a preliminary analysis to an independent data safety committee. After an interim analysis in 2007, the committee recommended that the trial continue for a total of 3 years to enable comparison with the Makwanpur study, in which the effect was measured from 9 months after the beginning of the intervention to allow exposure to the women's groups in pregnancy. The data safety committee also noted that 3 years would

allow analysis of possible seasonal variations in NMR. The committee undertook a final review of the data in December, 2008.

Our prospective surveillance from Nov 21, 2004, to July 30, 2005, showed a baseline NMR of 58 per 1000 livebirths (261 deaths per 4509 livebirths) and maternal mortality ratio of 510 per 100 000 (23 deaths per 4509 livebirths). The trial was planned for 3 years and was originally powered, like the Makwanpur trial,5 for a 2-year analysis of birth outcomes, after allowing a period of up to 1 year for the women's groups to be established and for pregnant women to be given the intervention. We assumed a between-cluster correlation coefficient of variation (k) of 0.15-0.25, and about 324 births per cluster during 2 years. On the basis of 10% loss to follow-up, a sample size of 18 clusters per group resulted in 64-81% power to detect a 25% reduction in NMR. With an estimated baseline prevalence of 15% and k of 0.3, the study had 79-81% power to detect a 30% reduction in maternal depression over 1 year. We used data for recorded births during the study to estimate that the study had a power of 92% to detect a 25% reduction in NMR.

Analysis was by intention to treat at cluster and participant levels. We excluded data from mothers who migrated out of the region and their infants from intention-to-treat analyses since many of these women probably came into the clusters at the time of delivery and would therefore not have been exposed to the intervention in pregnancy. We aimed to do the tests of significance for our primary and secondary outcomes on the basis of previously agreed hypotheses about the likely effect of the intervention. For comparison of mortality outcome, we used multivariate logistic regression with random effects on individual-level data in Stata (version 10.0).23 We compared secondary indicators using generalised estimating equations models with semirobust SEs at the cluster level. 33 Generalised estimating equations models were used for secondary indicators and categorical scores of maternal depression because these outcomes had high intracluster correlation coefficients (>0 · 30). We compared K10 scores grouped in three categories (none/mild, moderate, or severe) during years 2 and 3 of the trial. This method was chosen in favour of linear regression to address the data's strong positive skewness. We adjusted for stratification by including strata as variables in the regression analyses, and for multiple hypothesis testing by adjusting the p values for the primary outcomes using the Holm correction in the results tables. We did not adjust for clustering at the level of the mother. All results are presented as odds ratios with 95% CIs.

Cost-effectiveness analysis

We used a similar method of cost-effectiveness analysis as used by Borghi and colleagues. Costs were estimated at 2007 prices, and were calculated separately for the

women's group intervention and activities for healthservice strengthening. These were the financial and economic costs of setting up the intervention, and running costs during the trial. Costs were estimated from the perspective of a provider to give an indication of the potential costs of replication for the government and interested agencies, and discounted at 3%. Incremental cost effectiveness was measured in relation to a do-nothing alternative.

This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN21817853.

Role of the funding source

The funders had no role in the design of the study, data collection, data analysis, interpretation, or writing up of the findings, although they made a site visit early in the study implementation. The corresponding author had access to all the data and had final responsibility for the decision to submit for publication.

Results

Figure 6 shows the trial profile. All 18 selected clusters had the intervention. Loss to follow-up after birth as a result of migration or refusal of interview was 86 (<1%) of 9770 women in intervention clusters and 173 (2%) of 9260 in control clusters. In the study areas, 5661 (37%) of 15118 home deliveries were by a relative, friend, or neighbour, 5368 (36%) by traditional birth attendants, and 1913 (13%) by husbands.

Table 1 shows the baseline characteristics of identified births during 9 months of data gathering from Nov 21, 2004, to July 30, 2005. Numbers of births were similar in intervention and control clusters, but differences were noted in household assets, maternal education, literacy, and tribal membership, with women in the intervention clusters being generally poorer and more disadvantaged than those in the control clusters (table 1).

NMRs unadjusted for clustering decreased from year 1 to year 3 in the intervention clusters compared with an increase in the control clusters (table 2).

We noted a 32% reduction in NMR during the 3-year trial when data were adjusted for clustering. stratification, and baseline differences (table 3). NMR was reduced by 45% in intervention clusters compared with control clusters during the last 2 years (table 3). The reduction in NMR was still significant when migrated mothers and their babies were excluded from the intention-to-treat analyses during the 3 years (table 3). k. estimated from retrospective data from control clusters, was 0.10 when we took stratification into account, and corresponded to an intracluster correlation coefficient of 0.0005.23 In the analysis of neonatal mortality data at the cluster level, the risk ratio was 0.71 (95% CI 0.57-0.90, p=0.0011) for years 1 to 3 when adjusted for multiple hypothesis testing with the Holm procedure and unadjusted for baseline differences.

	Intervention area	Control area
Identified births	2457	2235
Socioeconomic characteristics		
Household assets		
Radio, cassette tape, bicycle, or electricity	1752 (71%)	1771 (79%)
More costly items (television, generator, battery, fan, fridge)	167 (7%)	225 (10%)
Ownership of agricultural land		
None	345 (14%)	364 (16%)
Own less than 2 bighas (<0.27 hectares)	1157 (47%)	969 (43%)
Own between 2-4 bighas (0·27-0·54 hectares)	653 (27%)	593 (27%)
Caste or tribal group		
Scheduled tribe*	1849 (75%)	1557 (70%)
Scheduled caste*	80 (3%)	64 (3%)
Other backward caste*	520 (21%)	606 (27%)
Maternal age		
<20 years	147 (6%)	253 (11%)
20-29 years	1370 (56%)	1385 (62%)
≥30 years	345 (14%)	348 (16%)
Not known	933 (38%)	592 (26%)
Maternal school education		
None	1908 (78%)	1533 (69%)
Primary	143 (6%)	125 (6%)
Secondary or higher	405 (16%)	577 (26%)
Maternal literacy		
Cannot read	1906 (78%)	1566 (70%)
Can read	550 (22%)	669 (30%)
are-seeking behaviour and home-care practices		
Any antenatal care	1460 (59%)	1532 (69%)
Three or more antenatal visits	539 (22%)	701 (31%)
Any iron tablets during pregnancy	1571 (64%)	1497 (67%)
Institutional delivery	277 (11%)	326 (15%)
Home delivery	2118 (86%)	1858 (83%)
Delivery attended by traditional birth attendant	778 (37%)	717 (39%)
Birth attendant washed hands†	609 (29%)	471 (25%)
Birth attendant used safe delivery kit†	195 (9%)	197 (11%)
Birth attendant used plastic sheet†	163 (8%)	141 (8%)
Cord cut with new or boiled bladet	1493 (70%)	1294 (70%)
Cord tied with boiled thread!	276 (13%)	232 (13%)
Infant wiped within 30 min‡	1247 (61%)	1130 (63%)
Infant wrapped within 30 min‡	787 (39%)	782 (43%)
Infants alive at 1 month	2202 (90%)	2046 (92%)
Exclusive breastfeeding for 6 weeks§	1387 (63%)	1168 (57%)

Data are number or number (%), "Standard terms used in Indian demographic surveys, "Home deliveries only (stillbirths were not excluded from the count), 4Stillbirths excluded. \$Number of infants alive at 6 weeks were 2202 in intervention clusters, and 2046 in control clusters.

Table 1: Baseline characteristics of identified births in intervention and control areas

After year 1. NMRs were considerably lower in the intervention clusters than in the control clusters (figure 7). In the third year of the study, NMR was almost half in the intervention clusters compared with the control clusters (odds ratio 0.53, 95% CI 0.41–0.68, adjusted for clustering and stratification only), much larger than the findings of the Makwanpur trial in Nepal. Figure 8 shows the cluster-level changes in NMR between baseline and

	Baseline	•		Year 1†		Year 2†		Year 3†		Years 1-3	f		Years 1-3	3*	
	Inter- vention	Control	All	Inter- vention	Control	Inter- vention	Control	Inter- vention	Control	Inter- vention	Control	All	Inter- vention	Control	All
Births	2457	2235	4692	3171	3052	3404	3135	3195	3073	9770	9260	19 030	9686	9089	1877
Livebirths	2347	2162	4509	3073	2960	3286	3035	3110	2985	9469	8980	18 449	9388	8819	1820
Stillbirths	109	73	183	98	92	118	100	85	88	301	280	581	298	270	56
Neonatal deaths	145	116	261	171	158	122	181	113	192	406	531	937	397	518	91
Early (0-6 days)	100	80	180	116	107	76	135	67	138	259	380	639	253	368	62
Late (7-28 days)	45	36	81	55	51	46	46	46	54	147	151	298	144	150	29
Perinatal deaths	209	153	362	214	199	194	235	152	226	560	660	1220	551	638	118
Maternal deaths	16	7	23	20	30	22	18	7	12	49	60	109	49	60	10
Stillbirth rate per 1000 births	44-4	32.7	39-0	30-9	30-1	34.7	31-9	26-6	28.6	30.8	30-2	30-5	30-7	29.7	3
Neonatal mortality rate per 1000 livebirths	61.8	53-6	57-9	55-6	53-4	37-1	59-6	36-3	64-3	42-9	59-1	50-8	42-3	58-7	5
Early neonatal mortality rate per 1000 livebirths (0–6 days)	42.6	37-0	40-0	37-8	36-1	23-1	44.4	21-5	46.2	27-3	42-3	34.6	26-9	41-7	3
Late neonatal mortality rate per 1000 livebirths (7–28 days)	19-1	16-6	18.0	17-9	17-2	14-0	15.1	14-7	18-0	15.5	16.8	16-1	15:3	17-0	1
Perinatal mortality rate per 1000 births	85-1	68-4	77-1	67.4	65-2	57-0	75-0	47-5	73.5	57-3	71.2	64-1	56-8	70-1	6
Maternal mortality ratio per 100 000 livebirths	681-7	323-8	510-1	650-8	1013-5	669-5	593-0	225-1	402-0	517-5	668-1	590-8	521-9	680-3	59

	Years 1-3 (including migrated)*	p value	Years 1-3 (excluding migrated)*	p value	Years 1-3†	p value	Years 2 and 3†	p value
Neonatal mortality rate per 1000 livebirths‡	0-71 (0-61-0-83)	<0.0005	0.69 (0.60-0.81)	<0.0005	0.68 (0.59-0.78)	<0.0005	0-55 (0-46-0-66)	<0.0005
Early neonatal mortality rate (0–6 days)	0-63 (0-54-0-75)	<0.0005	0-62 (0-53-0-74)	<0.0005	0.62 (0.52-0.73)	<0.0005	0.46 (0.37-0.57)	<0.0005
Late neonatal mortality rate (7–28 days)	0-92 (0-67-1-26)	0-476	0-89 (0-65-1-22)	0-463	0.84 (0.64-1.12)	0-236	0-80 (0-56-1-14)	0-217
Stillbirth rate per 1000 births	1-02 (0-85-1-23)	0.833	1-04 (0-85-1-25)	0.773	1-05 (0-86-1-28)	0-656	1-01 (0-80-1-28)	0.914
Perinatal mortality rate per 1000 births	0-79 (0-70-0-90)	<0.0005	0.79 (0.69-0.90)	<0.0005	0.79 (0.69-0.91)	<0.0005	0.68 (0.58-0.79)	<0.0005
Maternal mortality ratio per 100 000 livebirths	0.80 (0.51-1.24)	0.180	0.80 (0.51-1.24)	0.180	0-70 (0-46-1-07)	0.104	0.50 (0.48-1.49)	0.563

Data are odds ratio (95% CI). *Adjusted for stratification (by district and pre-existing women's groups) and clustering only. †Adjusted for stratification, clustering, maternal education, assets, and any tribal affiliation. ‡p values adjusted for multiple hypothesis testing with Holm correction were <0.001.

Table 3: Comparison of mortality rates in intervention and control clusters

Data are unadjusted. *Excluding migrated mothers and infants. †Including migrated mothers and infants.

Table 2: Births and deaths in intervention and control clusters at baseline and during trial

year 3—the NMRs fell below their baseline level in most intervention clusters. Between 2005 and 2008, perinatal mortality rates in the intervention clusters decreased compared with those in the control clusters when adjusted for clustering (table 2; table 3). Stillbirth rates did not differ between intervention and control clusters (table 2). Maternal mortality ratio was generally lower in intervention than in control clusters, but the study was not powered to detect significant differences (table 3). Qualitative evidence from the assessment of the trial's process showed that community mobilisation through

women's groups might have contributed to avoidance of some maternal deaths (panel 2).

There was no detectable difference in maternal depression K10 scores, when measured about 6 weeks after delivery, between intervention and control clusters in year 2 of the study or overall (table 4). However, in year 3, when 55% of all pregnant women in the intervention clusters had joined a group, a 57% reduction was noted in moderate depression among mothers in the intervention clusters compared with control clusters (table 4).

No significant differences were noted in health-care-seeking behaviour between control and intervention clusters (table 5). However, home-care practices showed substantial improvements—in intervention clusters, birth attendants were more likely to wash their hands, use a safe delivery kit and a plastic sheet, and boil the thread used to tie the cord than were those in the control clusters. The proportion of infants exclusively breastfed at 6 weeks was higher in intervention areas in adjusted analyses for years 2 and 3.

Cause-specific differences in mortality rate as a percentage of all causes—septicaemia, birth asphyxia, hypothermia, and prematurity—during the 3 years were not clearly discernable because there was a reduction in all causes (table 6). The incremental cost of the women's group intervention was US\$910 per newborn life saved, increasing to \$1308 (in 2007 prices) when health-service strengthening activities were included. The incremental cost per life-year saved was \$33 for the women's group intervention (\$48 inclusive of health-service strengthening activities). The women's group intervention in this setting was therefore more cost effective than that reported in Nepals as a result of the greater effect of women's groups on NMR combined with lower operating costs in the current context.

Discussion

Women's groups led by peer facilitators reduced NMR and moderate maternal depression at low cost in largely tribal, rural populations of eastern India. Our data show that mortality reduction in underserved rural settings was not associated with increased care-seeking behaviour or health-service use. The most likely mechanism of mortality reduction was through improved hygiene and care practices. The availability of safe delivery kits increased in both control and intervention areas, but women's groups seemed to generate more demand in intervention clusters than in control clusters. In places where kits were not provided, group members made them and provided information about their contents to mothers, then visited pregnant women during the eighth month of pregnancy to ensure that they had received kits and would use them. Birth outcomes might have been affected by the fact that these community members attended the groups or were advised by group members, thus generating increased social awareness and support for clean delivery practices.

The most striking reduction in mortality rate was noted in early neonatal deaths, which might be explained by the strong focus on intrapartum and early neonatal periods in several case studies and stories discussed during the cycle. Attribution of cause of newborn death on the basis of verbal autopsy is an imperfect science, and deaths might arise from several and overlapping causes. Early septicaemia could have been reduced with clean delivery practices, and premature babies might have survived

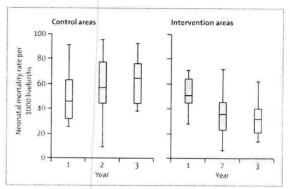


Figure 7: Boxplot of cluster-level neonatal mortality rates by allocation and study year

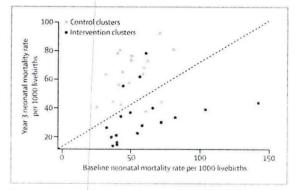


Figure 8: Scatterplot of cluster-specific neonatal mortality rates in year 3 with rates at baseline

Panel 2: Case-study effect of women's groups on strategies to avoid maternal deaths

A woman in the eighth month of her pregnancy, and her mother-in-law attended a monthly women's group meeting where they participated in a drill based on what to do in the event of post-partum bleeding. After a month, when the woman delivered at home and had severe bleeding, her mother-in-law remembered what had been said in the group, and, without wasting time, asked her daughter-in-law to breastfeed the baby while she rushed to get money from the group and asked her son to arrange for a vehicle. The daughter-in-law was immediately taken to the district hospital, where she was given medicines, intravenous fluid, and two pints of blood, and was discharged after 15 days.

with improved care. The reason for this combined reduction of asphyxia, prematurity, and septicaemia could also be improved intrapartum care. Potential mechanisms for reduction of mortality rate will be further assessed in future analyses of verbal autopsies and seasonal mortality trends.

Our findings also show that a low-cost intervention involving non-health-care workers might affect maternal

	Year 2			Year 3			Years 2 and 3			
	Intervention	Control	Adjusted odds ratio (95% CI)*	Intervention	Control	Adjusted odds ratio (95% CI)*	Intervention	Control	Adjusted odds ratio (95% CI)*	
Mothers (n)	3332	3016		3120	2963		6452	5979		
No or mild depression (10-15)	2922 (88%)	2612 (87%)	0.91 (0.41-2.01)	2962 (95%)	2665 (90%)	2-33 (1-25-4-38)	5884 (91%)	5277 (88%)	1.29 (0.68-2.44)	
Moderate depression (16-30)	383 (11%)	382 (13%)	1.04 (0.50-2.16)	154 (5%)	293 (10%)	0.43 (0.23-0.80)	536 (8%)	676 (11%)	0.74 (0.40-1.37)	
Severe depression (31-50)	28 (<1%)	21 (<1%)	1.53 (0.47-5.05)	4 (<1%)	5 (<1%)	0.70 (0.15-3.31)	32 (<1%)	26 (<1%)	1-29 (0-46-3-64)	

Data are number (%), unless otherwise indicated. "Results adjusted for clustering, stratification, maternal education, tribe affiliation, and household assets by use of generalised estimated equations with semirobust SEs for individual-level data.

Table 4: Kessler-10 depression scores in mothers in intervention and control clusters

	Intervention clusters	Control clusters	Odds ratio (95% CI) for years 1-3*	Odds ratio (95% CI) for years 1-3†	Odds ratio (95% CI for years 2 and 3†
Births‡	9468	8867	35.		
Any antenatal care	6990 (74%)	6623 (75%)	0.97 (0.48-1.97)	1.60 (0.65-3.92)	1-86 (0-80-4-34)
≥3 antenatal care visits	3001 (32%)	3621 (41%)	0.63 (0.37-1.06)	0.69 (0.37-1.26)	0.68 (0.37-1.24)
Iron tablets	6997 (74%)	6293 (71%)	1-12 (0-71-1-76)	1-31 (0-62-2-75)	1.34 (0.77-2.35)
Maternal tetanus-toxoid injection	7767 (82%)	7377 (83%)	0.90 (0.51-1.54)	1-39 (0-85-2-28)	1-40 (0-85-2-29)
Illness in pregnancy	5206 (55%)	4983 (56%)	1.03 (0.68-1.58)	1-10 (0-71-1-72)	1.01 (0.67-1.52)
Visited health facility in case of illness during pregnancy	945 (10%)	922 (10%)	0-78 (0-39-1-56)	0.86 (0.46-1.60)	0.80 (0.39-1.65)
Institutional deliveries	1364 (14%)	1811 (20%)	0.64 (0.39-1.04)	0.89 (0.51-1.53)	0.94 (0.50-1.76)
Birth attended by formal provider (doctor or nurse)	1490 (16%)	2067 (23%)	0-59 (0-37-1-94)	0.81 (0.50-1.31)	0.82 (0.47-1.43)
Home deliveries	8084	7034	***	100	500
Birth attended by traditional birth attendant	2692 (33%)	2676 (38%)	0.82 (0.43-1.60)	0.84 (0.43-1.64)	0.85 (0.44-1.65)
Birth attendant washed hands with soap	3291 (41%)	1583 (23%)	2.05 (1.14-3.73)	2-07 (1-24-3-45)	2.50 (1.35-4.62)
Safe-delivery kit used	2594 (32%)	1284 (18%)	2-08 (1-25-3-44)	1-87 (1-11-3-14)	2-28 (1-27-4-09)
Plastic sheet used	2088 (26%)	560 (8%)	3.85 (2.51-5.89)	3-74 (2-48-5-65)	2-98 (1-84-4-81)
Cord tied with boiled thread	2559 (32%)	786 (11%)	3-9 (1-82-6-30)	3.02 (1.61-5.65)	4-33 (2-06-9-11)
Cord cut with new or boiled blade	6679 (83%)	5570 (79%)	1-24 (0-82-1-87)	1-35 (0-86-2-12)	1.55 (0.96-2.51)
Livebirths (home deliveries)	7890	6873		34	36
Cord undressed or dressed with antiseptic	6600 (84%)	6115 (89%)	0.52 (0.24-1.12)	0-58 (0-27-1-26)	1.01 (0.39-2.62)
Infant wiped within 30 min	4741 (60%)	4227 (62%)	0-90 (0-38-2-14)	1.01 (0.43-2.36)	1.06 (0.44-2.57)
Infant wrapped within 30 min	2846 (36%)	2980 (43%)	0-74 (0-35-1-59)	0.78 (0.36-1.66)	0.81 (0.37-1.80)
Infant not bathed in first 24 h	2107 (27%)	1509 (22%)	1.06 (0.52-2.17)	0.95 (0.44-2.10)	1-22 (0-56-2-65)
Infants alive at 1 month	8807	8119	22		44
Any of three infant illnesses (cough, fever, diarrhoea)	1739 (20%)	2388 (29%)	0-62 (0-37-1-03)	0-67 (0-40-1-12)	0-61 (0-35-1-06)
Care-seeking behaviour in event of infant illness	940 (54%)§	1050 (44%)§	1-53 (0-77-3-05)	0.88 (0.97-3.61)	1-55 (0-79-3-04)
Infant put to breast within 4 h	5390 (61%)	4942 (61%)	1-01 (0-48-2-14)	0.90 (0.38-3.11)	1-11 (0-45-2-76)
Exclusive breastfeeding for first 6 weeks	7022 (80%)	5611 (69%)	1.82 (1.14-2.92)	1.44 (0.89-2.35)	1-74 (1-03-2-94)

Data are number (%), unless otherwise indicated. *Adjusted for clustering and stratification only. †Adjusted for clustering, stratification, maternal education, assets, and any tribal affiliation. ‡Excludes births to migrated mothers and twins. \$Denominators are number of infants with any of three infant illnesses: 1739 for intervention clusters and 2388 for control clusters.

Table 5: Process indicators in intervention and control clusters

mental health. We hypothesise that the large reduction in moderate depression seen in the third year could have occurred through improvements in social support and problem-solving skills of the groups. Adequate social support reduces the risk of depression during pregnancy and is an important social determinant of mental health.²⁵ In meetings, information was shared

about the difficulties encountered by mothers in the community, and practical ways to collectively address them were established. Group meetings also strengthened problem-solving skills, a component of psychotherapeutic interventions that has been shown to affect depression in other settings. The intervention seemed to have no effect on severe depression, perhaps

because it was more similar to primary prevention rather than treatment, or because severe depression is less amenable to psychotherapeutic interventions. A complete analysis and discussion of these findings will be presented in the future.

Two potential effect modifiers in this trial, on the basis of evidence, were differences in maternal education, and tribal membership and assets between the intervention and control populations. These were taken into account in adjusted analyses and mainly provided an advantage for the control areas. Additionally, the high significance of some of our results could be a result of an increase in mortality rate in the control areas between 2005–08. The control and intervention clusters were in similar geographic areas, so factors that affected NMR should have affected both groups equally, but further investigation is needed.

We believe that the study had two main weaknesses. First, as in several other community-based randomised control trials, the intervention and surveillance teams were not unaware of allocation. However, there were no incentives or disincentives for over-reporting or underreporting births and deaths, and several process mechanisms were in place to detect errors. Second, although migration out of districts was common, we cannot rule out some intercluster migration when women married out of their home cluster. Our intention-to-treat analysis might have affected the results positively or negatively.

In the Shivgarh study," in Uttar Pradesh, India, the effect of an intensive behaviour-change programme involving community meetings and home visits by a new cadre of paid, non-governmental community workers in a population of 104123 during 15 months resulted in a 54% reduction (relative risk 0.46, 95% CI 0.35-0.60) in NMR with changes in home-care practices, but no real change in care-seeking behaviour. No overall differences in NMR were noted during 30 months of intervention in the Projahnmo trial,78 in Bangladesh, but a 34% reduction (0.66, 0.47-0.93) was noted in the home-care group in the last 6 months of the programme. The investigators of the Projahnmo study²⁸ noted that "Availability of referral services and a strong supervisory system were crucial to this intervention and would be a necessary feature of scaling up the intervention.

Interventions with health-worker home visits have rarely achieved adequate coverage, quality, or effectiveness when taken to scale in poor populations. Participatory groups have the advantage of helping the poorest, being scalable at low cost, and producing potentially wideranging and long-lasting effects. By addressing critical consciousness, groups have the potential to create improved capability in communities to deal with the health and development difficulties arising from poverty and social inequalities. The intervention requires a training and support structure to manage facilitators in charge of 12–14 groups per month, with every group

	Intervention		Control	
	Years 1-3	Years 2 and 3	Year 1-3	Years 2 and
Early neonatal deaths	253	140	367	264
Birth asphyxia	92 (36%)	53 (38%)	142 (39%)	104 (39%)
Prematurity	85 (34%)	46 (33%)	110 (30%)	77 (29%)
Septicaemia	38 (15%)	15 (11%)	47 (13%)	29 (11%)
Hypothermia	16 (6%)	12 (9%)	26 (7%)	22 (8%)
Other	22 (9%)	14 (10%)	42 (11%)	32 (12%)
ata are number or number (%).			

responsible for a population of about 500 and for recruiting up to half of newly pregnant women. Costs are lower than for most other primary health-care interventions, and these interventions can complement existing self-help groups in the community.

Two other issues arising from our study are cost effectiveness and the effect on maternal mortality ratios. The interventions in the Ekjut trial were more cost effective than those in the Makwanpur study because of lower operating costs and greater effect of the intervention. In the Nepal trial, effect of women's groups on maternal mortality ratios was significant, although the number of deaths was small and maternal mortality ratio was not a stated primary outcome. In our trial the maternal mortality ratio was higher in the intervention areas at baseline, and 20% lower after 3 years of intervention, but this difference was not significant and the trial was not powered to measure differences in maternal mortality. Reduction in maternal mortality will depend mainly on improved access to health services and to life-saving drugs, but community mobilisation could help through improvement in hygiene at delivery and early care-seeking behaviour for complications by addressing the first-delay component.

This participatory intervention with women's groups could complement or be a potential alternative to healthworker led interventions, two examples of which have been discussed here. Our findings raise several important issues for policy makers in India. Could federal and state governments invest in this programme? Should government or non-government organisations be responsible for its scale-up? Could such a participatory intervention support and strengthen the National Rural Health Mission's mandate of communitisation of health and the Accredited Social Health Activist programme?10 Further assessments of this approach will involve a scale-up in large populations with little access to health services, and different delivery mechanisms of the intervention will need to be tested in partnership with government and non-government organisations.

Contributors

All authors contributed to the design of the study and criticised drafts of the report. PT, NN, SB. and AC were responsible for the conception and overall supervision of the trial. PT and NN managed the project, data gathering, data entry, and administration with assistance from ShR, SuR, RM, RG, and DM, SB and AC were technical advisers for the study. IB provided technical assistance with gathering and analysis of cost data. AC, PT, and SB helped design the original trial protocol. SB designed the methods for data gathering and epidemiological surveillance system. VP and RL provided technical advice about the K10 scale and commented on drafts of the report. RL trained interviewers to administer the K10 scale. NN, AP, CP, and SB did the quantitative analysis. AC, AP, PT, NN, and SB wrote the first draft of the report, and were responsible for subsequent collation of inputs and redrafting. PT and AC are guarantors for the report.

Conflicts of interest

We declare that we have no conflicts of interest.

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Effect of a participatory intervention with women's groups on birth outcomes and maternal depression in Jharkhand and Orissa, India: a cluster-randomised controlled trial

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Summary

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Ekjut, Chakradharpur, Jharkhand, India

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Background Community mobilisation through participatory women's groups might improve birth outcomes in poor rural communities. We therefore assessed this approach in a largely tribal and rural population in three districts in eastern India.

Methods From 36 clusters in Jharkhand and Orissa, with an estimated population of 228 186, we assigned 18 clusters to intervention or control using stratified randomisation. Women were eligible to participate if they were aged 15–49 years, residing in the project area, and had given birth during the study. In intervention clusters, a facilitator convened 13 groups every month to support participatory action and learning for women, and facilitated the development and implementation of strategies to address maternal and newborn health problems. The primary outcomes were reductions in neonatal mortality rate (NMR) and maternal depression scores. Analysis was by intention to treat. This trial is registered as an International Standard Randomised Controlled Trial, number ISRCTN21817853.

Findings After baseline surveillance of 4692 births, we monitored outcomes for 19 030 births during 3 years (2005–08). NMRs per 1000 were $55 \cdot 6$, $37 \cdot 1$, and $36 \cdot 3$ during the first, second, and third years, respectively, in intervention clusters, and $53 \cdot 4$, $59 \cdot 6$, and $64 \cdot 3$, respectively, in control clusters. NMR was 32% lower in intervention clusters adjusted for clustering, stratification, and baseline differences (odds ratio $0 \cdot 68$, 95% CI $0 \cdot 59 - 0 \cdot 78$) during the 3 years, and 45% lower in years 2 and 3 ($0 \cdot 55$, $0 \cdot 46 - 0 \cdot 66$). Although we did not note a significant effect on maternal depression overall, reduction in moderate depression was 57% in year 3 ($0 \cdot 43$, $0 \cdot 23 - 0 \cdot 80$).

Interpretation This intervention could be used with or as a potential alternative to health-worker-led interventions, and presents new opportunities for policy makers to improve maternal and newborn health outcomes in poor populations.

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Introduction

Every year, an estimated 3.7 million children worldwide die in the first month of life.^{1,2} Global progress in reduction of maternal and child mortality rates is insufficient—only 16 of 68 countries are on track to achieve Millennium Development Goal 4 (reduction of mortality rate in children <5 years by two-thirds between 1990–2015).¹ India accounts for 20% of maternal deaths worldwide, 21% of all child (<5 years) deaths, and 25% of all neonatal deaths.⁴ Urgent efforts are needed to reduce these mortality rates quickly through cost-effective and scalable interventions.

Large improvements were noted in birth outcomes in a poor rural population in Makwanpur, Nepal, after a low-cost, potentially sustainable, and scalable participatory intervention with women's groups. Newborn mortality rates were 30% lower in intervention areas than in control areas (odds ratio 0.70, 95% CI 0.53–0.94). Local female facilitators assisted women's groups every month to consider the causes and underlying problems leading to

maternal and newborn deaths, develop practical strategies with community leaders and men, and implement and assess the outcomes of these strategies. This community-action cycle, adapted from a programme developed in Bolivia, created health and non-health benefits at low cost.

Maternal depression is an increasing public health concern in low-income countries because of its high prevalence and wide-ranging implications for the health of the mother and infant.⁷ Delivery of appropriate interventions to prevent or treat maternal depression through health workers is a major challenge in countries with under-resourced health systems, and community groups assisted by non-health-care workers might have some advantage in helping the poorest women.⁸

Jharkhand and Orissa are two of the poorest states in eastern India. About 40% of their total combined population lives below the poverty line. The average life expectancy among women in both states is about 60 years, and an estimated 63% are illiterate. Neonatal mortality

rate (NMR) per 1000 livebirths is 49 in Jharkhand and 45 in Orissa, and maternal mortality ratio per 100 000 livebirths is 371 and 358, respectively. These are disproportionately higher than India's national estimates of 39 per 1000 for NMR and 301 per 100 000 for maternal mortality ratio. The second s

More than 20% of Jharkhand and Orissa's population is affiliated with Scheduled Tribes (or Adivasi—ie, indigenous groups), and about 12% with scheduled castes. Despite calls for inclusive development. Adivasi communities remain underserved—their employment rate is roughly half that of non-indigenous people, and nearly a third of Adivasi children in Jharkhand and Orissa do not receive primary education. Indigenous communities also have higher mortality rates and poorer access to health services than do the non-indigenous populations.

We hypothesised that a participatory intervention with women's groups could reduce neonatal mortality by at least 25% in underserved tribal communities of eastern India, and improve home-care practices and health-seeking behaviour of pregnant and postnatal women, and their family members: and that the women's group intervention could reduce maternal depression in the intervention areas by 30%.

Methods

Study location and population

Our study was done in three contiguous districts of Iharkhand and Orissa-Saraikela Kharswan, West Singhbhum, and Keonjhar (figure 1). The proportion of Adivasis within the study clusters was 58-70%. Eligible participants were women aged 15-49 years, residing in the project area, and who had given birth during the study (July 31, 2005, to July 30, 2008). The study population was an open cohort—ie, women could enter the study at any time during the trial period if they had given birth. Women who chose to participate gave their consent (written or left-thumb print) and were free to decline an interview at any time. Women who were identified by interviewers as having symptoms of severe depression were referred to the nearest tertiary mental health centre at Ranchi. Ethical approval was obtained from an independent ethical committee in Jamshedpur, India.

Randomisation

We identified 12 rural clusters per district, with a mean population of 6338 per cluster (range 3605–7467). The estimated population in these 36 clusters was 228186 (on the basis of the 2001 Indian census projections). In 18 clusters, existing women's groups were involved in savings and credit activities (seven in West Singhbhum, three in Saraikela Kharswan, and eight in Keonjhar). In the first district (West Singhbhum), an external observer from a partner non-governmental organisation (Professional Assistance for Development Action) drew folded papers with numbers corresponding to clusters

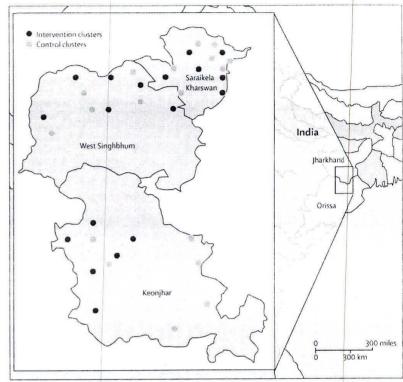


Figure 1: Map of districts and distribution of clusters

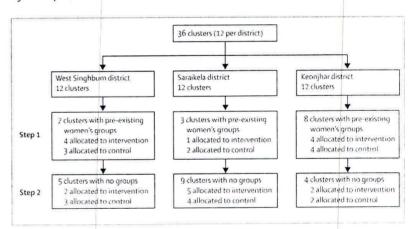


Figure 2: Randomisation process

with existing groups from a basket. The first four clusters were allocated to the intervention group, the rest to the control group. This process was repeated for clusters without women's groups and in the other two districts in the presence of external observers (figure 2). We chose this method because of simplicity and visibility, which were necessary to convince local communities that the process was transparent. Because of the nature of the intervention, neither the intervention team nor the participants were masked to group assignment during the trial.

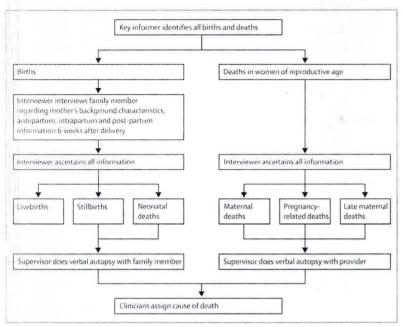


Figure 3: Surveillance system

Panel 1: Definitions

- Miscarriage: cessation of a presumptive pregnancy before 22 weeks of gestation before delivery of the baby's head¹⁷
- Neonatal death: death of a liveborn infant within 28 completed days of birth
- Early neonatal deaths: deaths arising within 6 completed days
- Late neonatal deaths: deaths arising from 7 to 28 completed days of birth
- · Perinatal death: a stillbirth or an early neonatal death
- Maternal death: death of a woman while pregnant or within 42 days of cessation of pregnancy from any cause related to the pregnancy or its management, but not from accidental causes

In September, 2004, we met with gram sabhas (village councils), headmen, and representatives from panchayats (elected representatives for basic governance) in the three districts. These representatives granted permission to start surveillance of births and deaths, and to work with women's groups.

Surveillance

A surveillance system with key informants was established in the three districts. Figure 3 shows this system, and Barnett and colleagues describe it in detail. One key informant, usually a traditional birth attendant or active village member, was responsible for about 250 households, and reported any births, maternal or newborn deaths, and deaths in women of reproductive

age every month within their allocated area. The key informant met with an interviewer once a month who verified births and interviewed all identified mothers to gather information about their sociodemographic characteristics, pregnancy, delivery, and postnatal period through a structured questionnaire about 6 weeks after delivery. As additional checks for the identification stage, all women identified were asked to locate any others of reproductive age who had recently given birth or died in the study area. Every district had 12 interviewers, one interviewer supervisor, and a district manager. The monitoring manager supervised fieldbased activities in all three districts and data entry at the head office. The intervention and surveillance teams were partitioned—interviewers and facilitators belonged to different villages, their training was done separately. and they had review meetings on separate days.

In the event of a stillbirth or neonatal death (panel 1), the interviewer administered a questionnaire and did a verbal autopsy with the mother and other individuals present at the time of death; the verbal autopsy included free text in which the mother was asked to narrate the details of events leading to the death of the neonate. For deaths among women of reproductive age, the interviewer spoke to family members to ascertain the age of the woman, cause of death, and whether she was pregnant or had recently given birth. In the event of a maternal death, the monitoring supervisors, initially accompanied by a physician, did verbal autopsies with a relative who was present at the time of the death. Supervisors completed a standard questionnaire with free text for elaboration of the sequence of events before the death. Verbal autopsies for maternal deaths were done by a physician (n=11), interviewer supervisor (n=96), or district manager (n=2).

Maternal depression was included as a trial outcome in the second year of the study because of delays in identification of a contextually appropriate scale. We used the Kessler-10 item scale (K10), a questionnaire for the detection of common mental disorders in community settings, that has been used in India and World Mental Health Surveys. A psychiatrist (RL) did three training sessions of 2 days each for groups of 12–15 interviewers that consisted of administration of the K10 questionnaire, aspects of understanding depression and body language, association between physical health and mental health, active listening skills, and confidentiality.

Clusters and coverage of women's groups

In the 18 intervention clusters, we used a participatory action cycle with 172 existing groups and created an additional 72 groups. Coverage of Ekjut groups was one group per 468 population. In year 1, 546 (18%) of 3119 newly pregnant women attended the groups, rising to 1718 (55%) of 3126 in year 3. We recorded 111006 group attendances over 3 years. 74715 (67%) of these were from married women of reproductive age, 15030 (14%) from

adolescent girls, 10452 (9%) from men, and 10809 (10%) from elderly women.

Women's group intervention

Every group met monthly for a total of 20 meetings, and a local woman, selected on the basis of criteria (including speaking the local language and having the ability to travel to meetings) identified by the community, facilitated the meetings. After a 7-day residential training course to review the cycle's contents, and to practice participatory communication techniques. facilitators were given support through fortnightly meetings with district coordinators. Facilitators coordinated an average of 13 meetings every month with as many groups.

Groups took part in a participatory learning and action cycle (figure 4). Community members who were not regular group members were also encouraged to participate in discussions. Information about clean delivery practices and care-seeking behaviour was shared through stories and games, rather than presented as key messages. By discussion of case studies imparted through contextually appropriate stories, group members identified and prioritised maternal and newborn health problems in the community, collectively selected relevant strategies to address these problems, implemented the strategies, and assessed the results. Although some strategies were common, each group was free to implement its own combination of strategies. The intervention team adapted facilitation materials from the study in Makwanpur, Nepal, to guide the meetings. Groups used methods such as picture-card games, role play, and story-telling to help discussions about the causes and effects of typical problems in mothers and infants, and devised strategies for prevention, homecare support, and consultations (figure 5).

Health-service inputs

We formed health committees in all intervention and control clusters so that community members would have the opportunity to express their opinions about the design and management of local health services. About ten village representatives within every cluster met once every 2 months and used a structured action cycle to discuss maternal and newborn health entitlement issues. As a result, committee members became more knowledgable about the government health system and assisted with the formation of village health committees as part of the National Rural Health Mission programme.² In addition to the creation of cluster-level health committees, we provided workshops for appreciative inquiry with frontline government health staff from seven clusters per district in Jharkhand.²² Participants assessed the programme qualitatively at the end of every training session. We expected that any improvement in performance or service quality would be equal in intervention and control clusters.

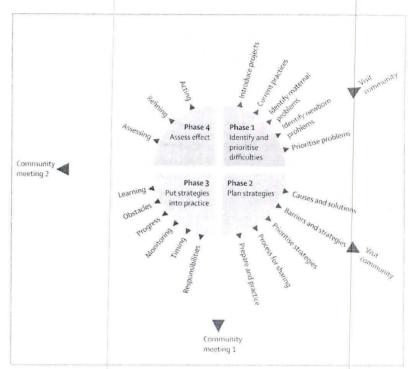


Figure 4: Meetings in women's group cycle

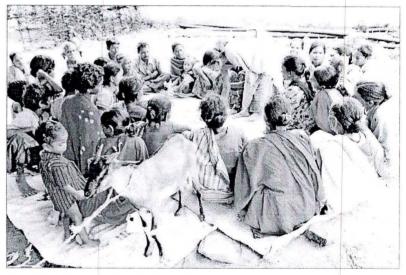


Figure S: Women's group meeting in Jharkhand, India Individuals in the photo provided permission (written or thumb print) for publication of image

Primary and secondary outcomes

The primary outcomes were reductions in NMR and maternal depression scores. Secondary outcomes were stillbirths, maternal and perinatal deaths, uptake of antenatal and delivery services, home-care practices during and after delivery, and health-care-seeking behaviour (seeking care from qualified providers in the

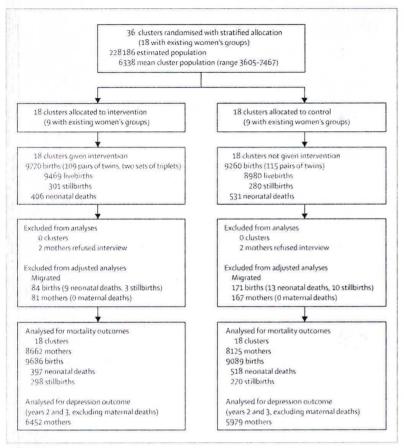


Figure 6: Trial profile

antenatal, delivery, and postnatal period, for checkups and problems).

Quality control of data

Data were double-entered in an electronic database. Surveillance supervisors manually checked information provided by key informants and interviewers. The field surveillance manager, data input officer, and data manager undertook manual and systematic data checks.

Statistical analysis

We did not expect the intervention to have adverse effects at cluster or participant level, and therefore did not have any rules for stopping the intervention. In December, 2007, we presented findings from a preliminary analysis to an independent data safety committee. After an interim analysis in 2007, the committee recommended that the trial continue for a total of 3 years to enable comparison with the Makwanpur study, in which the effect was measured from 9 months after the beginning of the intervention to allow exposure to the women's groups in pregnancy. The data safety committee also noted that 3 years would

allow analysis of possible seasonal variations in NMR. The committee undertook a final review of the data in December, 2008.

Our prospective surveillance from Nov 21, 2004, to July 30, 2005, showed a baseline NMR of 58 per 1000 livebirths (261 deaths per 4509 livebirths) and maternal mortality ratio of 510 per 100 000 (23 deaths per 4509 livebirths). The trial was planned for 3 years and was originally powered, like the Makwanpur trial,5 for a 2-year analysis of birth outcomes, after allowing a period of up to 1 year for the women's groups to be established and for pregnant women to be given the intervention. We assumed a between-cluster correlation coefficient of variation (k) of 0.15-0.25, and about 324 births per cluster during 2 years. On the basis of 10% loss to follow-up, a sample size of 18 clusters per group resulted in 64-81% power to detect a 25% reduction in NMR. With an estimated baseline prevalence of 15% and k of 0.3, the study had 79-81% power to detect a 30% reduction in maternal depression over 1 year. We used data for recorded births during the study to estimate that the study had a power of 92% to detect a 25% reduction in NMR.

Analysis was by intention to treat at cluster and participant levels. We excluded data from mothers who migrated out of the region and their infants from intention-to-treat analyses since many of these women probably came into the clusters at the time of delivery and would therefore not have been exposed to the intervention in pregnancy. We aimed to do the tests of significance for our primary and secondary outcomes on the basis of previously agreed hypotheses about the likely effect of the intervention. For comparison of mortality outcome, we used multivariate logistic regression with random effects on individual-level data in Stata (version 10.0).23 We compared secondary indicators using generalised estimating equations models with semirobust SEs at the cluster level.23 Generalised estimating equations models were used for secondary indicators and categorical scores of maternal depression because these outcomes had high intracluster correlation coefficients (>0.30). We compared K10 scores grouped in three categories (none/mild, moderate, or severe) during years 2 and 3 of the trial. This method was chosen in favour of linear regression to address the data's strong positive skewness. We adjusted for stratification by including strata as variables in the regression analyses, and for multiple hypothesis testing by adjusting the p values for the primary outcomes using the Holm correction in the results tables. We did not adjust for clustering at the level of the mother. All results are presented as odds ratios with 95% CIs.

Cost-effectiveness analysis

We used a similar method of cost-effectiveness analysis as used by Borghi and colleagues. A Costs were estimated at 2007 prices, and were calculated separately for the

women's group intervention and activities for health-service strengthening. These were the financial and economic costs of setting up the intervention, and running costs during the trial. Costs were estimated from the perspective of a provider to give an indication of the potential costs of replication for the government and interested agencies, and discounted at 3%. Incremental cost effectiveness was measured in relation to a do-nothing alternative.

This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN21817853.

Role of the funding source

The funders had no role in the design of the study, data collection, data analysis, interpretation, or writing up of the findings, although they made a site visit early in the study implementation. The corresponding author had access to all the data and had final responsibility for the decision to submit for publication.

Results

Figure 6 shows the trial profile. All 18 selected clusters had the intervention. Loss to follow-up after birth as a result of migration or refusal of interview was 86 (<1%) of 9770 women in intervention clusters and 173 (2%) of 9260 in control clusters. In the study areas, 5661 (37%) of 15 118 home deliveries were by a relative, friend, or neighbour. 5368 (36%) by traditional birth attendants, and 1913 (13%) by husbands.

Table 1 shows the baseline characteristics of identified births during 9 months of data gathering from Nov 21, 2004, to July 30, 2005. Numbers of births were similar in intervention and control clusters, but differences were noted in household assets, maternal education, literacy, and tribal membership, with women in the intervention clusters being generally poorer and more disadvantaged than those in the control clusters (table 1).

NMRs unadjusted for clustering decreased from year 1 to year 3 in the intervention clusters compared with an increase in the control clusters (table 2).

We noted a 32% reduction in NMR during the 3-year trial when data were adjusted for clustering, stratification, and baseline differences (table 3). NMR was reduced by 45% in intervention clusters compared with control clusters during the last 2 years (table 3). The reduction in NMR was still significant when migrated mothers and their babies were excluded from the intention-to-treat analyses during the 3 years (table 3). k, estimated from retrospective data from control clusters, was 0.10 when we took stratification into account, and corresponded to an intracluster correlation coefficient of 0.0005.23 In the analysis of neonatal mortality data at the cluster level, the risk ratio was 0.71 (95% CI 0.57-0.90, p=0.0011) for years 1 to 3 when adjusted for multiple hypothesis testing with the Holm procedure and unadjusted for baseline differences.

	Intervention area	Control area
Identified births	2457	2235
Socioeconomic characteristics		300-001 (4)
Household assets		
Radio, cassette tape, bicycle, or electricity	1752 (71%)	1771 (79%)
More costly items (television, generator, battery, fan, fridge)	167 (7%)	225 (10%)
Ownership of agricultural land		
None	345 (14%)	364 (16%)
Own less than 2 bighas (<0.27 hectares)	1157 (47%)	969 (43%)
Own between 2-4 bighas (0·27-0·54 hectares)	653 (27%)	593 (27%)
Caste or tribal group		1150
Scheduled tribe*	1849 (75%)	1557 (70%)
Scheduled caste*	80 (3%)	64 (3%)
Other backward caste*	520 (21%)	606 (27%)
Maternal age		
<20 years	147 (6%)	253 (11%)
20–29 years	1370 (56%)	1385 (62%)
≥30 years	345 (14%)	348 (16%)
Not known	933 (38%)	592 (26%)
Maternal school education		
None	1908 (78%)	1533 (69%)
Primary	143 (6%)	125 (6%)
Secondary or higher	405 (16%)	577 (26%)
Maternal literacy		
Cannot read	1906 (78%)	1566 (70%)
Can read	550 (22%)	669 (30%)
are-seeking behaviour and home-care practices		
Any antenatal care	1460 (59%)	1532 (69%)
Three or more antenatal visits	539 (22%)	701 (31%)
Any iron tablets during pregnancy	1571 (64%)	1497 (67%)
Institutional delivery	277 (11%)	326 (15%)
Home delivery	2118 (86%)	1858 (83%)
Delivery attended by traditional birth attendant!	778 (37%)	717 (39%)
Birth attendant washed hands†	609 (29%)	471 (25%)
Birth attendant used safe delivery kitt	195 (9%)	197 (11%)
Birth attendant used plastic sheet1	163 (8%)	141 (8%)
Cord cut with new or boiled blade†	1493 (70%)	1294 (70%)
Cord tied with boiled threadt	276 (13%)	232 (13%)
Infant wiped within 30 min‡	1247 (61%)	1130 (63%)
Infant wrapped within 30 min‡	787 (39%)	782 (43%)
Infants alive at 1 month	2202 (90%)	2046 (92%)
Exclusive breastfeeding for 6 weeks§	1387 (63%)	1168 (57%)
		2004000 DE

Data are number or number (%). "Standard terms used in Indian demographic surveys. †Home deliveries only (stillbirths were not excluded from the count). ‡Stillbirths excluded. \$Number of infants alive at 6 weeks were 2202 in intervention clusters, and 2046 in control clusters.

Table 1: Baseline characteristics of identified births in intervention and control areas

After year 1, NMRs were considerably lower in the intervention clusters than in the control clusters (figure 7). In the third year of the study, NMR was almost half in the intervention clusters compared with the control clusters (odds ratio 0.53, 95% CI 0.41-0.68, adjusted for clustering and stratification only), much larger than the findings of the Makwanpur trial in Nepal.⁵ Figure 8 shows the cluster-level changes in NMR between baseline and

	Baseline	*		Year 1†		Year 2†		Year 3† Years 1–3†					Years 1-3*			
	Inter- vention	Control	All	Inter- vention	Control	Inter- vention	Control	Inter- vention	Control	Inter- vention	Control	All	Inter- vention	Control	All	
Births	2457	2235	4692	3171	3052	3404	3135	3195	3073	9770	9260	19 030	9686	9089	18775	
Livebirths	2347	2162	4509	3073	2960	3286	3035	3110	2985	9469	8980	18 449	9388	8819	18207	
Stillbirths	109	73	183	98	92	118	100	85	88	301	280	581	298	270	568	
Neonatal deaths	145	116	261	171	158	122	181	113	192	406	531	937	397	518	915	
Early (0-6 days)	100	80	180	116	107	76	135	67	138	259	380	639	253	368	621	
Late (7-28 days)	45	36	81	55	51	46	46	46	54	147	151	298	144	150	294	
Perinatal deaths	209	153	362	214	199	194	235	152	226	560	660	1220	551	638	1189	
Maternal deaths	16	7	23	20	30	22	18	7	12	49	60	109	49	60	109	
Stillbirth rate per 1000 births	44-4	32-7	39-0	30-9	30-1	34.7	31.9	26.6	28.6	30-8	30-2	30.5	30.7	29.7	30	
Neonatal mortality rate per 1000 livebirths	61-8	53-6	57-9	55-6	53-4	37.1	59-6	36-3	64-3	42.9	59-1	50.8	42-3	58-7	50	
Early neonatal mortality rate per 1000 livebirths (0-6 days)	42.6	37-0	40.0	37-8	36-1	23-1	44-4	21.5	46-2	27-3	42-3	34.6	26-9	41-7	34	
Late neonatal mortality rate per 1000 livebirths (7–28 days)	19-1	16.6	18-0	17-9	17-2	14-0	15-1	14.7	18-0	15-5	16.8	16-1	15-3	17:0	16	
Perinatal mortality rate per 1000 births	85.1	68-4	77-1	67-4	65-2	57-0	75-0	47.5	73-5	57-3	71.2	64.1	56-8	70-1	63	
Maternal mortality ratio per 100 000 livebirths	681-7	323-8	510-1	650-8	1013-5	669-5	593-0	225-1	402.0	517-5	668-1	590-8	521-9	680-3	598	

	Years 1-3 (including migrated)*	p value	Years 1-3 (excluding migrated)*	p value	Years 1-3†	p value	Years 2 and 3†	p value
Neonatal mortality rate per 1000 livebirths‡	0-71 (0-61-0-83)	<0.0005	0.69 (0.60-0.81)	<0.0005	0.68 (0.59-0.78)	<0.0005	0-55 (0-46-0-66)	<0.0005
Early neonatal mortality rate (0–6 days)	0-63 (0-54-0-75)	<0.0005	0-62 (0-53-0-74)	<0.0005	0-62 (0-52-0-73)	<0.0005	0-46 (0-37-0-57)	<0.0005
Late neonatal mortality rate (7–28 days)	0-92 (0-67-1-26)	0.476	0-89 (0-65-1-22)	0.463	0.84 (0.64-1.12)	0.236	0.80 (0.56-1.14)	0.217
Stillbirth rate per 1000 births	1-02 (0-85-1-23)	0.833	1.04 (0.85-1.25)	0.773	1-05 (0-86-1-28)	0-656	1-01 (0-80-1-28)	0-914
Perinatal mortality rate per 1000 births	0-79 (0-70-0-90)	<0.0005	0-79 (0-69-0-90)	<0.0005	0.79 (0.69-0.91)	<0.0005	0.68 (0.58-0.79)	<0.0005
Maternal mortality ratio per 100 000 livebirths	0-80 (0-51-1-24)	0.180	0.80 (0.51-1.24)	0.180	0-70 (0-46-1-07)	0.104	0.50 (0.48-1.49)	0.563

Data are odds ratio (95% CI). *Adjusted for stratification (by district and pre-existing women's groups) and clustering only. †Adjusted for stratification, clustering, maternal education, assets, and any tribal affiliation. ‡p values adjusted for multiple hypothesis testing with Holm correction were <0.001.

Table 3: Comparison of mortality rates in intervention and control clusters

Data are unadjusted. *Excluding migrated mothers and infants. †Including migrated mothers and infants.

Table 2: Births and deaths in intervention and control clusters at baseline and during trial

year 3—the NMRs fell below their baseline level in most intervention clusters. Between 2005 and 2008, perinatal mortality rates in the intervention clusters decreased compared with those in the control clusters when adjusted for clustering (table 2; table 3). Stillbirth rates did not differ between intervention and control clusters (table 2). Maternal mortality ratio was generally lower in intervention than in control clusters, but the study was not powered to detect significant differences (table 3). Qualitative evidence from the assessment of the trial's process showed that community mobilisation through

women's groups might have contributed to avoidance of some maternal deaths (panel 2).

There was no detectable difference in maternal depression K10 scores, when measured about 6 weeks after delivery, between intervention and control clusters in year 2 of the study or overall (table 4). However, in year 3, when 55% of all pregnant women in the intervention clusters had joined a group, a 57% reduction was noted in moderate depression among mothers in the intervention clusters compared with control clusters (table 4).

No significant differences were noted in health-care-seeking behaviour between control and intervention clusters (table 5). However, home-care practices showed substantial improvements—in intervention clusters, birth attendants were more likely to wash their hands, use a safe delivery kit and a plastic sheet, and boil the thread used to tie the cord than were those in the control clusters. The proportion of infants exclusively breastfed at 6 weeks was higher in intervention areas in adjusted analyses for years 2 and 3.

Cause-specific differences in mortality rate as a percentage of all causes—septicaemia, birth asphyxia, hypothermia, and prematurity—during the 3 years were not clearly discernable because there was a reduction in all causes (table 6). The incremental cost of the women's group intervention was US\$910 per newborn life saved, increasing to \$1308 (in 2007 prices) when health-service strengthening activities were included. The incremental cost per life-year saved was \$33 for the women's group intervention (\$48 inclusive of health-service strengthening activities). The women's group intervention in this setting was therefore more cost effective than that reported in Nepal's as a result of the greater effect of women's groups on NMR combined with lower operating costs in the current context.

Discussion

Women's groups led by peer facilitators reduced NMR and moderate maternal depression at low cost in largely tribal, rural populations of eastern India. Our data show that mortality reduction in underserved rural settings was not associated with increased care-seeking behaviour or health-service use. The most likely mechanism of mortality reduction was through improved hygiene and care practices. The availability of safe delivery kits increased in both control and intervention areas, but women's groups seemed to generate more demand in intervention clusters than in control clusters. In places where kits were not provided, group members made them and provided information about their contents to mothers, then visited pregnant women during the eighth month of pregnancy to ensure that they had received kits and would use them. Birth outcomes might have been affected by the fact that these community members attended the groups or were advised by group members, thus generating increased social awareness and support for clean delivery practices.

The most striking reduction in mortality rate was noted in early neonatal deaths, which might be explained by the strong focus on intrapartum and early neonatal periods in several case studies and stories discussed during the cycle. Attribution of cause of newborn death on the basis of verbal autopsy is an imperfect science, and deaths might arise from several and overlapping causes. Early septicaemia could have been reduced with clean delivery practices, and premature babies might have survived

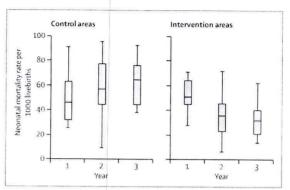


Figure 7: Boxplot of cluster-level neonatal mortality rates by allocation and study year

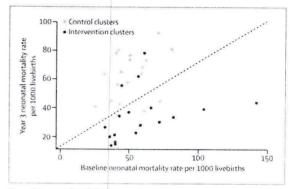


Figure 8: Scatterplot of cluster-specific neonatal mortality rates in year 3 with rates at baseline

Panel 2: Case-study effect of women's groups on strategies to avoid maternal deaths

A woman in the eighth month of her pregnancy, and her mother-in-law attended a monthly women's group meeting where they participated in a drill based on what to do in the event of post-partum bleeding. After a month, when the woman delivered at home and had severe bleeding, her mother-in-law remembered what had been said in the group, and, without wasting time, asked her daughter-in-law to breastfeed the baby while she rushed to get money from the group and asked her son to arrange for a vehicle. The daughter-in-law was immediately taken to the district hospital, where she was given medicines, intravenous fluid, and two pints of blood, and was discharged after 15 days.

with improved care. The reason for this combined reduction of asphyxia, prematurity, and septicaemia could also be improved intrapartum care. Potential mechanisms for reduction of mortality rate will be further assessed in future analyses of verbal autopsies and seasonal mortality trends.

Our findings also show that a low-cost intervention involving non-health-care workers might affect maternal

	Year 2			Year 3			Years 2 and 3		
	Intervention	Control	Adjusted odds ratio (95% CI)*	Intervention	Control	Adjusted odds ratio (95% CI)*	Intervention	Control	Adjusted odds ratio (95% CI)*
Mothers (n)	3332	3016		3120	2963	y ax	6452	5979	20V
No or mild depression (10-15)	2922 (88%)	2612 (87%)	0.91 (0.41-2.01)	2962 (95%)	2665 (90%)	2-33 (1-25-4-38)	5884 (91%)	5277 (88%)	1-29 (0-68-2-44)
Moderate depression (16-30)	383 (11%)	382 (13%)	1.04 (0.50-2.16)	154 (5%)	293 (10%)	0.43 (0.23-0.80)	536 (8%)	676 (11%)	0.74 (0.40-1.37)
Severe depression (31-50)	28 (<1%)	21 (<1%)	1.53 (0.47-5.05)	4 (<1%)	5 (<1%)	0.70 (0.15-3.31)	32 (<1%)	26 (<1%)	1-29 (0-46-3-64)

Data are number (%), unless otherwise indicated. "Results adjusted for clustering, stratification, maternal education, tribe affiliation, and household assets by use of generalised estimated equations with semirobust SFs for individual-level data.

Table 4: Kessler-10 depression scores in mothers in intervention and control clusters

	Intervention clusters	Control clusters	Odds ratio (95% CI) for years 1-3*	Odds ratio (95% CI) for years 1-3†	Odds ratio (95% CI) for years 2 and 3†
Births‡	9468	8867	(1)	8	a,
Any antenatal care	6990 (74%)	6623 (75%)	0.97 (0.48-1.97)	1.60 (0.65-3.92)	1-86 (0-80-4-34)
≥3 antenatal care visits	3001 (32%)	3621 (41%)	0.63 (0.37-1.06)	0.69 (0.37-1.26)	0.68 (0.37-1.24)
Iron tablets	6997 (74%)	6293 (71%)	1.12 (0.71-1.76)	1-31 (0-62-2-75)	1-34 (0-77-2-35)
Maternal tetanus-toxoid injection	7767 (82%)	7377 (83%)	0.90 (0.51-1.54)	1-39 (0-85-2-28)	1-40 (0-85-2-29)
Illness in pregnancy	5206 (55%)	4983 (56%)	1.03 (0.68-1.58)	1.10 (0.71-1.72)	1.01 (0.67-1.52)
Visited health facility in case of illness during pregnancy	945 (10%)	922 (10%)	0-78 (0-39-1-56)	0-86 (0-46-1-60)	0-80 (0-39-1-65)
Institutional deliveries	1364 (14%)	1811 (20%)	0.64 (0.39-1.04)	0.89 (0.51-1.53)	0.94 (0.50-1.76)
Birth attended by formal provider (doctor or nurse)	1490 (16%)	2067 (23%)	0-59 (0-37-1-94)	0.81 (0.50-1.31)	0.82 (0.47-1.43)
Home deliveries	8084	7034		9	
Birth attended by traditional birth attendant	2692 (33%)	2676 (38%)	0.82 (0.43-1.60)	0.84 (0.43-1.64)	0.85 (0.44-1.65)
Birth attendant washed hands with soap	3291 (41%)	1583 (23%)	2.05 (1.14-3.73)	2-07 (1-24-3-45)	2-50 (1-35-4-62)
Safe-delivery kit used	2594 (32%)	1284 (18%)	2.08 (1.25-3.44)	1-87 (1-11-3-14)	2-28 (1-27-4-09)
Plastic sheet used	2088 (26%)	560 (8%)	3-85 (2-51-5-89)	3-74 (2-48-5-65)	2-98 (1-84-4-81)
Cord tied with boiled thread	2559 (32%)	786 (11%)	3-9 (1-82-6-30)	3.02 (1.61-5.65)	4-33 (2-06-9-11)
Cord cut with new or boiled blade	6679 (83%)	5570 (79%)	1-24 (0-82-1-87)	1-35 (0-86-2-12)	1.55 (0.96-2.51)
Livebirths (home deliveries)	7890	6873	and	· ·	n .
Cord undressed or dressed with antiseptic	6600 (84%)	6115 (89%)	0.52 (0.24-1.12)	0.58 (0.27-1.26)	1.01 (0.39-2.62)
Infant wiped within 30 min	4741 (60%)	4227 (62%)	0-90 (0-38-2-14)	1.01 (0.43-2.36)	1.06 (0.44-2.57)
Infant wrapped within 30 min	2846 (36%)	2980 (43%)	0.74 (0.35-1.59)	0.78 (0.36-1.66)	0.81 (0.37-1.80)
Infant not bathed in first 24 h	2107 (27%)	1509 (22%)	1.06 (0.52-2.17)	0.95 (0.44-2.10)	1-22 (0-56-2-65)
Infants alive at 1 month	8807	8119			
Any of three infant illnesses (cough, fever, diarrhoea)	1739 (20%)	2388 (29%)	0-62 (0-37-1-03)	0-67 (0-40-1-12)	0-61 (0-35-1-06)
Care-seeking behaviour in event of infant illness	940 (54%)§	1050 (44%)§	1-53 (0-77-3-05)	0.88 (0.97-3.61)	1-55 (0-79-3-04)
Infant put to breast within 4 h	5390 (61%)	4942 (61%)	1-01 (0-48-2-14)	0.90 (0.38-3.11)	1.11 (0.45-2.76)
Exclusive breastfeeding for first 6 weeks	7022 (80%)	5611 (69%)	1-82 (1-14-2-92)	1.44 (0.89-2.35)	1.74 (1.03-2.94)

Data are number (%), unless otherwise indicated. *Adjusted for clustering and stratification only. †Adjusted for clustering, stratification, maternal education, assets, and any tribal affiliation. †Excludes births to migrated mothers and twins. 5Denominators are number of infants with any of three infant illnesses: 1739 for intervention clusters and 2388 for control clusters.

Table 5: Process indicators in intervention and control clusters

mental health. We hypothesise that the large reduction in moderate depression seen in the third year could have occurred through improvements in social support and problem-solving skills of the groups. Adequate social support reduces the risk of depression during pregnancy and is an important social determinant of mental health.²⁵ In meetings, information was shared

about the difficulties encountered by mothers in the community, and practical ways to collectively address them were established. Group meetings also strengthened problem-solving skills, a component of psychotherapeutic interventions that has been shown to affect depression in other settings. The intervention seemed to have no effect on severe depression, perhaps

because it was more similar to primary prevention rather than treatment, or because severe depression is less amenable to psychotherapeutic interventions. A complete analysis and discussion of these findings will be presented in the future.

Two potential effect modifiers in this trial, on the basis of evidence, were differences in maternal education, and tribal membership and assets between the intervention and control populations. These were taken into account in adjusted analyses and mainly provided an advantage for the control areas. Additionally, the high significance of some of our results could be a result of an increase in mortality rate in the control areas between 2005–08. The control and intervention clusters were in similar geographic areas, so factors that affected NMR should have affected both groups equally, but further investigation is needed.

We believe that the study had two main weaknesses. First, as in several other community-based randomised control trials, the intervention and surveillance teams were not unaware of allocation. However, there were no incentives or disincentives for over-reporting or underreporting births and deaths, and several process mechanisms were in place to detect errors. Second, although migration out of districts was common, we cannot rule out some intercluster migration when women married out of their home cluster. Our intention-to-reat analysis might have affected the results positively or negatively.

In the Shivgarh study,22 in Uttar Pradesh, India, the effect of an intensive behaviour-change programme involving community meetings and home visits by a new cadre of paid, non-governmental community workers in a population of 104123 during 15 months resulted in a 54% reduction (relative risk 0.46, 95% CI 0.35-0.60) in NMR with changes in home-care practices, but no real change in care-seeking behaviour. No overall differences in NMR were noted during 30 months of intervention in the Projahnmo trial,28 in Bangladesh, but a 34% reduction (0.66, 0.47-0.93) was noted in the home-care group in the last 6 months of the programme. The investigators of the Projahnmo study²⁸ noted that "Availability of referral services and a strong supervisory system were crucial to this intervention and would be a necessary feature of scaling up the intervention."

Interventions with health-worker home visits have rarely achieved adequate coverage, quality, or effectiveness when taken to scale in poor populations. Participatory groups have the advantage of helping the poorest, being scalable at low cost, and producing potentially wideranging and long-lasting effects. By addressing critical consciousness, groups have the potential to create improved capability in communities to deal with the health and development difficulties arising from poverty and social inequalities. The intervention requires a training and support structure to manage facilitators in charge of 12–14 groups per month, with every group

	Intervention		Control		
	Years 1-3	Years 2 and 3	Year 1-3	Years 2 and 3	
Early neonatal deaths	253	140	367	264	
Birth asphyxia	92 (36%)	53 (38%)	142 (39%)	104 (39%)	
Prematurity	85 (34%)	46 (33%)	110 (30%)	77 (29%)	
Septicaemia	38 (15%)	15 (11%)	47 (13%)	29 (11%)	
Hypothermia	16 (6%)	12 (9%)	26 (7%)	22 (8%)	
Other	22 (9%)	14 (10%)	42 (11%)	32 (12%)	
Data are number or number (%).				

responsible for a population of about 500 and for recruiting up to half of newly pregnant women. Costs are lower than for most other primary health-care interventions, and these interventions can complement existing self-help groups in the community.

Two other issues arising from our study are cost effectiveness and the effect on maternal mortality ratios. The interventions in the Ekjut trial were more cost effective than those in the Makwanpur study' because of lower operating costs and greater effect of the intervention. In the Nepal trial, effect of women's groups on maternal mortality ratios was significant, although the number of deaths was small and maternal mortality ratio was not a stated primary outcome. In our trial the maternal mortality ratio was higher in the intervention areas at baseline, and 20% lower after 3 years of intervention, but this difference was not significant and the trial was not powered to measure differences in maternal mortality. Reduction in maternal mortality will depend mainly on improved access to health services and to life-saving drugs, but community mobilisation could help through improvement in hygiene at delivery and early care-seeking behaviour for complications by addressing the first-delay component.

This participatory intervention with women's groups could complement or be a potential alternative to healthworker led interventions, two examples of which have been discussed here. Our findings raise several important issues for policy makers in India. Could federal and state governments invest in this programme? Should government or non-government organisations be responsible for its scale-up? Could such a participatory intervention support and strengthen the National Rural Health Mission's mandate of communitisation of health and the Accredited Social Health Activist programme?12 Further assessments of this approach will involve a scale-up in large populations with little access to health services, and different delivery mechanisms of the intervention will need to be tested in partnership with government and non-government organisations.

Contributors

All authors contributed to the design of the study and criticised drafts of the report. PT, NN, SB. and AC were responsible for the conception and overall supervision of the trial. PT and NN managed the project, data gathering, data entry, and administration with assistance from ShR. SuR, RM, RG, and DM. SB and AC were technical advisers for the study. IB provided technical assistance with gathering and analysis of cost data. AC, PT, and SB helped design the original trial protocol. SB designed the methods for data gathering and epidemiological surveillance system. VP and RL provided technical advice about the K10 scale and commented on drafts of the report. RL trained interviewers to administer the K10 scale. NN, AP, CP, and SB did the quantitative analysis. AC, AP, PT, NN, and SB wrote the first draft of the report, and were responsible for subsequent collation of inputs and redrafting. PT and AC are guarantors for the report.

Conflicts of interest

We declare that we have no conflicts of interest.

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Alma-Ata: Rebirth and Revision 5

Community participation: lessons for maternal, newborn, and child health

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rebirth and revision

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Primary health care was ratified as the health policy of WHO member states in 1978.¹ Participation in health care was a key principle in the Alma-Ata Declaration. In developing countries, antenatal, delivery, and postnatal experiences for women usually take place in communities rather than health facilities. Strategies to improve maternal and child health should therefore involve the community as a complement to any facility-based component. The fourth article of the Declaration stated that, "people have the right and duty to participate individually and collectively in the planning and implementation of their health care", and the seventh article stated that primary health care "requires and promotes maximum community and individual self-reliance and participation in the planning, organization, operation and control of primary health care". But is community participation an essential prerequisite for better health outcomes or simply a useful but non-essential companion to the delivery of treatments and preventive health education? Might it be essential only as a transitional strategy: crucial for the poorest and most deprived populations but largely irrelevant once health care systems are established? Or is the failure to incorporate community participation into large-scale primary health care programmes a major reason for why we are failing to achieve Millennium Development Goals (MDGs) 4 and 5 for reduction of maternal and child mortality?

Introduction

Soon after the Alma-Ata Declaration, arguments for selective rather than comprehensive primary health care dominated health system debates.² Policy makers in favour of selective primary health care argued that community interventions such as oral rehydration solution, immunisation, or vitamin A capsules could be targeted effectively at poor, albeit passive, recipients with immediate benefit. They recognised that community participation was important in supporting the provision of local health services and in delivering such interventions at scale, but believed that pilot programmes showing long-term benefits from more comprehensive community mobilisation had been much less successful when governments tried to take them to scale.

More recently the lack of progress with the Millennium Development Goals (MDG) and primary health care in many poor countries has encouraged those in favour of comprehensive primary health care to question whether the failure to address community care and participation effectively within health programmes is a major reason for poor sustainability and ineffective scaling-up of selective interventions of proven efficacy. The review of the WHO Integrated Management of Childhood Illness strategy reinforced these questions: "Delivery systems that rely solely on government health facilities must be expanded to include the full range of potential channels in a setting and strong community-based approaches. The focus on process within child health programmes must change to include greater accountability for intervention coverage at population level."3

A crucial policy question is whether specific community participation interventions aimed at women and their families have a direct effect on maternal and child health? If so, how do these interventions work most effectively, and how can they be taken to scale?

What are participation, mobilisation, and empowerment?

The closely related concepts of participation, mobilisation, and empowerment require definition. Participation has been used to indicate active or passive community involvement. In the past, mobilisation consisted of communities responding to directions given by professionals to improve their health. This process usually took the form of mass campaigns for immunisations where communities were passively involved as the setting where the interventions were implemented or the target of the specific intervention. More recently, health and development workers have begun to act as facilitators focusing on the process of health improvements as well as the outcomes. In this approach the facilitators support local communities to become actively involved—to participate—in both activities and decisions that affect their own health, either as a resource that can provide assets to address a health problem or an agent of change that uses its own supportive and developmental capacities to address its needs. In this paper we will discuss this more recent form of community mobilisation, which we define as "a capacity-building process through which community individuals, groups, or organizations plan, carry out, and evaluate activities on a participatory and sustained basis to improve their health and other needs, either on their own initiative or stimulated by others".4

Health programmes today often identify empowerment rather than participation as an objective. Empowerment can be defined as the process and outcome of those without power gaining information, skills, and confidence and thus control over decisions about their own lives, and can take place on an individual, organisational, and community level. Community mobilisation, by our definition, is a way to support this empowerment process and reach this empowerment outcome (figure 1).

What evidence led to Alma-Ata?

The Alma-Ata Declaration arose from evidence generated by the Joint WHO/UNICEF Study of Alternative Approaches to Meeting Basic Health Needs of Populations in Developing Countries under the leadership of Halfdan Mahler (Assistant Director-General at WHO, 1970-73) and Kenneth Newell (Director of Research in Epidemiology and Communications Science at WHO, 1962-72), who were influenced by the work of the Christian Medical Commission in Geneva and its growing commitment to community-oriented primary health care as the most appropriate approach to addressing the health needs of poor people.67.8 This evidence revealed the successes of national health programmes in China, Cuba, Sri Lanka, Tanzania, and Venezuela as well as in subnational programmes in Guatemala, India, Indonesia, Iran, Kenya, and Niger, which all used community participation as a fundamental component of primary health care.

The Jamkhed Project in the state of Maharastra in India and the Kakamega Project in Western Kenya are examples of successful smaller-scale subnational pilot programmes where community mobilisation was a key intervention (panel 1). 10,111 Communities were assisted to identify their own problems, collect their own data, and implement their own solutions. These demonstration projects provided clear evidence of a dramatic effect on health but could not be easily replicated by governments on a larger scale. Once part of a national programme, bureaucratic rules and top-down directives changed the nature of community participation and heavy donor support emphasised performance targets rather than the unhurried process necessary for engagement with communities. Miriam Were, director of Kakamega, lamented that "officials and international experts could not understand that successes had arisen from the process, not from the setting of performance targets, and that the forward momentum had been generated from within the community and not from external financing"."

The failure to scale-up Jamkhed, Kakamega, and other similar projects through national governments contributed to a move away from participatory approaches to primary health care. Since 1990 the focus of child survival efforts has been on increasing the coverage of health commodities with proven effectiveness—such as oral rehydration solution for diarrhoea, 12,13,14 cotrimoxazole for childhood pneumonia, 15,16 vitamin A supplementation, 17,18 insecticide-treated bednets, 19,20 and vaccinations. 21 At the



Figure 1: From passive to active community participation

same time, maternal survival efforts also moved away from community approaches focusing on traditional birth attendants, which lacked clear evidence of effectiveness, to efforts entirely focused on strengthening district hospital midwifery and obstetric care services and health systems.^{22,23}

These approaches to the diseases of poverty proved more saleable to policy makers for two main reasons. Firstly, the clear-cut and rapid public health gains shown by these approaches fitted well within the new culture of evidence-based medicine. Secondly, the scalability of distribution of these approaches seemed intrinsically easier and less expensive than more long-term comprehensive primary health care approaches involving community mobilisation despite strong evidence supporting their effectiveness and affordability.²⁴

What is the effect of community mobilisation on maternal, newborn, and child health?

Progress towards MDGs 4 and 5 in the poorest countries has remained slow in high-mortality settings. 25,26 Between 1990 and 2005 there was no substantial change in maternal mortality in sub-Saharan Africa, and of the 68 priority countries targeted for child survival improvements, 41% were deemed to have made insufficient progress and 38% made no progress. 26 Additionally, in 11 African countries there were reversals in under-5 mortality rates in the same period. 26 The evident ineffectiveness of existing programmes and conclusion that this may in part be due to the lack of community involvement has led to a renewed focus on community mobilisation strategies for maternal, newborn, and child survival. 3

Most studies of community mobilisation interventions have investigated the effectiveness of specific interventions targeted at a passive recipient community the old style of community mobilisation (for example, breastfeeding promotion, diarrhoea prevention and treatment, growth promotion, 27.28,29,30 promotion of complementary feeding after 6 months of age,31 treatment of severe acute malnutrition³² and pneumonia prevention and treatment 33,14,35). Far fewer studies have investigated effectiveness of community mobilisation interventions, either on their own or in combined packages with other interventions, where the community provides the resources and is the active agent of change (table). In Ethiopia a cluster randomised controlled trial (cRCT) showed that mobilising women's groups to effectively recognise and treat malaria at home led to a

Panel 1: Projects in rural India and Kenya which influenced Alma-Ata

Jamkhed Project (1970 to date)

In 1970, Raj and Mabelle Arole, two doctors, started a primary health care programme in Jamkhed, a rural area in Maharashtra state in India. 9.10 The project used a participatory approach to bring villages together and establish farmers clubs. These clubs identified problems facing the community and chose to focus on improvements to water supplies and sanitation. As the clubs evolved they became women's development organisations and implemented solutions such as: identifying women to be trained as health workers; funds for women with a household health emergency or food crisis; keep village clean drives; literacy programmes; advocacy for encounters with bureaucracy; and micro-credit schemes. The programme expanded to other villages, eventually covering a population of more than 250 000. Over the first 20 years (1972-1992) the project showed a reduction in infant mortality rate from 176 to 19 per 1000, and a birth rate decline from 40 to 20 per 1000.10 Additionally, rates of antenatal care, safe delivery, and immunisation are nearly universal and rates of malnutrition have declined from 40% to less than 5%.10 In parallel, the women's groups have developed a greater sense of their potential for agency, and caste barriers among women have gradually diminished.

Kakamega Project (1974 to 1982)

The Kakamega project led by Miriam Were was established in western Kenya in 1974.11 Women in communities were supported to identify their own problems, collect their own data and select their own community health workers with open community involvement. Among other things communities set up village funds and bank accounts and established transport schemes enabling access to secondary care. The project achieved improvements in primary care, immunisation, water supplies, family planning, and malaria control. It also increased community support and self-reliance. As the women became empowered the visits from outside facilitators became less frequent.

40% reduction in under-5 mortality. The reduction in under-5 mortality of a complex home-based newborn care package (which included community delivery of injectable antibiotics, health promotion, training of traditional birth attendants, and physician visits) within a programme where communities had been mobilised over an extended period. Bang and colleagues ascribe 36% of the reduction in neonatal mortality rate to sepsis management; assessing the contribution of community mobilisation within the intervention compared with control villages is more difficult, although important.

In Makwanpur district, Nepal, women's groups, led by a locally recruited woman facilitator, were supported through a community mobilisation action cycle where they discussed maternal and newborn health problems, developed strategies to address them, and then implemented and assessed the strategies in co-operation with local leaders, men, and health workers. ³⁹ The mobilisation intervention had been developed in Bolivia under the Warmi programme ^{40,41} (figure 2). The Warmi programme had seen a large reduction in perinatal mortality rate using before and after analysis of a small population, and the larger Makwanpur cRCT showed a 30% reduction in neonatal mortality rate, as well as significantly fewer maternal deaths (although the numbers of maternal deaths were few and maternal mortality ratio had not been a primary outcome for the trial). ³⁹

Two more recently published studies are the Hala and Projahnmo community effectiveness trials in Pakistan and Bangladesh, which combine demand and supplyside interventions, with different results. 42.43 The Hala trial was a pilot non-randomised controlled trial in which Lady Health Workers (government health workers responsible for about 200 families each) received training in home-based neonatal care and local traditional midwives (dais) received voluntary training. In addition, village health committees were established for maternal and newborn health. Compared with baseline rates the trial showed a 35% decline in perinatal mortality rate and a 28% decline in the neonatal mortality rate in the intervention villages. The control villages showed no decline. 42 The Projahnmo cRCT assessed the effectiveness of specially trained community health workers, who provided a home-care package including assessment of newborn infants on the first, third, and seventh days after birth, and referral or treatment of sick neonates. The study showed a 34% reduction in neonatal mortality rate in the final 6 months of the trial compared with the comparison group.43 However, unlike the studies outlined above, the third community care arm, in which community mobilisers held community meetings with women in villages, showed no effect on neonatal mortality compared with the control arm.43

What are the current controversies surrounding community mobilisation interventions?

Community mobilisation versus home care visits

Although increasing evidence favours the effectiveness of community mobilisation interventions, a comparison of the Makwanpur and Projahnmo trials is central to this policy dilemma. The Makwanpur trial suggests that community mobilisation through women's groups is a cost-effective approach to reduce neonatal mortality rate in remote villages where developing and maintaining a programme of home visits by outreach workers has been impossible. Projahnmo, by contrast, suggests that community mobilisation is less effective than a homecare strategy in reducing neonatal mortality rate in communities with a weak health system and low healthcare use. Several other trials testing different combinations of interventions, with mobilisation as a core

	Authors	Design	Type of interventions	Primary outcomes	Sample	Results	Comment
SOUTH STREET,	OʻRourke ^s 1998	Before and after analysis	Women's groups using community action cycle. Intervention focused on initiating and strengthening women's organisations, developing women's skills in problem identification and prioritisation, and training community members in safe birthing techniques	Newborn mortality rate; perinatal mortality rate	Remote Bolivian mountain villages, around 15 000 population.	Evaluated by comparing perinatal mortality rate and obstetric behaviour among 409 women before and after the intervention. Perinatal mortality rate decreased from 117 deaths per 1000 births before the intervention to 43-8 deaths per 1000 births after. The proportion of women receiving prenatal care and initiating breast-feeding on the first day after birth was also significantly larger. Number of infants attended to immediately after delivery increased, but the change was not statistically significant	
iadchiroli	Bang ¹²⁻¹⁸ 1999 and 2005	Controlled trial (not randomised) Baseline phase (1993–1995), observational phase (1995–1996), and the 7 years of intervention (1996–2003)	Home-based newborn care consisting of sepsis management, supportive care of low birthweight newborn babies, asphyxia management, primary prevention, health education and training of traditional birth attendants. Built upon a preexisting community mobilisation programme	Still birth rate; newborn mortality rate; perinatal mortality rate; newborn mortality rate; infant mortality rate	The baseline population was 39 312 in 39 intervention villages and 42 617 in 47 control villages. Livebirths in 10 years were 8811 in intervention villiages and 9990 in control villages	Newborn mortality rate in the control area showed an increase from 58 in 1993–1995 to 64 in 2001–2003. The rate fell by 70% (95% CI 59–81%) compared with the control area. Early newborn mortality rate decreased by 64% and late newborn mortality rate by 80%. Still birth rate decreased 49% and the perinatal mortality rate by 56%. Newborn mortality rate did not change, and the infant mortality rate decreased by 57%, (95% CI 46–68%). Cause-specific newborn mortality rate (1995–1996 vs 2001–2003) for sepsis decreased by 90%, for asphyxia by 53%, and for prematurity by 38%	Total reduction in newborn mortality rat during intervention (1996–2003) was ascribed to sepsis management (36%); supportive care of low birthweight newborn babies (34%); asphyxic management (19%); primary prevention (7%), and management of other illnesses or unexplained (4%). The contribution of community mobilisati in the intervention are is difficult to estimate
2000	Kidane ^{y6} 2000	Cluster randomised controlled trial (cRCT)	Mother coordinators trained to teach other local mothers to recognise symptoms of malaria in their children and to promptly give chloroquine	Under-5 mortality rate	Total population of 70 506 in 37 tabias (cluster of villages) in two district were paired according to under-5 mortality rates. 24 tabias with the highest malaria morbidity were	190 of 6383 (29-8 per 1000) children younger than 5 years died in the intervention tabias compared with 366 of 7294 (50-2 per 1000 children) in the control tabias. Under-5 mortality was reduced by 40% in the intervention localities (95% CI 29-2–50-6; paired t test, p<0.003). Of 190 verbal autopsies, 13 (19%) of 70 in the intervention tabias were consistent with possible malaria compared with 68 (57%) of 120 in the control tabias.	
AIRA Aakwanpur listict, Nepal	Manandhar ¹⁹ 2004	cRCT	Women's groups through community action cycle	Newborn mortality rate	selected 24 clusters of mean 7000 people per cluster	Newborn mortality rate was 26-2 per 1000 (76 deaths per 2899 livebirths) in intervention clusters compared with 36-9 per 1000 (119 deaths per 3226 livebirths) in controls (adjusted odds ratio 0-70 [95% CI 0-53–0-94]). Stillbirth rates were similar in both groups. Maternal mortality ratio was 69 per 100 000 (two deaths per 2899 livebirths) in intervention clusters compared with 341 per 100 000 (11 deaths per 3226 livebirths) in control clusters (0-22 [0-05–0-90]).	
HAMPION rial, Aahabubnagar istrict, Andhra radesh, India	Boone 2007	cRCT	Health promotion intervention includes a health education campaign, participatory discussion groups, training of village health workers and midwives, and improved coordination of	Newborn mortality rate	464 villages	Ongoing	Final data analysis due 2010
			antenatal services. The intervention group will also have subsidised access to pregnancy-related health care services at non-public health centres				

	Authors	Design	Type of interventions	Primary outcomes	Jample	Results	Comment
(Continued from	m previous page	2)					
Projahnmo Project, Shylet district, Bangladesh	Baqui*1 2008	cRCT	Female community workers doing home care visits (1 per 4000) and community mobilisers running health education groups every 4 months vs control comparison areas	Newborn mortality rate	24 clusters of 20 000 per cluster in. 14769 livebirths in the home-care groups, 16325 in the community- care groups, and 15350 in the comparison groups	Newborn mortality rate was reduced in the home-care arm by 34% (adjusted relative risk 0.66; 95% CI 0.47–0.93) during the last 6 months of the trial vs that in the comparison arm. No mortality reduction was noted in the community-care arm (0.95; 0.69–1.31).	The community care arm involved fairly infrequent contact with community groups (once every 4 months) and provided health education rather than community mobilisation
Hala, Pakistan	Bhutta ⁴² 2008	Before and after analysis	Lady Health Workers and traditional birth attendants providing health education and maternal and child health services	Still birth rate; newborn mortality rate; health service use	315 villages with a total population of 138 600	Still birth rate reduced from 66 to 43 per 1000 and newborn mortality rate 57 to 41 per 10000 before and after in intervention sites. Skilled birth attendance from 18 to 30%	Preliminary results to be confirmed in an adequately powered tria
SNEHA Project, Mumbai, India	More 2008	cRCT	Women's groups through community action cycle	Newborn mortality rate; maternal and newborn morbidity; care practices and health care use	48 urban slum clusters of 1000–1500 households each. 24 clusters randomly allocated to receive the community intervention. 24 clusters will act as control groups, but will benefit from health service quality improvement	Ongoing	Final data analysis due in 2010
MaiMwana Project, Mchinji district, Malawi	Unpublished	cRCT	Womens groups through community action cycle and volunteer infant care and feeding counsellors	Newborn mortality rate; still birth rate; perinatal mortality rate; maternal mortality ratio	48 clusters (3000 people per cluster)	Ongoing	Final data analysis of 20 000 births due in November 2008
Perinatal Care Project DAB, Bangladesh	Unpublished	cRCT	Womens groups through community action cycle and management of birth asphyxia in the home using traditional birth attendants trained in bag and mask resuscitation	Newborn mortality rate; still birth rate; perinatal mortality rate; maternal mortality ratio	18 union clusters in 3 districts (25000 people per cluster)	Ongoing	Final data analysis of 32 000 births due in November 2008
Ekjut, Jharkhand and Orissa, India	Unpublished	cRCT	Women's groups through community action cycle	Newborn mortality rate; still birth rate; perinatal mortality rate; maternal mortality ratio	36 clusters across 3 districts. 7000 people per cluster	Ongoing	Final data analysis of 20 000 births due in December 2008
MIRA, Dhanusha district, Nepal	Unpublished	cRCT	Womens groups through community action cycle and newborn sepsis management in the home using female community health volunteers	Newborn mortality rate; still birth rate; perinatal mortality rate; maternal mortality ratio; nutrition indicators	60 clusters, 7000 people per cluster	Ongoing	Final data analysis due in 2009
fakara, Tanzania	Unpublished	cRCT	Community-based package focussed around interpersonal communication through home visits in pregnancy and the early neonatal period by a village-based "agent of change" linked to existing village health volunteers.	Newborn mortality rate	24 divisions in 5 districts	Ongoing	Data analysis due in 201

component, are currently in progress (table). The interpretation of the findings of these trials must be considered carefully to guide policy makers. For example, the community mobilisation component of Projahnmo was less intensive than in Makwanpur. Thus, an important question to ask of these trials might be, what is the necessary level of intensity and coverage of community mobilisation and home-care interventions, to produce the most cost-effective effect? Other important questions include which are the most effective models of these interventions, can they be scaled up in the poorest communities, and what are the institutional and financial barriers to scale-up?

Community health workers

The use of so-called barefoot doctors in China inspired primary health care. This model involved local community residents—community health workers—liberating communities by providing first line health care and facilitating others to embrace changes brought about by the new government.45 This model was adopted by many governments and non-governmental organisations after the Alma-Ata Declaration and in many cases became the definition of primary health care. However, by the 1990s many government programmes for community health workers had vanished because of problems in integrating them into national programmes. 4 People also questioned whether community health workers actually empowered or oppressed as a result of the existing, socioeconomic political structures, bureaucracies, and lack of support from health professionals.47

Recently, community health workers have generated renewed interest, in part because they are seen as a cheap way of scaling up primary health care, and also because HIV/AIDS programmes demand more care at community level. The pandemic has claimed the lives of many health workers especially in Africa. The current interest lies mainly in community health workers as care providers but this can be problematic as large-scale government training programmes often lack standards, supervision, and resources. Furthermore, the evidence suggests that community health workers are most effective when they also facilitate change at the community level48,49 and participatory approaches promoted by the online journal Participatory Learning and Action have provided structures and frameworks that support this role.5 Overall, community health workers are most successful when they have the respect and support of governments, public service workers, and the communities they serve.

Does community mobilisation empower people to address socioenvironmental causes of ill-health?

Health, particularly in marginalised groups, is indirectly but powerfully affected by the social environment in which personal behaviours are embedded. Risk factors (such as isolation, lack of social support, low self-esteem) and risk conditions (such as poverty, discrimination,

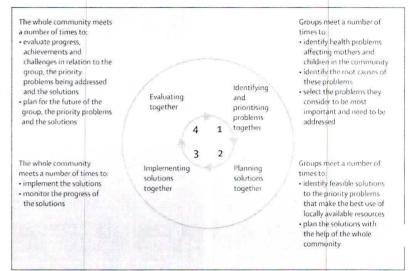


Figure 2: Women's groups community mobilisation action cycle
The Warmi project in Bolivia developed a model for community mobilisation using this community action cycle.**
Women's groups discuss and prioritise their problems, develop strategies to solve them, and, after engaging with
other community members, implement and evaluate these solutions. The completed Makwanpur (Nepal) trial and
ongoing trials in Mumbai (India), Jharkhand and Orissa (India), Mchinji (Malawi), Dhanusha (Nepal), and
Bangladesh are assessing the effect of different women's group models, developed from this model, on mother

steep power hierarchies) can impair control or capacity and the respectful relationships that enable good maternal and child health. 50.51 Community mobilisation initiatives reported to improve the socioenvironmental causes of ill health have addressed a range of concerns including alcohol related violence, breast cancer treatment, and safety in public environments. 59,60,61 The impetus to address these causes of ill-health began when there was sufficient support to form a community of interest. This community started a process of capacity building-community empowerment-toward gaining more control over the decisions for resource allocation such as the award of a grant or to decision making such as the development of policy or legislation (panel 2). The key to the success of community empowerment was the moment when the community engaged with the problemposing, problem-solving process and recognised that they could collectively change their circumstances. However, effect can vary greatly depending on decisions about the goal, who constitutes the community, who is facilitating and supporting the process, the social and political context, the duration of external or donor support, and the cost-effectiveness of the programme.62 Different forms of community mobilisation might simply mobilise communities to initiate localised actions based on their immediate needs rather than broader social and political actions

and child health (table).

What is not known is to what extent peoples' involvement can actually increase resources to support health care, whether participation can create a genuine social learning partnership between people and professionals, whether

Panel 2: Building community empowerment

Community empowerment is a synergistic interplay between individual empowerment, ⁵² organisational empowerment, ⁵³ and broader social and political actions. ⁵⁴ Empowered community-based organisations are at the heart of community empowerment, since they link empowered individuals and effective political action. ⁵⁵ This interplay can be conceptualised as a continuum of five progressively more organised and broadly based forms of social and collective action (main bullets). ^{56,52} These five forms can be further subdivided into domains (sub-bullets), which represent the means through which individuals and groups can organise themselves to harness the interpersonal elements of empowerment and address the broader determinants of their health. ⁵⁸

- · Personal action
 - · Community participation
- · Small mutual groups
 - · Problem assessment
 - Local leadership
- Community organisations
 - Local leadership
 - · Organisational structures
 - · Resource mobilisation
- Partnerships
 - · Organisational structures
 - · Resource mobilisation
 - Links to others
 - Asking why
- · Social and political action
 - · Links to others
 - Asking why
 - Role of outside agents
 - · Programme management

community mobilisation can really change a commitment to social justice and democracy, and whether community mobilisation can actually accelerate progress at scale toward achievement of MDGs 4 and 5 in high-mortality, resource-poor settings.

What are the mechanisms through which community mobilisation brings about improved health outcomes?

Some observers feel that community mobilisation works simply by bringing about changes in behavioural risk factors such as home care practices and decisions about care seeking. Although undoubtedly one important mechanism through which community mobilisation works, studies of health education suggest that simply providing key messages to improve maternal and newborn care cannot possibly account for all the effect these approaches have on morbidity and mortality. A large proportion of this effect is thought to be due to community mobilisation bringing about changes in socioenvironmental risk factors by developing the capacities of communities, the choices they make, and their ultimate

empowerment. This mechanism is enshrined in the Ottawa Charter (1986) and the Jakarta Declaration (1997), which equated health promotion with goals of empowerment and a more long term and fundamental shift in village, family, and gender power relations. 65

Women's groups in Malawi and Nepal are increasing the important capacities within communities, such as the ability to identify maternal and neonatal health problems and their root causes; the ability to mobilise resources necessary for improving the health of mothers and newborn infants; the internal and external social networks they can draw on when needed; and the development of strong local leaders who have the motivation and drive to improve maternal and neonatal health in the community. 66.67 The women's groups are also drawing on these social capacities to make fundamental choices to improve their health, such as about the equitable sharing of resources needed for better maternal and neonatal health; about planning feasible strategies to address maternal and neonatal health problems; about planning, implementation, evaluation, finances and reporting of programmes; and about which people and organisations to approach to address problems. Detailed longitudinal exploration of these processes is crucial to provide answers to policy makers about how community mobilisation works, to inform programme design, and to build the case for government investment.

Is community mobilisation less important than facility-based medical interventions?

Many safer motherhood analysts, such as policy makers and academics, would consider community mobilisation a peripheral component of a package to reduce maternal mortality, which is far more dependent on specific facility based interventions than is child survival.22 However, the evidence supports a more central role for community mobilisation. Firstly, numerous interventions such as family planning, nutritional support for women, and the treatment of haemorrhage, sepsis, and unsafe abortion are all potentially amenable to interventions in the community.68 Secondly, the so-called first delay (recognising a maternal problem in the home and deciding to seek care) is a key problem for safer motherhood programmes and solving it requires the participation of communities (panel 3). Thirdly, poverty and disadvantage are the underlying causes of many neonatal and maternal deaths; 99% of maternal and neonatal deaths occur in low-income and middle-income families and in poor countries, and maternal mortality is often more than twice as high in the poorest compared with the richest economic quintile household.6070 The link between social disadvantage and mortality is subtle and indirect but maternal and newborn survival and good health are ultimately the result of a society that values women and children irrespective of their race, social, economic, and political status and provides unimpeded

access to information and health services from the household to the hospital. Community mobilisation, in addressing inequality rather than only improving health services, is thus a priority strategy for improving survival of mothers and newborn infants.^{69,70}

Although maternal survival requires improvements in comprehensive and basic obstetric care at hospitals and health centres, community mobilisation has an important role in improving care practices, increasing the use of safer motherhood services, promoting timely referral when problems arise, and reducing social disadvantage. Some of the ongoing trials cited in the table could have the statistical power to add to this debate by exploring the extent to which community approaches reduce maternal mortality directly compared with indirectly by promoting deliveries in hospitals.

How can community mobilisation be taken to scale?

Scale-up of health interventions might involve increasing coverage by geographical expansion, adding technical interventions to an existing programme, advocacy to change policies, and strengthening capacity with more resources, new alliances, and technical skills.71 But how can governments, even in partnership with civil society organisations, achieve scale-up of community mobilisation interventions in these ways? Several approaches have been used including: government directed and implemented programmes;72 partnerships between government and non-governmental organisations;73,74,75 socalled living universities and centres of learning;72,76 dissemination of methods and results through manuals, training packages, internet, radio, video, TV, and university classes; and organic spread from community to community through word-of-mouth or direct observation. These approaches have succeeded in massive scale-up of community mobilisation interventions in countries such as Bangladesh, China, Cuba, Sri Lanka, and Tanzania. Thus, these interventions, due to their dependence only on facilitation and community resources, seem to be no more difficult to scale-up than others such as immunisation programmes, which depend on cold chains, drugs, technology, and a large network of paid health workers. However, in the poorest countries the capacity and commitment for scale-up remains weak and extensive coverage alone is insufficient to ensure that the most vulnerable populations benefit in the long-term.

Case studies, trials, and large-scale programmes have shown that, when given the opportunity, communities can develop effective strategies to address their needs and reduce mortality and morbidity. These strategies are often highly innovative, practical, and culturally acceptable. What is scaled-up is not solutions but a process to support communities to develop their own solutions. As a result, programmes must be flexible enough to respond to variations between, and within, communities and must allow adequate time for this process of capacity building. Also, a favourable

Panel 3: Case study of how women's groups are addressing first-delay in maternal and child care: Jharkhand, India

Sini Koda comes from Tipusai, a remote hamlet of Baraibir village in West Singhbhum district of Jharkhand state. It is 25 kms from a private facility where emergency obstetric care is available and receives infrequent visits from Auxiliary Nurse Midwives. She, her husband, mother-in-law, and other members of the family regularly attend women's group meetings, facilitated by Rani Kayam who was trained and is employed by Ekjut Project, a local non-governmental organisation. The group meets monthly and engages in participatory learning and action activities focusing on maternal and child health. During one of these meetings they engaged in a "woman in labour – emergency drill" role-play session. In this session they learnt how to mobilise quickly at the time of labour and avoid delays. When it came time to deliver, Sini's in-laws tried to perform traditional rituals that would delay her from getting to the health facility. However, her husband and other women's group members used what they had learnt to collect 5000 rupees from other community members for transport and hospital costs. As a result, Sini was able to get to the facility with the minimum of delay where she delivered normally and successfully.

environment for scaling up can be created if national policies are in place which support community mobilisation. Programmes are more successful if they communicate from the same belief system. This success can be achieved by seeking to understand and take into account the social norms and local cultural context around health, community participation, gender roles, use of health services, and household decision making. Importantly, programmes should not cut out or limit essential steps such as problem identification, prioritisation, and strategy formulation by communities.

Irrespective of whether the facilitating agent is a representative of a non-governmental organisation, member of a community based organisation, government fieldworker, or volunteer they must have: credibility in the communities; language skills and cultural sensitivity; knowledge of community structures and protocols; interest in being a facilitator and in maternal and newborn health; affiliation with and support from an organisation; good interpersonal communication skills; and availability of time to do the work.

The main programme cost is building human and community capacity, which needs adequate investment. This process means prioritising investment in ongoing training, facilitation, and capacity strengthening and the use of cost-effective methods such as cascade-training structures. Costs within the programme can in part be covered by contributions from the community but this must be done carefully while respecting roles and responsibilities and keeping in mind programme principles of community ownership and sustainability.

Partnerships of government, non-governmental organisations, private sector, and community-based organisations are essential, but can face differences in organisational cultures and values, competition for resources, and varying levels of capacity. Successful programmes define roles and responsibilities clearly, allocate resources fairly, and establish operational

guidelines, communication systems, parameters for implementation, and mechanisms for dealing with problems or disputes. Finally, new technologies such as community radio, mobile phones, internet, and digital and video cameras have rapidly become more accessible and could present new opportunities for communication, gathering information, organising, coordinating, and increasing participation.

Conclusion

There is evidence that community mobilisation is an effective method for promoting participation and empowering communities among a wide range of other non-health benefits. The experience of pilot programmes before the Alma-Ata Declaration, and subsequent trial evidence, also suggests that community mobilisation can bring about cost-effective and substantial reductions in mortality and improvements in the health of newborn infants, children, and mothers. Nonetheless community mobilisation is not a feature of most large-scale primary health care programmes, because it is characterised by several fundamental controversies. What form should it take to be most effective? Does it effectively address the socioenvironmental risk factors that underpin health problems and mortality? How does it work? What part does it have to play in interventions for maternal survival? How can it be scaled-up effectively? Continuing studies and future research, particularly focusing on process, are needed to address these controversies and fully unlock the potential that community mobilisation approaches have to improve health and reduce mortality.

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Health systems and the right to health: an assessment of 194 countries



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60 years ago, the Universal Declaration of Human Rights laid the foundations for the right to the highest attainable standard of health. This right is central to the creation of equitable health systems. We identify some of the right-to-health features of health systems, such as a comprehensive national health plan, and propose 72 indicators that reflect some of these features. We collect globally processed data on these indicators for 194 countries and national data for Ecuador, Mozambique, Peru, Romania, and Sweden. Globally processed data were not available for 18 indicators for any country, suggesting that organisations that obtain such data give insufficient attention to the right-to-health features of health systems. Where they are available, the indicators show where health systems need to be improved to better realise the right to health. We provide recommendations for governments, international bodies, civil-society organisations, and other institutions and suggest that these indicators and data, although not perfect, provide a basis for the monitoring of health systems and the progressive realisation of the right to health. Right-to-health features are not just good management, justice, or humanitarianism, they are obligations under human-rights law.

Introduction

December, 2008, marks the 60th anniversary of the Universal Declaration of Human Rights. The declaration provides the foundation for the international code of human rights. This code gives an internationally agreed set of standards to guide and assess the conduct of governments across a wide range of sectors and has a direct, close bearing on medicine, public health, and the strengthening of health systems.

The international code of human rights consists of legally binding international components. Among the most important of these components for health systems are the International Covenant on Economic, Social, and Cultural Rights (ICESCR)45 and the Convention on the Rights of the Child (CRC).6 Both these human-rights treaties are legally binding for those countries that have ratified them. Most states have ratified the ICESCR, and all but two (Somalia and the USA) have ratified the CRC. The right of everyone to enjoy the highest attainable standard of physical and mental health-sometimes known as the right to the highest attainable standard of health or the right to health-is an integral part of both of these international treaties. All countries have ratified one or more binding treaty that includes the right to health, such as the International Convention on the Elimination of All Forms of Racial Discrimination.7 Also, many countries include this right in their national constitutions.8 The Constitution of WHO," the Declaration of Alma-Ata,10 the Ottawa Charter for Health Promotion," the Bangkok Charter for Health Promotion in a Globalized World,12 and other important documents agreed by the health community also recognise this fundamental human right.

In recent years, national and international policy makers, courts, non-governmental organisations, and other stakeholders have adopted and applied features of the right to the highest attainable standard of health. Uganda's review of its health policy expressly uses a right-to-health analysis" as does WHO in, for example, its publication on

human rights, health, and poverty reduction.14 Courts, too, are explicitly relying on the right to health in their decisions, most recently in a landmark judgment of the Colombian Constitutional Court. 15-19 On the basis of a detailed understanding of the right to health, this court effectively ordered a phased restructuring of the country's health system by way of a participatory and transparent process based on current epidemiological information.20 Civil-society guides to the right to health are increasing in number, and many civil-society organisations use these in their work.21-24 Both the UN General Assembly and Human Rights Council have discussed numerous reports on the right to health, covering a wide range of issues, such as neglected diseases,25 sexual and reproductive health,25 maternal mortality, 26 mental disability, 27 the Millennium Development Goals (MDGs),28 medicines,26 and water and sanitation.29

Recognition that a strong health system is an essential element of a healthy and equitable society is growing. However, according to a recent WHO publication, health systems in many countries are failing and collapsing. Too many health systems are inequitable, regressive, and unsafe. WHO also confirms that sustainable development, including achievement of the MDGs, depends on effective health systems.

As with a fair court system, an effective health system is a core social institution and, for this reason, crucially, both systems are protected by human rights. Although many human rights are important to a well-functioning court system, the key one is the right to a fair trial. Through human-rights treaties, national laws and policies, judicial decisions, and so on, the right to a fair trial has helped to identify the key features of a fair court system, such as an independent judiciary and trials without undue delay. The right to a fair trial has not only identified unfair judicial processes but also led to welcome reforms in many countries.

By analogy, the right to the highest attainable standard of health can help to establish health systems that are

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reasonably equitable. However, to make this happen, the right-to-health features of health systems need to be identified. This process will take time, just as our understanding of the right to a fair trial has developed over many years. Once identified, the right-to-health features will not provide a neat blueprint or formula for a health system. There will be many grey areas, just as there are in relation to the right to a fair trial and court systems. The right to a fair trial does not provide detailed prescriptions, rather it insists upon key principles, such as fairness, independence and impartiality, and several important features that a court system must have if it is to be fair. The right to health has a similar role.

Of all the important human rights that bear upon health systems, the right to the highest attainable standard of health is the cornerstone of both an effective health system and the growing movement for health and human rights.¹⁵

In this Report, we aim to assess the degree to which the health systems of 194 countries include some of the features that arise from the right to health. We introduce the right to health and identify some of the right-to-health features of health systems. These features are not just a matter of good management, justice, or humanitarianism—they are a matter of human-rights law. We set out our methods and their limitations and identify 72 indicators of right-to-health features of health systems. We present some of the findings and results arising from the data on the indicators, and discuss these data and make recommendations for a range of stakeholders.

What is the right to health?

The right to the highest attainable standard of health encompasses medical care, access to safe drinking water, adequate sanitation, education, health-related information, and other underlying determinants of health; it includes freedoms, such as the right to be free from discrimination and involuntary medical treatment, and entitlements, such as the right to essential primary health care. Like other human rights, the right to health has particular concern for disadvantaged people and populations, including those living in poverty. The right to health requires an effective, responsive, integrated health system of good quality that is accessible to all.

International human-rights law recognises that the right to the highest attainable standard of health cannot be realised overnight; it is expressly subject to both progressive realisation and resource availability. Put simply, progressive realisation means that a country has to improve its human-rights performance steadily; if there is no progress, the government of that country has to provide a rational and objective explanation. Because of their greater resource availability, more is expected of high-income than of low-income countries. However, the right to health also imposes some obligations of immediate effect, such as non-discrimination, and the requirement that a state at least prepares a national plan for health care and

protection. Furthermore, the right to health requires that there are indicators and benchmarks to monitor progressive realisation and that individuals and communities have opportunities for active and informed participation in health decision making that affects them. Under international human rights law, developed countries have some responsibilities towards the realisation of the right to health in developing countries. Because the right to health gives rise to legal entitlements and obligations, effective mechanisms of monitoring and accountability are needed. The

Although the right to health adds power to campaigning and advocacy, it is not just a slogan, it has a concise and constructive contribution to make to health policy and practice. Health workers can use the right to devise equitable policies and programmes that strengthen health systems and place important health issues higher up national and international agendas. ^{17,18}

Medicine, public health, and human rights have much common ground. To one degree or another, each field stresses the importance of the underlying determinants of health and good-quality medical care, looks beyond the health sector, struggles against discrimination and disadvantage, demands respect for cultural diversity, and attaches importance to public information and education.

The right to health cannot be realised without the interventions and insights of health workers; and the classic, long-established objectives of public health and medicine can benefit from the newer, dynamic discipline of human rights. A few enlightened people understood these relations when the WHO Constitution was drafted in 1946° and when the Declaration of Alma-Ata was adopted in 1978, 10 affirming the right to the highest attainable standard of health.

However, until recently, the right to health was only dimly understood and attracted limited support from civil society or any other sector. The understanding and practice of health and human rights has improved since the Alma-Ata conference. One vital part of this process has been a deepening understanding of the right to health. But it was not until 2000 that an authoritative understanding of the right to health emerged when the UN Committee on Economic, Social, and Cultural Rights, working in close collaboration with WHO and many others, drafted and adopted general comment 14.

Although neither complete, perfect, nor binding, general comment 14 is compelling and groundbreaking. The comment shows a substantive understanding of the right to health that can be made operational and improved in the light of practical experience. The influence of Alma-Ata on general comment 14 is explicit and clear. Although much more work is needed to grasp all the implications of the right to the highest attainable standard of health, the general comment confirms that the right cannot be dismissed as a rhetorical device. General comment 14 provides a common right-to-health language for talking about health issues and sets out a way of

analysing the right to health, making it easier for policy makers and practitioners to use. Panel 1 summarises general comment 14, including the requirement that health facilities and services be available, accessible, and culturally acceptable.

The right-to-health analysis can be used to identify and expose, for example, the lack of available mental-health facilities properly serviced by trained staff. Health-related facilities and services, including mental-health facilities with properly trained staff, must be available in adequate number throughout a country. Of course, the need is subject to resource availability: more and better facilities are required of Canada than of Chad. Few nations, however, devote adequate funds to mental health. On a routine basis, mental-health facilities are neglected, workers untrained, and patients uncared for. Poor mental health gives rise to other profound problems, not least discrimination and stigmatisation, important to the right to health.

The test of availability can also be applied to harm-reduction initiatives. Provision of injecting drug users with comprehensive and integrated treatment, counselling, and clean needles and syringes is good for public health, reduces avoidable suffering, saves lives, and is cost-effective. An appropriate harm-reduction initiative is also a right-to-health initiative. However, most countries do not provide harm-reduction services for people who use drugs, and those that do, such as Sweden, provide a limited and scattered service. The right to health requires all countries to have an effective, national, comprehensive harm-reduction policy and plan, delivering essential services. A high-income country such as Sweden is expected to provide more than the essential services.

Health-related facilities and services can be available within a country but inaccessible to all those who need them. For example, access to essential medicines is an indispensable part of the right to health with several dimensions.49 First, medicines must be accessible in remote rural areas as well as in urban centres, which has major implications for the design of medicine supply systems. Second, medicines must be affordable to all, including those living in poverty, which has obvious implications for funding and pricing arrangements. Third, given the fundamental human-rights principles of non-discrimination and equality, a national medicines policy must be designed to ensure access for disadvantaged individuals and communities, such as women and girls, people living with HIV/AIDS, elderly people, and people with disabilities. Because equal access is not always secured by equal treatment, a state must sometimes take measures in favour of disadvantaged people. As far as possible, data must be disaggregated to identify marginalised groups and monitor their progress towards equal access. Fourth, reliable information about medicines must be accessible to patients and health workers so they can take well-informed decisions and use medicines safely.

Panel 1: Some important points from general comment 14

Article 12 of the International Covenant on Economic, Social, and Cultural Rights very briefly sets out the right to the highest attainable standard of health. General comment 14 provides the UN Committee on Economic, Social, and Cultural Rights' interpretation of article 12. Although not legally binding, the comment is highly authoritative.

- Encompassing physical and mental health, the right to health places obligations on governments in relation to health care and the underlying determinants of health—these obligations include provision of clean water, adequate sanitation, nutritious food, adequate shelter, education, a safe environment, health-related information, and freedom from discrimination.
- Governments have, for example, obligations regarding maternal, child, and reproductive health; healthy natural and workplace environments; the prevention, treatment, and control of diseases; health facilities, services, and goods.
- Governments have an obligation to give particular attention to marginal individuals, communities, and populations, creating a need for as much disaggregation of data as possible.
- Within a country, health facilities, services, and goods must be available in sufficient quantity, accessible (including affordable) to everyone without discrimination, culturally acceptable (eg, respectful of medical ethics and sensitive to gender and culture), and of good quality.
- · The right to health is subject to progressive realisation and resource availability.
- Nonetheless, governments must take deliberate, concrete, and targeted steps to ensure the progressive realisation of the right as expeditiously and effectively as possible.
- However, core obligations are subject to neither progressive realisation nor resource
 availability. Expressly taking into account the Declaration of Alma-Ata, they include
 obligations to ensure access to health facilities, goods, and services to everyone,
 including marginal groups, without discrimination; to ensure everyone is free from
 hunger; to ensure access to basic shelter, housing and sanitation, and an adequate
 supply of safe and potable water; to provide essential drugs, as defined under the WHO
 action programme on essential drugs; to ensure equitable distribution of all health
 facilities, goods, and services; and to adopt and implement a national public-health
 strategy and plan of action, by way of a participatory and transparent process.
- The right to health requires opportunities for as much participation as possible by individuals and communities in health-related decision making.
- Governments have an obligation to ensure that non-state stakeholders are respectful
 of the right to health (eq, do not discriminate).
- Developed states, and others in a position to assist, should provide international
 assistance and cooperation in health to developing countries (eg, economic and
 technical assistance to help developing countries fulfil their core obligations). All states
 "have an obligation to ensure that their actions as members of international
 organizations take due account of the right to health".
- Monitoring, accountability and redress are essential. Given progressive realisation, indicators and benchmarks are indispensable if governments are to be held to account.
- The right to health is closely related to, and dependent upon, numerous other human rights, such as the rights to life, education, and access to information.
- In narrowly defined circumstances and as a last resort, the enjoyment of some human
 rights may be interfered with to achieve a public health goal. For example, quarantine
 for a serious communicable disease, such as ebola fever, may, under certain
 circumstances, be necessary for the public good, and lawful under human rights, even
 though it limits an individual's freedom of movement.

Health-related facilities and services may be available and accessible but be insensitive to culture and gender. For example, improving the access to sexual and reproductive health care is not simply about scaling up technical interventions or making them affordable. A Peruvian project that studied indigenous communities with very high maternal mortality found an acute reluctance within the population to use the health facilities offered by the state, partly because they did not take account of local cultural conceptions of health and sickness. In close consultation with the indigenous communities, culturally sensitive facilities and services were introduced, such as sturdy ropes in delivery rooms so that women could give birth squatting and gripping the rope, as they were accustomed to. These changes led an increase in deliveries in local health centres, ⁵⁰ and the success of these local initiatives helped to generate a corresponding change in national health policy on deliveries in all primary health-care facilities. ⁵¹

Right-to-health features of health systems

The Declaration of Alma-Ata identifies some vital components of an effective health system. The declaration is especially instructive because of its public-health, medicine, and human-rights aspects (panel 2), and it provides compelling guidance on the core obligations of the right to health.¹⁶

Other attempts have been made to identify what constitutes a functioning health system. WHO identifies six essential building blocks that make up health systems: health services (medical and public health); health workforce; health information system; medical products, vaccines, and technologies; health financing; and leadership, governance, and stewardship. Although debatable, these building blocks provide a useful way of looking at health systems and can be thought of as building blocks for the realisation of the right to health. However, a health system might have all these building blocks but still not serve human rights. For example, the system might

Panel 2: The Declaration of Alma-Ata (1978)

Principal themes

- · The importance of equity
- The need for community participation
- The need for a multisectoral approach to health problems
- The need for effective planning
- · The importance of integrated referral systems
- An emphasis on health-promotional activities
- The crucial role of suitably trained human resources
- The importance of international cooperation

Essential health interventions

- · Education concerning prevailing health problems
- · Promotion of food supply and proper nutrition
- Adequate supply of safe water and basic sanitation
- Maternal and child health care, including family planning
- Immunisation against major infectious diseases
- · Prevention and control of locally endemic diseases
- Appropriate treatment of common diseases and injuries
- Provision of essential drugs

include both medical care and public health but not secure fair access, or there might be a health information system but key data might not be suitably disaggregated.

A major challenge for human rights is to apply or integrate the right to health across the six building blocks. The right-to-health analysis provided by general comment 14 has to be systematically and consistently applied to health services, health workforce, health information. medical products, financing, and stewardship—that is, all the elements that together constitute a functioning health system. Panel 3 identifies some of the issues that arise when the right-to-health analysis is applied to the second WHO building block—the health workforce. The right-to-health analysis of availability, accessibility, cultural acceptability, quality, participation, international assistance and cooperation, monitoring and accountability, and so on, can also be applied to health systems to identify some of the right-to-health features of health systems, encompassing what health systems do (for example, providing access to essential medicines and safe drinking water) and the way in which they function (for example, transparently, in a participatory process, and without discrimination). Health systems run the risk of being impersonal, top-down, and dominated by experts, but the right to health places the wellbeing of individuals. communities, and populations at the centre.53 Irrespective of which of the many definitions of a health system is used, 30,52,54 all the following features should be part of any health system.

Legal recognition—Countries should give recognition to the right to health in national law and by ratifying relevant human-rights treaties. In some countries legal provisions on the right to the highest attainable standard of health are generating significant case law. For example, Hogerzeil and colleagues analysed 71 court cases from 12 countries and concluded that in 59 cases access to essential medicines was enforced through the courts as part of the right to health. Legal recognition is just one of the first steps on a long and difficult journey to realising the right to health. Without follow-up from social movements, health workers, progressive government ministers and public officials, activist courts, and international support, in addition to governmental respect for the rule of law, legal recognition is likely to be an empty promise.

Standards—Although important, legal recognition of the right to health is usually confined to a general formulation that does not set out in any detail what is required of those with responsibilities for health. For this reason, countries must not only recognise the right to health in national law, but also ensure that there are more detailed provisions clarifying what society can expect by way of health-related services and facilities. For example, provisions are needed for quality and quantity of drinking water, essential medicines, the quality of medical care, and so on. Such clarifications may be provided by laws, regulations, protocols, guidelines, and codes of conduct. WHO has published important standards on various health issues. ⁵⁷⁻⁵⁰

Many others have also contributed; for example, the Sphere Project provides minimum standards for responses to disasters.⁶⁰ Clarification is important for providers, so they know what is expected of them and also for those for whom the service or facility is intended, so they know what they can legitimately expect.

Participation—Health systems must also include institutional arrangements for the active and informed participation in strategy development, policy making, implementation, and accountability by all relevant stakeholders, including disadvantaged individuals, communities, and populations. Examples of such participation include conferences to develop national health plans in Brazil and Peru; a legislative requirement of Maori participation in New Zealand's District Health Boards; village health teams in Uganda; and the participatory transfer of an HIV/AIDS clinic from Médecins Sans Frontières to the Guatemalan Ministry of Health. Participation improves health outcomes.

Transparency—Tempered by the confidentiality of personal data, this requirement applies to all those working in health-related sectors, including countries, international organisations, public–private partnerships, business enterprises, and civil-society organisations. The Medicines Transparency Alliance, funded by the UK Government, is an alliance of governments, international agencies, pharmaceutical companies, and civil-society organisations, committed to increasing transparency of information on the quality, availability, and pricing of essential medicines in the public, private, and non-profit sectors. The Medicines in the public, private, and non-profit sectors.

Equity, equality, and non-discrimination—Health systems must be accessible to all, including those living in poverty, minority groups, indigenous people, women, children, people living in slums and rural areas, people with disabilities, and other disadvantaged individuals, communities, and populations.36 Additionally, health systems must be responsive to the particular health needs of women, children, adolescents, elderly people, and so on.46 Outreach programmes are needed to ensure that disadvantaged people have the same access as more privileged people. Several European governments, for example, have established Roma health mediator programmes.64 As members of the Romani community themselves, the mediators aim to improve community health by mediating between patients and health workers during consultations and communicating with Romani communities on behalf of the public health system. Although the programmes have limitations, mediators have greatly assisted some Romani.64

The right-to-health principles of equality and non-discrimination are akin to the health concept of equity. All three concepts have a social-justice component. In some respects, equality and non-discrimination, being reinforced by law, are more powerful than equity. For example, if a government or other body does not take effective steps to tackle discrimination, it can be held to account and required to take remedial measures. 66.67

Panel 3: Some issues arising when the right to health is applied to health workforces

- General comment 14 requires a comprehensive national health plan
 (eg, paragraphs 43[6] and 55) encompassing human resources. So is there an up-to-date
 plan for human resources in preventive, curative, and rehabilitative health,
 encompassing physical and mental health?
- Is there a role for midlevel providers who can increase access to health care, such as assistant medical officers and surgical technicians, and public-health professionals?
- Are there outreach programmes for the recruitment of health workers from marginalised communities and populations, such as indigenous peoples, to reduce non-discrimination and improve respect for cultural difference?
- Are effective measures in place to achieve a gender balance among health workers in all fields to ensure equality, non-discrimination, and respect for cultural difference?
- Because health-related services must be available in sufficient quantity, subject to resource availability, are effective measures in place to ensure that the number of domestically trained health workers is commensurate with the health needs of the population?
- Is health information about the number of health workers by category (eg, nurses and public health professionals) collected, centralised, and made publicly available on a regular basis?
- Are human rights, including respect for cultural diversity, as well as the importance of treating patients and others with courtesy, a compulsory part of the training for all health workers?
- General comment 14 (paragraph 44[5]) requires appropriate training for health
 personnel, so are opportunities for further professional training in place for all health
 workers without discrimination?
- Are health workers receiving domestically competitive salaries as well as other reasonable terms and conditions of employment? A lack of reasonable terms and conditions of employment, one of the causes of the skills drain, is likely to undermine a health system
- Are incentives in place to encourage the appointment, and retention, of health workers in underserved areas to improve access, especially of marginal communities and populations?

Respect for cultural difference—From the right-to-health perspective, health systems must be respectful of cultural difference. 16, 18, 68 Health workers must be sensitive to issues of culture, ethnicity, and sex, strategies must be in place to enable indigenous people to study medicine and public health, and so on. 60

Quality—All health-related services and facilities must be of good quality. For example, water quality regulations and standards consistent with the WHO guidelines for the quality of drinking water should be in place. The good quality requirement also extends to the way patients and others are treated: health workers must treat patients and others politely and with respect. Because medicines may be counterfeit, states must establish appropriate regulatory systems. In Nigeria, for example, there is evidence that the National Agency for Food and Drug Administration and Control's dual strategy of strengthening the regulatory environment, while encouraging intolerance of counterfeit drugs through public enlightenment campaigns is improving medicine safety and quality.

Planning—Some important implications arise from the right to health being subject to progressive realisation and resource availability. The crucial importance of planning is recognised in the Declaration of Alma-Ata, ¹⁰ general



comment 14, 6 and elsewhere.7 States must have comprehensive national health plans, encompassing both the public and private sectors, for the development of health systems; because the plans have to be evidence-based, a situational analysis with disaggregated data is needed before the plan is drafted. Health research and development should also inform the planning process.7273

According to general comment 14, the plan must include certain features, such as clear objectives (and how these are to be achieved), timeframes, effective coordination mechanisms, reporting procedures, a detailed budget, financing arrangements (national and international), assessment arrangements, indicators and benchmarks to measure achievement, and one or more accountability devices. Indicators and benchmarks are already commonplace features of many health systems, but they rarely have all the elements that are important from a human-rights perspective, such as appropriate disaggregation. In

The identification of indicators and benchmarks to measure the progressive realisation of the right to health is a national and international process that involves countries, international organisations, the UN Committee on Economic, Social, and Cultural Rights, and others. A wealth of data is available at the global level, some of which is highly relevant to the right to health. But are international bodies making other data important to the right-to-health perspective available? If not, countries may wrongly assume that these other data, and the issues to which they relate, are less important. Many countries look to UN bodies for technical assistance, ideas, and leadership. Whether or not UN bodies are making data that are highly relevant to the right to health available at a global level is an important issue.

A fair, transparent, participatory, and inclusive process for prioritising competing health needs is required—one that takes into account explicit criteria, such as the well-being of those living in poverty, and not just the claims of powerful groups with vested interests. The process of prioritisation should give particular attention to the core obligations identified in general comment 14 because they are required of all countries, whatever their stage of economic development. The list of core obligations is illustrative rather than exhaustive (panel 1). One of the core obligations is to adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population.

Before the finalisation of the plan, key elements must undergo impact assessment to ensure that they are likely to be consistent with national and international legal obligations, including those relating to the right to the highest attainable standard of health.⁷⁵ In addition, the present realisation of the right to health must be maintained, although this might be waived in exceptional circumstances.⁴⁶

Progressive realisation does not mean that a government is free to choose whatever measures it wishes to take so

long as they reflect some degree of progress. General comment 14 requires that governments take deliberate, concrete, and targeted steps to ensure progressive realisation as quickly and effectively as possible. 16

Progressive realisation, maximum available resources, and core obligations need closer conceptual and operational attention. Some courts have rejected the idea of core obligations and required that government policies are reasonable. Other courts have taken the same position as the UN Committee on Economic, Social, and Cultural Rights in general comment 14 and found that some health-related responsibilities are so fundamental that they are subject to neither progressive realisation nor resource availability. This position most closely matches the right to health: progressive realisation is an important concept with a crucial role, but only up to the boundaries of core obligations.

Referral systems—Health systems should have a mix of primary (community-based), secondary (district-based), and tertiary (specialised) facilities and services, providing a continuum of prevention and care. The system also needs an effective process by which health workers assess whether patients will benefit from additional services and patients are referred from one facility or department to another. Referrals are needed between alternative health systems (eg, traditional health practitioners) and mainstream health systems. The absence of an effective referral system is inconsistent with the right to health.

Coordination—Health systems and the right to health depend on effective coordination across a range of public and private stakeholders (including non-governmental organisations) at the national and international levels. Effective coordination between various sectors and departments, such as health, environment, water, sanitation, education, food, shelter, finance, and transport is important for health systems, which also require coordination within sectors and departments, such as ministries of health. The need for coordination extends to policy making and delivery of services.36,52 Uganda has recently added several interventions, such as de-worming of children, supplementation with vitamin A, and health promotion information, to its Child Health Days. Now known as Child Health Days Plus, these days depend on, and reinforce, improved coordination between and within sectors and national and international partners, including civil society.78,76

International cooperation—Health systems have international dimensions, including the control of infectious diseases, the dissemination of health research, and regulatory initiatives, such as the International Health Regulations⁵⁸ and the WHO Framework Convention on Tobacco Control.⁵⁰ The international dimension of health systems is reflected in countries' human-rights responsibilities of international assistance and cooperation that can be traced through the Charter of the UN, the Universal Declaration of Human Rights, and some more-recent international human-rights declarations and binding treaties.^{51,52} At least, all countries have a

human-rights responsibility to cooperate on transboundary health issues and to do no harm to their neighbours.83 High-income countries have an additional responsibility to provide appropriate international assistance and cooperation in health for low-income countries. High-income countries should especially help others fulfil their core obligations.³⁶ The Swedish International Development Cooperation Agency (SIDA), for example, supports several stakeholders with crucial roles in relation to the right to health in Uganda. The agency has given funds to various organisations: the Ugandan Government; WHO for its human-rights work in Uganda; the Uganda Human Rights Commission; and civil-society organisations, including Straight Talk, which aims to increase understanding of adolescence, sexuality, and reproductive health.84 For their part, low-income countries have a responsibility to seek appropriate international assistance and cooperation to help them strengthen their health systems.85

General comment 14 confirms that the human-rights responsibility of international assistance and cooperation in health extends to countries' actions as members of international organisations. "Scandinavian countries, for example, have proposed a trust fund for justice and human rights in the World Bank."

Legal obligation—Crucially, the right to the highest attainable standard of health gives rise to legally binding obligations. The health system must have, for example, a comprehensive national health plan; outreach programmes for the disadvantaged; a minimum package of healthrelated services and facilities; effective referral systems; arrangements to ensure the participation of those affected by decision making in health; respect for cultural difference; and so on. One of the distinctive contributions of the right to the highest attainable standard of health is that it reinforces good health practices with legal obligation and accountability. States are legally obliged to take all appropriate steps to implement the right-to-health features of health systems. Of course, some governments implement these features without reference to the right to health. But many governments do not ensure that these features are in place, and, in these cases, the right to health has an especially important role.

Monitoring and accountability—Individuals and communities should have the opportunity to understand how those with responsibilities have discharged their duties and provide those with responsibilities the opportunity to explain what they have done and why.** Where mistakes have been made, accountability requires redress. Accountability is not a matter of blame and punishment but a fair and reasonable process to identify what works, so it can be repeated, and what does not, so it can be revised.**

Something as complex and important as health systems needs effective, transparent, accessible, and independent accountability mechanisms—health commissioners, national human-rights institutions, democratically elected local health councils, public hearings, patients' committees, impact assessments,

and judicial proceedings. The media and civil-society organisations also have crucial roles.**

Accountability in many health systems is extremely weak. In some countries, the same body provides and regulates health services, as well as holding those responsible to account. Accountability can also be little more than a device to check that health funds were spent as they should have been. Human-rights accountability is concerned with ensuring that health systems are improving, and the right to the highest attainable standard of health is being progressively realised, for all, including disadvantaged individuals, communities, and populations.

In some countries, although playing an important part, the private health sector is largely unregulated. The requirement of human-rights accountability extends to both the public and private health-related sectors of and to international bodies working on health-related issues.

Accountability mechanisms are urgently needed for all bodies—public, private, national, and international—working on health-related issues. The design of appropriate and independent accountability mechanisms needs creativity and leadership, such as recently shown by the Uganda Human Rights Commission with the launch of its new Right to Health Unit in Kampala.⁹⁰

Scope and objectives

We begin to assess the degree to which the health systems of 194 countries include features arising from the right to the highest attainable standard of health.

From the start, this project did not aim to give a weighting to indicators nor to rank countries in an index, although we are aware that ranking can appeal to politicians and sometimes might enhance monitoring and accountability, leading to improved health and respect for human rights. Ranking in league tables is also problematic with technical difficulties and problems of interpretation. However, indicators and benchmarks are needed to measure the present condition of a country's health system and to monitor its progress over time. We hope that this project will be repeated periodically so that the progress of individual countries, in relation to health systems and the right to health, can be monitored.

Although much more work has to be done to help governments identify the minimum package of health-related services and facilities needed by the right to the highest attainable standard of health, that vital task is not our aim here. In this Report, we do not attempt to provide a list of essential services and facilities needed for a well-functioning health system. Rather, we attempt to identify several additional, and commonly neglected, features arising from the right to health and informed by good practices that are required of all health systems.

Methodology

Development and selection of indicators

Our aim was to assess how much the health systems of all countries include some of the features that arise from



the right to health. To meet this aim, we identified the following objectives: to promote awareness of the complementary relation between a health system and the right to health; to select a manageable set of indicators to assess the degree to which a health system includes some of the right-to-health features; to assess if sufficient information is available about these features both nationally and internationally; to increase monitoring and accountability in relation to health systems and the right to the highest attainable standard of health; to deepen the understanding of the important role of health data and indicators in relation to the progressive realisation of the right to health; to consider the limitations of data for health and human rights in relation to the progressive realisation of the right to health; to provide a basis to monitor, over time, health systems and the progressive realisation of the right to the highest attainable standard of health.

We developed indicators to reflect right-to-health features of health systems. The features arise from general comment 14,36 including core obligations, and reflect many of the themes of the Declaration of Alma-Ata,94 and elements of the WHO building blocks of a health system.75 We also referred to article 24 of the Convention of the Right of the Child,6 general comments 3 and 4 of the Committee on the Rights of the Child, 95.96 and general recommendation 24 of the Committee on the Elimination of the Discrimination Against Women." We also relied on the framework of structure, process, and outcome indicators on the right to the highest attainable standard of health,98 and the requirement that health facilities and services should be available, accessible, culturally acceptable, and of good quality.36

To ensure that a similar project had not already been done, we reviewed existing projects (both published and in draft form) relying heavily on indicators, such as the Human Development Reports, the World Health Report 2000 on health systems, the WHO and Office of the High Commissioner of Human Rights (OHCHR) indicators joint project of 2008, the UN Millennium Development Goals, the poverty-reduction indicators from OHCHR, to WHO essential-medicine indicators, the WHO essential-medicine indicators, and indicators of UNICEF, to UNAIDS, to and the World Bank.

The development and selection of indicators was a lengthy process with numerous stages. We selected indicators according to the following criteria: scientific robustness, usefulness, representativeness, understandability, and importance." Data availability was not a determining factor. We also selected indicators that would be accessible to a broad group of professions, including policy makers in both health and human rights.

In an ongoing process over 18 months, we consulted different individuals who helped in the selection of indicators, including academics (eg, from political science, law, health, and sociology), UN bodies, national and local non-governmental organisations and associations, health practitioners, lawyers, economists, and anthropologists. Individuals were consulted from Africa, Latin America, Europe, North America, and Asia-Pacific, with balance between sexes. We also consulted people from indigenous communities. We used purpose sampling to address specific questions and right-to-health features. We also asked delegates at two health and human-rights conferences (Italy and Zimbabwe) for their views, and consulted Maori and non-Maori people in New Zealand. However, our

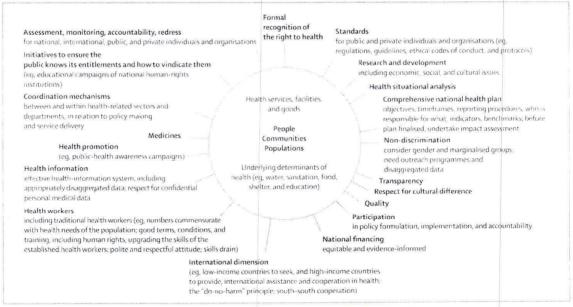


Figure 1: Right-to-health features of a health system underpinned by legal obligations based on general comment 14: preliminary working model

consultation process could have been better and we suggest that, when our selection of indicators is revisited, more consultations should take place.

We used five steps in the process of indicator selection. First, we reviewed the right-to-health features of health systems and WHO building blocks and, after numerous consultations, we created a preliminary working model as a way to assist development and selection of indicators (figure 1). We focused on the wellbeing of individuals, communities, and populations. We also recognised the importance of health-related services, facilities, and goods, including underlying determinants of health, water, sanitation, food, shelter, and education. Additionally, we identified a selection of features that were of particular importance to health systems. We revised and refined this preliminary model because we were aware that it had shortcomings—eg, the model did not clearly convey that several of the features, such as non-discrimination, are recurrent.

Second, we looked closely at health-related services and the underlying determinants of health (middle section of figure 1) in the context of the right-to-health requirements—ie, that these should be available, accessible, culturally acceptable, and of good quality. However, of these four requirements, we focused on the first (availability) and second (accessibility). From the right-to-health perspective, access is crucial because of its relation with non-discrimination, equality, and equity. Health care (eg, antenatal, mental-health, cancer care, and access to medicines), underlying health determinants (eg, drinking water), and government spending on health care were also taken into account (webtable 1).

Third, we considered the features shown in the perimeter of figure 1. Formulation of indicators for standards proved difficult. Formal recognition of the right to health is important but it is usually confined to a few vague sentences. A more detailed elaboration is needed by way of legislation, protocols, guidelines, codes of conduct, and others. We therefore considered formulating indicators that questioned whether countries had adopted international standards on blood safety and water quality, but we were unable to identify indicators conforming to our criteria.

We recognise that planning is only a means to an end. Nonetheless, general comment 14 underlines the importance of planning. An appropriate plan, prepared with a suitable process, is a vital vehicle for realising the right to health. Thus, we devoted great attention to the identification of appropriate indicators in relation to devising a comprehensive national health plan (webtable 2).

We struggled to identify indicators of participation that conformed to our criteria. Especially challenging were indicators capturing whether a country has appropriate institutional mechanisms for participation. Participation should not be confined to the development of the national health plan; it should also extend to the national health-workforce strategy, national medicine policy,

implementation measures, accountability, and so on. Furthermore, participation should not be confined to marginalised groups. However, the right to health has a special focus on disadvantaged people. But, if marginalised groups are participating, we can be confident that non-marginalised groups are too. In the end, we addressed participation in the context of national health planning.

Indicators for research and development in health were also challenging. We wanted to identify indicators that showed whether adequate and appropriate research and development are being undertaken in a country, but we failed to identify an indicator that conformed to our criteria, and so this issue is not present in our final selection.

Fourth, we aimed to merge the two sets of draft indicators already identified (webtables 1 and 2) and revise them where appropriate. Also, we wanted to add some new indicators. For example, we were looking for an indicator that reflected the right-to-health requirement that health-related services, facilities, and goods should be culturally acceptable. General comment 14 emphasises that special attention should be paid to indigenous people and so, prompted by the indicators joint project of WHO and the OHCHR, 100,108 we added a new draft indicator—ie, the proportion of people covered under indigenous or alternative systems of health care (webtable 3). However, placing indigenous and alternative health systems in the same indicator was confusing; therefore, this indicator was not included in our final list. Other indicators approach aspects of cultural acceptability, such as the indicator about participation of marginalised groups. Also, the definition of a comprehensive national health plan extends to the whole population, including indigenous people, and incorporates public and private sectors, including traditional and indigenous health practices and medicines.

Fifth, we made a final selection of 72 indicators (panel 4), divided into 15 groups. Some of the groups overlap; for example, the participation indicator overlaps with the planning indicators. Of course, many different health workers are crucially important, but some indicators use doctors and nurses as proxies. After consultations, we created a new group—additional safeguards—for indicators that did not fit neatly into any other group. By placing indicators on monitoring, assessment, accountability, and redress at the end of the list, we are not saying that such issues only arise at the end of a process. On the contrary, these issues must be seen as recurrent elements in a continuous process.

As prioritised by general comment 14, several indicators focus on maternal and child health. Women and children are among those groups that are often marginalised. In the past 2–3 years, maternal mortality has increasingly been recognised as a human-rights issue. 109-111

We prepared explanatory notes for each indicator, along the lines of the meta-sheets used in the recent indicators joint project of WHO and the OHCHR.¹⁰⁰ Explanatory



See Online for webtables 1-3



See Online for webappendix 1

notes for every indicator include: definitions, rationale, method of computation, data source, periodicity, comments, and limitations (webappendix 1). Each data source was assessed for its quality and any potential bias was noted.

To reduce the number of indicators, disaggregation of all appropriate indicators on all relevant grounds was not required, although we acknowledge that such data should be available. Several of the selected indicators, however, address discrimination, including the indicator on civil registration requiring disaggregation on five priority grounds: sex, ethnic origin, rural or urban residence, socioeconomic group, and age. We identified these priority grounds of disaggregation through a process of consultation between lawyers and health workers, including representatives from the British Medical Association, WHO, and academic institutions. Ideally, all appropriate data should be disaggregated, at least, by these five priority grounds. The civil registration system should be one of the most comprehensive data-collection systems in a country, and therefore this indicator was chosen as the proxy measure.

We did not identify indicators of all right-to-health features conforming to our selection criteria (eg, indicators related to coordination and research and development). Although several indicators exist addressing different dimensions of access, such as indicators 24 (access to clean water), 27 (antenatal care), and 46 (catastrophic health expenditure), we accept that issues of access demand more attention.

External review

After selection of draft indicators, we sent them and explanatory notes to 40 experts, who had not previously been part of this project, for their comments and review. 22 experts responded, including lawyers, human-rights professionals, clinicians, public-health practitioners, academics, and policy makers. We recognise the advantages of random sampling, but constraints of time and resources prevented this approach. However, expert comments were very constructive in deciding and devising the final version of our list of indicators.

Data collection

To fulfil the project's objectives, we needed to consider data availability at the global level and, in relation to five countries, at the national level as well. State For a few indicators, only the global perspective was necessary (eg, the number of international and regional treaties recognising the right to health ratified by a country). If information was not present about a particular indicator, it was marked as not available in the tables 1 and 2. If an indicator was not applicable to a particular country, it was marked as such. The time period for data collection was from August, 2007, to August, 2008, with the intention of obtaining data for the same indicators at about the same time.

We initially selected six countries for national data collection because one of us, PH (then the UN special rapporteur on the right to the highest attainable standard of health) had recently been to them on mission and prepared formal UN reports on each before this project began. Only five could commit to data collection in the allotted time: Sweden, Mozambique, Romania, Peru, and Ecuador. Although not globally representative, these high-income, middle-income, and low-income countries provided a range of different political background, history, geographical location, and cultural contexts. Countries such as China, Bangladesh, USA, and India would have been interesting to study, but they fell outside our selection criteria. In each of the five countries selected, we chose data collectors who, at the relevant time, were independent from the government (although they might have collaborated closely with the government) and had a good knowledge of the country, of health and human rights, and preferably of the right to health.

For every indicator, the information obtained was the response to the indicator, the source of the data, and the date of last update and of access (if from an internet source). Relevant comments to explain the answer were documented, in addition to exact legal provisions for indicators related to the law and exact quotes for indicators related to plans or policies. In addition to table 1 on global data (194 countries) and table 2 on national data (five countries), webtables 4 and 5 include extended tables with sources, comments, and other information. The International Committee of Medical Journal Editors Uniform Requirements was used as the basis for the referencing system.113 For internet sources, the date of access and of last update was of particular importance to document. The working currency for all monetary data was US dollars at the exchange rate at the time of data collection.

We clearly defined terms used for indicators that were strictly adhered to during data collection; although this rigidity might have led to reduced data availability. All relevant definitions can be found in the explanatory notes online (webappendix 1).

Data were accepted in any of the official UN languages: Arabic, Chinese, English, French, Russian, and Spanish, with translations into English done by the team where necessary. National data were received in English, Spanish, or Swedish, and translated where necessary.

Primary data were not collected; therefore, formal ethical approval was not necessary for this research project. Only secondary data were used on both global and national levels. All the information was in the public domain, defined to be any document that is in print and should be easily accessible, such as in a library or on the web.

To ease collection of global data, we created the so-called one-click rule, which defines that the limits of the search for data should only be no more than one mouse click away from the global source. For example, if, while navigating through the WHO website, a link to a national

See See for webtables 4 and 5

Panel 4: Indicators of right to health

Recognition of the right to the highest attainable standard of health

- 1 Number of international and regional human-rights treaties recognising the right to health ratified by the state
- 2 Does the state's constitution, bill of rights, or other statute recognise the right to health?

Non-discrimination

- 3 Number of treaty-based grounds of discrimination that the state protects out of: sex; ethnic origin, race, or colour; age; disability; language; religion; national origin; socioeconomic status, social status, social origin, or birth; civil status; political status, or political or other opinion; and property
- 4 Number of non-treaty-based grounds of discrimination that the state protects out of: health status (eg, HIV/AIDS); people living in rural areas; and sexual orientation
- 5 General provisions against discrimination

Health information

- 6 Does the state law protect the right to seek, receive, and disseminate information?
- 7 Does the state law require registration of births and deaths?
- 8 Does the state have a civil registration system?
- 9 Does the state disaggregate data in the civil registration system on grounds of: sex, ethnic origin, rural or urban residence, socioeconomic status, or age?
- 10 What proportion of births is registered?
- 11 Does the state regularly collect data, throughout the territory, for the number of maternal deaths?
- 12 Does the state centralise these data for the number of cases of maternal deaths?
- 13 Does the state make publicly available these data for the number of cases of maternal deaths?
- 14 Does the state regularly collect data, throughout the territory, for the number of neonatal deaths?
- 15 Does the state centralise these data for the number of cases of neonatal deaths?
- 16 Does the state make publicly available these data for the number of cases of neonatal deaths?

National health plan

- 17 Does the state have a comprehensive national health plan encompassing public and private sectors?
- 18 Has the state undertaken a comprehensive national situational analysis?
- 19 Before adopting its national health plan, did the state undertake a health impact assessment?
- 20 Before adopting its national health plan, did the state undertake any impact assessment explicitly including the right to health?
- 21 Does the state's national health plan explicitly recognise the right to health?
- 22 Does the state's national health plan include explicit commitment to universal access to health services?

Participation

23 Is there a legal requirement for participation with marginalised groups in the development of the national health plan?

Underlying determinants of health

- 24 What percentage of the rural and urban population has access to clean water?
- 25 What are the CO, emissions per capita?
- 26 Prevalence rate of violence against women

Access to health services

27 Proportion of women with a livebirth in the last 5 years who, during their last pregnancy, were seen at least three times by a health-care professional, had their blood pressure checked, had a blood sample taken, and were informed of signs of complications

Medicines

- 28 Is access to essential medicines or technologies, as part of the fulfilment of the right to health, recognised in the constitution or national legislation?
- 29 Is there a published national medicines policy?
- 30 Is there a published national list of essential medicines?
- 31 What is the public per capita expenditure on medicines?
- 32 What is the average availability of selected essential medicines in public-health facilities?
- 33 What is the average availability of selected essential medicines in private-health facilities?
- 34 Percentage of 1-year-old children immunised against measles
- 35 Percentage of 1-year-old children immunised against diphtheria, tetanus, and pertussis

(Continues on next page)

(Continued from previous page)

Health promotion

- 36 Does state law require comprehensive sexual and reproductive-health education during the compulsory school years for boys and girls?
- 37 Proportion of 15-24-year-old boys and girls with comprehensive HIV and AIDS knowledge

Health workers

- 38 Does the state have a national health-workforce strategy?
- 39 Does the state law include provision for adequate remuneration for doctors?
- 40 Does the state law include provision for adequate remuneration for nurses?
- 41 Do the state's workforce policies or programmes include a plan for national self-sufficiency for doctors?
- 42 Do the state's workforce policies or programmes include a plan for national self-sufficiency for nurses?
- 43 Do the state's workforce policies or programmes provide incentives to promote stationing in rural areas of doctors?
- 44 Do the state's workforce policies or programmes provide incentives to promote stationing in rural areas of nurses?

National financing

- 45 Is the per capita government expenditure on health greater than the minimum required for a basic effective public-health system?
- 46 What is the proportion of households with catastrophic health expenditures?
- 47 Total government spending on health as percentage of gross domestic product (GDP)
- 48 Total government spending on military expenditure as percentage of GDP
- 49 Total government spending on debt service as percentage of GDP
- 50 Proportion of national health budget allocated to mental health

International assistance and cooperation

- 51 Does the state's international development policy explicitly include specific provisions to promote and protect the right to health?
- 52 Does the state's international development policy explicitly include specific provisions to support the strengthening of health systems?
- 53 Proportion of net official development assistance directed to health sectors

Additional safeguards

- 54 Does the state law require protection of confidentiality of personal health data?
- 55 Does the state law require informed consent to treatment and other health interventions?
- 56 Does the constitution protect freedom of expression?
- 57 Does the constitution protect freedom of association?
- 58 Does the state have a patients' rights charter?
- 59 Is the patients' rights charter available in all official languages?

Awareness raising about the right to the highest attainable standard of health

- 60 Does the state have a national human-rights institution with a programme of budgeted activities to raise awareness of the right to health among the public?
- 61 Does the state have a national human-rights institution with a programme of budgeted activities to raise awareness of the right to health among doctors?
- 62 Does the state have a national human-rights institution with a programme of budgeted activities to raise awareness of the right to health among nurses?
- 63 Are human rights a compulsory part of the national curriculum for the training of doctors?
- 64 Are human rights a compulsory part of the national curriculum for the training of nurses?

Monitoring, assessment, accountability, and redress

- 65 Infant mortality rate
- 66 Mortality rate of children younger than 5 years
- 67 Maternal mortality ratio
- 68 Life expectancy
- 69 Does the state have a national human-rights institution with a mandate that includes the right to health?
- 70 Number of judicial decisions, nationally, that considered the right to health during 2000-05
- 71 Does the state have a national human-rights institution with a mandate to monitor international assistance and cooperation?
- 72 In the past report submitted by the state to the UN in relation to the International Covenant on Economic, Social, and Cultural Rights, was there a detailed account of the international assistance and cooperation in health that the state is providing?

website was found, then the link would be opened. If the required information was accessible on that webpage, then it would be judged as globally processed data and therefore acceptable. If, however, there was need to follow more than one link, open tabs, or for any navigation other than scrolling up and down, the information was not judged as globally available. This rule only applied to links to webpages outside the global source, with no limitations imposed on navigation within the global source. We decided that this rule was needed to provide a practical limit to what could otherwise become an eternal internet search, but still allowing adequate and useful data collection.

We generated a list of global websites (webappendix 2). If any data were unavailable in any of these websites, we did a more detailed search. We identified suitable search terms where necessary; these are documented in the explanatory notes that accompany each indicator (webappendix 1).

Sometimes, the presence of a right-to-health feature was not apparent at the global level, which could be interpreted as the data were not existing. However, in these situations we reported that the information was not available, which meant that it might exist and be documented elsewhere. For example, if there was no mention of a national health-workforce strategy in the information available at the global level, then the data were listed as unavailable for that country. However, if the information stated that there was no health-workforce strategy, then that was recorded with a 'no'.

Methods for data collection nationally were slightly different and defined as accessible information in the public domain. These data were needed to be publicly available and therefore included information available on the internet, published reports, or information publicly available on request. We requested documentation of the source. Data that were only available to selected groups or information acquired through interviews were not allowed. National teams of data collectors could decide how best to search for the information as long as it fulfilled the methodological requirements. National teams searched relevant websites and published documents unrestricted by the one-click rule. However, they were restricted to national sources and could not access global databases, such as UN sources. We relied on the same explanatory notes (webappendix 1) to ensure that definitions and criteria were consistent with the global data and the same referencing guidelines were applied. We are aware of some limitations of the methods.

For some indicators, a year was included from which data were collected (identified in webappendix 1). The project started in 2007 and data were often not yet available for 2007, or even 2006, and therefore data from 2005 were often the most up-to-date (further information is available in webtables 4 and 5 and explanatory notes in the webappendix 1). Furthermore, the indicator relating to judicial decisions was restricted to cases within a 5-year period (2000-05) because we thought that this was a manageable recent timeframe.

Several indicators we selected are commonly used (eg, indicator 68 on life expectancy), and information is available in published material about their usefulness, validity, and limitations.

Because of the many differing lists of states worldwide, we opted to use a list of 194 countries generated from the WHO member-state list of 200052 and those countries listed by the UN Development Programme, 112 acknowledging that other lists may differ. Several indicators were only applicable to donor states, and the list of states to be considered for these indicators was compiled from Organisation for Economic Co-operation and Development (OECD) members¹¹⁴ and the International Development Association of the World Bank list of donors from March, 2008115 (webpanel). However, the indicator may be related to an See Online for webpanel event that happened before a state was a donor, such as the past report in relation to the International Covenant on Economic, Social, and Cultural Rights.



We discuss some of the key findings and results arising from the data collected for the 72 indicators, giving special attention to three of our objectives. Do countries' health systems have the relevant right-to-health features? Are the relevant data available at the global level? Do the data provide a basis to monitor, over time, health systems and the progressive realisation of the right to the highest attainable standard of health.

We did not try to find directional relations between variables, such as treaty ratification and health outcomes. Several indicators in our list illustrate that, no matter how sophisticated they are, indicators never provide a complete picture and they need to be supplemented with qualitative information. Table 1 summarises the global data from 194 countries and table 2 the national data from five countries. All data are available in webtables 4 and 5.

Recognition of the right to health

Recognition of the right to the highest attainable standard of physical and mental health is a right-to-health feature of a health system. Although recognition can have various forms, we focused on international (indicator 1) and national (indicator 2) recognition (panel 4). Figure 2 shows the number of countries that have ratified three international human-rights treaties that include the right to health. The step after ratification of treaties is the recognition of the right to health in the national constitution or other statute, but more than two-thirds of countries do not have this recognition. Only 56 countries that have ratified the International Covenant on Economic, Social, and Cultural Rights include the right to health in their constitution or other statute. International recognition of the right to health (indicator 1) is substantially more widespread than national recognition (indicator 2), probably because international accountability is weaker than national accountability.



See Online for webappendix 2



Although legal recognition of the right to the highest attainable standard of health can mean commitment towards the realisation of the right to health, this does not capture the actual process or success of implementation. Other indicators attempt to do this and are discussed later. Legal recognition is important because it can increase accountability of stakeholders with responsibilities to, and within, a health system.

Although eight indicators explicitly mention the right to health, different countries use different terminology for this human right. Some countries use terminology that does not match our wording, and negative results were recorded in these cases (webappendix 1). Online documents were sometimes translations of original documents, introducing another possible reason for different terminology.

Non-discrimination

We aimed to record aspects of non-discrimination, equality, and equity—key right-to-health features of health systems. Indicator 3, for example, lists 11 treaty-based grounds of discrimination, and indicator 4 lists three non-treaty-based grounds of discrimination (panel 4). The treaty-based ground of discrimination most commonly protected by law was ethnic origin (122 countries), whereas the least-protected was age (13 countries; figure 3). However, 95 countries protect only five or less treaty-based grounds of discrimination, and none protects all 11.

We addressed non-discrimination asking whether data in the civil registration system were disaggregated on the five priority grounds of sex, ethnic origin, rural or urban status, socioeconomic group, and age (indicator 9). None of the five countries studied nationally disaggregate these data by ethnic origin, and therefore they cannot show any inequity between ethnic groups. Disaggregation of data on the basis of ethnic origin is a controversial issue and, although such information can be used in a positive way, it can also be used in a negative way (eg, to reinforce stigmatisation). Therefore, article 8 of the EU Data Directive prohibits the "processing of personal data revealing racial or ethnic origin", but with important exemptions related to data processed by health professionals."

For non-treaty-based grounds of discrimination, protection was even less widespread than for treaty-based grounds (figure 3). For example, according to our approach, only three countries (Fiji, South Africa, and Ecuador) protected against discrimination on the ground of sexual orientation.

People with mental illnesses are frequently neglected and discriminated against, and this might lead to inadequate financial provision for mental health." Therefore, we took into account the proportion of the national health budget allocated to mental health (indicator 50). Of 98 countries for which data were available, almost half allocated 2% or less of their national budget to mental health. Sweden and Ecuador did not allocate a specific budget for mental health. The team

gathering data in Sweden remarked that this is "partly a consequence of the objective to not stigmatise the group" (webtable 4). We do not agree that a specific budget allocation for mental health could stigmatise those with mental-health problems or that it is inconsistent with the integration of mental-health care across health systems. By contrast, the absence of a specific budget allocation might maintain the marginalisation and neglect experienced by many people with mental disabilities.

Later, we consider the indicator on access to clean water (indicator 24). Disaggregated on the basis of urban or rural residence, this indicator confirms the disadvantage of rural dwellers in most countries.

Health information

Because of its crucial importance in relation to both the right to health and the WHO building blocks, health information is prominent in our profile indicators (indicators 6-16). We focused on maternal and neonatal deaths, and the civil registration system. We questioned whether countries obtained data for the number of maternal deaths throughout their territory. On the basis of global data and our approach, 69 countries obtained, centralised, and made publicly available these data; whereas 88 countries did not. Data for the remaining 37 countries were unavailable at the global level, including those for Ecuador and Peru. Compared with data for maternal deaths, data for neonatal deaths were available at a global level for even fewer countries. Nationally, data were gathered, centralised, and made publicly available by Ecuador, Romania, and Sweden (panel 5); however, Mozambique did not do this for maternal deaths (they only include those deaths occurring in institutions) and Peru did not for neonatal deaths. Overall, on the basis of our approach, 88 countries do not seem to have in place an adequate health information system for maternal deaths, suggesting that their health systems are seriously deficient in terms of both the right to health and relevant WHO building blocks. Also, despite their importance, global data for maternal and neonatal deaths are inadequate.

As with equity, human rights have a particular concern for marginalised individuals, groups, and populations. Several indicators in the profile take into account disadvantaged groups, such as indicators on discrimination (indicators 3-5), participation with marginalised groups (indicator 23), and whether or not the patients' rights charter is available in all official languages (indicator 59). Disadvantage cannot be monitored without data that are disaggregated on key grounds.117 We questioned whether a country disaggregates data from the civil registration system on the priority grounds of sex, ethnic origin, rural or urban residence, socioeconomic group, and age (indicator 9). On the basis of our approach, no global data were available for any country. However, research in the five selected countries showed that national data were available.

All five countries disaggregated on two of the five grounds (sex and age); only one country (Romania) disaggregated on four of the five grounds, and none disaggregated on the ground of ethnic origin, which makes the design of appropriate interventions that address ethnic disadvantage very difficult for policy makers. Lack of disaggregated data also makes it difficult to hold countries accountable for accessibility of their health systems. From the right-to-health perspective, this shortcoming is important.

Overall, our data confirmed that disaggregated information, which is crucial for right to health, even when available nationally, is not always made available globally.

National health plan

According to general comment 14, the adoption of a national public-health strategy and plan of action is a core obligation.³⁶

An essential precondition for the development of a comprehensive national-health plan is a national health situational analysis (indicator 18). Global data showed that 57 countries had done health situational analyses, although all were done as a part of the WHO country cooperation strategy development process.118 However, global data were not available for the other 137 countries. Data were more readily available nationally than they were globally. For example, although global data are not available for Romania, national data confirmed that they have not done a health situational analysis. Indicator 18 does not capture whether the analysis was used to develop the national health plan or the quality of the analysis, as shown in panel 6 for Mozambique. Nonetheless, the existence of a health situational analysis is an important precondition for a national health plan and a step in the right direction. Our research confirmed that, despite the importance of health situational analyses, global data collection neglects this right-to-health feature.

Assessments of health and human-rights effects are also needed, together with a comprehensive national health plan. There is a growing trend to undertake health impact assessments before a health initiative is finalised, adopted, and implemented.75 We asked whether countries undertook either a health impact assessment (indicator 19) or any impact assessment that included the right to health (indicator 20) before adopting their national health plan. Of course, indicators have limitations; for example, even with an impact assessment, any negative findings might be ignored and the plan implemented without revision. No global data were available with our approach for any country regarding either indicator. Nationally, none of the five countries did a health impact assessment before adopting their national health plans. We confirmed that, despite the importance of such assessments, global data collection ignores this important right-to-health feature of a health system.

We asked whether a country has a comprehensive national health plan encompassing public and private

sectors (indicator 17). Our explanatory notes (webappendix 1) identified the essential criteria of a plan, such as clear objectives, timeframes, indicators, benchmarks, and reporting procedures. For 181 countries, we were unable to gather global data with our approach, and 13 countries do not have a comprehensive national health plan-ie, their health systems lack this important rightto-health feature. However, the indicators for national health plans highlighted limitations of the internet as a resource. Dates of last updates are commonly unavailable, and therefore information might be out of date. Although we made every effort to gather data as completely and accurately as possible, with such an extensive database there might be inaccuracies. Nonetheless, despite the importance of a comprehensive national health plan, global data collection seems to neglect this important right-to-health feature of a health system.

More-detailed national data were available for the comprehensive national health-plan indicators, showing that Mozambique, Romania, and Sweden have comprehensive national health plans, whereas global data were not available. At the time of data collection, Peru was preparing a national health plan but it did not include all the features of a comprehensive health plan (panel 7).

We asked whether the national health plan includes an explicit commitment to universal access to health services, defined as access to primary, secondary, and tertiary physical and mental care (indicator 22). We regarded a commitment to basic or essential care as inadequate. A low-income country might not be in a position to deliver universal access to health services, but a comprehensive national health plan should include a commitment to reach this aim. 46 Such a commitment is the minimum expected from all countries, whatever their stage of economic development. A developing country's commitment to universal access gives an important message to health workers, the public, and donors. When a country cannot provide universal access, it must have fair, transparent, rational, evidence-informed processes (eg, protocols and guidelines) in place to ensure that reasonable decisions are made when determining who has access to health-related facilities and services, and on which terms.

On the basis of global data and our approach, national health plans of 15 countries (Antigua and Barbuda, Bahrain, Botswana, Chile, North Korea, Dominican Republic, Honduras, Libya, Mauritius, Mozambique, Peru, Seychelles, Timor-Leste, Uruguay, and Yemen) include an explicit commitment to universal access to health services, whereas plans of 14 countries (Afghanistan, Argentina, Bangladesh, Bolivia, Costa Rica, Croatia, Egypt, El Salvador, Lesotho, Malawi, Nepal, Papua New Guinea, Romania, and Tanzania) do not. However, global data are not available for 165 countries. Again, our research suggests that global data collection neglects information that is important for the right to health.



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ad 6	8/8	N	6	811	ō	N			9												55.7		0.0614	2005 - 10			110180		Υ
le 6	5/7	N			1	Ν	100	Υ										N			40.9		0.0127	15t		6.2	100		Υ
na 5	/5 1	V				N				١								5			66		3.8712		7	861			Y
ombia 7	/7 Y	1	7			Υ	Υ	Υ	9								1	5					3.8393			49-4	2019	N '	
noros 7	/8 1	V		ä	300	N	6		8										14							is .	200		
go 7. zzaville)	/8 1	1	6	1	**	Ν	1904	N											20							44·1 25·5	N ,	`	
k Islands 2	/5 N	ı	5	0	1	N		γ					٨	I N	Ν						97.5	00.5							
a Rica 7/	/7 N	1			1	N		Υ	300	Υ	Υ	Υ			Y				N				-54					N 1	
d'Ivoire 7/	/8 N		. :			N	**		55	N	N	N			N	١.							F					V Y	
tia 6/	/6 Y		3 .	œ	1	Υ		Υ	350	Υ	Υ	Υ	Υ		Y		Ĵ		N							12.7	N 1		
4/	7 Y		1 -		1	N		Υ	10		Υ	Υ	Y	Y	Y		194							9		70-3	Ν .		
us 6/	6 N	. 5	,		1	N		Υ		Υ	Υ	Υ		3.0	100			***	27		77-7	94.9	2-2956				N I	1 Y	K 3

							Heal	th wo	rkers	Nat	ional fir	nancing	ı			IAC	Add	lition	al saf	egua	rds				, assess ity, and			
31§	32¶	33¶	34†	35†	37m	37f †	38	43	44	45	46t	47†	48t	49t	50†	53†	54	55	56	57	58	59	65	66	67**	68 ††	70	72
 			57	45		.,	Υ			N	12	5.2	1.5			NA		w	Υ	Υ		200	165	257	1800	42		N/
221	Vic.	59	61	52	186	24	100	500		Υ	on:	6.5	1.3	1	6	NA	200	360	Υ	Υ	Xer:	198	15	17	92	71		N
100		300	91	92			341	200		Υ	200	3.5	2.9	5.8	NA	NA	955		Υ	Υ			33	38	180	71		N
	8511	122	188	ž.		6				Y		6-3			4	NA	377		Υ	Υ	10		3	4		82	122	N
	w	144	53	34	42.7	35-2	Y	144	w	N	100	1.8	4.1	6.8	NA	NA			Υ	Υ		***	154	260	1400	41	10	N
•••		**	**		**	9	**	×	100	Υ		4.8	28	***	3	NA	***	**	N	Υ	80	1355	10	11	**	73	4	N
227	221	100	1991	и	W	ži.	**		1441	Υ	5.77	10-2	1	5.8	NA		Υ	Υ	Ν	Ν	æ	1996	14	17	77	75	100	N
1.57	945	1.0	72	71	er .		(84)	:00	(4.0)	N	360	5.4	2.9	2.8	5	NA	N	3885	Υ	Υ	007	355	21	24	76	69	11	N
331-02	**	136		55		52	(2.5)		2005	Υ	200	8.8	1.8	250	10	4.2	N	Υ	N	••		••	5	6	4	82	4	N
171-98		758	250	73	8	ž.				Υ		10.2	0.9		NA	7.97	Υ	1440	Ν	Υ	201	***	4	4	4	80	ii.	N
			88	94		12	N	NA	NA	N	7.15	3.9	2.3	1.9	2	NA			N	Υ	**0		73	89	82	64	200	N
30.55	900	100		60	**		**		18.85	Υ	24.5	6.7	0.6		11	NA	3.	***	N	Y	5.50	175	13	14	16	74	ě	N
57-36	223		94	90	ü		••			Υ		3.8	3.6			NA			Y	Υ	w	147	9	10	32	75		N
			81	88	22	ñ	144		and the	N	1.21	2.8	1	1.3	1	NA		900	N	Υ	100		52	69	570	63		N
W2 1 1		340	500	e:	140		Ν	NA	NA	Υ	30 IS	6.8	0.8	3.1	12	25	- 22		N	Υ	200	355	11	12	16	75	22	N
36-12		135	100		2					Υ	15.5	6.6	1.5	2.3	NA	NA	9		Υ	Υ			6	8	18	69		N
500.02			**	24		8			10	Υ	0.09	9.6	1.1		6	2.21	Υ	Υ	N	Υ	· ve	SW	4	5	8	79		Y
440		144	83	83	li.	72	1886		**	Υ	940	4.9	1.4	20.7	1	NA		**	N	Υ		22.5	14	16	52	69		٨
		300	72	79	10.6	8.1		200		N		5.4	1.1	1.6	34	NA			Y	Υ		324	88	148	840	55		١
3.7	**	200	96	99				355		N	**	4		0.8	0	NA	0				44	144	63	70	440	64		١
4-19			64	72	18					Υ	142	6.9	1.6	5.7	0	NA	N	100	Υ	Υ		30	50	61	290	66		١
	741	ane	64	88	ä	a.	34	724	500	Υ	266	8-8	1.8	2.7	NA	**	**	300	Υ	Υ	200	ins.	13	15	3	75	*	١
		285	90	97	33	40		•		Υ		8.3	2.9	0.5	1	NA	24		N	Υ		***	90	124	380	52		١
			87	81	10	15	100	200	300	Y	10.27	7.9	1.4	7.9	3	(6.6)	Υ	Ν	Y	Υ	967		19	20	110	72	w	N
75-4	4.0	7.9	198	***			Sec		980	Υ	144	2	3.9		NA	NA	22	85		(**)	eto.	131	8	9	13	77	9	٨
37-55	00	98	330	200	8		355	1000	0.0	Υ	2.00	7.7	2.4	21.7	3	NA	Υ	**	Y	Υ		***	10	12	11	73	n	1
250	2.0	157	56	57	23	15	**	**		N		6.7	1.1	0.9	NA	NA	161	100	Υ	Υ	900	-33	122	204	700	47		N
w		177	83	83	16		Y	366	144	N	(4.0)	2.2	1.3	340	1	NA	0.7		3.0	10.	0.0	1.0	74	104	380	60	**	N
**	**	10	75	74	3.6	3.6	100	580	**	N	**	3.4	6.2	4.9	NA	NA		12.5	Υ	Υ	200	-15	109	181	1100	49		N
2.6	**	1221	77	78			22	555	3.5	N	5.02	6.4	1.1	0.5	NA	NA	**		Υ	Y	**	ĕ	65	82	540	62	77	N
1.25			71	75	34.3	27.2	••	**		N		5.2	1.3	4.7	0	NA	24		Υ	Υ		a	87	149	1000	51	0.	V
279-34	100		120	990	15	io.	100	154	122	Υ	0.09	9.7	1.1	383	6	6.43	Ν	Υ	Υ	Υ	**	93	5	6	7	81	1	Y
8.45	**	2006	75	85		***				Υ	***	5.6	0.7	3.4		NA	525	185	Υ	Υ	0.01		25	34	210	70		١
	22	22.5	52	48		220	1,55	555		N		4	1.1	0.4	NA	NA	60		Υ	Y			114	174	980	48	×	1
	31.3	13.6	23	20	21	8		144	124	N	144	3.7	0.9	1.1		NA	••1	**	Υ	Υ	••		124	209	1500	46	7.00	٨
157-91		100	200	300		940	144	200	(94)	Υ	***	5.4	3.7	6.7	2	NA	N	N	Υ	Υ	9.50		8	9	16	78	22	N
15.17	19.2	10	84	73			**	***		N	**	4.7	1.9	1.2	2		N	N	N	Y		-	20	24	45	73		١
200	200	285	82	81		550	155			Y	6.26	7.3	4	8.3	0	92	N	177	Υ	Υ	**	**	17	21	130	74		١
· ·	1227	174	73	70		W	Υ	111	**	Ν	30	3	199	1	NA	NA	K40	99	Ν	Υ	335		51	68	400	65	**:	ı
	W	74	66	68	20	900)	300	64	144	N	(**)	1.9	1.4	2-3	NA	NA	181	395	Υ	Υ	5.5	М	79	126	740	54	**	1
40-32	122		e.	441					**	Υ	**	4.6	544		NA	NA	***	1.00	Υ	Υ	100	-0	16	19		73	- ••	1
15	300	is .	92	87	**	**	N	NA	NA	Υ	0-12	7.1	0	3	8	NA	N	200	Υ	Υ	200		11	12	30	78		1
1.19	(44)	0	69	70	**	(4.5)	**			N		3.9	1.5	2.8	0	NA	14.		Υ	Υ	**		90	127	810	53	••	١
				12	÷.			6	**	Υ	0-2	7.4	1.9	12-8	8		**	377	Y	Y	997	13	5	6	7	76		١
11.54	× ×	a			**:	**	Υ			Υ	**	7.6	. 69	300	5	NA	880	120	Υ	Υ	**	22	5	7	45	78	550	١
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	tion	ogni- 1		on- icrim on	in-	H	ealth	info	mation	1						Nat plar		healt	h	Unde	erlying de	eterminant	ts		Acc- ess	Med	dicine	s
	1*	2	3	4	5	6	7	8	10†	11	12	13	14	15	16	17	18	21	22	24† rural	24† urban	25‡	26† rural	26† urban	27†	28	29	30
Continued fro	om pr	evious	page)								-						-			Edit Hali		- Ioidi	Orban		-	-	
Zzech Republic	6/6	Υ	8	**	1	Υ		Υ		Υ	Υ	Υ	Υ	Υ	Υ	***	+		a.	.,,		11-4759		194	61.6	N	Υ	Υ
DRC	6/8	N	6	1	14	N	551	925	34	N	Ν	N	N	Ν	N	**				28.5	83.8	0.037		192	75.7	N	Υ	Υ
enmark	6/6	Ν	2	300		Υ		Υ	- 14	Υ	Υ	Υ		***		11 ₂₂		16	144			9.8013		247		N	N	N
jibouti	5/8	10.0	(30%)	**	100	Ν	**	N	89	Ν	N	N	N	N	N	***	Y			51.5	70.5	0.4639	840	(8.6)	••	N	N	Y
ominica	5/7	(55)	155	22	369	Ν		Y	21				Υ	Y	Υ	100			344	90	100	1.5636				N		30
ominican epublic	6/7	Ν	33	ū	125	Υ	**	Υ	78	Ν	N	Ν	N	Ν	Ν	27		++	Υ	72.9	91.4	2.1063	ñ.		73.7	N	Y	Υ
cuador	7/7	Υ	8	2	1	Y	Υ	Υ	122	N	N	N	N	N	Ν				900	89.7	96-4	2-2658			40.5	N	Υ	Υ
gypt	7/8	N	3		1	Ν	388	Υ	194	N	Ν	Ν	N	Ν	N	N	Υ	N	N	96	100	2.2116	744			N	Y	Y
Salvador	7/7	Ν	4	**	1	Ν		Υ		N	N	Ν	N	Ν	N	744			N	67.1	96	0.9378	••		522	N	N	Υ
quatorial uinea	6/8	N	3	30	300	Ν	144		32	N	N	N	N	N	Ν	-		94	Ser.	42.4	45.3	11-4748	(88)	***	344	N	1.	
ritrea	6/8	N	7	140	1	Ν	355	155	(88)	Ν	N	N	N	N	N	N	Υ	45	200	53.7	71.7	0.1735	1991	25	122	N	Υ	Υ
stonia	6/6	Υ	7	(4.4)	1	Y	7.0	**	**	Υ	Υ	Υ	Υ	Υ	Y	Ν				98	99	14.0496	(84)	18	55.9	N	Υ	N
thiopia	7/8	Ν	8	200	1	Ν	1460		7	Ν	Ν	N	Ν	N	N	200		w	**	39.7	96.4	0.1037	71		7.4	N	Υ	Υ
M	2/5	Υ	**	200	2	N	900	Υ	9.00	33	144		N	N	N	2.5		260		86.1	98.8				75	N	906	
Ĭ	3/5	N	9	2	1	N	440	Υ	(8.6)	N	Ν	Ν	Ν	Ν	Ν			••		5.5	(16.6	1.301	700		vii.	N	Υ	Υ
nland	6/6		7	1 300	1	Υ	••	Υ	•	Υ	Υ	Υ	Υ	Υ	Υ	***				100	100	12.5782	200	Sec.		N	Υ	N
ance	6/6	N	3	**		Υ	***	Υ		Υ	Y	Υ	Υ	Υ	Υ							6.1608		***	961	N	N	Υ
abon	7/8	N	2	***	255	Ν	**)	900	89	N	N	N	N	N	N	***			246	46.9	94.9	1.0796		**	MS	N	Y	Υ
ne Gambia	7/8	77	7		. 1	Ν	200	•••	55	N	N	N	Ν	N	Ν		Y	er .		77-1	94.6	0.1821	**			N	N	Υ
eorgia	5/6	Υ	8	1	111	Y	**	Υ	93	N	N	N	Ν	N	N	220		2		95.5	99.8	0.866	m:	xv.	64-6	N	17	
ermany	6/6	N	7	**	38	Υ		Υ		Y	Y	Υ	Υ	Υ	Υ			a		100	100	9.7881		an.	0	N	ŭ	144
nana	7/8	200	6	1	1	N	es.	100	51	N	N	Ν	N	N	N			ø	**	398		0.326	8		41.8	N	Υ	Υ
eece	6/6	N	1	155	***	Υ	055	Υ	194	Υ	Υ	Υ	Υ	Υ	Y	ë			**	66.5	88.4	8.7275	86			N	25	**
enada	4/7	N	5	1	**	N	255	Υ	**	(*K)	**	**	N	N	N		•		**	0.0	***	2.0693	588	TO:	Sale Control	Ν	Ν	Υ
	7/7	Y	2	**	1	Υ	**	Υ	•		N	N	N	N	N	100				93	97	0.9857		•••	ox.	Ν	Υ	N
	7/8	Y	80.		**	N	***		43		N	N	N	N	N	304			**	98.9	89-8	0.1515	4.6	650		66	Y	Υ
sau	4/8	Υ	4	155	(55)	N	***	100000	39		N	N	N	N	N	523		900	**.	33.8	79-1	0.1752	47	n .		N	N	Υ
	5/7	N	10	1	990	N	**	N	97			N	N	N	N	-	Υ	940	900	49.1	79-2	1.9547	(57)			Ν	Ν	Υ
	4/7	Y	5	2000	200	N	3000	37	81						N	200		A.C.	100	83-2	83.4	0.1919	SW	ě		N	***	811
	6/7	Y	2	300	80	Y	(200)	Y	94			Υ	N	N	N	**	1	100	Υ	54.3		1-1362	541	in .		N	Y	Υ
	6/6 6/6	N	7	1497	1	Y		Y	200			Y				99	1	••	ě			5.6543		u	71-6	N	Υ	N
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		N N	4	1	1	Y	**	Ν	41						N	255	Υ	us:	0				••		11.8	N	Υ	Υ
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N · · · by Obt 6z 9z · · · · A A · · · · · VN							197		Υ	**									. 42									
N · · · b 9	Ν					570	.00	٨	٨	100	**	AN						٨	••	**	•		**	20.00	185	75%	32	
N · · · b 9 · Obt 6z 9z · · · · A A · · · · · · N VN Z T EZ T 6 E · · · A · · · · · · · · · · · · · · ·	٠. ٧	08	ı	Þ	Þ		٨	Υ	X		٨	12.3	1	300	9.0	2.8		λ			**		**	1088			**	ISE
N b9 Obt 6z 9z A A NN	۰۰ ۱	18	Þ	S	Þ	***	Y	Ν	Ν	Ν	N	549	9		6.7	8.7	SE-0	Y	••		14.0			199	30.1	980	366	349
N 49 OPT 6Z 9Z A A N VN Z TEZ T 6E A TS ZZ OZ O 86 S6 08 8ZZ ZI-ZZ A E8 9 7 E A A N N EIT S T Z-8 A		18	3	Þ	3	***	***	٨	Y		٨	84.71			6·1	6.8	: = sw	Y	**				25	56	95		144	SZZ
N 49 OFT 6Z 9Z A A VN Z T-EZ T 6-E A TS ZZ OZ O TS ZZ OZ OZ O 86 S6 O8 8-ZZ ZI-ZZ				35										1.01	9.0		1.86		44	**		- 6	6	100	30			
N 19 OPT 6Z 9Z A A VN L T.EZ T 6.E A TS ZL OL O								٨	٨	N							200	14	2.5		***							
							244				N		-					٨	320	325	40							
		40	OLT															14										

	tio		a 	Non- discri		-	H	ealth	info	rmatio	n	1					Nat plai		healt	th	Und	erlying d	eterminan	ts	77413044	Acc- ess	Me	dicine	es
	1*	2			4	5	6	7	8	10†	11	12	13	14	15	16	17	18	21	22	24† rural	24† urban	25‡	26† rural	26† urban	27†	28	29	30
(Continued f	rom p	revio	us pag	je)																-			-	10141	orbari	-			
Kiribati	2/5		5		1	1	N	**	N	22			, n 1	N	N	N	2				51.9	96.4	0.3244				N	Ν	Υ
Kuwait	4/5		5		4	1	N	988	Υ	336	Υ	Y	Y	**:	122	***	100	Υ	100				37-9684	· ·			N		
Kyrgyzstan	4/5		6			1	Υ		Υ	94	N	N	N	N	Ν	N	288	**:			14		1.1114		900	524	N	Υ	Υ
Laos	5/5	N	4			300	N	122	••	59	Ν	Ν	N	Ν	Ν	N	3.	150	30		47.8	82.6	0.2296			6.4	N	Y	Y
Latvia	5/6	Y	9	100		1	Υ	74.0	Y	4	Y	Υ	Υ	Υ	Y	Υ	177		175	**	200		3.0657	122		52.9	N	Y	Υ
Lebanon	5/5	N				551	N	100	Υ	300	Ν	N	Ν	Ν	N	N	N	Υ		9	100	100	4.1019	900	W.		N	120	1
Lesotho	7/8	Ν	8			1	N	***	Ν	26	Ν	Ν	N	N	N	N	Ν	Υ		N	78-3	96.3		**		44	N	***	
Liberia	6/8	Ν	5	1	L.	1	N	••	**	200	N	N	Ν	Ν	Ν	N	400	Υ	800		49-4	74.5	0.1401	***		100	N	Y	Y
Libya	8/8	Υ	52.5	**	8 3	**	N	100	Y		N	Ν	Ν	Ν	N	N	N	Υ	550	Υ	68-4	72.1	10.331				N		
Liechtenstein		N	1	9		25	Υ	**	Υ	6	122	**	25	(8)	**/	0.	100		V4		100	100		60	174	8	N		200
Lithuania	6/6	Ν	6	74		1	Y	22	Υ		Υ	Y	Υ	Υ	Υ	Υ	91		÷i.	144	***		3.8686		300		N	Υ	N
Luxembourg	6/6	N	300	**		22	N	**	Υ	10	Υ	Υ	Υ	Υ	Υ	Y	25	300		44	100	100	24-9271		**		N	Y	Y
Macedonia	6/6	Υ	7	3.88			Y	100	Y	94	Y	Υ	Υ	Υ	Υ	Υ	ë	0.00		**	**	241					N	Y	Y
Madagascar	7/8	Y	6	100		100	N	94	100	75	N	N	Ν	N	N	N	100			250	34.3	78-3	0.1506	122	100	100	N	Y	Y
Malawi	8/8	N	9	**	Ś	1	Ν	(900)	Υ	344	N	N	N	N	N	N	**	Υ	w	N	77	99	0.081	D.K.		18-2	N	N	Y
Malaysia	3/5	Ν	73	322	-	•	Ν	200	Υ	300	Ν	N	N	8		200	306	Υ		14.7	96	100	7.0494		11	48.8			
Maldives	5/5	Ν		••			N		Y	73	Ν	N	Ν	N	N	N	1881			***	79.9	98.8	2.4981				N	Y	Y
Лali	8/8	Y	6	(88)	,		N	***	N	47	N	Ν	N	N	N	N			220		54.4	83.6	0.0501			5		Y	Y
Лalta	6/6	N	5	1			N	•	Υ	We:	Y	Y	Υ	Υ	Υ	Υ	N					100	6.1299	**				Y	Y
Marshall Slands	2/5	Y	7	230	1	1	N	##.1	(88)	***	100	ora		N	N	N			**	396	95.9	84.1		***	tes	RRU		N	N
lauritania	7/8	N	4		(2)		N			55	N	N	N	N	N	N		×	ñ.			225	0.8866			12.5	N	Υ	Υ
Mauritius Maurit	7/8	N	-	20	33		N	9	Υ		Υ	Y	Y	Υ	Υ	Υ		(**	Y	42.3	54-2	2.598	e i		57.6			Υ
Mexico	7/7	Y	3	:344	544		Υ	••	Υ		Υ	Υ	Υ	Υ .	Υ	Y			**	300	100	100	4-2387	ü	m:	55.8			Υ
Aoldova Aonasa	6/6	N	8	3.00	35	6	Υ		Υ	98	Υ	Υ	Υ	Υ	Y	Υ				200	92.1	94.4	1.9578	1722	**				Υ
Monaco	5/6	N	127	855	303		N	*	Υ	140			2.5	N	N	N		8 1			***	100		**	W		N		***
longolia	4/5	Υ	9	**				200	Υ	98	Υ	Υ	Υ	N	N	N	N '	,	216	900	34.7	90.9	3.3455	**	0			Υ	Υ
Montenegro	5/6	Υ	1	***	1		Υ	25	1955	98	Υ	Υ	Υ			111				860	AGO	ii.	9	25	**	96	1400	921	
lorocco	5/8	N		(4.6)	10		N	**	Υ	85	Ν	N	N	N	N I	N	1	e	Υ	19	56.9	97-3	1.3654			19-7		Ν	Y
lozambique	7/8	N	6	2	0		N		W		N	N	N	N I	N I	N	1	ē.,		Υ	24.4	73.3	0.1079			OCCUPATION			Y
amibia	8/8	N	4	850	1		N		300	71	N	N	N I	N I	N I	V	\			ii.	88-6	32	1.2394	ser 1	36				Y
auru	1/5	N	5	1			N	11.	340	***			.)	V I	1 1	V			. 8										Y
	5/5	N	5				N			35	N	N I	N I	1 1	N 1	N	у	,	. 1	N	79	93	0.1146		2		N		
	6/6	N	4	**	1		Υ				Υ	Υ '	Υ \	/)	/ Y	1					100	100	8.7349	. ,			N 1	,	Y
		N	5	1.55	200						Y	Υ '	Υ 1	/ · · · \	Y	1		19									N N		N
		Y	7	100	1	1	N	Υ	Υ	81	Υ '	Y 1	Y 1	1 1	1 1	1					56.7						N Y		Y
	27724	Υ	4	150	Will	- 1	N		9	32 1	N I	N 1	N 1	1 1	1 1	١.		225		•							N Y		Y
		N	6	1		1	N .			33 1	N 1	1	N 1	1 1	1 1					90			- 0				N Y		Y
		N		390	**	1	Ν .		Υ		. ,			1 1	1 1								2.1941				N N		Y
		N	-ti	3.00	55%	1	ν.				1 1	1 1	1 1	1 1	ı N		. Y	Y	١ ١				3.3645				N Y		
		**	**	1227	0	١	Υ .	8)	()	′ Y	′ Y	Y	Υ								19.0086				N Y		
		N	6	903	Tes	1	١.		Υ	1	1 1	1 1	1 1	l N	l N		. Y				100		12-4662				N Y		
		N			130	Y	<i>(</i> .	5 3		. 1	1 1	1 1	1 1	l N	N		. Y	**	199				0.809				N		
		N	6	1	1	١	١.		Y		100	39	N	N	N								1.9017				N N		
		N	6		1	Y			Υ	N	1 1	l N	I Y	Υ	Υ		8 10	8	100				.7827					Y	
		N	5	1	12.0	N	۱		Υ .		1 1	l N	l N	N	N		Υ		N				.4126						
aguay 7	7/7	Y	340	**	1	٨	1 Y		γ.	. Y	Y	Υ	N	N	N			200		. 1			.7215				, ,		

The second secon

								Heal	th wo	rkers	Nati	ional fi	nancing	9			IAC	Add	ition	al saf	egua	rds				, assessi ity, and			
31	15	32¶	33¶	34†	35†	37m †	37ft	38	43	44	45	46†	47†	48t	49†	50†	53†	54	55	56	57	58	59	65	66	67**	68 ††	70	72
16	6-3					921		775			Y	11	12.7	12		2	NA		30	N	Υ			47	64		65	285	N
	0 3	12	0	96	98						Y		2.2	4.7						Υ	Υ			9	11	4	78		N
0.	-23		80					N	NA	NA	N	0.62	6	3.1	5.2	8	NA			Υ	Υ			36	41	150	66	600	N
	-5			62	28			ě			N		3.6	2.1	6	NA	NA	240		N	Υ	300	**	59	75	660	60	**	N
			22		· w fi		14 140	Υ			Υ	2.75	6.4	1.7	19.6	6		Υ	500	Υ	Υ			8	9	10	71		Ν
100		0	83.8	88	90	**		N	NA	NA	Y	5.17	8.7	4.5	16.1	NA	NA	650	120	Υ	Υ	33	6.	27	31	150	70		٨
				85	83			N	NA	NA	N		5.5	2-3	3.7	7	NA			N	Υ	980		102	132	960	42	***	N
0-	-27			41	27		447	22	п	1949	N	194	6.4	1.2	0.2	NA	NA	N	794	Υ	Υ	300		157	235	1200	44	20.0	N
966		44	ö	92	96		**		20		Υ	0	3.2	1.8		NA	NA	N	222	Ν	Ν	2.5	153	17	18	97	72		N
		26.6	10	10	200	(8.0)	2.5	55		122		100	100	17		25.	NA		144	Y	Υ	144	121		W.	n	ii.	347	N
8:	2-29						••	ë	5		Y	1.34	5.9	1.2	10.1	7	NA	Ν	Y*	Υ	Υ	Υ	Υ	7	9	11	71	***	N
4	49	w.		11	**		3942			**	Υ		7.7	0.8	**	13	1.42	Υ	Υ	Ν	Υ	300	***	3	4	12	80	**	Ν
542			25	92	98	**	***		**	**	Υ		7.8	2.2	4.1	***			355	Υ	Υ	20	.,	15	17	10	73		N
0.	-08	300	9 1	59	61	15.7	19.4	e.		11.5	N	11	3.2	1.1	1.5	1	NA		ë	Y	Y		447	72	115	510	59	**	N
		12.5		85	86	36	23.5	Y	ŷ.	**	N	ě	12-2	1.6	4.6	2	NA	120	ü	Υ	Υ		a.	76	120	1100	50	***	١
13	3.4	25	43.8		44		920	8	*)	1,4	Υ		4.2	2.4	7.2	. 2	NA	Ν	10	Y	Υ	Υ	Υ	10	12	62	72	**	D
100		97	20	92	91	**		Υ	**	**	Υ	α	12.4		4.4	NA	NA	Υ	22	N	Υ	32		26	30	120	72		1
0-	-5	81	70	49	40	15	9	22		(24)	N	12	5.8	2.3	1.7	0	NA	••	ĕ	N	Y	12	140	119	217	970	46	547	1
		••	9	8.		247	••	9	257	744	Υ	ä	8-4	0.7	**	10	NA	N		Ν	Υ	**	930	5	6	8	79	***	١
18	8-43	ST.	ik.		000	1881	**	2	**	144	Υ	ř.	15.4	**		0	NA	***		Υ	Υ	155	***	50	56	44.0	63	(8.5)	١
0.	.85	ei.		84	84					ë	N		2.7	3.6	3.6	1	NA			Υ	Υ			78	125	820	58	. 300	١
7.	.99	944	40	57	89			Υ	***		Υ	1.28	4.3	0.2	4.5	0	NA	***		255	110	(8.5)	225	12	15	15	73	2.5	١
11	1		**	59	34	(00)		***	***		Υ	1.54	6.4	0.4	5.7	1	199	N	Υ	Υ	Y	**		29	35	60	74	W	1
7.00		198	200	91	92	(88)	25	440	550		Ν	2	7.5	0.4	8.6		NA	14.0		Y	Y	192	NI.	16	19	22	68	***	1
											Y	**	4.6	1250	· .	***	NA			N	Υ	300	300	3	4	***	82	920	1
4	.95	100	80	86	89	3	5	**:	100		N	**:	4.3	1.6	2.4	5	NA	Υ		Υ	Υ	0.000	200	35	42	46	66	(1.2)	1
**		THE STATE OF THE S	**	***	(4.4)	***	200	**8	100		••	MC:	8.2	***	10.5	223	225	**		Υ	Y	••		9	10		74		1
1.	.92	0	52.5	90	95	(86)	12	Ν	NA	NA	Ν	0-17	5.3	3.9	5.3		NA	**	9	Υ	Υ	122	**	34	37	240	72	997	1
2.	-81	325	550	77	72	33	20	Υ			N	91	4.3	0.9	1.4		NA	**	**	Υ	Y	100	**	96	138	520	50	300	١
10	0.41	122		80	79	SE .		Y	300	**	Y	0.11	5.3	3.1	100	NA	NA	300		Υ	Υ	***	**	45	61	210	61	(2.2)	1
4	5-31	or -	w.	***	**	**			***	60	Υ	***	10.3	**	244	NA	NA	(2.5)		N	Υ	**	**	25	30		61		- 1
		120	200	85	89	1951	.000	250	3.71		Ν	•	5.8	1.9	1.6	0	NA	1977	10	Υ	Υ		127	46	59	830	62	300	1
		ě		**	97	100	122	77	140	2011	Y	**	9.2	1.5	188	7	14.44	N	100	Y	Υ	Υ	Υ	4	5	6	80	78.90	1
10	03-2	iii		W0	744	1906	946	300	(4)	800	Υ	**	8.9	1.1	14	11	3.45	N	160	Υ	Υ	575	(5,5)	5	6	9	80		1
	.09		100	86	83	200	35.0	325	225	500	N	2.05	8.3	0.7	3.5	1	NA	*		Y	Υ	••	35	29	36	170	71	** -	
	0.2		AN	47	39	100		24	**		N	••	3.8	1	1.1	**	NA	42	***	Υ	Υ	**	372	148	253	1800	42		
1 5		26-2	36.4	62	54	21	18	**	40	***		**	3.9	0.6	9		NA	N	***	Υ	Υ	•		99		1100	48		
	3.9	a	***	141	198	346	100	880	360	**:	Υ		14.5	101		NA	NA		***	200	2	12.5	9.0	34	42		70		
		o	991	92	96	3900	(8.0	850	(0.0)	***	N		3.5			NA	NA			N	Y	••		42	55	370	66		
	22	55	100	11/	Ett.	925	22.5	6.5		**)	Υ	0.28	9	1.6	9	0	4.65	N	N	Υ	N		**	3	4	7	80		1
		2		98	98			440	**	440	Υ	663	2.5	11.8		SVE:		34	***	Υ	Υ	Tiex	••	10	11	64	74		
W		3.3	31.3	63	65	(632)	544	Ν	NA	NA	N	**1	2.1	3.4	2.2	0	NA	100	330	9		300	(2.5)	78	97	320	63		
4	19-44		**	300	3.88	**	18.6	1,000	14	**:		1,000	9.6	••		2	NA	••	***	Υ	Υ		15	10	11		69		
*		ē					72	440			Y	2.35	7.3	0	13.5	NA	NA		300	Y	Y	**		18	23	130	76		1
	3-22		-30	76	47	(**	0000		N	N	N		4.2	0.6	7.9	1	NA	12/21	***	N	Υ	10.55	355	54	73	470	62		1
5	.39	22	255	67	61	22	255	Y	2.5	**	N	3.51	7.3	0.8	6.7	0	NA	N		Y	Y		**	19	22	150	75	**	

	tio		d	on- iscrir tion	min-		Hea	alth i	infor	matio	1						Na pla		healt	h	Und	erlying d	eterminar	nts		Acc- ess	Med	dicine	es
	1*	2	3		4 9	5	6	7	8	10†	11	12	13	14	15	16	17	18	21	22	24† rural	24† urban	25‡	26† rural	26† urban	27†	28	29	30
(Continued fr			s pag	5)																	7								-
Peru	7/7	Y	**		(4)		Υ	- j y	Υ	93	N	Ν	N	N	N	N		.,	*	Υ	40.2	91	1.1682	69	51		N	Υ	Υ
Philippines Poland	5/5	Y	••		353		Υ	**	Υ	83	•	••	22	Ν	Ν	N	***	Υ			82	87	0.9716			23	Υ	Υ	N
	6/6		**		1		Υ	**	3.83		Υ	Y	Y	Y	Υ	Υ	**			(44)		100	8.0331		acc.	w.	N	Υ	Υ
Portugal	6/6		7	1			Ý	ű.	Υ	15	Υ	Y	Υ		ä		22			0.00	300	12	5-6253	122	ers.		N	Υ	202
Qatar	3/5	N	4		1		N	197	Y	**	Υ	Υ	Y	Ν	N	N	N	Υ	155	200	100	100	69-221	744		0.55	N	N	Υ
outh Korea	5/5	N	3	325	92		Υ	100	Υ	***	Y	Υ	Υ	Ν	N	N	330		12	**	71-4	97	9.7652	30	io:		N	Y	N
Romania	6/6	Υ	8	4.0	**	10	Υ	225	Υ	386	Y	Υ	Υ	Y	Y	Υ	155		**	N	16	91	4.1621	(24)		200	N	Y	N
Russia	4/5	Υ	8	1	1	- 1	N	Y	Y	1550	Υ	Υ	Υ	Y	Υ	Υ	(E.,		300	(40)	95.2	99.7	10.5393			56.4	N		IN
Rwanda	7/8	Y	6	355		1	N	100	W	82	N	N	N	N	N	N					67.6	90.9	0.0632		ä			A.1	600
aint Kitts nd Nevis	3/7	Ν	155	155		1	N	**	Υ	ii.	79	6	(55)	N	N	N	990		22	ų	99	99	2.5697	300	22 244	200	N	N	Υ
aint Lucia	3/7	Ν	**	9.0	188	1	V		Υ	66.5	255	33	100	Y	Υ	Υ					0.0	0.0	2 200=						
aint Vincent nd the	4/7	Ν	111	300		١	1		Υ	440	•	155		Y	Y	Y	8	Ĭ.	8	in the second	98	98	2·2997 1·6708	HI HI	10. 12.	6	N	89	186
renadines amoa	7/5	N 1	-																										
	2/5	Ν	7	. 1	1	1		**	Υ	ii .			**	N	N	N	0	Y			87.7	91.6	0.8236		(4)	a.	N	N	Υ
an Marino ão Tomé	5/6 3/8	Υ	**			1			 Y	69				 N	 N	 N				 			 0.6106		986	(368		W	**
nd Principe audi Arabia	4/5	N				Ν					N	N	N	N										355	***		N	N	Υ
enegal	8/8	N	3	1	1	N				CC						N		Y	1000		64.3	100	13.3811	**		100	N	N	50
erbia	5/6	Υ	10	1	1	Y				55	N	N		N	N	N	10	1	**	***	65.3	93.2	0.4353	300	**	8.5	N	Υ	Υ
eychelles	8/8	Y			1	-				99			Y				**	Ť	2.0		***		es .	927	6	200	N	N	Υ
erra Leone	7/8	N	4	1	1	N		**	Υ							N	300	Y		Υ	2		6.4395	× .	74	TE.	N	N	Υ
ngapore			4	1	11	N				48					N	N	900	Y	100	ii.	45.6	74.8	0.1843	201	30	300	N	Υ	Υ
ovakia	2/5	N.	3	1	18	N	,	***	Υ	201			Υ	Y	Υ	Υ	441				349	**	12-2252	551	**		N	N	Υ
	6/6	N	8	9900	1	Υ		.,	Υ	MI	Υ	Υ	Υ	500				+	251		99	100	6.7367			63-4	N	Υ	Υ
ovenia	6/6	Υ	7	**	1	Υ		ű.	Υ		Υ	Υ	Υ	Υ	Υ	Υ			ü			19.85	8-1175	24			N	Υ	Υ
ands	4/5	N	5	1	346	Ν			W.	ii.	••			N	N	N		-	п	(c)	65	94	0.3819						Υ
	3/8	N	6	æ	(10)	Ν	10			3				Ν	N I	N					200		880	192		22	N .		
uth Africa	7/8	Υ	10	2	1	Y	296	×	N	100	Υ	Υ	Υ	N	N 1	V					87	100	9-1927				N	,	Υ
ain	6/6	Y	5	••	1	Υ				50E	Υ	Υ	Υ	Υ	Υ ١	1	55				100		7.7227	200					Y
Lanka	5/5	Ν	7	1		N			Υ	**	N	N	N	N	N 1	١ .		Y		•••			0.6058			_			
dan	5/8	Ν	4	300	1	N				64				N I	N N	١.		Υ .			127		0.287				N Y		Y
riname	7/7	Υ	22	200	860	Ν	165	. 9	Υ	95	Y	1			Y Y												N Y		Υ
raziland	6/8		7	20	1	N				53					N N								5·0805 0·8589				N Y		Υ
reden	6/6	N	2	100	8	Υ		. ,			γ ,		Υ .												•		N Y		Υ
itzerland .	4/6	N	9	**	1	Υ					γ ,		Y 1					1					5.894				N Y		Υ
		N		**)		N				95								,			02		5.4731				N Y		Υ
		Υ	7		1	Y	.,								, ,										× .	.	Y	,	Υ
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A Te		N		4			22				, ,		4 I		1 N				. 1	N	42.5			56 4	11 .	. 1	N N	I Y	Y
70			9	1	1	Y	1.55				1 1						٠ ١				97-9	98.5	4.2849	47 4	11 .		N	(*)	
	4/5		8	1	300	N	(900	9		53						fi	Y		1	(62	80-3	0.1737	M 10	5 0		N Y	81	27
		Y	227	••		N	100			78 1	1 1	1 1			N N						34-2	76.4	3805		u	. 1	N Y	Υ	1
		N	990	**	1	Ν	1	Y				8 089	١	1 1	I N	34					100	100 1	1.1852	n n	- 4		v	Υ	
ago		N	4	18.8	**	Υ	300	Υ	1	96 1	Y	Υ	Y	′ Y	Y	_ N	1 Y		40	.)	89	93 2	24-6802	e	18.		N Y		
sia 6	5/8	N		300	W)	Ν	(22)	Υ				166	N	1 1	I N	***	Y				78.5	95.7 2	-2895		3	6-7 N	N N	Y	

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							Hea	ith wo	rkers	Nat	ionai ii	nancin	9			IAC	Add	aition	al saf	egua	iras				, assess lity, and			
315	32¶	33¶	34†	35†	37m †	37f†	38	43	44	45	46t	47 [†]	48†	49†	50†	53†	54	55	56	57	58	59	65	66	67**	68 ††	70	7
													B													-	10. W.	
1.81	61.5	60.9	87	85						Υ	3-21	4.3	1.5	7	2	NA	N	Υ	Υ	Υ	100		21	25	240	73	1	Ν
8.47	15.4	26.5	80	79				342	14	N	0.78	3.2	0.9	10	0	NA	N				100	3.55	24	32	230	68		1
76.15								244	500	Υ		6.2	2.1	11.2	NA		Υ		Υ	Υ			6	7	8	75		- 1
224			99	98	100	535	35.5	(55)	(6.6)	Υ	2.71	10-2	2		2	8.91	N	Y	Υ	Υ	**	toc	3	4	11	79		1
2.			90	91	144		N	NA	NA	Υ		4.1			1	NA		N	Υ	Υ		300	9	11	12	77	0.88	1
187-3		36	(44)	10	568	1000	300	100		Υ	1.73	5.9	2.6		3		N		N	Υ	ē		5	5	14	79	**	
59-35		ges -		le v			an.	N	N	Υ	0.09	5.5	2	7	3	NA	· N	- 1	Υ	Υ			14	16	24	73		
	24					••				Υ	441	5.2	3.7	5.5	NA		N	200	Υ	Υ		22	10	13	28	66		
	V. 58		86	87			Υ			N		7.2	1.9	1.1	1	NA			Υ	Υ	.,		97	160	1300	52		V)
				7**	:**		140	500	**	Υ		5.5		10.6		NA	**	**		ē.			17	19		71		1
		221	41		122		Υ	**	•	Υ		5.9	••	4	4	NA	555	**	**	**		25	12	14		75	175	1
	**	(4.6)	100	144	(346)	548	100	1660	940	Y	400	6	127	5.5	5	NA		**	9	ij.		**	17	20	**	70		1
8.55		(4.4)	1001	3≪	(30)		Υ		¥43)	Υ	XX:	4.9	347	5.5	NA	NA	**		Υ	Υ	36	777	23	28	10	68		
		200	200	ins.	2.0		***	**		Υ	861	7.3			NA	NA	N	**:			iv.		3	3	46	82		
			88	83			27			Υ		9.8	**	13.8	100	NA		***	195	.95	23.8		63	96	200	61	***	
												8		75W										15,50		100.00		
388		80	97	93	100	000	Υ	**	10	Y	**:	3.4	8	100	1461		(8.9)	66	N	Ν	60	**	21	26	18	70	900	
**		*	74	78		(55)	2011	550		N	0.55	5.4	1.4	2.3	9	NA	34.6		Υ	Υ		**:	60	116	980	59	340	
26.67	527	4411	87	96	117			•	ē	Υ		8	**		250	12	255		Υ	Υ	12.5	881	7	8	203	73	1575	
37.74		**)	900	346	940		w	***		Y		6.8	2.1	7.9	3	NA	***		Υ			••	12	13		72		
0.81	355	22.1	76	63	3890	**	N	NA	NA	N		3.7	2	2.1	NA	NA	990	**	N	Y	1800		159	269	2100	40	100	
38-34		11/2	22.0	on,	251		**	***		Υ	mm'r	3.5	4.7		6	10.6	N		Υ	Y		×e	3	3	14	80	14.61	
237-13	144	60	201	700	201		9		ē	Y	0.00	7	1.7	12.6	5	655	Υ	**	Υ	Υ		***	7	8	6	74	10.00	1
	**	**	***	34	***	••				Y	0.06	8.5	1.5		NA	122	N		Υ	Y			3	4	6	78		-
2.48	35.6	25.5		**	(22)			***	200	N		4.3	10 0	4.7	1	NA	**	**	Ν	Υ	***	**	55	72	220	67	340	
			38	36	12.5	7.9				N				1.2	NA	NA	***		Υ	Y			90	145	1400	55		i
139-76	12.5		82	76				22		Υ	0.03	8.7	1.6	2		0.0	100	Υ	Υ	Υ	Υ	N	56	69	400	51	1	
355	w					• •		÷		Υ	0.48	8-2	1	100	NA	3.67	N	Υ	Υ	Υ		**	4	4	4	81	***	
2.5	1920	ii .	67	91	120			9		N	1.25	4.1	2.6	1.9	2	NA	N	10.00	Υ	Υ	**		11	13	58	72	200	1
1.3	51.4	77.2	51	44	80					N		3.8	4.4	1.4	440	NA			Υ	Υ			62	89	450	60		
6.76			60	79	887		Υ			Υ	500	5.3			4	NA	**	Sin	Υ	Υ	**	10 2	29	39	72	68	100	-
.,			96	97				7.0		Υ	100	6.3		1.6	0	NA			N					164	390	42		
462-44	140 140	10			247	40		ě	••	Υ	0.18	9.2	1.5		11	5.62	Υ	100	Υ	Υ	120	9:	3	4	3	81	807	
402	- 00	**	ä	**	300	¥4.	n	ä	200	Υ	0.57	11.4	1	ar.	NA	6.1	Υ	Ν	Υ	Υ		6	4	5	5	82	553	1
	**	98-2	80	83		**6		0	300	N	1900	4-2	5.3	0.8	vi	NA	940	W.	Υ	N	400	13		13	130	72	100	ũ
0-35	75	85	89	86			22	9	(3.5)	N	**	5	2.2	3.4	yo.	NA			Υ	Υ	100	0	56	68	170	64	**	1
0.8	23-4	47-9	80	86	49	44		ĕ		N		5-1	1.1	1.1	7	NA	553			***	55	22		118	950	50	251	1
		w	96	98		**	100		**	Υ	0.8	3.5	1.1	11	3	NA	N	Υ	Υ	Υ		ä	7	8	110		2.	1
720	651	**	55	57		***	Υ		18.6	N		13.7	эх	·		NA		100	Υ	Υ		a .	47	55	380			1
	129/		58	64					and III	N		5.3	1.6	0.8	0	NA		100						107	510			1
6.01		154	84	96	n		44	**	**	Υ		5	1.1	1.9	1	NA			Υ	N		ě	20	24		71		1
29-3			58	81		. 1		NA	ŊA	Υ		4.5		2.6	4	NA			Υ	Υ		sn i	33	38	45	69	- 6	Ì
44-05	64.3	95.1	71	96			Jack			Υ	av .	5.5	1.6	7.2	NA	NA			Υ	Υ		194	19	23	100	72		ı
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	1*	2	3	4	5	6	7	8	10†	11	12	13	14	15	16	17	18	21	22	24† rural	24† urban	25‡	26† rural	26† urban	27†	28	29	30
(Continued fro	om pre	vious	page)																	-			151705152001			-	
Turkey	6/6	Ν	5	200	1	Υ	340		***	N	N	N	N	N	N	300	oc:	100		93.8	98-3	3.1395				N		
Turkmenistan	4/5	Y	7	1	650	Ν	200	Υ	96	12	11	120	N	N	N			300		53.6	93.1	8.7549		12 13		N		
Tuvalu	2/5	Ν	4	1	74.	N		Υ				1000	N	N	Ν	0.0				91.6	93.9		**	ii a	200		78.40	**
Uganda	7/8	Ν	6	100	1	Υ	**		4	N	N	N	N	N	N	144	v	247		57	84	0.0651			***	N	55.5 10.0	551
Jkraine	5/6	N	8	1	1	Υ	300	Υ	100	Υ	Υ	Υ	Υ	Υ	Υ	***	i.			89.3		6.9802	***	300	-0-	N	Υ	Υ
JAE	4/5	N	-12			N	220	200	90	100			N	N	N		v	***		100	99.1		3.5	055	58.7	N	**	**
JK	6/6	Ν	8	220	1	Υ	100	Υ		Υ	٧	V	v	Y	Y		ľ		- 55		99.6	37-7966	**	36	33-1	N	Ν	Ν
JSA	1/7	Ν	300		1	Υ	20.1	Υ		Y	· V	·	v	v	V			***	Est	100	100	9.7934	307	***	**	N	Υ	Υ
Jruguay	7/7	N	200		1	N	**	Y		V	v	·	V	V	Y	100				100	100	20-3792	800	one.	5	N	II.	
Jzbekistan	4/5	N	6			V		v	100	V	Y		20	27		3001		**	Y	100	100	1.6479	M	900	76.7	Ν	N	Y
/anuatu	3/5	N	6	1		N			100	100	86	Ţ	N	N	N	N	**	55	exe:	79.9	97-4	5.2619	10		2	N	Υ	Υ
/enezuela	5/7	Y	4										N	Ν	N	**	*	55	300	94	63	0.4192	25	947	6	Ν	Ν	Υ
/ietnam	500	Y	4		1	N	**	Υ	92	Υ	Υ	Υ	Υ	Υ	Y	84	20	**		70.5	84.6	6.5735	н	(4.4)	197	N		1553
	5/5	Υ.	1	335	1	Ν	986	n	87	**	••	1555	N	N	N		Υ	Con.	**	87-3	96-2	1.1768	30.5	***	9.5	N	Y	Υ
emen	5/5	N	5	35	2.0	N	9.0	0	24.0	***	440	720	N	N	N	100	Υ	100	Υ	65.5	71	1.0311		151	355	N	N	Υ
	7/8	N	6	1		N	100	Υ	10	N	N	N	N	Ν	N		Υ	**		44.5	90.4	0.203			28.9	N	Υ	Υ
imbabwe	6/8	Ν	7	1	995	Y			42	**	200	ine.	Ν	Ν	N	**	Υ			69-2	96.8	0.8106			40.6	N	Υ .	Y

Data are numbers or Y=yes or N=no, unless otherwise stated. NA=not applicable. --=not available. IAC=international assistance and cooperation. Indicators 9, 19, 20, 23, 36, 39–42, 51, 52, 60–64, 69, and 71 are Emirates. *Number of treaties actually ratified/number of treaties the state is eligible to ratify. †Proportion (%). ‡CO, emissions per capita. §US\$ value per capita. ¶Median availability (%). ||Probability per 1000

Table 1: Globally processed data	for indicators of health systems and right to health
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	No dis- atio	crim	in-	He	ealth	info	orma	ation							Na	tiona	l hea	lth p	lan		Partici- pation	Unde	rlying d	etermi	nants	Acc- ess	Media	ines		alth moti	on
	3	4	5	6	7	8	9	10*	11	12	13	14	15	16	17	18	19	20	21	22	23	24* rural	24* urban	25†	26*	27*	34*	35*	36	37 m*	37 f*
cuador	8	2	1	Υ	Υ	Υ	3	**	Υ	Υ	Υ	Υ	Υ	Υ	25	Υ	N	N	Υ	Y	N	39.3	78-3	346			100	102	Υ		
Mozambique	7	0	0	Υ	Υ	Υ	2	90	N	N	Ν	Υ	Υ	Υ	Υ	Υ	N	N	Υ	Υ	N	48.5	40	(22)	54-2	(88)	(10)	10	N		921
Peru	7	1	1	Υ	Y	Y	3	86.6	Υ	Y	Υ	N	N	N	N	Υ	N	N	Ν	N	N	62	84	3.87			90.6	80-2	Y	201	10
Romania	11	0	1	Y	Υ	Υ	4	99.9	Υ	Υ	Y	Y	Y	Y	Y	N	N	Ν	Υ	Y	N	34	92	2430	17.8	76	97	97	N	3	6
Sweden	6	0	0	Y	Y	Y	2	100	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Ν	Υ		N	Υ	N	100	100	6.25		100	96	99	Υ		

Data are numbers or Y=yes or N=no, unless otherwise stated. NA=not applicable. =not available. IAC=international assistance and cooperation. Data not collected for indicators 1, 2, 28–33, and 72 at the national

Table 2: National data for indicators of health systems and right to health

We also asked whether the country's national health plan explicitly recognises the right to the highest attainable standard of health (indicator 21). Explicit human-rights language can be useful for policy makers and empower disadvantaged individuals, communities, and populations. On the basis of global data and our approach, two national health plans secured a yes, four secured a no, and data were not available for the remaining 188 countries. From the right-to-health perspective, global data collection is seriously deficient.

Participation and its preconditions

Despite the importance of participation to both health systems and the right to health, no global data, with our

approach, were available for any country for indicator 23. At the national level, of the five countries, none legally required participation of marginalised groups in the development of their national health plan. This finding suggests that participation is not receiving the attention it demands; although some countries have made provision for the participation of citizens, without specifying marginalised groups. WHO building blocks of a health system give insufficient attention to the role of participation.¹⁰

Active and informed participation depends on several factors. Preconditions for meaningful participation include having access to information (eg, access to the health budget), being free to speak openly without intimidation

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AN		19	430	182	201			Y	Y	100	**	AN	AN	3.3	1.2	9·S	62·Z	N			λ	S·07	1.94	08	48 54	06	S	2.14
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N	**	64	8	9	S	٨	٨	100	***	198	٨	7.37	OL	**	1.7	2.8	40.0	٨	- 12	200	288	1000	988		155	.055	200	
ΑN		87	48	8	8		220	227	110	122	(5.5)				6·1	9.2		٨	.8	**	99		57.5	58	83	6.87	1.19	92.
VΝ		49	18	77	50			٨	٨		٨	AN	ΑN	1.7	8.2	4	78.€	٨			- 22	30	12.0	14	- 12		**	2
VΝ	363	os	oss	134	87	300	900	λ	٨	197	N	AN	τ	7	7.4	Z	1906	N	N	Ν	ON	144	(44)	SS	23	08	50	91·t
VN	38.0	59	250	38	15	385	250	٨	λ	128	(992)	AN	AN	2.07		8.8		٨	22	200	185	22.00	999	250	195	655	22.5	
VN	**	63	130	ιs	St	**	•	٨	٨		10	AN	AN	8.5	6.2	8.4	44	٨	- 4	**	**	90	537	85	94	324	227	
Ν	in.	23	tt	97	Þζ	λ	λ	Υ	٨	SW.	N	2.	AN	9.11	8.2	2.5	000	Υ	**	544		(48)	39	79	64	744	**	
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However, reality is worse than these data suggest. Although the law might protect information, expression, association, and assembly, in some countries a wide gap exists between law and implementation. This does not mean that the law is without value. Rather, it recognises that the law is without value. Rather, it recognises on circumstances, including the creativity of those who use it. We addressed this more-practical, non-legal dimension of preconditions, with special attention to access to information. Global data showed that 88 countries do not gather, centralise, and make publicly available the number of maternal deaths (indicators II–I3). Without such vital health information, meaningful participation can be an empty promise.

(eg, publicly criticise a local health council), being free to organise with no restriction (eg, establish an independent medical association or patients' group), and meeting without impediment (eg, hold a public meeting). These are also necessary safeguards for meaningful implementation of other right-to-health features, such as health promotion. Some of these preconditions are present in our selection of indicators. For example, the law in 121 countries does not protect the right to information (indicator 6); the law in 41 countries does not protect the right of association (indicator 50). In these protect the right of association (indicator 57). In these countries, preconditions for meaningful participation or countries, preconditions for meaningful participation or effective health promotion do not exist.

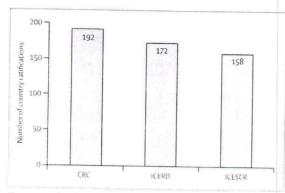


Figure 2: Number of countries that have ratified treaties that include the right to health

CRC=Convention on the Rights of the Child. ICERD=International Convention on the Elimination of Racial Discrimination. ICESCR=International Covenant on Economic, Social, and Cultural Rights.

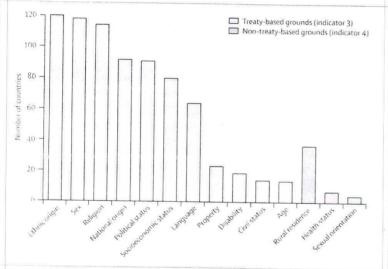


Figure 3: Number of countries protecting grounds of discrimination

Underlying determinants of health

We included indicators on the underlying determinants of health (eg, access to clean water, CO₂ emissions per person, and violence against women [indicators 24–26]). The relation between diarrhoea (and other health conditions) and access to clean water is well known.¹¹⁹ Thus, we asked what percentage of the population has access to clean water—defined as at least 20 L per person per day from a source within 1 km of the user's dwelling (indicator 24).^{119,120} This indicator raised important definitional issues that were briefly considered in the explanatory notes (webappendix 1).

Only 54 countries had more than 90% of their rural population with access to clean water and only 115 countries had more than 90% of their urban population with access to clean water (panel 8). Rural dwellers are disadvantaged in most countries for clean water access (figure 4). We used the joint monitoring programme as the source for

these data because it shows where the original data come from, as opposed to some other sources that do not or only use estimates. We identified the method and year of data collection in the extended data tables (webtables 4 and 5) to emphasise that data were obtained from various sources, including national surveys and the joint monitoring programme estimates, and that were from 1990.¹²¹ Comparison of data between countries is therefore difficult, which is why we did not rank countries. Romania has less than 20% of its rural population with access to water, and the difference in access to water between rural and urban populations is striking (16% vs 91%).¹²¹ Data available at the national level were more recent and showed that, by 2005, the gap had narrowed a little but was still extreme (34% vs 92%).¹²²

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We aimed to provide a basis to monitor, over time, the progressive realisation of the right to the highest attainable standard of health. The indicator for access to clean water is especially useful for monitoring a country's progressive realisation. Romania's data for access to clean water in rural and urban areas should be revisited in a few years. If there is an acceptable measure of improvement, the government will be able to argue that, in accordance with its international human-rights obligations, it is progressively realising this aspect of the right to health. But if access to clean water remains the same or becomes worse, the government will have the burden of proving that all has been done to try to improve access to clean water. If the government cannot show that all that is possible has been done, it will be in breach of its international human-rights obligations. This example illustrates the importance of independent, transparent, and accessible accountability mechanisms that can decide whether any improvement that might have occurred is acceptable in the circumstances. If the government has fallen short of its responsibilities. accountability mechanisms should consider appropriate redress, which ranges from guarantees of non-repetition to compensation.89

Definitional issues restricted data availability for violence against women (indicator 26), the indicator of which has suitable data only for eight countries (Bangladesh, Brazil, Ethiopia, Japan, Namibia, Peru, Tanzania, and Thailand from the WHO multicountry study on women's health and domestic violence against women). Although a lot of data exist for this subject, definitions vary for violence, domestic violence, violence against women, and even women (as defined by age), making it challenging to find comparable data.

Access to health services

We addressed different dimensions of access, such as those of antenatal care (indicator 27), access to clean water (indicator 24), and catastrophic health expenditure (indicator 46), but more work is needed to identify appropriate indicators that measure access. We asked what is the proportion of women with a livebirth in the last 5 years who, for their last pregnancy, were seen at least three times

by a health-care professional, had their blood pressure checked, had a blood sample taken, and were informed of signs of complications (indicator 27). This indicator uses antenatal care as a proxy for primary care and coverage to represent access. We obtained data for this composite indicator from the world health survey with information available for 51 countries, 19 of which are categorised as low-income and 22 as middle-income countries. 124,125

The world health survey includes women aged 18 years and older, and therefore data exclude those under 18 years who also need antenatal care and might be a group with reduced access to services. Those women whose pregnancy did not result in a livebirth are not included and they may be less likely to have received adequate antenatal care. Furthermore, women could be reluctant to acknowledge a livebirth when the child only survived a few minutes, and could falsely refer to this as a stillbirth. These are a few examples of limitations associated with this indicator showing an overestimation of the percentage of women who received care. Even with these overestimations, less than 50% of women had comprehensive antenatal care in 33 of 51 countries (figure 5).

Similar to the indicator on access to clean water, the antenatal-care indicator can be used to measure the progressive realisation of an important aspect of the right to health. For example, according to global data and our approach, only 12% of women in India have comprehensive care. India's data should be revisited in the future to assess whether the government is progressively realising this important aspect of the right to health.

Health workers

One of the WHO building blocks of a health system, health workers have a key role in the implementation of the right to the highest attainable standard of health (panel 9). Because of their importance, 11 indicators address issues directly related to them (indicators 38–44 and 61–64). On the basis of global data and our approach, we found that 21 countries have a national health-workforce strategy and 12 do not, whereas for 161 countries data were not available. Using doctors and nurses as proxies, we looked at remuneration, national self-sufficiency, incentives to promote stationing in rural areas, awareness raising, and human-rights training. Of the 11 indicators that relate to health workforce, eight do not have global data available (including four in the awareness-raising group).

International assistance and cooperation

Human-rights responsibility has several components, including the duty of high-income countries to provide, and low-income countries to seek, international assistance and cooperation. We set five indicators for human-rights responsibility in health (indicators 51–53,71, and 72). All five indicators focus on the responsibility of donors rather than on the responsibility of recipient countries.

We asked whether donors' international development policies explicitly include specific provisions to promote and protect the right to health in recipient countries (indicator 51), and whether these policies explicitly include provisions to support the strengthening of health systems (indicator 52). No global data based on our approach were available for any donor in relation to either indicator. Nationally, however, some data were available. National data in Sweden confirmed that the country's international development policies explicitly include specific provisions on the right to health, whereas national data in Romania led to the opposite conclusion. Also, national data in Sweden and Romania confirmed that both countries' international development policies explicitly include provisions to support the strengthening of health systems.

We also asked about the percentage of net official development assistance directed to health sectors (indicator 53): Italy (17%), Ireland (15%), Netherlands (14%), and Denmark (11%) seemed to be far ahead, whereas Japan, Greece, and Luxembourg (all 1%) seemed to be a long way behind (panel 10).

However, in recent years some donors have moved away from the provision of funds for specific sectors towards general budget support. Because of the Paris Declaration

Panel 5: Civil registration in Sweden

The law on national civil registration in Sweden provides registration of births to registered parents. When a child is born in Sweden to non-registered parents, such as undocumented immigrants, the child will not be registered. Information about number of births to non-registered parents is unreliable. The picture is complicated by the fear of many non-registered people of Swedish authorities.

Panel 6: National health situational analysis in Mozambique

Before the development of its national health sector strategic plan, Mozambique undertook a comprehensive national health situational analysis. This analysis identified health problems of disaggregated population groups, such as children, and the feminisation of HIV. It also showed the effect of gender in the fight against HIV, and the need to improve human resources for health at all levels. It identified possible interventions, such as high vaccination coverage, to control diseases in children younger than 5 years and the improvement of campaigns on behaviour change. The analysis emphasised the need to reinforce support systems and focused attention on the importance of monitoring and assessing health programmes and services. However, close examination also showed issues with the quality of the information gathered and data analysis.

Panel 7: Participation in Peru's health councils

Representatives of Peru's ForoSalud (a nationwide civil-society network) obtained support from the minister of health and the national health council for their proposal to change the composition of national, regional, and provincial health councils. The existing composition included nine representatives of health providers and only one of health-service users. The new proposal promotes a more bottom-up approach to participation, including discussion of new health policies, with a plan to repeat the participatory process in 2 years and 6 months. The aim is to promote accountability of government officers for both the achievements and shortcomings of health policy.

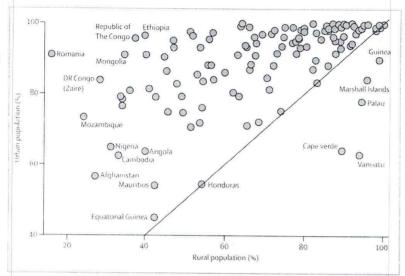
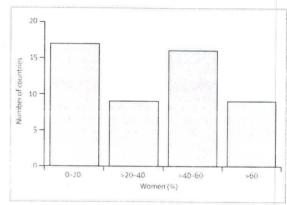


Figure 4: Percentage of urban and rural populations with access to clean water



Carried States - 1

Figure 5: Percentage of women by number of countries who had comprehensive antenatal examinations during their last pregnancy N=51 countries.

Panel 8: Access to clean water in Mozambique

In Mozambique, poor access to clean water is responsible for serious illnesses and leads to frequent outbreaks of cholera. Access to clean water has improved in rural communities through close coordination with the ministry of public works and with support from various donors. Recent data confirmed this improvement and showed a higher rate of access to clean water in rural (48-5%) than in urban (40%) areas. However, urbanisation has taken place across Mozambique in recent years, leading to a large influx of people into cities and, therefore, in provision of the necessary infrastructure to ensure access to water in urban areas.

on Aid Effectiveness, this trend is likely to accelerate.⁸² For this reason, a brief narrative should accompany this indicator to explain each country's approach to overseas development assistance and health, for example, to signal if the donor is moving away from sectoral support towards general budget support. Donors' support should be in line with the growing international recognition that, if the health-related Millennium Development Goals are to be achieved, health systems must be strengthened.

Our research suggests that, for indicators 51 and 52, the relevant global data, based on our approach, are globally unavailable. We also noted that the relevant national data were available for Sweden and Romania. Data gathered for indicator 53 provided a basis to monitor, over time, donors' progressive realisation of their human-rights responsibility of international assistance and in health.

Monitoring, assessment, accountability, and redress

Eight indicators were grouped together under monitoring and accountability (indicators 65–72); however, several others might properly be regarded as monitoring and accountability indicators, such as those on impact assessments (indicators 19 and 20).88

Monitoring and accountability depend on the availability of reliable and relevant data. Without indicators, benchmarks, and data, it is not possible to monitor the progressive realisation of the right to health. Several traditional health outcome measures have a key role. A worsening health outcome, such as maternal mortality, does not necessarily mean that a country is failing its right-to-health responsibilities. However, it obliges a country to explain to an appropriate accountability body why the situation is deteriorating.

We took into account three mortality measures: infant mortality (indicator 65), mortality of children younger than 5 years (indicator 66), and maternal mortality ratio (indicator 67), together with life expectancy (indicator 68). Of these, the one with the least global data available was maternal mortality ratio. Data exist for 169 countries with a range from 1 (Ireland) to 2100 (Sierra Leone) per 100 000 livebirths (mean 331). 126 This range is astounding because most deaths are preventable and a high ratio shows that the health system is failing.

As with other indicators already discussed, such as antenatal care and access to water, indicators 65–69 can be used as a basis to monitor, over time, aspects of the progressive realisation of the right to health.

111 countries have national human-rights institutions, many of which make a substantial contribution to the promotion and protection of human rights. Although independent, these institutions are non-judicial and designed to be more accessible, flexible, and informal than courts.127 One of their functions is to monitor and hold governments accountable. We asked whether a country has a national human-rights institution with a mandate that includes the right to the highest attainable standard of health (indicator 69). Is the institution empowered to monitor public and private health and hold accountable those with right-to-health responsibilities? No global data for this indicator were available with our approach for any country. Data were available, however, nationally. Of the five countries, three (Ecuador, Peru, and Romania) have national human-rights institutions, and the mandate of each extends to the right health. With leadership and resources, these

institutions could contribute greatly to constructive accountability for the right to health (panel 11).

We also asked whether national human-rights institutions have a mandate to monitor donors' human-rights responsibility of international assistance and cooperation (indicator 71). However, no global data based on our approach were available for any donor for this indicator. National data showed that, although three of the five countries have national human-rights institutions, none of these institutions has a mandate to monitor international assistance and cooperation in health.

Countries that have ratified international human-rights treaties have an obligation to report on their activities related to that treaty usually within 2 years.⁵ A committee of independent human-rights experts publicly considers the report and may ask country's representatives challenging questions about the government's record, publishing its concerns and recommendations. A few years later the process is repeated and the experts' committee asks the country to explain what has been done in relation to the earlier recommendations. Under the International Covenant on Economic, Social, and Cultural Rights, donor countries should report on their human-rights responsibilities of international assistance and cooperation in health. Therefore, we took into account country's reporting on international assistance and cooperation in health to the UN Committee on Economic, Social, and Cultural Rights (indicator 72). We showed that only three donor countries (Belgium, Canada, and Japan) reported adequately on this crucial issue.

Low-income countries have the perception that high-income countries escape accountability when failing to fulfil their international pledges and commitments that are important to developing countries. Data seem to confirm that this perception is right. Our national data suggest that the mandates of national human-right institutions do not extend to holding donors to account for their human-rights responsibility of international assistance and cooperation. Also, most donor countries are not being held accountable by a key UN human-rights treaty body for their responsibility of international assistance and cooperation in health. We conclude that donor countries are subject to only feeble independent, institutional scrutiny for their international responsibilities.

In 63 countries, the constitution, bill of rights, or other statute recognise the right to health. Legal recognition serves many purposes. In several countries, for example, it made the authorities accountable before the courts, leading to tangible improvements in health services. 55.56 We, therefore, enquired about the number of judicial decisions that took into account the right to health in 2000–05 (indicator 70). However, it is possible that the decision may not promote and protect this fundamental human right. Nonetheless, even in this case, at least the country is held accountable for the right to health, having to explain itself before an independent accountability body.

Global data disclosed, on the basis of our approach, only five countries (Canada, Nigeria, Peru, South Africa, and Venezuela) with judicial decisions conforming to this indicator. The combined number of judicial decisions is less than ten. This is striking because in recent years numerous national courts have decided right-to-health cases, and yet our data show that they are not globally available in accordance with our approach. 55.56

Here, we looked at some of the right-to-health features and their data, and conclude that health systems in numerous countries do not have the features required by the right to health. Also, there are insufficient data currently available, especially at the global level, to assess these indicators in relation to many countries. Figure 6

Panel 9: Health workers in Romania

Romania has one of the lowest densities of health personnel in Europe in relation to doctors, nurses, dentists, and pharmacists. Furthermore, there is an imbalance between regions of the country. In rural areas, there are 98 communities (villages) without any doctor, and the situation is comparable for nurses and other health workers. In a third of Romania, more than 30% of medical specialties are not available. The accession of Romania to the EU aggravated the situation with 10% of doctors seeking work outside Romania, according to a recent survey of the Romanian College of Physicians. This situation increases already existing inequities between rural and urban populations. Payment types currently compensate rural better than urban clinicians for the same type of services. However, the existing additional benefit payment programme has not met its goal of providing a sufficient health workforce in the underserved areas. These data suggest that a comprehensive approach is needed to tackle more than the financial dimension of the issue. The ministry of health has proposed additional incentives to try to increase and stabilise the number of health workers in rural areas.

Panel 10: Official development assistance for G8 member countries (global level data)

Italy—17-48%
USA—7-26%
Canada—6-43%
France—3-74%
Germany—2-93%
UK—2-37%
Japan—1-13%
Russia Federation—Not available

Panel 11: Monitoring and accountability in Peru

Over the past year, Cooperative for Assistance and Relief Everywhere (CARE)-Peru and Physicians for Human Rights have supported the development of citizen and civil-society accountability mechanisms at both district and local levels. An example is in the Piura and Puno regions, where Quechua and Aymara women community leaders have been linked to regional offices of the human-rights ombudsman to monitor women's health rights, particularly their right to good quality, appropriate maternal health services. Rural women's leaders have also been empowered by a joint agreement between ForoSalud and the human-rights ombudsman office in Puno. Partnerships have been mutually enriched, with women leaders feeling better positioned to demand information and changes in health services.

shows the unavailability of global data in relation to a selection of 25 indicators for which it is clear that, in many cases, international bodies are not collecting the appropriate right-to-health data. An overarching conclusion is that those at the international and national levels with responsibilities for health systems seem to be giving inadequate attention to the right-to-health analysis and some of the features required by the right to highest attainable standard of health.

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Opportunities and challenges

On a country-by-country basis, table 1 summarises the degree to which health systems of countries include some features that arise from the right to health in relation to 72 indicators. Table 2 summarises national

data for the same indicators in relation to five countries. When considering the performance of an individual country, the country's stage of economic development (what human-rights treaties refer to as the countries resource availability) is important.

Some of our findings are positive: for example, we record high rates of vaccination with measles-containing vaccine (MCV) and diphtheria, tetanus, pertussis (DTP3) vaccine (indicators 34 and 35). General comment 14 places a high priority on immunisation programmes. Although such programmes can occur as vertical interventions, whenever possible they should strengthen health systems. Weak health systems impede high immunisation coverage and the GAVI Alliance and Fund Boards recently increased funding for health system strength-

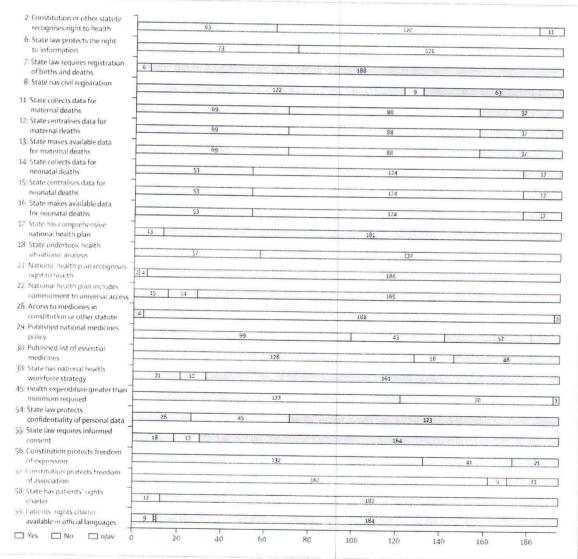


Figure 6: Availability of global data for a selection of 25 indicators n/av=not available.

ening to US\$800 million.¹²⁸ We recorded good practices for the implementation of right-to-health features of health systems, such as Mozambique's effective coordination between different stakeholders to improve access to safe water in rural communities (panel 8). Also, Sweden has recently introduced the legal requirement for inclusion of human rights in the training curriculum of health workers, reflective of indicators 63 and 64.¹²⁹

Countries that have not put in place some of the key features of a health system—eg, a comprehensive national health plan (indicator 17), a published national list of essential medicines (indicator 30), a national health workforce strategy (indicator 38), or government expenditure on health per person above the minimum required for a basic effective public health system (indicator 45)—are in breach of their right-to-health responsibilities whatever their stage of economic development.

We provide a basis on which to monitor health systems and the progressive realisation of the right to health. A suitably improved version of this project repeated in a few years' time will give an indication of whether countries have progressively realised the right to health. Take, for example, a high-income country in which prevalence of violence against women has increased (indicator 26); access to health services (indicator 27) has worsened; immunisation of 1-year-old children against measles (indicator 34) has decreased; total government spending on health as a percentage of GDP (indicator 47) has lessened; and life expectancy has fallen. In such a case, progressive realisation of the right to health has not been achieved. Unless the government has a rational, objective explanation for the worsening situation (eg, a natural disaster), this country would be in breach of its right-tohealth responsibilities.

We have emphasised the limitations of indicators generally and some of our indicators specifically. Moreover, as we have seen, there are some inconsistencies between global data (table 1) and national data (table 2). So the data must be used with caution.

In this Report, we concentrate on recognition of the right to health; non-discrimination; health information; national health plan; participation; underlying determinants of health; access to health services; health workers; international assistance and cooperation; and monitoring, assessment, accountability, and redress. We do not discuss some important right-to-health features and their data, such as finance and medicines, because space restrictions compelled us to be selective.

Limitations to indicator selection and data collection do not contradict the profile of indicators or the findings, but should be considered when analysing the results. We hope that the profile of indicators will prompt discussion and that subsequent revisions will make indicators more robust.

This project relies on secondary data published by others, and any limitations of the primary data affect our dataset. Because of resource constraints, triangulation of data collection was not included in the methods, except when checking for an unexpected result. The number of indicators is large, but we did not want to compromise too much. When the project is repeated, we suggest an assessment of concordance of the data. Although one of the objectives of this project was to assist with monitoring progressive realisation of the right to health, some of the indicators, such as maternal mortality ratio, are not sensitive to change over short periods. Additionally, so-called yes or no indicators do not lend themselves to measurement of gradual change over time, although many are complemented by a commentary (webtables 4 and 5) to explain the result that could indicate improvement with time.

For this project, restrictions on collection of worldwide data were needed. However, the one-click rule introduced elements of inconsistency in the data collection. Some regions tended to have more information available within the limits of the one-click confines than others-for example, lists of WHO member states each link to some documents about that country. For some regions, detailed information was available on global websites, whereas, for others, global websites were structured in such a way that the one-click rule allowed only an index page for the region, not the actual information, to be reached. Also, there was a risk of further discrepancy in data available for developed countries and those available for developing countries. This discrepancy might arise because international organisations assist developing more than developed countries in data collection or analysis, and these data are subsequently more readily available worldwide.

Our research shows that insufficient data are available, especially at the global level, in relation to right-to-health features. From the perspective of health systems and the right to health, UN bodies and other international stakeholders are not collecting appropriate data. International and national institutions with responsibilities for health systems seem to be giving inadequate attention to the right-to-health analysis and some of the features needed for the right to the highest attainable standard of health. Here we focus on other areas of concern and make recommendations. We do not attempt to discuss all our concerns and recommendations but focus on those arising from some key areas. Taking into account both the right-to-health analysis outlined in this report and the data collected, we make additional recommendations in panel 12.

Recognition of the right to health

Recognition of the right to health in international treaties, national constitutions, and other statutes gives rise to a legal obligation for countries to ensure that their health systems have certain features, as discussed, and also that the performance and quality of health systems do not regress or stagnate but improve over



Panel 12: Recommendations

We recommend WHO and the Office of the High Commissioner for Human Rights

- adopt a stewardship role in the collection and collation of data for right-to-health features of a health system
- lead the process to establish universal definitions for commonly used terms and standardised units of measurement regarding the right-to-health features of a health system
- maintain and regularly update a global data repository on the right-to-health features
 of a health system
- lead the process to establish, where appropriate, international benchmarks to assess country performance regarding the right-to-health features of health systems
- ensure that the Global Health Workforce Alliance gathers data relevant to the right to health, such as for human rights training for health workers

We recommend other UN specialised agencies and bodies

- coordinate with WHO, national governments, civil-society organisations, and other international, regional, and national stakeholders to ensure coherence in global monitoring with respect to the right-to-health features of a health system
- provide technical assistance to national governments to facilitate data collection on the right-to-health features of a health system
- · record descriptive and numerical data
- cooperate with WHO, national governments, civil-society organisations, and other relevant stakeholders to establish universal definitions for common terms and standardised units of measurement of right-to-health features of health systems
- ensure that the activities of the UN specialised agency or other body are aligned with the comprehensive national health plan

We recommend national governments

- explicitly recognise the right to health, and right-to-health features, such as access to
 essential medicines, in the national constitution or statute
- ensure explicit recognition of the right to health in the comprehensive national health plan
- ensure sufficient expenditure on medicines to provide, as a minimum, equitable access to essential medicines
- collect data on marginalised groups to inform the planning and development of the health system
- do health and human-rights impact assessments before finalising the comprehensive national health plan
- in partnership with WHO, UN specialised agencies, civil society, and others, collect and regularly update information on right-to-health features of health systems
- disaggregate data on at least the five priority prohibited grounds of discrimination sex, age, ethnicity, socioeconomic status, and rural or urban residence
- regularly submit information updates about the right-to-health features of health systems to the global data repository maintained by WHO/OHCHR
- cooperate with the WHO, UN bodies, and others in establishing national and international benchmarks to monitor the right-to-health features of health systems
- · ensure registration of births and deaths within a civil registration system
- establish national human-rights institutions with a mandate that includes the right-to-health and budgeted programme of activities for raising awareness about the right to health
- ensure the mandate of the national human-rights institution includes monitoring and accountability with respect to international assistance and cooperation in health
- include compulsory human-rights and right-to-health training for health workers, judges, and lawyers
- submit timely, full reports to the UN Committee on Economic, Social, and Cultural Rights and other relevant UN treaty bodies

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time. However, most countries (121 of the 184 for which data are available) do not recognise the right to health in their national constitutions or other statute, although every country has ratified at least one international treaty that recognises the right to health. Recognition of the right to health has not only generated judicial decisions that have improved the delivery of health-related services,55 it has also led to non-judicial mechanisms of accountability, such as the Right to Health Unit established by the Uganda Human Rights Commission, and led to enhanced health policy and practice. For example, the Department of Health in the United Kingdom recently commissioned an assessment of the effectiveness of implementing a human-rights based approach in health and social care.130 Focusing on five pilot projects, the assessment concluded that such an approach had a noticeable effect on the treatment and care of health-service users, and that it is one way of achieving good practice. Thus, we recommend that countries ratify treaties that encompass the right to health, explicitly recognise this human right in their national constitutions or other statute, and integrate the right to health into their national health plans.36

Health information

Health information is the life-blood of effective, accessible health systems and the right to health. Information enables individuals and communities to promote their own health and allows governments to formulate evidence-based health plans. Monitoring, accountability, and participation depend upon access to information. Without reliable disaggregated data, whether health systems are delivering access to services and facilities without discrimination is impossible to know. However, our research suggested that health information systems in many countries are seriously deficient in several ways.

Health information systems include a range of data sources, such as censuses, household surveys, vital registration systems, and other health-facility data sources.131 Ideally, systems should not duplicate but complement each other, providing accurate information making best use of limited resources. 152 Data for maternal and neonatal deaths, for example, should be included within the vital registration system, but the data then need to be specifically extracted, a position supported by the WHO Maternal Mortality Report in 2005. 126 Of 194 countries, 122 have a civil registration system; however, many of these are incomplete, with fewer than 90% of events registered. Accurate recording of cause of death according to international standards is important,133 and the statistics generated should then form a part of the situational analysis that contributes to health-system planning. We recommend that all countries should legally require registration of births, deaths, and cause of death according to international standards (using the international classification of disease).134

The USAID-supported Demographic Health Surveys, the Multiple Indicator Cluster Survey programme developed by UNICEF, and other surveys provide much information. Data provided by these surveys were used as sources for many indicators in this profile, and for some indicators, such as those considering access to water and vaccination coverage (see extended data in webtables 4 and 5) the survey type and year were recorded along with the score. Although surveys fill an important role, they are not the best long-term solution to collection of routine data if not done regularly and they should be included in a civil registration system that is permanent, continuous, compulsory, and universal.¹³² At the very least, a system is needed to record reliable information on birth and death registration in all regions. Such a system would have implications for several human rights. Without birth registration, many entitlements may be denied throughout life, such as access to health care, education, international travel, and the right to own property. However, data for the percentage of births registered in rural and urban areas are only available for 78 countries. Furthermore, only 69 countries regularly collect, centralise, and make publicly available data throughout the territory for numbers of maternal deaths. We recommend, at a minimum, continuous registration of births and deaths in all areas within a vital registration system.

Descriptive information is needed to understand the issues behind quantitative data; however, we often found a shortage of this information. In this project, all indicators have been reduced to a number or to yes or no answers, but the accompanying data and commentaries (webtables 4 and 5 and webappendix 1) are crucial to understanding our findings. Some issues are difficult to accurately capture with purely quantitative data, and we encourage greater emphasis on a complementary brief narrative in some cases.¹³⁵

As part of their human-rights responsibility of international assistance and cooperation in health, donors (webpanel) should accelerate their coordinated efforts to provide training and technical assistance for sustainable data collection and processing and to make data available worldwide. Additionally, donors should facilitate the establishment of national health information systems, including a comprehensive civil registration system in all countries, with clear mechanisms for relaying this information to a globally accessible data repository. WHO and the UN Office of the High Commissioner for Human Rights should have a leadership role in establishing and maintaining a global system for collection and collation of up-to-date information from different countries and UN bodies on right-to-health features of health systems.

Disaggregation

Policy makers and health practitioners need accurate information about marginalised groups as many are at risk of worse health,¹³⁶ because, in many cases, of

(Continued from previous page)

We recommend national and international civil society

- · participates in health system planning and monitoring
- advocates that right to health is properly incorporated in health system planning
- · advocates the inclusion of marginalised groups in health decision making
- advocates that the mandates of national human-rights institutions include the right-to-health and budgeted programme of activities for raising awareness of right-to-health
- disseminate information about key judicial decisions about the right to health
- ensure that the activities of the civil society organisation are in alignment with the comprehensive national health plans

We recommend research institutions

- provide assistance to national governments to do health and human-rights impact assessments
- · do or commission research on the right-to-health features of health systems;
- actively promote knowledge sharing among academics on the right-to-health and right-to-health features of health systems
- collaborate with national governments, WHO, UN bodies, civil-society organisations, and others to promote a greater understanding of the right to health and right-to-health features of a health system

We recommend donors

- recognise the importance of strengthening health systems in international assistance strategies
- · allocate greater funding for health in low-income and middle-income countries
- ensure donor accountability for international assistance and cooperation in health in both donor and recipient countries
- align international assistance and cooperation strategies with the comprehensive national health plans of recipient countries

problems in accessing health-related services. From the human-rights perspective, the goal is to disaggregate data in relation to as many of the internationally prohibited grounds of discrimination as possible (indicators 3 and 4), although some data cannot be disaggregated. The collection of disaggregated data remains an enormous challenge for many countries and, because of limited capacity, reliable disaggregated data are often unavailable. The contextual natures of vulnerability and discrimination further hamper collection of relevant data: a group might be especially vulnerable in one context but not in another. We had difficulty identifying indicators that captured vulnerability and marginalisation, probably because of their contextual nature. We recommend five priority grounds-sex, age, ethnic origin, rural or urban residence, and socioeconomic group-for disaggregation as a minimum.98 These ground are similar to those identified by the Health Metrics Network.55

Some health issues demand disaggregation on particular grounds; for example, in the context of sexual and reproductive health, disaggregation on the basis of sex and age are crucial. Of the 21 countries with information about the proportion of men and women with comprehensive knowledge of HIV/AIDS, men fared better than did women in 16, suggesting that different



strategies for education of women are required. The Guidelines on Construction of Core Indicators in relation to monitoring the Declaration of Commitment on HIV/AIDS note that an important lesson from the UNAIDS Global Progress Report of 2003 was that without disaggregated data monitoring of access, equity, and change over time is difficult.¹⁹⁷ The guidelines acknowledge that this disaggregation requires effort, but point out that such data are commonly collected at the subnational level but subsequently lost when passed to the national level. Another recommendation therefore is that coordinated efforts are made to collate and present reliable data at the national and global levels broken down on the basis of the five priority grounds.

Coordination of data

Because the right to health involves policies and practices that lie beyond the health sector, effective coordination is needed between different sectors (including health, transport, environment, and education) and different health services. General comment 14 recognised coordination as a right-to-health feature of health systems.46 Data collection is one example of where coordination is needed—as happens with global maternal mortality data. UNICEF, WHO, UNFPA, and the World Bank periodically assess maternal-mortality data.138 As a result of joint assessment the data on maternal mortality are the same at WHO and UNICEF. However, life expectancy data differ between the two sources; for example, WHO reports a life expectancy of 61 years in Namibia, UNICEF reports 52 years. The cause of this large discrepancy is unclear. We recommend coordination and collaboration between countries, regional stakeholders, UN bodies, and others to establish a global repository for health data with up-to-date and consistent reporting.

For some indicators more information is available worldwide for low-income than for high-income countries, such as the data on DTP3 and MCV vaccination. However, high-income countries have the resources to collect and process the relevant data, which should be logged in a global repository.

Standardisation

When developing the indicators and collecting data, one major difficulty was the lack of universal definitions for many commonly used and important terms, such as clear definitions for rural and urban. Disaggregation of data on these grounds was therefore difficult; in practice, individual data collectors decide whether a location is rural or urban. **Similarly, violence against women does not have a standard definition. **I Specific criteria and definitions should be created, although they might not capture every nuance of the relevant issue, to allow consistency of data collection and comparison over time.

Standard definitions are needed to create national and international benchmarks against which to measure a country's progress. General comment 14 anticipates that

countries and the UN Committee on Economic, Social, and Cultural Rights will agree key indicators and then identify appropriate benchmarks or targets to be achieved by the country over the next few years in relation to the selected indicators. 46 Agreed indicators and country-specific benchmarks are needed to measure progressive realisation and hold governments to account. Sometimes benchmarks are agreed internationally for all countries, or a group of countries-for example, all donors should devote 0.7% of their gross national income to overseas development assistance, and all African leaders have pledged to allocate 15% of their annual budgets to health, 142 Whether benchmarks are set nationally or internationally, standard definitions are important. For example, CO2 emissions are recorded in various ways, which makes benchmarking difficult.143 Although indicators and benchmarks are vital if we wish to measure progressive realisation and hold countries to account, their usefulness depends on widely agreed definitions.

Standard formatting for data collection would be especially helpful in low-income and middle-income countries that have to collect similar information in different formats to fulfil the demands of different donors and international bodies.

We warmly welcome the Health Metrics Network, a global partnership of UN bodies, donors and others aiming to improve health information at country, regional, and global levels.⁵⁹ The network hopes that by 2011 its detailed framework and standards for country health information systems will be the universally accepted standard for all developing countries and global agencies. The network comments on the inappropriate use of data collection methods (eg, surveys used to record adult mortality) and advocates the disaggregation of health-status data. We recommend that the network encourages the collection of data outlined in this report, which is needed to measure the right-to-health features of a health system.

Access to information is part of the right to health. However, in addition, information is protected by national and international codes of civil and political rights. Handy of these codes provide stronger accountability mechanisms than are available to the right to health. We recommend that human-rights workers in the domain of civil and political rights use their expertise to improve access to health information, following the example of the London-based civil society organisation Article 19.

Comprehensive national health plans

Within the confines of our methods, no data currently are available at the global level to show that any country has a comprehensive national health plan, whereas 13 countries have data available on the WHO website indicating that they do not have a comprehensive national health plan. We recommend adoption of a universal definition of a comprehensive national health plan. Countries should develop comprehensive national health plans consistent with defined criteria, including budget allocation for all

proposed activities. Information about all such plans should be available both nationally and internationally. Monitoring and assessment of these plans both nationally and at the global level are also needed to ensure compliance with agreed criteria. Any gaps identified should be systematically addressed; for example, if a national health plan does not encompass the private sector then this shortcoming needs to be identified and remedial action taken.

Appropriate national and international human-rights bodies should monitor whether or not a country has a comprehensive national health plan conforming to the agreed criteria. For example, a national human-rights institution should check whether or not the government has an appropriate national plan. Most national humanrights institutions report annually to the legislature and the status of a national plan could be publicly reported this way. Also, appropriate international committees of humanrights experts, such as the UN Committee on Economic, Social, and Cultural Rights, should routinely ask countries appearing before the committee about their comprehensive national health plans. The UN Human Rights Council has recently established a new procedure that all countries must follow. Known as the universal periodic review, a comprehensive national health plan is so important that the council should routinely ask all countries about the status of their plan.145

Monitoring, assessment, accountability, and redress

We recommend that much closer attention be devoted to establishing accessible, transparent, and effective mechanisms for monitoring and accountability of health systems and the right to health. Analysis of the data collected in this project reveals weak mechanisms at international and national levels. Without indicators and reliable data, neither the condition of health systems nor the progressive realisation of the right to health is possible. Accountability, however, is much more than monitoring. Organisations and individuals with right-to-health responsibilities must be held to account in relation to the fulfilment of their duties, with a view to identifying successes and difficulties—what Freedman³¹ calls constructive accountability. In this way, accountability strengthens health systems.

As explored by Potts,** there are many different mechanisms of monitoring and accountability for the right to health—social, political, administrative, quasijudicial, and judicial—each with a crucial role. Our indicator 69 tried to address quasijudicial accountability by asking if countries have national human-rights institutions with mandates that include the right to health. However, there was no globally available data for this indicator revealing either a shortfall in the data available or in the mandates themselves. We recommend that national human-rights institutions include the right to health in their mandates and budgets for programmes.\(^{146}\) In close collaboration with the health sector, these institutions could provide

human-rights training for health workers, raise public awareness of right-to-health entitlements and processes, work with public officials to integrate the right to health into policies, help to prepare right-to-health protocols and guidelines for health workers, monitor right-to-health features (eg, comprehensive national health plans and international assistance and cooperation in health), and undertake independent public inquiries into particular right-to-health issues, hold those responsible to account, and make recommendations. Australia's Human Rights and Equal Opportunity Commission has made health inquiries on several occasions, for example, in its Social Justice Report 2005 that applies human rights to indigenous health policy.147 With the recent change of government in Canberra, this important report is now shaping health policy and practice. National human-rights institutions should forge strategic partnerships with the media, health workers, patients' groups, judges, lawyers, academics, and others.

Mechanisms of social accountability include public hearings and social audits. The People's Health Movement in India has set up the People's Rural Health Watch to conduct independent health monitoring in seven states in northern India. This initiative supplements the community monitoring that is part of the National Rural Health Mission launched by the government in 2005.** In some situations, Médecins Sans Frontières, after listening to patients to understand why a situation is occurring, will draw attention to the issues, problems, and responsibilities.**

One example of administrative accountability is addressed in the indicators for impact assessment (a process through which the potential effects of a policy, programme, or plan on the health of the population is assessed). However, data for the national level show that none of the five countries had made a health impact assessment or any impact assessment including the right to health before the implementation of their national health plan. We recommend that countries make such assessments before adopting their national health plan; there should at least be an impact assessment in relation to key elements of a plan. Such assessments can be crucial to progressive realisation of the right to health.⁷⁵

Effective monitoring and accountability depends on numerous factors, including the recognition of the right to health as a legally enforceable right. Where the rule of law is respected, it helps to be able to say to the relevant minister, local health council, or hospital director that a particular health initiative is not only ethically appropriate and good practice but is also required under binding national and international human-rights law. Accountability is not judicial accountability. As discussed, judicial accountability is one narrow, limited form; moreover, it is accountability of last resort. Judges and lawyers must be willing to learn about, and apply in a balanced manner, such right-to-health concepts as progressive realisation, resource availability, core obligations, and disadvantage; they must be willing to listen to health experts and those





using health-related services. Information about key judicial decisions for realisation of the right to health should be widely accessible. Also, countries must report regularly on regional and international treaties that they have ratified.

Redress is another important component of accountability.* It comes in many forms, such as full and public disclosure of the truth, apology, acknowledgment of responsibility, a change in policy, law reform, rehabilitation (eg, the provision of health-related services), and compensation

Finally, careful attention must be given to the human-rights accountability of international bodies, as well as the private sector. The Human Rights Guidelines of Pharmaceutical Companies in relation to Access to Medicines can deepen the accountability of the pharmaceutical sector. 149

Additional research

This project highlights the need for more research on the right to health. For example, what are the core obligations signalled in paragraph 43 of general comment 14? Research is needed on the application of the right to health to the six WHO building blocks of a health system and within both public and private sectors. More attention should be devoted to right-to-health features of health systems: for example, what are appropriate mechanisms of monitoring and accountability? More research is needed on the most appropriate indicators for assessing the degree to which health systems include these right-to-health features. We had particular difficulty identifying appropriate indicators in relation to access (including access for marginal groups), respect for cultural difference, quality, participation, referral systems, standards (ie, provisions that elaborate in more detail upon the general right-to-health formulations found in treaties, constitutions, and statutes), coordination (ie, the need for effective coordination across a range of public and private stakeholders, at the national and international levels, both within and between health-related sectors), and monitoring and accountability. We recommend that particular thought be given to identifying appropriate indicators for these issues. Echoing Gruskin and colleagues,39 we also recognise the need to build evidence of the effects of the application of the right to health on health systems.

Conclusion

Over 18 months of research, our interdisciplinary project has depended upon the insights of experts in both health and human rights. UN bodies, non-governmental organisations, policy makers, academics, and others have made indispensable contributions. We strongly recommend that all those sharing the common ground between health and human rights deepen their dialogue, cooperation, and collaboration. Our findings have implications for professions and institutions at all levels and

in both public and private sectors. For example, health ministries and national human-rights institutions need to meet and talk, and UN organisations must routinely discuss health and human-rights issues. For example, WHO, UNFPA, and the World Bank must engage with the UN Human Rights Council, Office of the High Commissioner for Human Rights, and human-rightstreaty bodies. All these organisations—and many others—have the common aim of strengthening health systems.

Countries have a legal obligation to progressively realise the right to the highest attainable standard of health and therefore to improve their health systems progressively. Indicators and benchmarks are needed to measure present conditions of health systems and to monitor them over time. Indicators selected in this profile and methods of data collection have limitations, but the findings have generated several recommendations. We are drawn to the conclusion that those with responsibilities for health systems are giving inadequate attention to the right-to-health analysis. Our main, overarching recommendation is that all those with health-related responsibilities explicitly consider the right-to-health analysis and integrate this human right into their policies and practices, with a view to strengthening health systems. We hope that this project will be repeated periodically so that the progress of individual countries will be monitored. No doubt improvements will be introduced to the methodology and profile of indicators before the exercise is repeated in a few years' time.

This project rests on the conviction that an equitable health system is a core social institution, no less than a fair court system or democratic political system. Because of its importance, a health system is reinforced and protected by the right to the highest attainable standard of health and other human rights. Health systems should have certain right-to-health features identified in this report. These features are legally binding requirements, not optional extras. Governments must be held to account to ensure that health systems have, in practice, the features required by international human-rights law.

Contributor

As project director, GB contributed to the drafting of all sections and explanatory notes and collected global data. PH contributed to the drafting of all sections. GB and PH prepared figure 1. RK contributed to the drafting of the introductory, key findings, and opportunities and challenges sections and explanatory notes and collected global data. CJ-S and BMF contributed to the drafting of the methodology section and the explanatory notes and collected global data. CR contributed to the drafting of the methodology, key findings, the opportunities and challenges sections and explanatory notes and collected global data. DP contributed by advising on statistical analysis and developing several and reviewing all of the figures in the key findings section. DA and MAP collected national data on Ecuador. AF and DT collected national data on Peru and drafted some panels. MM collected national data on Mozambique and drafted some panels. CV and DF collected national data on Romania and drafted some panels. DAP, CJ-S, AF, and DT, write in a personal capacity and the views expressed are not those of their affiliations.

Conflict of interest statement

We declare that we have no conflict of interest.

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Abstract

Background: Neonatal mortality rates are high in rural Nepal where more than 90% of deliveries are in the home. Evidence suggests that death rates can be reduced by interventions at community level. We describe an intervention which aimed to harness the power of community planning and decision making to improve maternal and newborn care in rural Nepal.

Methods: The development of 111 women's groups in a population of 86 704 in Makwanpur district, Nepal is described. The groups, facilitated by local women, were the intervention component of a randomized controlled trial to reduce perinatal and neonatal mortality rates. Through participant observation and analysis of reports, we describe the implementation of this intervention: the community entry process, the facilitation of monthly meetings through a participatory action cycle of problem identification, community planning, and implementation and evaluation of strategies to tackle the identified problems.

Results: In response to the needs of the group, participatory health education was added to the intervention and the women's groups developed varied strategies to tackle problems of maternal and newborn care: establishing mother and child health funds, producing clean home delivery kits and operating stretcher schemes. Close linkages with community leaders and community health workers improved strategy implementation. There were also indications of positive effects on group members and health services, and most groups remained active after 30 months.

Conclusion: A large scale and potentially sustainable participatory intervention with women's groups, which focused on pregnancy, childbirth and the newborn period, resulted in innovative strategies identified by local communities to tackle perinatal care problems.

Background

Participatory approaches to health have been advocated since the 1978 Alma Ata declaration in which the World Health Organisation emphasised the need for citizen participation in primary health care [1]. This paper details the development and implementation of a participatory project to improve perinatal care at the community level in rural Nepal.

Community participation in health care

The vision of Alma Ata was that increasing community participation in planning and implementation would lead to more cost-effective delivery of health care and increases in service utilisation. As communities took greater ownership of services they would become more culturally acceptable and responsive to local needs. Community participation also aimed to increase self-reliance and social awareness, which would lead to better health outcomes [2-4]. Opinions differ about the extent to which participation can achieve these results, and to what degree governments and agencies have facilitated participation, but the appeal of participatory approaches remains strong. Participation may be considered as a continuum [5]. In fully participatory approaches, needs are identified by the community themselves, who then may seek external support. At the other end of the continuum, superficial participation of community representatives is sought to validate the aims of programme planners, usually already decided.

Harnessing the strengths of participation in community based interventions

Reproductive health is an area where participatory approaches have been attempted. A structured literature search for community-based interventions focusing on perinatal health revealed no randomized, controlled trials, but two studies in developing countries which had evaluated impact on Perinatal health outcomes. The Warmi project in Bolivia, initiated by a collaboration of Save the Children Federation, USA and USAID Mother-Care project [6], worked with women's groups to reduce maternal and neonatal mortality and morbidity. They used a participatory approach involving community diagnosis, planning together, implementation of plans, and participatory evaluation. The Warmi project, though neither randomized nor controlled, and based on a beforeand-after analysis of 639 and 708 births, did report a reduction in the perinatal mortality rate from 117 to 44 per thousand births. The activities initiated by women's groups included literacy programmes, savings and credit schemes, and programmes to increase access to family planning.

Studies based in the community that are towards the low end of the participation continuum also appear to have been successful in enabling improvements in pregnancy outcomes. A study in Maharashtra state, India, tested the effectiveness of early detection of warning signs of illness and village level management of neonatal sepsis (a cause of many neonatal deaths in developing countries)[7]. Village health workers were trained to visit newborn infants in their homes and identify and treat neonatal sepsis. This intervention appeared highly successful as a drop in neonatal mortality of 62% occurred. Village health workers were intensively managed and supported by the research team, and therefore large-scale implementation may be difficult. The study did, however, provide evidence that community level interventions to prevent or treat problems of the perinatal period in developing countries could be cost-effective.

The Nepal MIRA Makwanpur trial

The MIRA Makwanpur trial was designed to test the impact on neonatal mortality of a participatory intervention with women's groups, based on the Warmi Bolivia model, but on a much larger scale and using a randomized and controlled design. In south Asia infant mortality rates fell steadily from 1970 to 1990, but the decline has subsequently plateaued. In order to reduce infant mortality rates further, a focus on the neonatal period, in which most infant deaths occur, is necessary [8,9]. Primary and secondary care are deficient in rural areas of Nepal and where services exist, the reasons for their underuse are complex. The topographical barriers combined with limited expenditure on public health, poor quality of care, a high turnover of service providers, a lack of drugs and supplies and a lack of ownership of health programmes by communities all contribute to issues of demand and supply.

The trial was implemented by a Nepali non-governmental organization, MIRA (Mother & Infant Research Activities). MIRA has been working in Nepal since 1992, conducting research specifically about newborn care, and is headed by a senior pediatrician (DM). The trial involved 24 Village Development Committees in rural Makwanpur district. Ethical approval was sought from the Nepal Health Research Council, and local meetings were held with the District Development Office and Chief District Officer to discuss the aims and objectives of the study. The chairpersons for each Village Development Committee agreed to take part in the study and provided signed consent, and links were made with community leaders, district health services and non governmental organisations. Each Village Development Committee has an average population of 7000 (range 1576 to 23 429) divided between nine wards. In twelve of the Village Development Committees a trained, locally based facilitator was employed to mobilize women's groups. All pregnancies and births to married women of reproductive age were monitored in the

community. Details of the monitoring and the design of the trial have been described elsewhere [10] and the effect of this intervention on birth outcomes was reported in a recent publication [11]. Astonishingly, there was a reduction in neonatal mortality by 30% in intervention clusters, and an even larger and statistically significant effect on maternal mortality rates (78% reduction), although caution is required in interpretation given the relatively few maternal deaths. This paper describes and analyses the implementation of the first stages of the participatory intervention over a 30 month period.

Methods

Setting of intervention

Nepal has a population of 23 million and a per capita gross national product of 240 US dollars. Literacy rates have improved steadily, particularly for females (currently 43%), but there remain gender disparities in literacy, school enrolment, and school dropout rates [12].

Life expectancy is now 61 years [13]. The total fertility rate is 4.1, the under-five mortality rate 91, the infant mortality rate 64, the neonatal mortality rate 39 per thousand live births, and the perinatal mortality rate 47 per thousand births [9]. The maternal mortality ratio is estimated at 539 per 100 000 live births [14]. Access to health care is limited as a result of geography, limited expenditure on public health, variable quality of care, high turnover of service providers, a lack of drugs and supplies, and lack of ownership of health programmes by communities.

Makwanpur district, south west of Kathmandu, has a population of 376 000 [15] and a Human Development Index of 0.31, close to the national median. Makwanpur comprises hill and plain areas, with 15 different ethnic groups, the largest being Tamangs, a Tibeto-Burman group. Data from our baseline survey showed that more than 90% births take place at home and only five percent are attended by a trained birth attendant. The first health care provider in times of maternal or neonatal illness is the shaman (*dhami jhankri*) or traditional healer [16].

The intervention process

The first ten meetings of the women's group participatory intervention were based on the design of the Warmi project in Bolivia [17]. In order to enter the communities successfully we gathered detailed information on local social networks and organizations, as well as attitudes and practice around the time of pregnancy and birth. Social mapping and qualitative research were conducted and served as a training exercise in facilitating focus group discussions and building rapport in the community [18]

Establishing facilitated women's groups

Meetings were facilitated by a paid, locally based woman, who was selected on merit and trained in facilitation techniques. The position of facilitator was locally advertised and suitable candidates were interviewed by senior MIRA employees. Each facilitator is paid a salary slightly higher than the government equivalent (5330 Nepalese rupees, or 71 US dollars). Her full-time responsibility was to plan and facilitate monthly women's group meetings, each facilitator leading nine groups per month, covering an average population of 7000. Meetings were organized in co-ordination with the local Female Community Health Volunteer, an unpaid community based health worker. In profiling our study area, we found that nongovernmental organisations or community based organisations did not routinely work in all 24 of our study Village Development Committees and had different agendas. The female community health volunteer works at ward level, and as part of her job description she runs women's groups to conduct health promotion activities.

The facilitator used a meeting manual, adapted from the Warmi project, to guide the women's groups through problem identification and community planning using participatory iterative methods (see Figure 1 and Table 1). Facilitators were trained in the use of this manual and were allowed scope for their own input. Facilitation supervisors were also appointed after national advertisement and formal interview, and two men and three women were selected. One supervisor was provided for every three facilitators, providing support through community visits and regular meetings.

First meetings and problem identification

Facilitators and supervisors were responsible for creating awareness and interest in their communities about the meetings, and in most wards at least 20 women attended the first few meetings (see Figure 2). Time was taken to introduce the study agenda to the groups, especially important in areas where many non governmental organisations work and expectations were often high. The first three meetings facilitated discussion of the reasons why mothers and newborn infants die in the community. The reasons for death were discussed in terms of social as well as medical factors with the aid of a story [19]. Women were introduced to the concept of 'learning together' through another story, and were encouraged to discuss perinatal problems within the group and with their neighbours and friends. In this way the facilitator and the women learned which perinatal problems affected their community. Each group prioritised three problems of newborn infants and/or pregnancy which were recorded with justification for their inclusion. Most group members were illiterate and therefore facilitators used pictures and voting with stones to prioritise problems.

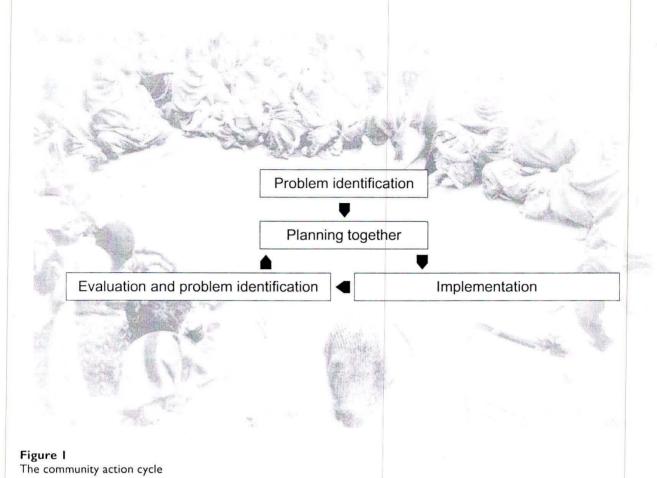


Table I: Content of first ten women's group meetings

Stage in the cycle	Meeting	Content			
Introduction	ĵ	To introduce the group to MIRA Makwanpur's work			
	2	To discuss why mothers and newborn infants die To introduce how MIRA will work in the community			
Problem	3	To find out how women understand maternal and neonatal problems			
Identification	4	To find out what kind of maternal and neonatal problems are in the community			
	5	To discuss whether the maternal and neonatal problems are common To identify strategies to collect information from the community			
Problem Prioritisation	6	To share the information collected from other women in the community To decide what are the three most important maternal and neonatal health problems			
Planning together	7	To discuss possible strategies for addressing the prioritised problems			
	8	To discuss which other community members should be involved in developing strategies			
	9	To discuss how to prepare for the community members meeting			
	10	The community members will learn about what the women have been doing The community members will learn about the three problems identified by the women The community members will learn about the possible strategies To reach a consensus of the strategies			

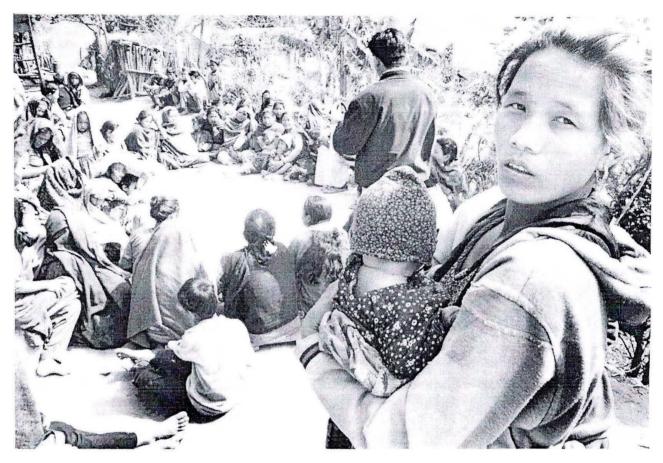


Figure 2
Women's group and facilitation manager

Planning together

The objective of these meetings was to encourage women to identify local and low cost ways of tackling the prioritised problems using local resources. Many examples were listed in the manual and the supervisor was encouraged to support the facilitator during these meetings. The idea behind these meetings was to enable the women to prepare a plan to tackle the problems they had found, which would then be presented to their community.

The community meeting

A community meeting was planned and organized by the groups to enable increased community participation and to legitimize the work of the group. The community was invited to hear what the women's group had been doing, and to participate in *planning together* strategies. Most groups decided that community leaders would be invited by letter, and other households would be verbally invited.

The groups also discussed the way they would present their findings and practised to develop their confidence.

The supervisor supported the local facilitator and the group, and played a key role in facilitating the meeting. After introducing MIRA and its role in the community, the women's group presented their prioritised problems and suggested strategies to tackle them.

Methods of data collection and analysis

Data were collected through a variety of qualitative techniques. Participant observation was carried out by the technical advisors to MIRA (NM and JM). They helped design and implement the intervention, and lived in the vicinity of the head office in Hetauda, Nepal, throughout the study period (JM succeeded NM). They visited the field many times and attended facilitation team meetings regularly. The advisors are of British nationality but have

an excellent spoken command of Nepali language and have a background in anthropology and sociology. Although they did not keep a diary as is usual in participant observation, their reflections and observations were noted in monthly reports and topic reports which have been used in this analysis. These reports were also contributed to and discussed with the facilitation team (facilitators, supervisors, and senior facilitation manager) who also added their reflections and observations. The technical advisor (JM) and senior facilitation manager (ST) analysed monthly reports and meeting minutes and reached consensus on themes emerging from the data, and issues of interest. Although there are limitations to this method of data analysis (the cultural background of the technical advisors and the fact that a diary was not kept), we wished to present the results of operational research that makes use of less formally recognized qualitative data collection techniques. Analysis of the data by more than one person strengthens the analysis and using different methods of data collection enables triangulation of the data.

Results

Out of 111 women's groups, 77 moved on to develop and implement strategies and 100 groups continue to meet to discuss perinatal health. Particular reasons for which the remaining groups did not meet include the unstable security situation, lack of support from local leaders, husbands or health workers, and general lack of interest.

What makes an active women's group?

The continuing activity of most groups suggests that usually group members found the experience useful and enjoyable. Not surprisingly, the activity of the groups varied. We found no specific formula for an active women's group. Previous studies suggested that homogeneity of members was conducive to a successful group [20,21], but our groups showed much ethnic and social diversity. Issues of ethnicity, geography and distance from a market area did not uniformly affect the activity of groups. For example, there were two particularly active groups near market areas, but in other areas factors concurrent with living near a market – such as higher socioeconomic status and less cohesion between households - did not facilitate enthusiastic women's groups. Some groups were dominated by women from higher castes, but in others these higher castes served as a stimulant to more traditionally subservient or timid ethnic groups. Issues of local support from political groups, local health staff and men also seemed important. Other studies have also found that supportive husbands make it easier for women to participate in groups [22]. In most communities supervisors and facilitators had been successful in establishing good community rapport, and strategies were agreed to help maintain community support, such as facilitators attending

Table 2: Problems prioritised by women's groups

Neonatal Problems	Number of groups
Pneumonia in the newborn infant	31
Low birth weight	16
Jaundice in the newborn infant	12
Neonatal death	7
Breathing problem in the newborn infant	6
Infant not feeding	4
Green stool in the newborn infant	3
Wounds in the newborn infant	2
Tetanus in the newborn infant	1
Eye and ear infection in the newborn infant	I
Maternal problems	
Retained placenta	58
Vaginal Discharge	42
Malpresentation	30
Headache in the mother	22
Post partum haemorrhage	20
Fever (unspecified if in mother or baby)	15
Breast problems	13
Ante partum haemorrhage	11
Miscarriage	11
Abdominal pain in the mother	6
Oedema of hands and legs in the mother	6
Prolonged labour	5
Maternal death (delivery complications)	2
Anaemia in the mother	2
Vomiting in the mother	1
Missing data	3
Total	330

antenatal clinics and supervisors presenting reports to Village Development Committee chairpersons.

Problem prioritization

Women actively participated in learning together and gathered much information from their communities. The prioritized problems reflected local perceptions of the seriousness and frequency of specific problems and hence were different in each community (See Table 2).

Planning together

During the community planning meeting groups nominated members to present their findings and eight groups performed small socio-dramas. When local health personnel and area chairmen attended, discussions were livelier and planning more productive. Issues of health care underutilization by the community or issues of poor service delivery were often raised. In nine places, communities appeared apathetic towards the group and were not prepared to commit or participate in planning. In these

instances, they were happy for the group to plan and implement strategies and little discussion took place. In four places the group met with hostility from community leaders or health personnel or exceptionally low attendance from the community, usually due to local grievances with staff selection procedures or to the unstable security situation.

Strategy development and implementation

The strategies that were discussed during planning together and have been most successfully implemented were the mother and child health fund, locally produced clean home delivery kits, management and production of stretchers, and awareness raising through video shows.

Mother and child health fund schemes

69 groups favoured mother and child health funds as a way of overcoming the cost barriers to seeking and obtaining care. The cost of consultation, medicine and transport is a real reason that families do not gain access to services in Nepal [23]. MIRA provided training to fund management committee members elected from each group. These committees sometimes included literate community members not attending the group. Each group developed their own policy with regard to how money would be collected, who would be able to access it, how often it would be collected, and who would be responsible for managing it. 23 months after the first mother and child health fund was established, groups had generated between 731 rupees (10.5 US dollars) and 9635 rupees (133.8 US dollars).

Clean home delivery kits

The clean home delivery kit is advocated by the World Health Organisation as an effective way to promote cleanliness during home delivery and to reduce the risk of maternal and neonatal infection [24,25]. In Nepal, a local private company (MCH Products Pvt Ltd) has produced a clean home delivery kit, approved by the Ministry of Health, which contains a blade, a bar of soap, three cord ties, a plastic coin for cord cutting, a plastic sheet, and a set of pictorial instructions. There are problems with distribution to remote rural areas and other difficulties regarding local acceptability and price [26].

A few groups were keen to develop their own locally produced clean home delivery kit, and facilitators disseminated this idea to motivate other groups by example. 19 groups have made clean home delivery kits and four groups have reproduced subsequent batches. Groups have decided the price, but all groups sell at a lower price than the MCH products kit, with profits going into the mother and child health fund. The pictorial instruction leaflet was developed with a local artist and was piloted in the community. The groups have also

explored different selling points: local shops, Female Community Health Volunteers and Traditional Birth Attendants, and group members sold kits to their friends and neighbours. Recently, groups from one Village Development Committee have used free distribution of clean home delivery kits as an incentive to attend for antenatal care; the kits are free for women who attend at least four times.

Stretchers

In the study area, most births take place in the home [27] and transportation of women who encounter problems is difficult. Women's groups therefore identified the need for stretchers. 19 groups decided to raise money for stretchers themselves and the other 23 groups utilized local resources such as forest user groups or Village Development Committee offices. Women's groups investigated if there were any existing stretchers in their area, or if these needed repair. One group felt that the modern style of stretcher was not suitable for carrying women across difficult terrain, and therefore made a bamboo basket (dhoko) which is traditionally used to carry fodder or crops using a head strap (tump line). Some women's groups assumed management of unused stretchers, ensuring their accessibility and promoting their use, with 35 groups levying a fee for usage

Awareness raising through video shows

During the community meetings, many groups felt that there was a lack of awareness about perinatal health problems and how to deal with them. MIRA had previously researched and produced a 20 minute film about newborn care in Makwanpur and the groups were keen to use it in their communities. Group members approached those households in the community with electricity and a television, and the video was shown in homes or public buildings. Although not all of the study area has electricity, the video was shown in 10 out of 12 Village Development Committee areas, attracting an audience of more than 2100.

Participatory health education

During the identification of strategies to address problems, there was a tendency to mismatch prioritized problems and strategies. For example, one group suggested tackling the problem of post-partum hemorrhage by attending antenatal care. Another group considered that the problem of vaginal discharge during pregnancy could be addressed by training new Traditional Birth Attendants. During the first ten meetings, and from previous data analyses, the team found an overwhelming preference for care within the community, in terms of place of birth and seeking solutions to health problems [16,27]. Home practices with unequivocal allopathic clinical benefit were rarely mentioned. There was also little knowledge about

what kind of problems could be managed at different health service institutions, and it appeared that communities define the "seriousness" of a problem in a different manner to the allopathic model.

Therefore, the team concluded that perinatal health education would be useful during the development of the strategies. It was felt important to avoid turning the facilitators into educators, and therefore a participatory form of health education was developed, based around a picture card game.

The picture card game

A packet of small hand held cards of different shapes was developed in order to address the mismatch between problems and strategies and to promote participatory learning. Each shape of card represents either a problem (circle shape), a prevention activity (triangle shape), a home-care activity (house shape), or a health institution (square shape). The cards are pictorial and were developed with the MIRA health team and a local artist (see Figures 3 and 4). They were extensively piloted with women's groups and adapted accordingly. A manual for facilitators was also developed to accompany the cards. The card game is played in the group by passing round the cards and discussing the pictures. The group members match problem cards to their corresponding prevention activities, home care activities or type of health institution that could treat that problem. The card game worked well in facilitating discussion, and women and facilitators both enjoyed the learning experience. The team completed a participatory evaluation of the game with a sample of groups which indicated that the game also facilitated learning about danger signs, home care and prevention activities. Group members are presently taking the picture cards on visits to pregnant women in the community who are not group members.

Service quality spin-offs

Community health volunteers

The facilitator has worked to involve and support female community health volunteers with their work in the community. 70 group meetings have regular attendance and active involvement of the local female community health volunteer and traditional birth attendant. The female community health volunteer is the lowest cadre of government appointed health staff and is responsible for one ward. She is unpaid and has a broad job description mainly focused around health education. In theory, she should run monthly women's group meetings to facilitate health education and discuss issues of maternal and newborn health. Although she receives initial and refresher training, she is often left to work unsupervised and unsupported, and in practice female community health volunteers find it difficult to run women's groups. By seeking

the participation of the female community health volunteer in the groups, we gave her a forum to conduct her work and increase her contact with her user group.

In twelve wards the women's group was invited by the local health institution to play an active role in selection of new female community health volunteers and traditional birth attendants. The group had created good links with the health institution, which could be exploited for future service quality improvements. Clearly, the health institution and the community consider many groups as legitimate entities with a role to play in the health of women and their children. It also appears that members of women's groups have become more involved with their local health services.

In one area women's group members responded to the needs of women visiting an outreach clinic for antenatal care and family planning. Women were complaining of a lack of privacy and there was no furniture in the clinic. The group contacted the local forest user group to supply materials for rudimentary furniture and collected money for the purchase of cloth for curtains. In several cases, the women's group was a medium for brokered links between health service providers and users.

Proxies for empowerment effects?

One group put a sign on the door of their meeting place indicating a sense of ownership. Ten out of 12 facilitators have been invited to participate in other meetings and community activities as their role as key actors in the community is being recognized and developed. Women's groups have sung the song from the video film at the annual women's festival, and a supervisor initiated discussion about newborn health in a local bus using a cassette of the song from the film. Another women's group organised a perinatal care quiz that was carried out with nearby women's groups and community members.

Discussion

We have described the development and implementation of a large scale participatory intervention with women's groups. This was adapted from a smaller scale project developed in Bolivia, and implemented in a poor rural population of 86 000 in Nepal. The effects on health outcomes, reported elsewhere, were dramatic.

During the process of developing and implementing the intervention we had to be flexible and respond to the needs of the group. Group members and the wider community clearly faced difficulties when thinking about ways to tackle perinatal problems. These difficulties raised issues around culture and our facilitation role.



Figure 3
Women's group using picture cards

Striking a balance between support and directiveness

It is highly likely that the facilitation team's attempts to adequately support the facilitators may have led to less participatory processes taking place, especially in the case of strategy development. The facilitation manual was considered by the facilitation team as an essential resource. Examples were often given to enable facilitators to grasp key concepts before conducting a meeting. The manual was designed as a reference guide but evidently became more like an instruction booklet, as the strategies most commonly adopted during community meetings were those given as examples in the manual. The reasons behind this usage of the manual illustrate some of the key issues in implementing a participatory project. To truly facilitate, and not be directive, is a difficult technique to learn, especially in a hierarchical society where the facili-

tator's education has emphasised rote learning rather than independence of thought [28]. Our facilitators were also keen to educate and provide the answers, and it may have appeared easier (in the short term) to suggest things for groups to do than to facilitate open discussion. The self-confidence or ability of the facilitator to manage the chaos and unpredictability resulting from a truly participatory process was often lacking, although their facilitation skills developed with time.

Power and culture

Difficulties in linking problems to strategies may also be explained in part by the cultural phenomenon of fatalism, 'ke garne' (what to do?). Bista described 'ke garne' as a belief in fatalism which leads to the feeling that "one has no personal control over one's life circumstances, which are deter-

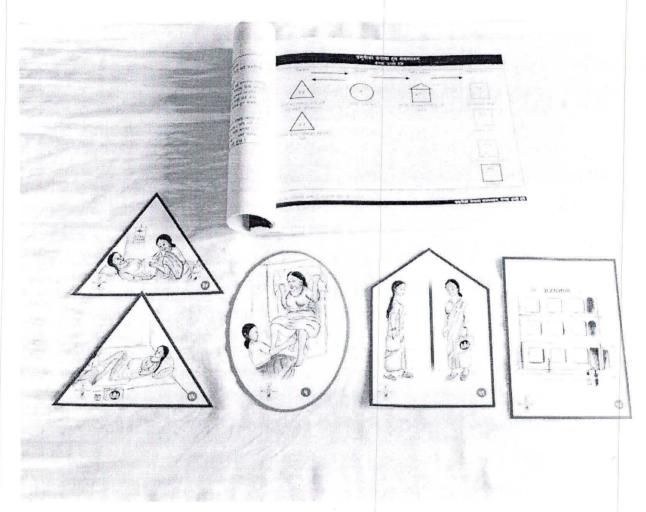


Figure 4
Picture card game and manual

mined through a divine or powerful external agency" [29]. He argued that this fatalism and dependency affects the work ethic and achievement motivation in Nepal. Concepts of planning, orientation to the future, and sense of causality, are all affected. Our study experience was that fatalism affected both the way people viewed themselves in relation to a problem, and also the power and capacity they believed themselves to have in overcoming it.

What has been the impact of the women's groups and their strategies?

In cases where there was a mismatch between problem and strategy, or when groups developed strategies suggested by MIRA, we hope that these groups will benefit from the implementation process alone. The strategies in the manual are not necessarily evidence-based, and it may

be that the process of implementation is more beneficial than the strategy itself. Through implementation, interaction between the wider community and the group may be increased, knowledge about the group may spread, and more people may become interested and involved in issues of perinatal health. To enable a better understanding of the intervention process, evaluations using both qualitative and quantitative methodologies are underway. The impact of the women's group intervention was evaluated in a cluster randomized controlled trial which showed a 30% reduction in neonatal mortality rates and a reduction in maternal mortality rates in the first 30 months of the trial[11]. Qualitative analysis will explore perceptions and process indicators to assess how the intervention affected the study area and community stakeholders. Cost analysis of the intervention will enable estimates

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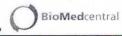
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of cost-effectiveness and sustainability to be made. A comparison of the socio-economic status of women's group members with non-group members will allow an estimate of the equitability of the intervention.

The Millennium Development Goals for reductions in maternal and neonatal mortality in developing countries are unlikely to be met by 2015. In populations where maternal and newborn mortality rates are highest, most deliveries occur at home. It is essential that Safer Motherhood and Newborn Care Programmes design interventions which reach out to the poorest groups in order to change care practices at home, and care seeking for illness or complications of childbirth. Our participatory work with women's groups provides a model for an intervention that can be scaled rapidly in even the poorest and most remote communities.

Conclusion

A large scale participatory intervention to improve pregnancy outcomes in rural Nepal through 111 women's groups has been described. Although we have faced contextual, cultural and security problems, we believe that the participatory approach can be a powerful tool in unleashing the creative potential to solve perinatal health problems in communities. Such an approach may have lasting benefits, affecting behaviour in subsequent pregnancies.

Competing interests

The author(s) declare that they have no competing interests.

Contribution by authors

IM wrote the first draft of the paper and contributed to the study design and collection of field data. ST, and BS contributed to the study design, collection of field data and analysis, and criticised later drafts of the paper. NM and DO contributed to the study design and analysis, and criticised later drafts of the paper. MM and HS contributed to the design of the study and criticised drafts of the paper. DM and AC contributed to the design of the study and supervision of the field programme, and criticised drafts of the paper. JM and AC will act as guarantors for the paper.

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Summary

Background Neonatal deaths in developing countries make the largest contribution to global mortality in children younger than 5 years. 90% of deliveries in the poorest quintile of households happen at home. We postulated that a community-based participatory intervention could significantly reduce neonatal mortality rates.

Methods We pair-matched 42 geopolitical clusters in Makwanpur district, Nepal, selected 12 pairs randomly, and randomly assigned one of each pair to intervention or control. In each intervention cluster (average population 7000), a female facilitator convened nine women's group meetings every month. The facilitator supported groups through an action-learning cycle in which they identified local perinatal problems and formulated strategies to address them. We monitored birth outcomes in a cohort of 28 931 women, of whom 8% joined the groups. The primary outcome was neonatal mortality rate. Other outcomes included stillbirths and maternal deaths, uptake of antenatal and delivery services, home care practices, infant morbidity, and health-care seeking. Analysis was by intention to treat. The study is registered as an International Standard Randomised Controlled Trial, number ISRCTN31137309.

Findings From 2001 to 2003, the neonatal mortality rate was 26-2 per 1000 (76 deaths per 2899 livebirths) in intervention clusters compared with 36-9 per 1000 (119 deaths per 3226 livebirths) in controls (adjusted odds ratio 0.70 [95% CI 0.53-0.94]). Stillbirth rates were similar in both groups. The maternal mortality ratio was 69 per 100 000 (two deaths per 2899 livebirths) in intervention clusters compared with 341 per 100 000 (11 deaths per 3226 livebirths) in control clusters (0.22 [0.05-0.90]). Women in intervention clusters were more likely to have antenatal care, institutional delivery, trained birth attendance, and hygienic care than were controls.

Interpretation Birth outcomes in a poor rural population improved greatly through a low cost, potentially sustainable and scalable, participatory intervention with women's groups.

Introduction

Of the world's 4 million annual neonatal deaths, 98% occur in developing countries. Infant and child mortality rates have declined, notably through better control of diarrhoea, pneumonia, and vaccinepreventable disease, and the importance of the newborn period has increased. In India, neonatal mortality now accounts for up to 70% of infant mortality.2 Most perinatal and neonatal deaths happen at home, and many could be avoided with changes in antenatal. delivery, and newborn care practices.' However, primary and secondary health-care systems have difficulties in reaching poor rural residents, and a potentially effective perinatal health strategy must recognise this reality. In Makwanpur district, Nepal, for example, 90% of women give birth at home, and trained attendance at delivery is

We are unaware of any randomised controlled trial of community-based strategies to reduce neonatal mortality, a shortfall that indicates the absence of information on demand-side interventions.5 Two studies have made important contributions in this area. Bolivia's Warmi

project-an uncontrolled before-and-after study-was implemented in a poor rural population of 15 000 people with little health-system infrastructure. The project worked with women's groups to encourage participatory planning for mother and infant care," and showed a fall in perinatal mortality rate from 117 to 44 per 1000 births over 3 years. In India, the SEARCH group reported a nonrandomised controlled study from a rural population of 80 000 in Gadchiroli, Maharashtra.9 The intervention entailed training of traditional birth attendants, health education, and a new cadre of supervised village health workers who visited newborn infants at home, identified warning signs, and managed sepsis with antibiotics. After 3 years the neonatal mortality rate had fallen by 62%. Replication and scaling up of this exciting communitybased model presents policy makers with some challenges, particularly because of the need for a new cadre of community health worker to deliver injectable antibiotics at home

Community participation has long been advocated to build links between primary services and their users," and to improve service quality.15-15 However, the evidence base for the effectiveness of participatory models is scarce. The Previously, we showed no effect of direct education by health workers on infant care practices and care-seeking behaviour after delivery. In view of the Bolivian model, we thought that a participatory approach might have more effect on perinatal care practices and might increase consultation for difficulties in pregnancy and the newborn period. Although external facilitators of user groups have proven valuable in agriculture and forestry, in to our knowledge no study has rigorously assessed such a potentially scalable approach to improving reproductive health outcomes.

We postulated that a community-based participatory intervention could reduce the neonatal mortality rate from 60 to 40 per 1000 livebirths. The MIRA Makwanpur trial was a cluster-randomised controlled trial of such an intervention in a rural mountainous area of Nepal. The trial tested a large-scale intervention, using facilitators to work with women's groups in a population of 170 000 covering 1600 km². A cluster design was chosen because the intervention was structured around communities rather than individuals.

Methods

Study location and population

With a population of more than 23 million and a gross national income of US\$240 per person,²⁰ Nepal is a poor country whose development challenges are exacerbated by its geography and unstable political situation. Life expectancy is 61 years. The total fertility rate is 4.4 children per woman in rural areas,²¹ and the estimated maternal mortality ratio is 539 per 100 000 livebirths.²¹ 57% of women cannot read.²¹ The estimated infant mortality rate is 64 per 1000 livebirths, the neonatal mortality rate is 64 per 1000 livebirths, and the perinatal mortality rate 47 per 1000 births.²¹ In rural areas, 94% of babies are born at home.²¹ and only 13% of births are attended by trained health workers.²¹

Makwanpur district lies in Nepal's central region where the middle hills join the plains. The population of about 400 000 subsists mainly on agriculture and the largest ethnic groups are Tamang and Brahmin-Chhetri. The district hospital in the municipality of Hetauda has facilities for antenatal care and delivery, although operative delivery was not available during the study period. There are 7852 people per hospital bed. The district health system makes perinatal care available through a network of primary health centres. health posts, subhealth posts, and outreach clinics. Traditional birth attendants are available throughout the district, but their attendance at births is less common than in some other parts of south Asia.

Nepal is administratively divided—in descending order of size—into development regions, zones, districts, village development committees, and wards. We chose the village development committee as the cluster unit of randomisation for the following reasons: it is a standard

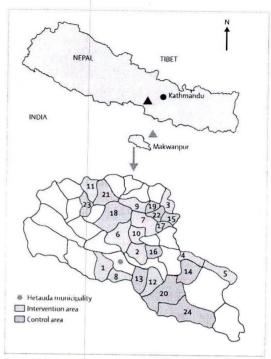


Figure 1: Makwanpur District, Nepal, and distribution of study village development committees

geopolitical unit, committee representatives were key points of liaison, and discussions with local people suggested that randomisation of smaller units would increase the risk of contamination. All 43 village development committees in Makwanpur district were eligible for randomisation, of which one was excluded at baseline for security reasons.

We enrolled a closed cohort of married women of reproductive age. Inclusion criteria were: consent given for involvement; age 15–49 years inclusive on June 15, 2000: married; and potential to become pregnant. Exclusion criteria included long-term separation from spouse and widowhood. Women who chose to participate in the study gave verbal consent and were free to decline to be interviewed at any time.

Procedures

We matched 42 village development committees into 21 pairs. Because we did not have disaggregated neonatal mortality figures, pairing was based on a process of topographic stratification, grouping of village development committees with similar ethnic group distributions, and matching of pairs with similar population densities. We used a list of random numbers to select 12 pairs. These 24 village development committees formed the study clusters. We randomly allocated one cluster in each pair to either intervention or control on the basis of a coin toss (figure 1). Because of the



Figure 2: Typical women's group meeting
Picture courtesy of Thomas Kelly and Save the Children, USA.

nature of the intervention the trial allocation was not masked, but analysis of primary and secondary outcomes was not done until just before the data monitoring committee meeting at 30 months. We generated the cluster allocation sequence in Kathmandu before enrolment of participants.

Enrolment activities were done from September, 1999, to November, 2000. A team of local enumerators mapped the 24 village development committees on foot, identified and allocated a unique identification number to every household (defined as a group of individuals sharing one kitchen), did a baseline census of demographic and socioeconomic indicators, and generated a list of female household members according to predefined written protocols. This document was scrutinised by a data auditor, a surveillance manager, and a group of local supervisors and converted into a list of women meeting the inclusion criteria for the cohort. From March, 2001, to July, 2001, a team of 44 field interviewers visited every potential member of the cohort, reassessed her for inclusion, explained the study, asked for her consent, allocated her a unique identification number, and completed an individual questionnaire, which included questions on demography, education, maternity history, details of any preceding pregnancy, home-care practices, and use of health services for perinatal illness."

Surveillance began in February, 2001, and involved 28 931 participants in 28 376 households. The strategy we used was adapted from one used by the Nepal Nutrition Intervention Project, Sarlahi, and has been described in detail elsewhere. It entailed 255 ward enumerators, 25 field interviewers, and nine field coordinators. The local female enumerator visited all cohort members in the ward she was responsible for every month over the study period to record menstrual status. She recorded data on individualised printed forms. The nine ward

enumerators of every cluster met with a cluster interviewer once a week. In the absence of other explanatory circumstances, pregnancy was registered when a cohort member ceased menstruation for 3 months. The cluster interviewer did two interviews for every pregnancy: the first at 7 months of gestation, as near as possible to the transition between our definitions of miscarriage and stillbirth; and the second at 1 month postpartum, as near as possible to the transition between neonatal and infancy periods. In the event of an unfortunate outcome (miscarriage, maternal death, stillbirth, or neonatal death), the interview was done by a senior field coordinator. The interview was developed in Nepali and piloted and repiloted by the local team. It was modular to deal with different outcomes, covering antenatal, delivery and postpartum care, home care practices, maternal morbidity, neonatal morbidity, health service usage, and cause of death in the event

In the event of neonatal death, we used an approach refined and locally adapted from existing questionnaires to establish cause of death. An open question about the cause of death was followed by a modular series of closed questions. The answers to these questions were designed to produce a classification of 14 causes of neonatal death based on those used by SEARCH in India," and were classified by a paediatrician (DO) on

Phase	Meeting	Aim
Introducti	on	
	1.	To introduce the study to the group
	2	To discuss why mothers and newborn infants die and
		how the intervention will work in the community
Problem		
identificat	tion	
	3	To ascertain how women understand maternal and
		neonatal problems
	4	To find out about maternal and neonatal problems in
		the community
	5	To understand the frequency of maternal and
		neonatal problems and to identify strategies to obtain
		information in the community
Problem		
prioritisat	ion	
	6	To share information from other women in the
		community and to prioritise three important material
		and neonatal health problems
Planning		
together		
	7	To discuss possible strategies for addressing the
		priority problems
	8	To discuss involvement of other community members
		in developing strategies
	9	To discuss preparation for a meeting of community
		members
	10	To hold a meeting involving other community
		members to discuss the activities of the
		women's groups, the priority problems identified
		by the groups, and possible strategies, and reach
		consensus

the basis of open text responses, modular closed questions, and a computer algorithm.

The average population per cluster was about 7000, spread over an area of 60 km². For every intervention cluster we recruited one local female facilitator. Shortlists for this role were derived from nomination by community leaders, advertisement, and word of mouth, after which all potential candidates were interviewed. A cluster consisted of nine wards. The facilitator—a literate locally resident woman—convened one women's group meeting a month in every ward (figure 2). Some groups set up by local female community health volunteers already existed but their activity was sporadic. The role of the facilitator was to activate and strengthen groups and support them through an action research cycle.

The intervention needed a facilitator rather than a teacher, with abilities and training in participatory communication techniques. She needed to have a grasp of perinatal health issues and some knowledge of potential interventions so she could act as a broker of information and a catalyst for change. Although it was important that none of the facilitators had a health background, we gave them brief training in perinatal health issues. Supervision, and a manual based on the Warmi project methodology,* was integral to facilitator training and support. One supervisor provided support for every three facilitators by attending group meetings and making regular community visits.

The first step of the intervention was to discuss issues around childbirth and care behaviours in the community, which allowed facilitators to develop participatory learning skills and generated information on pregnancy and childbirth, covering beliefs and practices in both uncomplicated and complicated pregnancies. Das The facilitators then supported the women's groups through monthly meetings (table 1). This phase of ten meetings lasted almost a year. In the next steps of the intervention, the women's groups implemented and assessed their strategies. One result of the process was that women sought more information about perinatal health. This information was provided through the iterative design and playing of a picture card game that addressed prevention, treatment, and consultation for typical problems in mothers and babies.

The form and content of discussions within women's groups varied, as did levels of involvement and potential strategies. Some typical strategies were community-generated funds for maternal or infant care, stretcher schemes, production and distribution of clean delivery kits, home visits by group members to newly pregnant mothers, and awareness raising with a locally made film to create a forum for discussion. Throughout the process the groups were involved in other health-related activities in their communities.

A baseline service audit identified weaknesses in the provision of antenatal, delivery, and newborn care in Makwanpur district. Because we aimed to test solely the effects of the women's group intervention, health-service strengthening activities were undertaken in both intervention and control areas. We decided to do this process on ethical grounds because we hoped that it would benefit control areas" and on theoretical grounds because we thought that a degree of improvement in services would be necessary for the success of the trial intervention. We therefore ensured that primary health centres in the study area were equipped with locally made resuscitaires (open incubators that allow access to newborn babies while keeping them warm), phototherapy units, warm cots, and neonatal resuscitation equipment. We remedied some shortfalls in essential neonatal drugs once only and discussed strategies for resupply with local health-service managers. In partnership with the District Public Health Office, we organised training in essential newborn care for all cadres of government health staff and for female community health volunteers and traditional birth attendants. Community-based workers received a basic newborn care kit containing a rubber bulb for suction, tube-and-mask for assisted respiration, iodine, gauze, a baby wrapping cloth, and a pictorial manual.

We postulated that the women's group activities might lead to reductions in neonatal mortality rates in intervention clusters compared with control clusters. At the outset, we did not think perinatal mortality rates would be affected much, since we did not envisage that changes in home-care practices would lead to reductions in stillbirth rates.

The primary outcome was neonatal mortality rate (deaths in the first 28 days per 1000 livebirths). Prospective interviews undertaken through the surveillance system provided information on several other outcomes, including stillbirths and maternal deaths, uptake of antenatal and delivery services, homecare practices at delivery and postpartum, infant morbidity, and health-care seeking. We obtained background demographic and socioeconomic information to investigate cluster comparability.

Surveillance coordinators observed 10% of interviews and reviewed all questionnaires at nodal points in the field before transmitting them for review by data auditors. After audit and correction, sometimes needing transfer back to the site of collection, data were double-entered into a relational database management system in Microsoft SQL Server 7.0 (Microsoft Corporation, Redmond, WA, USA). The system further addressed data quality through predefined acceptability constraints.

We defined miscarriage as cessation of a presumptive pregnancy before 28 weeks of gestation and stillbirth as fetal death after 28 weeks of gestation but before delivery of the baby's head, which was a modification of the 22-week definition to meet local practicalities. We classified neonatal death as death of a liveborn infant within 28 completed days of birth. Early neonatal deaths refer to deaths within 7 completed

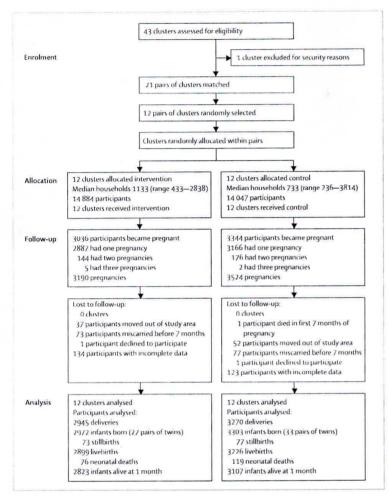


Figure 3: Trial profile

days and late neonatal deaths from 7 to 28 completed days of birth. Perinatal death describes either a stillbirth or an early neonatal death.

The study was approved by the Nepal Health Research Council and the ethics committee of the Institute of Child Health and Great Ormond Street Hospital for Children, and was done in collaboration with His Majesty's Government Ministry of Health, Nepal. We discussed the aims and design of the trial at a national meeting in 1998. After this time, we held a series of meetings with members of the Makwanpur District Development Committee, the Chief District Officer, and local stakeholders. In early 2000, the chairpersons of the 24 village development committees involved in the study gave signed consent on behalf of their communities.

Benefits to the control clusters were improvements in equipment and training provided at all levels of the healthcare system. All community-based members of the study team were recruited locally and undertook their activities in their home areas. When the study surveillance team noted minor illness in mothers or infants, they encouraged attendance at an appropriate health facility. In the event of severe illness, team members had an ethical responsibility to assist with rapid and appropriate transport and treatment, irrespective of allocation. All information provided by participants remained confidential. Access to information was restricted to interviewers, supervisors, data auditors, and officers, and research staff at the analytical level. No analyses or outputs included the names of participants.

Statistical analysis

To determine the number of cluster pairs to be enrolled, we had to estimate the coefficient of variation in outcome between clusters within matched pairs (k_m) and the expected number of births per cluster over the timescale of the study. Based on national and district estimates, we assumed a neonatal mortality rate of 60 per 1000 livebirths, an average of 480 births per cluster, and a k_m value in the range 0.15-0.3. We estimated that inclusion of 12 pairs of clusters would allow us to detect a reduction in neonatal mortality of between 27% and 38% (37-44 per 1000 livebirths) with 80% power at a 5% significance level." The corresponding estimates of intraclass correlation are between 0.0055 and 0.0061. Because we did not envisage any adverse effects of the intervention at either cluster or participant level we did not use any stopping rules. After the first year of surveillance, we saw that birth rates were lower than expected on the basis of estimates. The trial steering group decided not to assess neonatal mortality rates until we had obtained data for 2 complete years of births from introduction of the intervention. We therefore undertook a preliminary analysis in November, 2003, and presented the findings to an independent data monitoring committee. The committee considered issues of quality, confidentiality, and analysis and recommended definitive analysis and publication of the 2-year findings.

The analysis was undertaken as intention to treat at both cluster and participant levels. Participants who had begun the trial as residents of a given cluster were retained as residents even if they had moved to another cluster during the trial period.

Within the prospective cohort, we compared neonatal mortality rates, stillbirth rates, and maternal mortality ratios between control and intervention groups, taking account of clustering and the paired nature of the data, with hierarchical logistic models (Mlwin version 1.1). We estimated intraclass correlation coefficients from retrospective neonatal mortality and stillbirth data by analysis of variance within Stata version 8. Secondary outcomes and process indicators were compared with adjustment for clustering. All estimates are presented with 95% CIs. This study is registered as an

International Standard Randomised Controlled Trial, number ISRCTN31137309.

Role of the funding source

Representatives of the UK Department for International Development (DFID) suggested that no health-care activities should be carried out in parallel with existing government services and that—for sustainability reasons—no funding should be available for women's group activities. Apart from these issues, the sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Figure 3 shows the trial profile. All 24 clusters selected for inclusion received their allocated intervention. Between Nov 1, 2001, and Oct 31, 2003, 3190 pregnancies happened in intervention clusters and 3524 in controls. Presumptive miscarriage rates were $2\cdot3\%$ (73/3190) in intervention clusters and $2\cdot2\%$ (77/3524) in control clusters. Loss to pregnancy follow-up as a result of migration, withdrawal of consent, or incompleteness of surveillance data was $5\cdot4\%$ (172/3190) in intervention clusters and $5\cdot0\%$ (176/3524) in control clusters. 2972 births (including 54 twins) were available for analysis in intervention clusters and 3303 (including 66 twins) in control clusters.

Table 2 presents baseline characteristics of intervention and control clusters. Although the median number of households per cluster was lower in control clusters, the total numbers of households and participants who became pregnant were similar. Some evidence exists of less poverty in intervention than control clusters: household asset scores and participant schooling—but not recalled annual food sufficiency—seem to slightly favour the pooled intervention clusters. The age breakdown does not suggest differences between intervention and control clusters, either for population structure or for participants who became pregnant.

For estimated baseline mortality rates, participants in intervention clusters recalled 11415 livebirths and 290 neonatal deaths in the 5 years preceding our census (neonatal mortality rate 25-4 per 1000 livebirths). Participants in control clusters recalled 12132 livebirths and 304 neonatal deaths (neonatal mortality rate 25-1 per 1000 livebirths). Cluster-specific breakdown of these pooled data showed that neonatal mortality rates were higher in intervention than control clusters in four pairs, similar in four pairs, and higher in control than intervention clusters in four pairs. Although valid for cluster comparison, the prospective findings in the same population suggest that maternity histories substantially underestimated actual neonatal mortality rates.

	Intervention clusters	Control clusters	Pregnancies in intervention clusters	Pregnancies in control clusters
Number of households	14879	13497	2923	3189
Median per cluster (range)	1133 (433-2838)	733 (236-381	4) 207 (158-451)	248 (59-706
Number of participants	14884	14047	3036	3344
Median per cluster (range)	1110 (487-2824)	777 (219-406	9) 214 (164-463)	264 (61-835)
Household asset score	13532	12170	3036	3344
None of the assets on the list	6122 (45%)	6233 (51%)	1545 (51%)	1866 (56%)
Clock, radio, iron, or bicycle	4094 (30%)	4476 (37%)	954 (31%)	1171 (35%)
More costly appliances	3316 (25%)	1461 (12%)	537 (18%)	(07 (9%)
Household food sufficiency	13532	12170	3036	3344
Less than 8 months annually	4099 (30%)	3372 (28%)	972 (3.2%)	1002 (30%)
Participant age	13532	12170	3036	3344
Younger than 20 years	1130 (8%)	923 (8%)	719 (24%)	731 (22%)
20-29 years	5192 (38%)	4758 (39%)	1696 (50%)	1804 (54%)
30-39 years	4265 (32%)	3782 (31%)	556 (18%)	704 (21%)
40 years or older	2945 (22%)	2657 (22%)	65 (2%)	105 (3%)
Participant schooling	13532	12170	2893	3141
None	11031 (82%)	10741 (88%)	2122 (73%)	2681 (85%)
Primary	1562 (12%)	957 (8%)	503 (17%)	307 (10%)
Secondary or higher	939 (7%)	472 (4%)	268 (9%)	153 (5%)
Participant could not read	8981 (66%)	9664 (79%)	1734 (60%)	2418 (77%)

Table 2: Baseline characteristics of intervention and control clusters and pregnancies in intervention and control areas

Figure 4 shows within-cluster neonatal mortality rates for each of the 12 cluster pairs. The line of equality has been superimposed on this graph. In 11 cluster pairs, neonatal mortality rates were lower in the intervention group. The pooled rate in the intervention group was nearly 30% lower than in the control group (table 3). Hierarchical modelling—taking clustering into account—yielded an odds ratio of 0.70 (95% CI 0.53–0.94) for neonatal mortality in the intervention clusters compared with the control clusters. The intraclass correlation coefficient estimated from retrospective data was 0.00644 (95% CI 0.00004–0.0128).

Stillbirth rates did not differ between intervention and control clusters (table 3). The intraclass correlation coefficient estimated from the retrospective data was

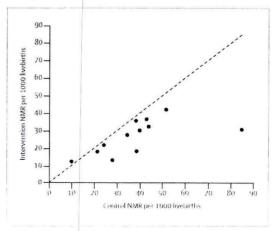


Figure 4: Neonatal mortality rates in intervention and control areas NMR=neonatal mortality rate.

	Intervention clusters	Control clusters	Adjusted odds ratio (95% CI)
Documented births	2972	3303	
Livebirths	2899	3226	
Stillbirths	73	77	
Neonatal deaths	76	119	
Early (0-6 days)	50	70	
Late (7-28 days)	26	49	
Maternal deaths	2	11	
Stillbirth rate per 1000 births	24.6	23.3	1-06 (0-76-1-47)
Neonatal mortality rate per 1000 livebirths	26-2	36-9	0-70 (0-530-94
Maternal mortality ratio per 100 000 livebirths	69	341	0-22 (0-05-0-90)

Table 3: Mortality rate comparisons between intervention and control clusters

0.00438 (95% CI 0–0.00948) for the stillbirth rate. With limited sample size, maternal mortality was not a predefined outcome of the study. The maternal mortality ratio was about 80% lower with intervention than with control clusters (adjusted odds ratio 0.22 [95% CI 0.05–0.90]).

Table 4 presents process indicator outcomes. In general, they suggest so-called healthier behaviours in intervention clusters: women in these clusters were more likely than those in the control clusters to have had antenatal care, to have taken haematinic supplements, to have given birth in a health facility, with a trained attendant or a government health worker, to have used a clean home delivery kit or a boiled blade to cut the umbilical cord, and for the birth attendant to have washed her hands. No differences were noted in delayed

	Intervention clusters	Control clusters	Adjusted odds ratio (95% CI)
Pregnancies	3190	3524	
Any antenatal care	1747 (55%)	1051 (30%)	2-82 (1-41-5-62
Any iron and folic acid supplements	1574 (49%)	1152 (27%)	1-99 (1-14-3-46
Any perceived maternal illness from 7 months gestation to 1 month postpartum	668 (21%)	926 (26%)	0-74 (0-43-1-28
Visited health facility in event of illness	333 (50%)	207 (22%)	3-37 (1-78-6-37
Deliveries	2945	3270	
Institutional deliveries	201 (7%)	66 (2%)	3-55 (1-56-8-05
Birth attended by government health provider	2/2 (9%)	102 (3%)	3-12 (1-62-6-0
specifically, doctor, nurse, or midwife	207 (7%)	69 (2%)	3-53 (1-54-8-10
Birth attended by traditional birth attendant	199 (7%)	129 (4%)	1-70 (0-93-3-1
Used a clean home delivery kit.	550 (19%)	154 (5%)	4-59 (2-83-7-4
Used a boiled blade to cut the cord	1580 (54%)	827 (26%)	3-47 (1-39-8-69
Attendant washed her hands	1988 (68%)	1064 (33%)	5-5 (2-40-12-6)
Livebirths	2899	3226	
Cord undressed or dressed with antiseptic	2356 (81%)	2349 (73%)	1 62 (0 58-4 5
Baby wrapped within 30 min	1975 (68%)	2257 (70%)	0-92 (0-37-2-3
Baby bathed within 1 h	2880 (99%)	3207 (99%)	1-11 (0-46-2-7)
Infants alive at 1 month	2823	3107	
Any of three infant illnesses (cough, fever, diarrhoea)	919 (33%)	1320 (42%)	0-65 (0-36-1-20
laken to health facility in event of illness	219 (24%)	131 (10%)	2 84 (1 65-4 88
Breastfed infants	2864	3181	
Initiated within 1 h	1/80 (62%)	1/18 (54%)	1-40 (0-52-3-79
Discarded colostrum	820 (29%)	1344 (42%)	0.55 (0.27-1.10

wrapping of newborn infants, early bathing, or breastfeeding. Rates of maternal morbidity were similar, but women in intervention clusters were more likely than those in control clusters to have visited a health facility in the event of illness. Likewise, infant illness was more likely to have led to a visit to a health facility.

The most usual causes of neonatal death were complications of preterm birth, presumptive birth asphyxia, and infection. The pattern of causes did not differ between groups, but we noted that infection-related deaths were less frequent in intervention clusters.

Discussion

We have shown that an intervention in rural Nepal, entailing women's groups convened by a local woman facilitator, reduced neonatal mortality by 30%. Maternal mortality, although not a primary outcome of the trial, was also significantly lower in intervention areas. The intervention seemed to bring about changes in home-care practices and health-care seeking for both neonatal and maternal morbidity. The activities of one facilitator in a population of 7000 rapidly reached a high proportion of pregnant women, even in poor and remote communities. Only 8% of married women of reproductive age ever attended a group, but the groups attracted 37% of newly pregnant women, and members raised awareness of perinatal issues outside the groups themselves.

Cluster-randomised trials are susceptible to bias. The intervention and control areas had similar retrospective neonatal mortality rates, but some differences were noted in literacy and poverty indicators. We do not think these factors could account for the noted differences in mortality rates, but they do merit further investigation. Surveillance methods could have affected outcomes, although this activity would have taken place in both intervention and control areas.

Two potential effect modifiers were the convening of women's groups in collaboration with government-trained female community health volunteers and health-system strengthening activities across intervention and control areas. Would work with women's groups have the same degree of effect in areas where no community health volunteer was present or no training of health workers in essential newborn care took place?

Security problems in the district escalated during the third year of the study. Supervisory activities were intermittently compromised in four clusters (two intervention and two control), and although no women's group was disbanded, four groups had to postpone their meetings several times.

The intervention seemed to be acceptable: 95% of groups remained active at the end of the trial despite no financial incentives and the opportunity costs incurred by women spending time away from other tasks. With appropriate investment and political commitment, we think the intervention could be scaled up rapidly. Scaling-

up could be achieved through both government and nongovernment organisations and would not necessarily need to be managed by health-sector personnel, although coordination would be essential. Local rather than central government might be preferable to lead the process for reasons of participation, accountability, and sustainability.

A cost-effectiveness analysis was done alongside the study. The cost per newborn life saved was US\$3442 (\$4397 including health-service strengthening costs) and per life year saved \$111 (\$142 including health-service strengthening costs). This value compares favourably with the World Bank's recommendations that interventions less than US\$127 per disability-adjusted life year saved are some of the most cost effective." Our estimates probably underestimate the programme's cost-effectiveness. They do not include benefits to infants born outside the closed cohort surveillance; they ignore longer-term benefits of the intervention to subsequent pregnancies; they exclude benefits to infants of reduced morbidity and to mothers from reduced morbidity and mortality; and they omit potential savings in set-up and supervision costs if the activities were replicated elsewhere.

Two key elements distinguished our approach from conventional health education. First, women's groups looked at demand-side and supply-side issues. Second, the approach emphasised participatory learning rather than instruction. The women's group strategies—the picture card game, health funds, stretcher schemes, production and distribution of clean delivery kits, and home visits—also entailed interaction outside the groups, which increased awareness of perinatal issues.

The renewed interest in community participation in health care³² is attributable partly to the scarcity of resources committed to primary care and partly to the perceived failure of conventional health education and primary health care to deliver substantial health benefits. The A major challenge has been to engage users and enable them to adopt positive health care behaviours. In many countries, local-health committees have had little accountability to their communities, and the level of representation of beneficiaries such as women is low. The Beneficiaries themselves can be passive in the face of service bureaucracies because of an absence of local ownership, different perceptions of priorities, and capture of resources by powerful groups.

If participation is a key element of primary health care then few controlled studies have been done of its effect on health outcomes. Participation is typically seen as an adjunct to implementation rather than as a primary intervention, and the distinction between a didactic approach to health education at community level and a participatory approach to developing strategies is blurred. For example, community-based health promoters have increased exclusive breastfeeding rates in Mexico¹⁰ and India,¹¹ where diarrhoeal morbidity was also diminished. In Ethiopia, a randomised controlled trial of mother coordinators trained to teach other local

mothers to recognise symptoms of malaria in their children and to promptly give chloroquine achieved a 40% reduction in under-five mortality."

The procedure used to establish cause of death suggested that infection accounted for fewer deaths in intervention than control clusters. This finding lends support to the noted rises in antenatal care, trained birth attendance, clean delivery kit use, hand washing by birth attendants, and care seeking in the event of neonatal morbidity. These data complement the work of SEARCH, whose intervention consisted of a package of activities. Scaling up the use of injectable antibiotics by community health workers presents difficulties for policy makers, and our less intensive intervention achieved half the SEARCH mortality reduction.

The effect of the intervention on maternal mortality was surprising in view of the size and power of the study and obviously needs replication. If validated, the finding would be noteworthy for the potential of this approach to achieve Millennium Development Goals." The participatory strategy could benefit other health outcomes such as stillbirths, infant and childhood mortality, and malaria and HIV infection in pregnancy. The absence of effect on stillbirth rates shown in this trial does not rule out future success if issues such as nutrition received greater emphasis in women's groups."

The trial findings raise several issues that we intend to address in subsequent work: differential changes in care practices between group members and non-members, the process of diffusion of behaviour changes within the population, an examination of potential confounding within the cluster-randomised design, further analysis and refinement of the verbal autopsies, and a detailed discussion of cost-effectiveness.

Progress towards the Millennium Development Goals for maternal and child mortality reduction has faltered. Our findings suggest that a demand-side intervention can achieve great reductions in neonatal and maternal mortality in poor and remote communities. The approach—a local woman facilitating women's groups—is potentially acceptable, scalable, sustainable, and cost effective as a public-health intervention. Assessment of demand-side interventions needs greater attention in primary care. Studies are needed to assess how we can replicate the approach in different settings, as are large trials to examine effects on maternal morbidity and mortality.

Contributors

All authors contributed to the design of the study and criticised drafts of the paper. D S Manandhar and A M de L Costello were responsible for the conception and overall supervision of the trial. B P Shrestha managed the project under mutal guidance from LR Shrestha. K M Tumbahangphe, S Tamang, S Thapa, D Shrestha, and B Thapa managed data collection, field intervention, health service activities, data entry and administration, respectively. N Mesko and J Morrison were technical advisors on intervention and qualitative aspects of the study, and D Osrin on quantitative aspects. J Borghi conducted the economic analysis with help from B Thapa. M Manandhar and H Standing advised on the facilitation process. D Osrin and A Wade carried out the

quantitative analysis. A M de L Costello and D Osrin wrote the first draft of the paper and were responsible for subsequent collation of inputs and redrafting.

Conflict of interest statement

We declare that we have no conflict of interest.

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Impact of community organization of women on perinatal outcomes in rural Bolivia

Kathleen O'Rourke, Lisa Howard-Grabman, and Guillermo Seoane²

ABSTRACT

An intervention to improve maternal and child health was conducted in a remote Bolivian province with limited access to modern medical facilities. The intervention focused on initiating and strengthening women's organizations, developing women's skills in problem identification and prioritization, and training community members in safe birthing techniques. Its impact was evaluated by comparing perinatal mortality rates and obstetric behavior among 409 women before and after the intervention. Perinatal mortality decreased from 117 deaths per 1 000 births before the intervention to 43.8 deaths per 1 000 births after. There was a significant increase in the number of women participating in women's organizations following the intervention, as well as in the number of organizations. The proportion of women receiving prenatal care and initiating breast-feeding on the first day after birth was also significantly larger. The number of infants attended to immediately after delivery likewise increased, but the change was not statistically significant. This study demonstrates that community organization can improve maternal and child health in remote areas.

INTRODUCTION

Infant mortality has been attacked in developing countries with varying degrees of success. Costa Rica, with one of the most successful programs, lowered infant mortality from 68 per 1 000 live births in 1970 to 20 per 1 000 in 1980 (1). Costa Rica's success has been attributed largely to the development of primary and secondary health care (2). Increasing access to health services and to primary care practitioners, predominantly nurses, also dramatically reduced infant mortality in Nicaragua (3).

Bolivia has one of the highest rates of infant mortality in Latin America. Estimates indicate that in 1994, between 75 and 105 of every 1 000 Bolivian infants died in the first year of life (4). Within Bolivia, infant mortality varies regionally and rates are approximately 50% higher in rural areas than in urban areas. Rates are higher among the country's Aymara and Quechua indigenous groups than in the Ladino population (persons of Spanish or mixed heritage) (4). Because health care resources are limited in many rural areas, one recommended approach for reducing infant mortality is through training relatively inexpensive and culturally appropriate providers, such as nurses and community health workers (5).

An evaluation of local community health workers in Bolivia concluded that they did not fit easily into leadership roles in either modern or traditional medicine (6). The medical and local communities were more accepting of community health workers whose roles and responsibilities they helped define (6). Training women to evaluate the health status of their children and family members has been shown to be a cost-effective means of improving the health of communities in which there is limited access to modern health care (7).

The Warmi project

The Warmi project, conducted from July 1990 to June 1993, attempted to improve maternal and child health through involving communities in health care. The World Health Organization (WHO) endorsed this strategy at the Alma-Ata conference (1978),

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with the recommendation that health programs strive for "community participation and ultimately self-reliance, with individuals, families, and communities assuming more responsibility for their [own] health" (8).

The province of Inquivisi was selected as the Warmi project site based on its remoteness, rural character, and limited access to modern medical care. In addition, this area had previously been the site of Save the Children/Bolivia projects. Consequently, population census results and maternal mortality data were available.

Key project components included (a) organizing women's groups, (b) developing an approach to identifying problems, (c) implementing a "formal action plan" for the problems identified, and (d) training birth attendants and husbands in safe birthing techniques.

The primary purpose of this study was to evaluate the potential effect of organizing women's groups on perinatal mortality in a remote, rural area of a developing country. A secondary goal was to identify the impact of specific components of the project, such as increasing prenatal care, improving immediate newborn care and breast-feeding, and increasing the number of deliveries attended by trained personnel.

Health care infrastructure

Inquivisi Province encompasses three geographic zones—Inquivisi, Licoma, and Circuata—each of which has one health post. The posts in Inquivisi and Licoma are staffed by one physician and an auxiliary nurse, while the one in Circuata has only an auxiliary nurse. All three posts possess only basic medicines and equipment. Two referral hospitals are located outside the project area at a distance of one to two hours' travel. These hospitals fall short of minimum WHO standards, lacking sterilization and anesthesia equipment and properly trained staff.

Local health facilities are underutilized by the population. This is partly due to economic and cultural factors,

but also because people do not consider the facilities adequate to deal with medically complicated situations. Consequently, women who develop obstetric complications during pregnancy and labor are usually referred to hospitals in La Paz or Oruro, a journey of four to six hours by road.

In rural Bolivia, only 23% of deliveries are attended by either a physician or trained nurse. The majority of births (55%) are attended by relatives, usually the fathers; 14% are attended by midwives or traditional birth attendants; 6% are unattended (i.e., the woman gives birth without a helper); and the circumstances are unknown for the remaining 2% (9). In Bolivia the term "midwife" refers to trained medical personnel who deliver babies, while traditional birth attendants (TBAs) are individuals within the community who deliver babies but are not trained as part of the formal medical system.

MATERIALS AND METHODS

Fifty communities in Inquivisi Province participated in the Warmi project. They varied greatly in traditions and demographic characteristics depending on the geographic zone in which they were located. Settlements in the zone of Inquivisi consist of longestablished, stable communities with widely dispersed houses. The villages in Circuata, in contrast, are newer and contain large numbers of recent immigrants. Housing is more densely concentrated than in Inquivisi, and the women are more apt to be bilingual. Licoma is a mixed zone that combines characteristics found in both of the others (10). Villages comprise 40 to 300 families. The total population in the demonstration area is 15 000.

Study personnel included five to six teams, each consisting of two auxiliary nurses from the Save the Children staff. Monthly or more frequently, each team met individually with all of the zone's women's organizations, which numbered approximately 50. At these meetings, attended by approximately 10–30 group members, a tech-

nique called "autodiagnosis" was employed to address community problems. Autodiagnosis consists of the following four steps: (a) identification and prioritization of problems, (b) group development of a formal action plan, (c) implementation of the plan, and (d) evaluation.

Each community identified a different set of problems and approaches, and, accordingly, specific interventions varied by community. However, certain objectives were addressed by all the women's groups: to (a) increase knowledge of reproduction, contraceptive use, danger signs of complications, and self-care, (b) improve immediate newborn care, and (c) increase the percentage of women who receive delivery care from trained birth attendants. Further details of the study protocol can be found in the project implementers' manual (10).

Prior to the implementation of the Warmi project interventions, a study of perinatal mortality (infant deaths occurring from the 28th week of pregnancy through 28 days of life) was conducted. This study identified all births and perinatal deaths in the community area for the prior two years (November 1988-October 1990). For each infant who died, two community controls were randomly selected among children who were born in the same year, lived in similar communities, and survived for at least 28 days. Following the intervention, which took place from January 1991 through June 1993, a second case-control study was conducted. Again, all births and perinatal deaths that occurred in the two years prior to the survey (April 1991-March 1993) were identified, and each deceased infant was matched with four to five controls.

During the first case-control study, a questionnaire was administered to 237 mothers in their homes (or to other family members when the mothers were not available). Demographic characteristics, obstetric history, and details of the most recent childbirth were elicited. In the second study, 172 questionnaires were administered.

Outcome variables included perinatal mortality; the numbers of women's

organizations and the extent of women's participation in them; the prevalence of specific obstetric practices, including prenatal care and utilization of trained birth attendants; and the timing of newborn care and initiation of breast-feeding. Mortality data were based upon total numbers of births and perinatal deaths recorded in the community registry and thus were not limited to the study population. In the analysis of assistance at delivery, trained attendants were considered to include TBAs, health promoters,³ physicians, and nurses.

The central program strategy was to increase participation in women's groups. As described elsewhere (10), there were a variety of types of women's groups in the Inquivisi area, including women's organizations, cooperatives, mothers' clubs, and agrarian unions. The groups' functions varied together with their degrees of effectiveness. The project staff considered women's organizations best able to organize women around health issues. Consequently, the staff focused on these groups, initiating or strengthening 50 women's organizations.

Statistical analyses were performed using SPSS statistical software (11). Chi-square tests were performed on categorical outcomes as defined above. The Breslow-Day test for homogeneity of odds ratios was used to compare the degrees of change seen in cases and controls (12).

RESULTS

Demographic comparisons of communities

Table 1 compares relevant sociodemographic characteristics in the three study zones at baseline. Women in Inquivisi were more likely to be married than women in Circuata and Licoma. The language spoken at home was used as a surrogate for ethnicity. By this criterion, the majority of women in all communities were Aymara, with Inquivisi having a higher percentage of Aymaras and fewer Quechuas than the other zones. The presence of a dirt floor was used as an indicator of lower socioeconomic status. The majority of women in every community had dirt floors, but the highest percentage was found in Inquivisi. Overall, prior to the study intervention, women in Circuata participated in women's organizations at a higher rate than women in the other zones.

Mortality

Perinatal and neonatal mortality decreased significantly between the pre-intervention and the post-intervention periods (Table 2). During the first study period, 639 births were identified. Of these, 36 infants were classified as either fetal deaths or stillbirths, and 38 others were born alive but died within 28 days of birth (data not shown). One perinatal death could not be classified as prenatal or postnatal. During the second period, 708 births were identified. Of these, 21 were classified as fetal deaths or stillbirths, and 10 as postnatal deaths. Therefore, the perinatal mortality rate decreased from 117 per 1 000 before the intervention to 43.8 per 1 000 births after.

Intermediate outcome data

Table 3 presents the numbers of women who were aware of women's

TABLE 1. Comparison of baseline sociodemographic characteristics of women living in three zones of Inquivisi Province, Bolivia

			Z	one			
Characteristic	Inquivisi No.	si (n = 72) (%)	Licoma No.	a (n = 68) (%)	Circuata No.	a (n = 97) (%)	Pa
Married ^b	67	(93.1)	57	(83.8)	83	(85.6)	0.206
Language spokenc							
Spanish	66	(95.7)	56	(87.5)	85	(95.5)	0.094
Aymara	65	(94.2)	53	(82.8)	66	(74.2)	0.004
Quechua	15	(21.7)	16	(25.0)	26	(29.2)	0.560
Literate	58	(80.6)	53	(77.9)	80	(82.5)	0.769
Dirt floor	66	(91.7)	49	(72.1)	82	(84.5)	0.007
Participate in women's organizations	27	(37.5)	20	(29.4)	53	(54.6)	0.003

a Chi-square test.

b Includes women living with a partner but not legally married.

TABLE 2. Outcome of births during two study periods (n = 1 347), showing number of infants surviving at least 28 days ("living") and number dying in the perinatal period ("not living"), Inquivisi Province, Bolivia

Period	Living No. (%)	Not living ^a No. (%) ^b	Total	
Pre-intervention (1988–1990)	564 (88.3)	75 (11.7)	639	
Post-intervention (1991–1993)	677 (95.6)	31 (4.4)	708	

a Includes deaths from 28 weeks gestation through 28 days after birth.

b χ^2 : P < 0.001, 1 df

³ Health promoters are health workers, both male and female, selected by the community to provide care. They receive training in primary health care from the Ministry of Health.

c Information not available for three women from Inquivisi, four from Licoma, and eight from Circuata.

TABLE 3. Awareness of and participation of women in women's organizations in pre- and post-intervention periods (n = 409)

	Awareness	of groups	Participation in group		
Group	Aware n (%)	<i>P</i> -value	Member n (%)	<i>P</i> -value	
Mother's clubs		<0.001	.ne 16	0.072	
Pre-intervention	41 (17.3)		26 (11.0)		
Post-intervention	1 (0.6)		10 (5.8)		
Women's organization		< 0.001		< 0.001	
Pre-intervention	75 (31.6)		18 (7.6)		
Post-intervention	119 (69.2)		93 (54.4)		
Any group ^a		0.779		< 0.001	
Pre-intervention	231 (97.5)		100 (42.2)		
Post-intervention	162 (97.0)		147 (86.5)		

^a Includes mother's clubs, women's organizations, agrarian unions, co-operatives, neighborhood committees, and credit programs.

groups in their communities together with the numbers of women participating in groups, pre- and post-intervention. Mothers' clubs had distributed food prior to this study, but had recently ceased doing so because the international organization that supplied the food left the area. Their numbers declined sharply from pre- to post-intervention. Meanwhile, women's organizations proliferated with growing membership. Overall, more women were participating in groups of one kind or another at the end of the intervention.

Table 4 presents changes in the use of prenatal care, the presence of a trained attendant at birth, and the timing of newborn care between the two study periods. Separate results are presented for cases and controls, together with the results of Breslow-Day tests for significant differences in the magnitudes of change in the two groups.

Prenatal care. Both cases and controls were more likely to receive prenatal care following the intervention, with a statistically significant change

for controls. However, the increases in use of prenatal care were not statistically different in cases and controls.

Presence of traditional birth attendants. Results were mixed for this objective. While the percentage of childbearing women attended by TBAs increased for cases following the intervention, it decreased for controls. These differences, however, were not statistically significant.

Timing of newborn care. The percentage of newborn controls who were attended immediately after delivery rose between studies, while the opposite occurred among cases. The Breslow-Day test for homogeneity approached statistical significance (P = 0.058), suggesting a difference in the amount of change registered between the two groups.

Timing of breast-feeding. This objective was evaluated for control infants only, as most of the cases did not survive childbirth. A significantly greater percentage of control infants were breast-fed on the first day of life following the intervention—50.3% as compared with 25.3% prior to the intervention ($\chi^2 = 18.77$, P < 0.001, data not shown).

TABLE 4. Comparison of obstetrical practices in pre- and post-intervention periods for cases and controls, Inquivisi Province, Bolivia

	Cases		Controls		
Variable	Yes n (%)	P-value	Yes n (%)	P-value	Breslow-Day <i>P</i> -value ^a
Received prenatal care		0.175		0.009	0.952
Pre-intervention	34 (45.3)		74 (49.0)		
Post-intervention	18 (60.0)		86 (64.2)		
Trained attendant at birth		0.497		0.169	0.206
Pre-intervention	21 (28.8)		56 (37.1)		
Post-intervention	11 (35.5)		40 (29.4)		
Immediate newborn care		0.106		0.276	0.058
Pre-intervention	15 (24.6)		50 (34.2)		
Post-intervention	2 (8.7)		52 (40.6)		

^a Breslow-Day test for homogeneity of the odds ratios

DISCUSSION

Mortality rates

Infant mortality rates provide an important measure of community health status and are often used as an indicator of overall socioeconomic development. Perinatal mortality rates, on the other hand, are a measure of women's health and the quality of health care provided during pregnancy and the intrapartum period (13).

Prior to the intervention described here, rates of perinatal mortality were extremely high in the Inquivisi area, with approximately 117 deaths per 1 000 births. Following the intervention, perinatal mortality in the project area decreased by 65%.

Because there was no control community, it is difficult to say with certainty whether the intervention or other factors caused the decrease in mortality. A possible alternative explanation credits the effect of changes in the survey populations between the two studies. Such changes could occur in more than one way: (a) if more women from a given zone were surveyed following the intervention than before, or (b) if demographic changes occurred within the area due to migration. However, neither of these explanations is likely. The pre-intervention and post-intervention surveys both sampled the same percentages of women from each zone. Furthermore, between the pre-intervention and postintervention periods, there was no statistically significant change in socioeconomic variables such as maternal literacy, housing characteristics, or language spoken (data not shown).

One possible cause of the decrease in perinatal mortality may have been a regression towards the mean owing to the initially high rate during the first period. This is not likely to be the full explanation, however, because of the magnitude of the decrease. Thus, while it is not possible to say with certainty that the decrease in mortality resulted from the intervention program, it seems reasonable that the program was responsible for at least some of the impact.

Women's organizations

One of the greatest changes observed in this study was a doubling of participation in women's organizations. Women in these groups were encouraged to become more actively involved in identifying health needs and designing programs to address them. They were encouraged to discuss obstetric complications, and in the process they learned that many features of reproduction which they had supposed to be matters of course could in fact be altered. For example, women were taught to care for their

babies immediately after delivery rather than wait for the delivery of the placenta. Other specific activities varied by community and included training in literacy, fostering use of credit programs, presenting educational programs about safe pregnancy, and implementing family planning.

The increase in participation in women's organizations was accompanied by a concurrent decrease in the number of mothers' clubs. As a result, there was not an overall increase in the numbers of groups in the community, but rather a restructuring of the types of groups women attended.

Improvement in pre- and postnatal practices

The number of women who received prenatal care during their pregnancies was significantly greater after the intervention. Previous studies have identified decreased risk of stillbirth and neonatal mortality for women who receive prenatal care (14). In Mexico, expanded use of prenatal care was identified as a major determinant of lower perinatal mortality (15). While the exact mechanism by which prenatal care reduces mortality is not known, such care provides health professionals with a means of identifying potential problems and educating women about health in pregnancy, labor, delivery, and postpartum.

Although changes in the timing of infant care were not statistically significant, there was an increase in the percentage of control infants who received care immediately after delivery. Fewer cases received immediate care, but this may be due in part to the lack of attention given to stillborn infants.

There was also a significant increase in the number of women who breast-fed their infants on the first day of life. While changes in breast-feeding practices would not affect fetal deaths or stillbirths, early breast-feeding can increase the likelihood that breast-feeding is successful and could prevent mortality related to unsanitary infant feeding practices (16).

Study limitations

Reporting bias could potentially influence results. This is unlikely, however, since the same community registration methodology was utilized for the studies before and after the intervention. In fact, the project staff identified more births along with fewer deaths during the second set of interviews

Classification of the time of death was based upon maternal recall and should be considered approximate. It is not clear how well women were able to differentiate between a fetal death. which occurred prior to the onset of labor, and death that occurred during labor and delivery. Furthermore, infants were not always attended to immediately after delivery. It is therefore possible that some infants who were born alive but died shortly after delivery were incorrectly classified as stillborn. Consequently, for purposes of this evaluation, all deaths were grouped together and no subanalyses were done by time of death.

One project goal that could not be fully evaluated was the training of birth attendants and husbands in safe birthing techniques. In Inquivisi, few individuals function in the role of traditional birth attendant—that is, a person within the community who delivers babies and has acquired her skills by working with other TBAs. Thus, in the project, the objective of increasing the pool of trained birth attendants led to a focus on teaching basic skills to individuals who were identified as potential birth attendants rather than on improving the skills of existing traditional birth attendants. Husbands were trained in safe birthing skills, but it was not possible to identify the training status of the husband from the women's interview responses. Thus, the analysis of care provided by trained birth attendants did not include trained husbands.

CONCLUSIONS

Indirect causes of infant mortality are not well understood. Infant mor-

tality has been consistently associated with low socioeconomic status (13), decreased maternal educational level (17), and low social status of women (18). These associations remain even when analyses control for access to care (19). It is not known precisely how improving women's decision-making ability could affect the outcome of their pregnancies.

In general, the results of this study support the use of community training and organization of women as a means of improving pregnancy outcomes for women residing in remote areas with limited access to modern health care. However, there is limited evidence defining the impact of individual components of the program, such as increasing prenatal care, improving immediate newborn care and breastfeeding, and providing trained birth attendants. Further studies should focus on specific aspects of this type of program to identify which components are most effective, as well as the efficacy of this approach in urbanized areas and in different populations.

Acknowledgments. The authors are grateful to Dr. Marge Koblinsky, Colleen Conroy, and Dr. Alfred Bartlett for their assistance on this project.

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RESUMEN

Impacto de la organización de las mujeres en la comunidad sobre los resultados perinatales en zonas rurales de Bolivia Se llevó a cabo una intervención destinada a mejorar la salud materna e infantil en una provincia aislada de Bolivia con acceso limitado a instalaciones de salud modernas. La intervención se centró en la creación y el fortalecimiento de organizaciones para mujeres, en el desarrollo de habilidades entre las mujeres, en la identificación de problemas y la determinación de prioridades y en el adiestramiento de habitantes de la comunidad en la aplicación de técnicas seguras para la atención del parto. Para evaluar su impacto se compararon las tasas de mortalidad perinatal y las prácticas obstétricas de 409 mujeres antes y después de la intervención. La mortalidad perinatal bajó de 117 defunciones por 1 000 nacimientos antes de la intervención a 43,8 defunciones por 1 000 nacimientos después de ella. Se produjo un aumento significativo del número de mujeres que participaron en organizaciones femeninas después de la intervención, así como del número de dichas organizaciones. Asimismo, hubo un aumento significativo de la proporción de mujeres que recibieron atención prenatal y que iniciaron la lactancia materna desde el primer día después del parto. El número de neonatos atendidos inmediatamente después del alumbramiento también aumentó, pero el cambio no fue estadísticamente significativo. Este estudio demuestra que la organización comunitaria puede mejorar la salud materna e infantil en lugares aislados.

The Lancet articles

7 messages

Deepak <deepak@sochara.org>

31 May 2010 21:08

To: Thelma Narayan <thelma@sochara.org>

Dear Thelma

Attached are the articles from The Lancet. The references are done with the help of reference manager

Rosato, M., Laverack, G., Grabman, L. H., Tripathy, P., Nair, N., Mwansambo, C., Azad, K., Morrison, J., Bhutta, Z., Perry, H., Rifkin, S., & Costello, A. 2008, "Community participation: lessons for maternal, newborn, and child health", Lancet, vol. 372, no. 9642, pp. 962-971.

Tripathy, P., Nair, N., Barnett, S., Mahapatra, R., Borghi, J., Rath, S., Rath, S., Gope, R., Mahto, D., Sinha, R., Lakshminarayana, R., Patel, V., Pagel, C., Prost, A., & Costello, A. 2010, "Effect of a participatory intervention with women's groups on birth outcomes and maternal depression in Jharkhand and Orissa, India: a cluster-randomised controlled trial", Lancet, vol. 375, no. 9721, pp. 1182-1192.

Also located this interesting video by Ekjut available from http://www.youtube.com/watch?v=en1ubgj69wg

Some other articles that might be of interest

Azad, K., Barnett, S., Banerjee, B., Shaha, S., Khan, K., Rego, A. R., Barua, S., Flatman, D., Pagel, C., Prost, A., Ellis, M., & Costello, A. 2010, "Effect of scaling up women's groups on birth outcomes in three rural districts in Bangladesh: a cluster-randomised controlled trial", Lancet, vol. 375, no. 9721, pp. 1193-1202

Backman, G., Hunt, P., Khosla, R., Jaramillo-Strouss, C., Fikre, B. M., Rumble, C., Pevalin, D., Paez, D. A., Pineda, M. A., Frisancho, A., Tarco, D., Motlagh, M., Farcasanu, D., & Vladescu, C. 2008, "Health systems and the right to health: an assessment of 194 countries", Lancet, vol. 372, no. 9655, pp. 2047-2085.

Hope this is Helpful

Thanks Deepak

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eepak <deepak@sochara.org> o: Lavanya Devdas <lavanya.devdas@gmail.com></lavanya.devdas@gmail.com></deepak@sochara.org>	31 May 2010 21:1
Dear Lavanya	
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Thelma Narayan <thelma@sochara.org>

1 June 2010 09:48

To: Deepak <deepak@sochara.org>

Dear Deepak,

→ 890K

Thank you for tracing the Lancet articles that I had requested you for and the additional articles from the Lancet series. I am marking this to SOCHARA team members. I have met the Director of Ekjut the organisation in Jharkand where some of this work has been done. They have developed their thinking based on their previous experience, but it is a very good collaboration between several institutions, development projects and academics. It is worhtwhile for us in SOCHARA to consider whether we should engage in such collaborative research work.

I would suggest that all our team members go through the articles. Circulation to fellows and interns can be done after each team has discussed the artice themselves as part of the weekly journal club sessions.

with best wishes,

Thelma

[Quoted text hidden]

Dr. Thelma Narayan, MBBS, M.Sc (Epidemiology) Ph.D (London)

Public Health Consultant,

Centre for Public Health And Equity

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1 June 2010 10:07

To: Thelma Narayan <thelma@sochara.org>

Cc: Deepak <deepak@sochara.org>, Rakhal Gaitonde <rakhal@sochara.org>, "E. Premdas" <premdas@sochara.org>, Ruth Vivek <ruth@sochara.org>, Ravi Narayan <chcravi@gmail.com>

Dear Deepak,

Did you attach the articles? If so, Thelma's mail has left it out because of it being a reply mail rather than a forwarded mail. In a reply mail, the attachments get left out. Let me know. Otherwise if you have not got the articles I can extract them and send it to the group

Best Wishes, Prasanna

[Quoted text hidden]

Project Manager,
Center for Public Health & Equity (CPHE)
Society for Community Health Awareness Research and Action (SOCHARA)
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Deepak <deepak@sochara.org>

1 June 2010 10:16

3/5

Cc: Thelma Narayan <thelma@sochara.org>, Rakhal Gaitonde <rakhal@sochara.org>, "E. Premdas" cpremdas@sochara.org>, Ruth Vivek <ruth@sochara.org>, Ravi Narayan <chcravi@gmail.com>

Dear Prasanna

I just dropped into office, I had attached the articles in the mail to Thelma, those attachments might have got discarded when the reply was sent, am attaching the articles for the teams perusal, Very sorry for the delay

[Quoted text hidden]

Thanks

Deepak

[Quoted text hidden]

[Quoted text hidden]

4 attachments

lancet 2010; 375 1182-92.pdf

Lancet 2008; 372; 962–71.pdf

Lancet 2010; 375; 1193–202.pdf

Lancet 2008; 372; 2047–85.pdf 890K

Ruth Vivek <ruth@sochara.org>

4 June 2010 10:01

To: Thelma Narayan <thelma@sochara.org>

Cc: Deepak <deepak@sochara.org>, Prasanna Saligram <prasanna.saligram@sochara.org>, Rakhal Gaitonde <rakhal@sochara.org>, "E. Premdas" crakhal@sochara.org>, "E. Premdas" chcravi@gmail.com>

Dear Thelma

I think it will be good to be involved in such collaborative research initiatives to strengthen our networks as well as to hone our technical skills.

I too had met Dr. Tripathy, his wife and the team once when I visited their organisation during one of the community monitoring visits. They seemed to have a good team working there. Even then they were involved in some sort of study. I was actually surprised to see such kind of work happening in a remote part of Jharkhand.

So we should certainly start thinking on these lines.

Regards

Ruth

On Tue, Jun 1, 2010 at 9:48 AM, Thelma Narayan < thelma@sochara.org > wrote:

[Quoted text hidden]

Ruth Vivek V.
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Rakhal Gaitonde <rakhal@sochara.org>

4 June 2010 13:08

To: Deepak <deepak@sochara.org>, Prasanna Saligram <prasanna.saligram@sochara.org>
Cc: Thelma Narayan <thelma@sochara.org>, "E. Premdas" premdas@sochara.org>, Ruth Vivek
<ruth@sochara.org>, Ravi Narayan <chcravi@gmail.com>, shabanaameer2006@gmail.com, suresh@sochara.org

Dear Friends,

The following articles on the studies in Nepal and from Bolivia were the pioneers in studying community based interventions using the cluster randomised trials. The bolivia study was probably the first study of this kind (though it did not use the cluster randomised design).

There is one more study in this genre that I know of but have not been able to lay my hands on - and that is the IMAGE study in south africa - this showed a decrease in domestic violence through community action - this was just one of the outcomes - the main outcomes focusing on HIV / AIDS - this study was done by LSHTM and John Porter is an author - so maybe we can get the references from him.

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s makes a very impressive collection
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chal
Original Message From: "Deepak" <deepak@sochara.org> : "Prasanna Saligram" <pre> : "Prasanna Saligram" <pre> : "Thelma Narayan" <thelma@sochara.org>; "Rakhal Gaitonde" <rakhal@sochara.org>; "E. Premdas" remdas@sochara.org>; "Ruth Vivek" <ruth@sochara.org>; "Ravi Narayan" <chcravi@gmail.com> ent: Tuesday, June 01, 2010 10:16 AM abject: Re: The Lancet articles</chcravi@gmail.com></ruth@sochara.org></rakhal@sochara.org></thelma@sochara.org></pre></pre></deepak@sochara.org>
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attachments
bolivia warmi.pdf 325K
LancetManandhar.pdf 495K
nepal womens group manandhar.pdf

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