

Reviewing the impact of complex neonatal care interventions on rates of early initiation of breastfeeding (EIBF), skin-to-skin contact, and neonatal mortality

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Executive Summary

We previously wrote a report concluding that early initiation of breastfeeding (EIBF) and immediate skin-to-skin contact (SSC) substantially reduce neonatal mortality. Subsequently we became aware of a study in which a complex intervention substantially increased EIBF and SSC rates but did not decrease mortality, calling into question our prior conclusion. Here we contextualize that study by reviewing and synthesizing evidence from other complex or "package" neonatal interventions.

We identified 24 randomized and quasi-experimental trials in low- and middle-income countries that reported both neonatal mortality outcomes and rates of EIBF and/or SSC in intervention and control groups. Interventions increased EIBF rates by an average of 19 percentage points and SSC by 26 percentage points. Meta-analysis showed a 23% reduction in neonatal mortality (RR 0.77, 95% CI 0.65-0.91) for interventions increasing EIBF by ≥10 percentage points. Observed mortality benefits far exceeded what we would attribute to EIBF alone, suggesting additive or synergistic effects from other intervention components.

We conclude that the balance of evidence remains compatible with mortality benefits from EIBF and SSC. Secondarily, we have increased confidence that EIBF rates are highly variable between settings and generally responsive to intervention.

Why we performed this review

In <u>our prior report</u> on early initiation of breastfeeding (EIBF) and immediate skin-to-skin contact (SSC), we argued that these practices¹ are likely to substantially reduce neonatal mortality. This conclusion followed from a body of observational evidence linking EIBF to higher infant survival, randomized evidence showing impacts of SSC on intermediate clinical outcomes, a close connection between these two practices, and highly plausible biological mechanisms linking both to reductions in mortality.

Our prior report focused on studies specifically examining EIBF and SSC. At the time we did not seek to review studies of "complex" or "package" neonatal health interventions², some of which might raise rates of EIBF and/or SSC as part of their effects. Mortality reductions in such studies would be consistent with our understanding that EIBF and SSC save newborn lives, but would not be directly helpful in confirming or quantifying the

¹ We use the term "practices" rather than "outcomes" to describe both EIBF and SSC, though terminology is arguable. SSC is more directly within the control of delivery attendants while EIBF is a more complex behavior.

² Which we define here as "interventions designed to produce changes in multiple determinants of neonatal health".



magnitude of benefit (since many practices could be influenced by such interventions and we could not robustly differentiate between the benefits of any measured or unmeasured components).

Although "package" interventions showing mortality benefits would not credit any specific practice, strong null studies – in which EIBF and/or SSC improve as part of an intervention, but mortality does not – could cast doubt on their benefit. When we became aware of such a study (Semrau et al. 2017) we felt it was important to more deeply survey the literature to assess whether its findings were representative of other complex interventions, which would reduce our confidence that EIBF and SSC reduce mortality.

Our approach

Our intention was to efficiently improve our understanding of these practices to inform HealthLearn's implementation and evaluation strategy, rather than to perform a comprehensive systematic review suitable for academic publication. Therefore we relied on pragmatic, non-systematic, internet-based searches of English-language, peer-reviewed literature.

We used the following criteria to identify studies of interest:

- Randomized or quasi-experimental trials that report neonatal or early neonatal mortality outcomes³.
- Rates of EIBF and/or SSC are reported in both control and intervention groups⁴.
- Conducted in low- or middle-income countries⁵, with no other restrictions on the setting of the intervention.

We used a combination of search engines (Google, Google Scholar) and large language models (Claude, ChatGPT, and Google Gemini) to identify primary literature, review articles, meta-analyses, and evidence summaries (such as those published by GiveWell).

³ We considered including morbidity outcomes in case we were unable to identify enough studies assessing mortality, but this did not end up being necessary.

⁴ These did not need to be the only or primary practices targeted and/or improved. We did not restrict our search to studies in which EIBF and/or SSC rates *changed* (which would be necessary to draw any conclusions regarding mortality), since we were secondarily interested in knowing whether package interventions typically affected these practices at all.

⁵ We believe that EIBF and SSC are most impactful in settings with high baseline rates of neonatal mortality. The <u>distribution of causes of neonatal deaths shifts as overall mortality rates decline</u>: in high-mortality settings, risks which EIBF and SSC likely reduce such as infections account for a larger proportion of deaths, whereas in lower-mortality settings, a larger proportion of deaths relate to underlying conditions unlikely to be influenced by EIBF and SSC.



From those initial results, we used "snowballing" to examine citations within those studies⁶.

We manually extracted data on study design, setting, intervention, rates of EIBF and SSC, and changes in neonatal mortality. We planned to perform meta-analysis on the outcome of neonatal mortality for randomized trials that reported increases in EIBF and/or SSC⁷. Secondarily, we planned to summarize measured changes in EIBF and/or SSC in randomized and quasi-experimental trials to better understand the tractability of improving these practices⁸.

Our findings

Studies identified

24 studies matched our criteria (Appendix A). An additional 35 studies were closely reviewed and excluded. <u>This spreadsheet</u> contains the list of studies we screened.

Study characteristics

Designs

19 were cluster RCTs (including one stepped-wedge and two 3-arm trials) and five were quasi-experimental designs (three difference-in-differences with non-equivalent comparison groups, two single-group pre-post comparisons).

Settings

21 studies were conducted in Asia and three in Sub-Saharan Africa. 17 primarily involved community-based interventions, five involved facility-based interventions, and two involved both settings. Study activities were carried out between 1999 and 2017.

Interventions

Interventions were heterogeneous. Frequently included elements included perinatal home visits (typically by community health workers, CHWs⁹), CHW training in maternal and/or

⁶ We specifically screened studies cited by and citing Semrau 2017, all of the citations in GiveWell's summaries of <u>community-based</u> and <u>facility-based</u> maternal and neonatal care programs, and all of the studies included in the neonatal mortality meta-analysis from this <u>2019 Cochrane review</u>.

⁷ A priori we did not have a specific cutoff in mind for how substantial an increase in EIBF and/or SSC would need to be.

⁸ In prior external conversations, we have encountered speculation that EIBF rates are determined by difficult-to-modify factors, including hypotheses that cultural factors may limit tractability.

⁹ Non-licensed lay health workers, with varying levels of training and experience.



newborn care, facilitated community women's groups, facility-based implementation of care quality checklists, and algorithmic treatment of neonatal illness by CHWs.

Changes in EIBF and/or SSC

Rates of EIBF were reported in all studies, while rates of SSC were reported in only 12 studies. For EIBF, most reported breastfeeding within one hour of birth¹⁰, but two reported breastfeeding within 30 minutes and one used a cutoff of four hours. In most cases EIBF rates were ascertained by surveying mothers, with questionnaires conducted at various timepoints after delivery (from the first day up to 12 months). Four studies used direct observation of deliveries to determine EIBF rates. Compared with EIBF, the time windows used to define SSC were much more heterogeneous (e.g., "within 30 minutes", "within 24 hours", "at any time on day of birth", "for at least six hours", not defined).

	Number of trial arms ¹¹	Mean (SD)	Range
Control group EIBF (percent) ¹²	24	41.1 (22.9)	0.2, 75.6
Intervention group EIBF (percent) ¹³	26	59.9 (20.7)	0.1, 94.8
Change in EIBF (percentage points) ¹⁴	26	+19.1 (19.3) ¹⁵	-7.0, +66.1
Control group SSC (percent)	11	29.0 (25.0)	0, 70
Intervention group SSC (percent)	12	53.0 (29.3)	1.7, 85.5
Change in SSC (percentage points)	12	+25.6 (30.7) ¹⁶	-15, +75.5

Table 1. Changes in rates of early initiation of breastfeeding (EIBF) and skin-to-skin contact (SSC) reported in randomized and quasi-experimental studies that include neonatal mortality.

¹⁰ Breastfeeding within one hour of birth is the most commonly accepted definition of EIBF.

¹¹ Two randomized studies included multiple intervention arms, considered here as separate trials.

 $^{^{12}}$ For quasi-experimental trials, "control group" is reported as pre-intervention (in pre-post studies, n=2) or comparison group endline (in studies with difference-in-differences analysis, n=3).

¹³ For quasi-experimental trials, "intervention group" is reported as post-intervention for pre-post studies (n=2) or intervention group endline in studies with difference-in-differences analysis (n=3). ¹⁴ For quasi-experimental trials, reported as pre-post difference (n=2) or difference-in-differences

⁽n=3) in line with study methodology.

¹⁵ This does not exactly match the difference between intervention and control group means because of studies using difference-in-differences analysis

¹⁶ This does not exactly match the difference between intervention and control group means because of studies using difference-in-differences analysis



Changes in neonatal mortality

Most studies reported mortality in the full neonatal period (day 0-28 after birth). One study (Semrau 2017) reported only early neonatal mortality (0-7 days). One study (Kaplan 2021) did not report a risk ratio, hazard ratio, or odds ratio¹⁷ of neonatal mortality and was therefore excluded from meta-analysis.

For meta-analysis of mortality outcomes (R code here), we included only randomized trials and set arbitrary cutoffs of 5 and 10 percentage point increases in EIBF. Included studies had a range of 7.4 to 66.1 percentage point increases in EIBF. Using our prior estimate that EIBF should result in a relative decrease in neonatal mortality of 7% to 24%, we would expect a reduction in population risk ratio (RR) of neonatal mortality attributable to EIBF between 0.5% and 16.0% In other words, we would expect risk ratios ranging from 0.995 to 0.840 in the included studies due to increased EIBF.

A <u>2019 Cochrane review</u> performed meta-analysis of neonatal mortality outcomes in a set of studies that overlapped heavily with ours (12 of our 16 study arms were included among the 29 arms in the Cochrane meta-analysis). In several cases the numbers reported by Cochrane diverged slightly from what we extracted manually, and in the two cases with substantial discrepancies we believe there were data entry errors in the Cochrane review²⁰. We primarily report results of our meta-analysis using the mortality data we manually extracted, but include the corresponding numbers using data from the Cochrane review in footnotes. The results are robust to these discrepancies.

Including studies that raised EIBF rates by at least 10 percentage points (Figure 1), neonatal mortality was reduced by 23% (RR 0.77, 95% confidence interval (CI) 0.65 to 0.91; random-effects model; 12 studies; $I^2 = 78.6\%$)²¹. With a 5 percentage point cutoff (Figure 2), neonatal mortality was reduced by 21% (RR 0.79, 95% CI 0.69 to 0.90, random-effects model; 16 studies; $I^2 = 77.1\%$)²².

¹⁷ Due to the rarity of mortality outcomes, we used reported odds ratios (OR) <u>interchangeably</u> with risk ratios (RR) and hazard ratios (HR).

¹⁸ With a 7.4 percentage point increase in EIBF and a 7% mortality reduction.

¹⁹ With a 66.1 percentage point increase in EIBF and a 24% mortality reduction.

²⁰ For the "community care" arm of Baqui 2008a, the authors report adjusted mortality RR of 0.95 (95% CI 0.69-1.31), while the Cochrane review reports RR 1.31 (95% CI 0.95-1.81). We suspect there could have been a transcription error given that 2 of 3 numbers match exactly: the central RR reported by Cochrane matches the upper 95% CI reported by the authors, and the lower 95% CI reported by Cochrane matches the central RR reported by the authors. Similarly, there were large discrepancies in the RRs reported for Tripathy 2016. The Cochrane review appears to switch the authors' reported RRs for neonatal and perinatal mortality (Figure 4 and Figure 16). We were unable to find numbers resembling Cochrane's neonatal RR estimate in either paper.

²¹ Using data extracted from Cochrane, the same studies had an RR of 0.78, 95% CI 0.65 to 0.94.

²² Using data extracted from Cochrane, the same studies had an RR of 0.81, 95% CI 0.70 to 0.93.



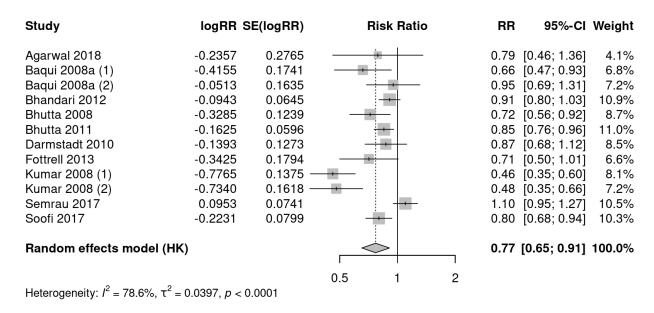


Figure 1: Meta-analysis of risk of early neonatal (n=1; Semrau 2017) and neonatal mortality (n=11) in randomized trials whose interventions increased rates of early initiation of breastfeeding by at least 10 percentage points.

Study	logRR S	E(logRR)	Risk Ratio	RR	95%-CI	Weight
Agarwal 2018	-0.2357	0.2765		0.79	[0.46; 1.36]	2.8%
Baqui 2008a (1)	-0.4155	0.1741		0.66	[0.47; 0.93]	4.8%
Baqui 2008a (2)	-0.0513	0.1635	-	0.95	[0.69; 1.31]	5.1%
Bhandari 2012	-0.0943	0.0645	-	0.91	[0.80; 1.03]	8.2%
Bhutta 2008	-0.3285	0.1239		0.72	[0.56; 0.92]	6.3%
Bhutta 2011	-0.1625	0.0596		0.85	[0.76; 0.96]	8.3%
Darmstadt 2010	-0.1393	0.1273	- • 	0.87	[0.68; 1.12]	6.2%
Fottrell 2013	-0.3425	0.1794		0.71	[0.50; 1.01]	4.7%
Hanson 2015*	0.0000	0.0535	-	1.00	[0.90; 1.11]	8.5%
Kirkwood 2013	-0.0834	0.1023	+	0.92	[0.75; 1.12]	7.0%
Kumar 2008 (1)	-0.7765	0.1375 -		0.46	[0.35; 0.60]	5.9%
Kumar 2008 (2)	-0.7340	0.1618 -	-	0.48	[0.35; 0.66]	5.1%
Manandhar 2004	-0.3567	0.1462		0.70	[0.53; 0.93]	5.6%
Semrau 2017	0.0953	0.0741	+	1.10	[0.95; 1.27]	7.9%
Soofi 2017	-0.2231	0.0799	-	0.80	[0.68; 0.94]	7.7%
Tripathy 2016	-0.3711	0.1322		0.69	[0.53; 0.89]	6.0%
Random effects model (H	K)			0.79	[0.69; 0.90]	100.0%
			0.5 1 2			
Heterogeneity: $I^2 = 77.1\%$, $\tau^2 = 77.1\%$	= 0.0327. p < 0	.0001				

Figure 2: Meta-analysis of risk of early neonatal (n=1; Semrau 2017) and neonatal mortality (n=15) in randomized trials whose interventions increased rates of early initiation of breastfeeding by at least 5 percentage points. * Hanson 2015 is reported as Penfold 2014 in the Cochrane review.



Changes in EIBF vs. changes in neonatal mortality

Interventions producing larger increases in EIBF rates generally also showed greater reductions in neonatal mortality (Figure 3).

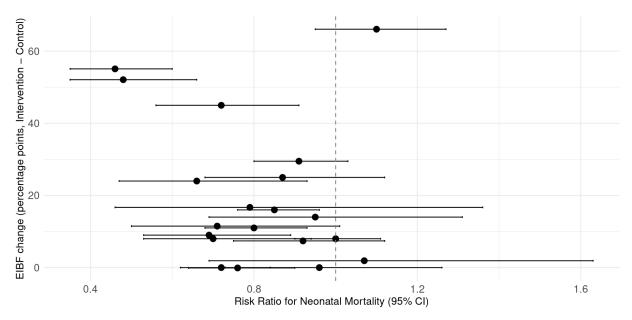


Figure 3. Change in rates of early initiation of breastfeeding (EIBF) versus change in neonatal mortality reported in randomized studies (n=20).

Our interpretation

EIBF and mortality

Our primary conclusion is that the balance of evidence is *not incompatible with* the degree of mortality benefit that we previously ascribed to EIBF. By the nature of the studies examined in this exercise, we cannot determine whether EIBF itself contributed to the mortality reductions. Most interventions included many potentially mortality-relevant components, and on balance, the benefits observed are far greater than we would expect from EIBF alone (even taking the top of the impact range we previously estimated). This is unsurprising, since the effects of "package" interventions could be additive or synergistic.

Only a few studies produced large (e.g., >25 percentage point) increases in EIBF. With the exception of the study that led us to conduct this exercise (Semrau 2017), all of these studies showed a mortality reduction that was at least as great as we would attribute to the observed increase in EIBF alone. The high degree of statistical heterogeneity we found in the meta-analysis likely reflects very heterogeneous interventions, endpoints, and study methods. This indicates mortality benefits that are robust across many different



complex neonatal interventions, but also complicates identification of any particularly effective program components.

There appeared to be an inverse "dose-response" relationship between increases in EIBF and mortality (Figure 3), which would be consistent with a causal mortality benefit. We suspect that large changes in EIBF, in addition to any direct impacts on mortality, may also identify effective interventions that produced mortality benefits in additional ways.

SSC and mortality

As we expected due to the close association of EIBF and SSC, changes in SSC (where reported) tended to be similar in direction and magnitude as changes in EIBF – i.e., interventions typically produced similar effects on both practices, and the inverse relationship with SSC and mortality was similar (data not shown).

Variability in EIBF and SSC rates

This review supports our understanding, based on our prior evidence review, that baseline EIBF rates are very heterogeneous between contexts for reasons we don't fully understand. Control group rates of EIBF ranged from 0.2% to 75.6%. At least some of this probably relates to the methods of ascertaining EIBF outcomes used in different studies. Prior work suggests that <u>direct observation results in much lower estimates than maternal self-report</u>, and we think that contextual factors affecting perceived social desirability could bias survey responses. However, <u>national rates</u> ascertained using consistent methodologies such as the Demographic and Health Survey (DHS) and Multiple Indicator Cluster Survey (MICS) also demonstrate a wide range.

We were previously very confident that immediate SSC rates are similarly heterogeneous (not least because the two practices are <u>strongly correlated</u> and breastfeeding necessitates a degree of skin contact). This exercise added little additional confidence to this conclusion due to the variety of definitions of SSC that were used.

Tractability of improving EIBF rates

Intervention effects on EIBF rates were highly variable, though almost universally positive in direction. Given that interventions were heterogeneous and none seemed to focus with great salience on EIBF relative to other practices, we view this as an encouraging sign. This supports our prior view that raising EIBF rates is tractable and they are not typically bounded near current rates by deeply entrenched factors.



Limitations and remaining uncertainties

Only a few studies in this review were highly relevant to our main question on the mortality impacts of EIBF and/or SSC. Negative studies (i.e., those with no reduction in mortality) could have challenged our view only if there was a large enough change in EIBF / SSC to expect a measurable mortality reduction. Most studies did not reach this level; the majority produced more modest changes in EIBF (and many did not even report rates of SSC) so they provided little relevant information about the impact of these practices.

This review was not optimized to determine the tractability of changing EIBF and/or SSC rates because we limited the scope to studies that also reported mortality changes. We suspect many studies have assessed interventions impacting EIBF rates without being powered for mortality outcomes (which requires large sample sizes). Additionally, because most studies involved community-based interventions, we gained less knowledge about the tractability of changing EIBF and/or SSC rates in facility-based deliveries.

It is likely that the reported increases in EIBF and SSC are inflated if the intervention exposed mothers to positive messaging around this practice. In the large majority of studies, these outcomes were reported by mothers, and social desirability bias could have led more mothers in intervention groups to report EIBF and/or SSC (regardless of whether it happened). Likewise, in studies where practices were directly recorded, observer effects seem probable: birth attendants who were exposed to messaging around neonatal care practices and whose deliveries were watched might be particularly careful to follow guidelines.

Studies were primarily conducted in South Asian contexts, with few studies in sub-Saharan Africa (where HealthLearn currently operates). Our mechanistic understanding of EIBF/SSC (plus the well-established benefits of "kangaroo care") suggests that low birth weight (LBW) infants may experience a greater benefit from EIBF and SSC. Given that global incidence of LBW tends to be highest in South Asia, studies done in other contexts may have been more likely to show smaller effects.

We may have missed relevant studies. Our objective was to conduct a rapid assessment, rather than to perform a <u>systematic meta-analysis</u> suitable for publication in a peer-reviewed journal, so relevant studies may have been missed.



How this changes our prior views

- 1. No change to our confidence that EIBF meaningfully reduces neonatal mortality (previously high confidence, remains high).
- 2. Slight increase in our confidence that measured rates of EIBF and SSC are highly variable between settings (previously high confidence, now very high confidence).
- 3. Increase in our confidence that EIBF rates may respond to relatively untargeted interventions (*no strong prior view, now moderate confidence*).
- 4. Slight increase in our confidence that EIBF (and likely SSC) rates should respond well to targeted intervention (previously moderate confidence, now moderate-to-high confidence).

Disclosures

Vijay Kotecha is an internal medicine physician with over 10 years of experience, including research and clinical work in low-resource settings. He recently completed <u>Ambitious Impact's</u> Research Training Program.

Marshall Thomas is Executive Director of <u>HealthLearn</u>. He has a decade of experience in online learning, medical education, and global health. He has a PhD in biomedical sciences from Harvard Medical School.

HealthLearn is an Ambitious Impact-incubated charity that funded this research.



Appendix A: Studies included in this review

Randomized trials	Year	Reference
Agarwal et al.	2018	Improving quality of care during childbirth in primary health centres: a stepped-wedge cluster-randomised trial in India
Baqui et al. (a)	2008	Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial
Bhandari et al.	2012	Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomised controlled trial
Bhutta et al.	2008	Implementing community-based perinatal care: results from a pilot study in rural Pakistan
Bhutta et al.	2011	Improvement of perinatal and newborn care in rural Pakistan through community-based strategies: a cluster-randomised effectiveness trial
Boone et al.	2017	Community health promotion and medical provision for neonatal health—CHAMPION cluster randomised trial in Nagarkurnool district, Telangana (formerly Andhra Pradesh), India
Darmstadt et al.	2010	Evaluation of a Cluster-Randomized Controlled Trial of a Package of Community-Based Maternal and Newborn Interventions in Mirzapur, Bangladesh
Fottrell et al.	2013	The Effect of Increased Coverage of Participatory Women's Groups on Neonatal Mortality in Bangladesh: A Cluster Randomized Trial
Hanson et al. (reported as Penfold 2014 by Cochrane)	2015	Effectiveness of a Home-Based Counselling Strategy on Neonatal Care and Survival: A Cluster-Randomised Trial in Six Districts of Rural Southern Tanzania
Kaplan et al.	2021	Effects of the World Health Organization Safe Childbirth Checklist on Quality of Care and Birth Outcomes in Aceh, Indonesia: A Cluster-Randomized Clinical Trial
Kirkwood et al.	2013	Effect of the Newhints home-visits intervention on neonatal mortality rate and care practices in Ghana: a cluster randomised controlled trial
Kumar et al.	2008	Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial
Manandhar et al.	2004	Effect of a participatory intervention with women's groups on birth outcomes in Nepal: cluster-randomised controlled trial
Persson et al.	2013	Effect of Facilitation of Local Maternal-and-Newborn Stakeholder Groups on Neonatal Mortality: Cluster-Randomized Controlled Trial



Semrau et al.	2017	Outcomes of a Coaching-Based WHO Safe Childbirth Checklist Program in India
Soofi et al.	2017	Effect of provision of home-based curative health services by public sector health-care providers on neonatal survival: a community-based cluster-randomised trial in rural Pakistan
Tomlinson et al.	2014	Goodstart: a cluster randomised effectiveness trial of an integrated, community-based package for maternal and newborn care, with prevention of mother-to-child transmission of HIV in a South African township
Tripathy et al.	2016	Effect of participatory women's groups facilitated by Accredited Social Health Activists on birth outcomes in rural eastern India: a cluster-randomised controlled trial
Tripathy et al.	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
Quasi-Experimental trials	Year	Reference
		Reference Impact of an integrated nutrition and health programme on neonatal mortality in rural northern India
trials	2008	Impact of an integrated nutrition and health programme on
Baqui et al. (b)	2008	Impact of an integrated nutrition and health programme on neonatal mortality in rural northern India Stillbirth and Newborn Mortality in India After Helping Babies Breathe Training Evaluation of a maternal, neonatal and child health intervention package in a rural district of Pakistan: a quasi-experimental
Baqui et al. (b) Goudar et al.	2008	Impact of an integrated nutrition and health programme on neonatal mortality in rural northern India Stillbirth and Newborn Mortality in India After Helping Babies Breathe Training Evaluation of a maternal, neonatal and child health intervention package in a rural district of Pakistan: a quasi-experimental study Impact of a community-based perinatal and newborn preventive care package on perinatal and neonatal mortality in a remote