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Neonatal resuscitation and immediate newborn assessment and stimulation for the prevention of neonatal deaths: a systematic review, meta-analysis and Delphi estimation of mortality effect

A CC L[1,2], i m C s s[3], a[4] sa i m [5], Gar L Dar a[1,6], a A Car [7], ia J K a[8], i ar A B a[9], C ris Gi [10], J E La[4*]

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Initiation of breathing is critical in the physiologic transition from intra-uterine to extra-uterine life. Between 5-10% of all newborns require assistance to establish breathing at birth [1-6], and simple warming, drying, stimulation and resuscitation may reduce neonatal mortality and morbidity. Each year an estimated 814,000 neonatal deaths [8] are related to intrapartum hypoxic events in term infants, previously termed "birth asphyxia" [7], and over one intrapartum million stillbirths occur. Especially in under-resourced settings it may be challenging to distinguish a still-not associated with survival benefit in term infants [12], although the effect may differ in very preterm infants [13-15].

While systematic training in resuscitation of the newborn is a cornerstone of modern neonatology, there have been few rigorous evaluations of its effectiveness,

risk ratio, was estimated together with a 95% confidence interval (CI). We summarized the overall quality of evidence for each outcome and each data input type using an adapted version of the GRADE protocol table [21,24].

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a i a L a 2005 44	A s ias i i B aia	B - a - a s	E -B aia a s s iai , ai i i a s i a si	1) As ia a a M ai ICD 9 ' i a a a i a a as ia', 2) Ea a a ai (s 7 a s) 3) a i ICD-9 'i i a ' a s a is ss s '	E a a i s ICD-9	A) 67,948; B) 67,647	1) 0.83 (0.54-1.27) 2) 0.86 (0.74-1.01) 3) 1.33 (1.03-1.73)
Ca , a 2010 38 / C a E a 2008 39	18 a L is s, a ia	B - a - a s ,	H E C a a , i i asi s s i a i i a - as , a s ai , i a a i s ssi s, a a a i s; i ai i i i a - as ia i a s ssi s	1) As ia Ea a a M ai (7), a i a ; 2) Ea a a M ai s 7 a s; 3) M ai B <1500	LB (< 1500) as s a a s a , i a s i i si a s a	A) 8,148; B) 20,534	1) 0.56 ( ) 2) 0.60 (0.48-0.76) 3) 0.74 ( )

and pediatric infectious disease (n=1). Expert opinion was requested for 5 mortality effects (see additional file 2): facility based basic resuscitation on preterm mortality community based basic resuscitation and immediate newborn assessment and stimulation on both intrapartum-related and preterm mortality Consensus was reached in the first round for all 5 estimates.

E

Of 16 observational, facility based studies of neonatal resuscitation, 14 were before-after studies and 2 were historical reports. Details of each study and the main results are shown in Tables 2 and 3 and the assessment of quality of evidence according to GRADE is shown in table 4.

l c

The content and context of the resuscitation training for all facility studies are shown in Tables 2 and 3. Some studies evaluated neonatal resuscitation training as part of a comprehensive perinatal [33-36] or obstetric care program [37], and these evaluations were excluded. In the First Breath study basic neonatal resuscitation was taught in the first phase as part of an essential newborn care package including bag mask ventilation, then followed by a more in-depth training using elements of the American Academy of Pediatrics Neonatal Resuscitation Program, including immediate assessment and stimulation, bag-mask ventilation and chest compressions [38,39]. Several studies implemented full advanced neonatal resuscitation (American Academy of Pediatrics Neonatal Resuscitation Program [2,3,40-43], French Bulgarian [44], ABCDE [45], or UK resuscitation council training [46]). However, advanced procedures are rarely used (i.e. chest compressions or medications required in < 0.1% of births [11]), the approaches are similar in content, and the additional benefit is likely to be small in low-resource settings. Thus, studies of basic and basic with advanced neonatal resuscitation were combined as long as they had comparable study design and outcome measures.

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a* 1993 45	H a [illegible], [illegible] i s a , C i a	B [illegible] - a -a [illegible] s	ABCDE [illegible] m [illegible] s s i a i i a [illegible] a [illegible] s	1) As ia Cas Fa ai	a	A) [illegible] m [illegible] s s i a i s 184 223	1) [illegible] 0.94
T a i [illegible] a* 2000 40	32 [illegible] i [illegible] a [illegible] a [illegible] s; K [illegible] a a, I ia	B [illegible] - a -a [illegible] s					

Several training programs required written and/or clinical practical exam to ensure trainee competency (AAP NRP, UK resuscitation council). Refresher training was conducted in some studies to promote skill maintenance, and is shown in Tables 2 and 3 if reported by investigators.

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The case definitions for intrapartum-related neonatal deaths ("birth asphyxia") and preterm mortality varied between studies (Tables 2 and 3). "Asphyxia" mortality was reported in six facility studies [2,3,38-41,44], and was considered in three studies to correspond to term intrapartum-related neonatal mortality [2,38,44]. Among these three studies which were included in the meta-analysis, the sources of cause-of-death data were hospital records in the Indian study [2,3], the National Health Information Centre in the Bulgarian study [44], and a prospective research tracking system with midwives trained in assigning cause-of-death in Zambia [38,39]. The Indian and Bulgarian studies used standard ICD rules to assign a single underlying cause of death. The Zambian study did not use a standard hierarchy to assign single cause of death, and some preterm deaths were possibly assigned to asphyxia. Neonatal mortality due to complications of prematurity was reported separately in the same three studies [2,38,44]. The Bulgarian study [44] used ICD-9 coding to assign cause of death (Immaturity related or Respiratory Distress Syndrome). The Indian study also used ICD cause of death rules, however required birthweight <1000 with complications of prematurity [2]. The Zambian study used gestational age or weight cutoff (<1500g or <37 weeks) [38,39].

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We performed meta analyses to summarize the results of studies of neonatal resuscitation training as an isolated intervention with comparable study design for the following outcomesnts(s)-19(e)-9soimmediate death among those with Apgar score <7 in the delivery room, which does not capture all intrapartum-related neonatal deaths nor distinguish deaths due to preterm or other complications. The principal investigators of the study were contacted to try to obtain early neonatal mortality data, but this was not available [41]. The Boo study was not included in the meta-analysis as this ecological study spanned 8 years, the coverage of the intervention was unclear and unequally distributed by state, and intrapartum-related outcomes were not reported [43]. The O'Hare and Duran data were excluded as only deaths among those admitted to the Neonatal Intensive Care Unit were reported [42,49].

1) Basic neonatal resuscitation effect on intrapartum-related term neonatal deaths ("Birth asphyxia") in facilities

In this meta-analysis of three studies [2,38,44], training in neonatal resuscitation in the facility setting was associated with a 30% reduction in intrapartum-related mortality (RR=0.70, 95% CI 0.59-0.84) (Figure 3). The direction of effect was protective in all studies, and while effect estimates appeared slightly greater in the higher mortality settings (India, asphyxia-specific mortality rate [ASMR] = 15.7/1000; Zambia, ASMR = 3.4/1000) than in Bulgaria, an upper-middle income country with relatively low mortality (baseline NMR 7.8, ASMR 0.7/1000), there was not strong evidence of heterogeneity of mortality effect between studies (P=0.47). Given the consistency of the data and generalizability to low-middle income countries, the overall grade of evidence for the effect on intrapartum-related mortality was upgraded to moderate.

2) Basic neonatal resuscitation effect on neonatal deaths due to direct complications of preterm birth in facilities

The same three studies [2,38,44] reported the impact of resuscitation on preterm mortality. However, the study definitions of preterm mortality were heterogenous between studies (Tables 2 and 3) and in 2 studies a very low birth weight cutoff was used [2,38] that would have excluded moderately preterm infants who would be most likely to be saved by basic resuscitation without ongoing intensive care. Thus the study data was not pooled in a meta-analysis. Given the strong biologic plausibility (ie. stimulation, thermoregulation, and positive pressure ventilation at birth may prevent hypoxia and hypothermia, particularly in moderate preterm infants), in combination with the low quality of the evidence, further expert opinion was sought. In the Delphi process, basic neonatal resuscitation was estimated to reduce preterm mortality by about 10% in addition to immediate assessment and stimulation (median opinion 10%, Range 4-30%, IQR 10-20%) (table 5).

3) Neonatal resuscitation effect on early neonatal deaths (within 7 days) in facilities

Almost all (98%) intrapartum-related deaths occur in the first week of life, thus, early neonatal mortality may be a useful proxy measure [47,48]. Three studies were included [3,38,44] in a meta-analysis which suggested that neonatal resuscitation training in the facility setting (2 advanced [3,38,44], 1 basic [38]) was associated with

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coverage of the intervention (~20% of deliveries). Two studies were quasi-experimental with non-random allocation of the intervention and considered to provide low to moderate quality evidence [5,55]. Four other studies were before-and-after studies [50-52,54], providing very low to low quality evidence by GRADE criteria.

Because of substantial heterogeneity in the interventions implemented, the inability to isolate the effect of resuscitation training in community newborn care packages, differences in study design, and the lack of consistent outcomes definitions separating neonatal deaths due to term-intrapartum events vs. preterm birth, no meta-analysis was performed using the community data and the data is summarized.

1) Basic neonatal resuscitation effect on all cause mortality in community based studies

Five studies reported the intervention package effect on community by 20%, in addition to assessment and stimulation (median opinion 20%, Range 10-50%, IQR 15-25%).

3) Basic neonatal resuscitation effect on neonatal deaths due to preterm birth complications in community-based studies

No studies were identified that met criteria for intervention and outcome definitions. The Lunesp study reported no significant reduction in mortality attributed to preterm birth [53]. Given the biologic plausibility, expert opinion was also sought. The Delphi process estimated a 5% reduction, in addition to assessment and stimulation (Range 1-40%, IQR 5-10%) in neonatal deaths due to neonatal resuscitation with positive pressure ventilation in the community (table 5).

4) Basic neonatal resuscitation effect on stillbirths in community-based studies

In the First Breath study the stillbirth rate was reduced by 31% after the intervention, and in the SEARCH study the fresh stillbirth rate was 32% lower during the period of bag-mask compared to tube-mask resuscitation (p< 0.09). In the Lunesp study there was no significant effect of the intervention on stillbirth rate [53].

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We identified no studies which reported mortality outcomes for newborn assessment and stimulation alone in the community or in facilities; therefore, an expert Delphi process was undertaken.

1) Intrapartum-related neonatal deaths

The median opinion was for a 10% reduction (Range 0-25%, IQR 5-15%) in term intrapartum-related deaths with immediate newborn assessment and stimulation alone.

2) Neonatal deaths due to direct complications of preterm birth

The median opinion was for a 10% reduction (Range 0-20%, IQR 5-10%) in preterm deaths following immediate newborn assessment and stimulation alone.

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The total effect of basic resuscitation is estimated as the effect of newborn assessment and stimulation, and the additional effect of basic resuscitation on the remaining deaths, after subtracting the lives saved from initial newborn assessment and stimulation (table 5). In the meta-analysis, the additional effect of basic resuscitation included studies where training with bag-and-mask was implemented on top of existing basic newborn care. In the Delphi, the effect of basic resuscitation was incremental to newborn assessment and stimulation. For example, if there are 1000 intrapartum related deaths in the absence of any care, introducing newborn assessment and stimulation for all children would be expected to prevent 10% of these deaths (=100), leaving 900 deaths still occurring. Adding basic resuscitation in the community to newborn assessment and stimulation would prevent 20% of these remaining deaths (=180). Thus, the total number of deaths prevented would be 280 (=28%). In the LiST software, assessment and stimulation is included with skilled attendance for facility birth and the basic resuscitation is a separate additional option.

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The LiST mortality effects for the two interventions (immediate newborn assessment and stimulation, and basic neonatal resuscitation) on the two causal categories of neonatal death (term intrapartum-related and preterm birth complications) are summarized in table 7, along with evaluations of quality of evidence, or expert

Simple immediate newborn assessment and warming, drying and tactile stimulation is the first step of neonatal

The impact of resuscitation training may be greater in higher mortality settings where obstetric care is more limited. In Bulgaria, an upper-middle income country where the baseline intrapartum-related mortality was relatively low, the estimated effect was smaller (16%) than in higher mortality settings such as Zambia and India, where neonatal resuscitation training was associated with a 30-43% reduction in intrapartum-related mortality. In settings with high coverage of high quality intrapartum management, the majority of term infants who die from intrapartum-related causes may be severely asphyxiated infants who require interventions beyond neonatal resuscitation alone, such as ongoing ventilation and therapeutic hypothermia.

The evidence for basic resuscitation in community settings was too heterogeneous to combine: study designs varied substantially, resuscitation training was one of numerous interventions in newborn care packages, and the outcome measure of cause-specific mortality differed across studies, often reflecting reduction in other causes of death such as preterm birth and infections. Significant reductions in all-cause neonatal or perinatal mortality were observed in 4 studies, ranging from 25-61% [5,53-55], and reported "asphyxia" specific mortality was reduced in four studies, ranging from 61-70% [5,53-55]. In the multi-center "First Breath" study [52], although no overall impact on PMR was observed, there was a significant 19% PMR reduction for deliveries with trained birth attendants, and a reduction in intrapartum-related morbidity (prevalence of 5 minute Apgar scores <4 and abnormal neurologic exams at 7 days). On the other hand, preliminary results from a cRCT in Bangladesh failed to demonstrate a reduction in ENMR with the additional training of TBAs in bag-mask resuscitation beyond immediate care and mouth-to-mouth resuscitation. Although it was not possible to derive a cause-specific mortality estimate from existing evidence, our expert panel agreed on the presence of an effect (20% for intrapartum-related mortality, 5% for preterm mortality), albeit slightly smaller than for facility based resuscitation, reflecting the additional challenges in implementation in such contexts, with a single provider and variable cadres. There is a need for consistency in future studies with respect to intervention content, study design, outcome measurement and definitions in order to more precisely evaluate the potential impact of resuscitation training at community level.

Important programmatic considerations for resuscitation training in resource limited settings include the benefit of teaching advanced procedures, provider competency and skill maintenance. Two of the studies in our meta-analysis included some aspects of advanced neonatal resuscitation; however, advanced procedures are more complex to teach (i.e. chest compressions, intubation, or medications) and are required for ~2% of all babies who do not breathe at birth[2,56], and fewer than 1% of all babies born[6,11]. Basic neonatal resuscitation is sufficient for most babies who would be saved by resuscitation in low-middle income settings, and the additional benefit of advanced procedures is likely to be low. For the purposes of this LiST estimate, the effect of facility based neonatal resuscitation was assumed to be achievable with basic neonatal resuscitation, which is the clear priority for rapid scale up in facilities in low and middle income countries, given feasibility, skills required, and equipment costs. Furthermore, training programs should emphasize routine assessment of provider knowledge, competency and skill maintenance. Provider knowledge and performance skills to conduct resuscitation decline significantly over time[57]. Regular refresher training programs, practice drills, and DVD videos of resuscitation are methods of ensuring skill maintenance and program effectiveness[1,58] .

A reduction in stillbirth rate has been observed in 2 community based studies, after training programs including bag-mask resuscitation [5,52]. A live newborn with severe neonatal depression is difficult to distinguish from a stillborn, and there is the potential for misclassification in low-resource settings where newborns are not typically assessed for signs of life at birth (particularly heart rate) [59,60]. In addition to reducing misclassification, training in neonatal assessment and resuscitation may also increase survival in apparently stillborn infants (Apgar score assessed as 0 at 1 minute). Among apparently stillbirth infants who were resuscitated, case fatality ranges between 16-65% in high income settings [61-63], with major intensive care support, and long term outcomes that are significantly worse than for resuscitated babies who did have a heart rate detected [64]. These findings emphasize the need to accurately count stillbirths and assess long term outcomes to capture the full impact of obstetric and immediate newborn care interventions [65,66].

Consistent case definitions are required for comparable population-level surveillance of disease burden and for evaluation of intervention effectiveness. A survey of policy makers revealed that "confusing terminology" and "lack of valid measurement indicators at the community level" were key barriers to obtaining the necessary information to make policy decisions[19]. Recent advances have been made in case definitions and verbal autopsy hierarchies to distinguish intrapartum-related events in term or almost term babies from preterm babies, although the issue of distinguishing growth restricted infants remains a challenge and is especially important in South Asia. Consistent use of such verbal autopsy tools, and more importantly the hierarchies, is critical [67]. This review emphasizes the need to minimize

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