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Original Article

How to Identify Neonates at Risk of Death in Rural India: Clinical Criteria for the Risk Approach

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OBJECTIVE:

Majority of neonates in developing countries are born at home and most neonatal deaths occur without receiving medical care. This retrospective analysis was undertaken to develop simple clinical criteria for use in rural community to identify neonates at risk of death.

STUDY DESIGN:

By analyzing the observational data on two cohorts of neonates in 39 villages in different years of the Gadchiroli field trial, we selected a minimum set of clinical features. We evaluated this set for its sensitivity, specificity and predictive value to detect eventual neonatal death, the primary study outcome.

RESULTS:

The cohorts included 763 neonates with 40 deaths in 1995 to 1996, a year with minimum interventions, and 1598 neonates with 38 deaths in 1996 to 1998, the years of intensive interventions. On the day of birth, presence of any one of the three: (1) birth weight <2000 g, (2) preterm birth or (3) baby not taking feeds; or, during the rest of neonatal life, mother's report of reduced or stopped sucking by baby, were identified as the predictors of neonatal deaths. The combined set gave a sensitivity of 95%, specificity, 77.3%; predictive value, 18.8%; and the yield, 26.5% in 1995 to 1996 and, respectively, 86.8, 78, 8.8, and 23.5% in 1996 to 1998. The mean lead time gained was 3.4 to 6.6 days.

CONCLUSION:

Presence of any one of the four predictors will identify with high sensitivity and moderate specificity nearly a quarter of the neonates in rural community as high risk, 3.4 to 6.6 days in advance, for intensive attention at home or referral.

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INTRODUCTION

The State of the World's Newborn report acknowledges that 98% of the estimated four million neonatal deaths globally occur in developing countries, most of them at home.[1] In India, nearly two-thirds of babies are born at home,[2] and few are taken for medical care, even if sick.[3–5] Thus, a crucial question in providing care and reducing neonatal mortality is, how can the home-cared neonates at higher risk of death be identified early?

By screening a population to identify those at higher risk of disease or death, one can select a smaller number for intensive attention, early treatment or referral. Screening tests are usually evaluated for their performance against some recognized standard. The measures of performance are *sensitivity* (ability of the test to correctly identify true positive individuals) and *specificity* (ability to correctly identify those who do not have the disease or risk of death, i.e. true negative individuals). The amount of time the diagnosis is early is called the *lead time*.[6]

Higher sensitivity is desirable, especially when the outcome being screened for is death. However, it is specificity that determines the total number of false positives.[6] Even a small loss of specificity can result in a large increase in the total number identified as positives, *the yield*, which includes true positives and false positives. The lower the specificity, the higher the yield (and false positives), making it more difficult and costly to find the true positives and to provide focused attention or care or referral. This attribute, the proportion of the yield that is truly positive is expressed by the *positive predictive value*.

There is a need to develop validated criteria to screen neonates at home and identify those at the risk of death. Integrated Management of Childhood Illnesses (IMCI) program of the WHO and UNICEF suggests a set of clinical danger signs for the referral of sick young infants.[7] But these have never been evaluated in community and validated. Low birth weight (LBW) or its surrogates identify high-risk neonates but may identify too many, nearly one-third, neonates in community in South Asia,[1] or may fail to identify some neonates dying of other causes such as infection or asphyxia.

The objective of this study is to develop simple clinical criteria for use in home-cared neonates for early identification of risk of death.

METHODS

To develop the criteria for identifying neonates at risk of death, we used the data collected in the field trial of home-based neonatal

care in rural Gadchiroli[5,8,9] on a cohort of 763 neonates in 39 villages for the year April 1995 to March 1996, among whom 40 neonatal deaths occurred. Rothman and Greenland recommend that a screening test developed on one population usually performs less satisfactorily when applied to another. Hence, to assess the performance of a test, it should also be tested on another population besides the one on which it was originally used.[6] Accordingly, the screening criteria developed on this cohort were then further evaluated on the another cohort of neonates in the same 39 villages in the subsequent years April 1996 to March 1998, a period of active interventions in the field trial. We evaluated the criteria against neonatal deaths during days 0 to 28.

In the first year of the field trial, 39 trained female village health workers (VHWs) in 39 villages examined the neonates born in their villages. They did this on the day of birth within 6 hours and, subsequently, by making seven more home visits on days 2, 3, 5, 7, 15, 21, and 28. On the first day, they measured the birth weight using Salter weighing scales. They estimated the period of gestation from the history of the last menstrual period, usually recorded by them during the fourth month of pregnancy. In each home visit, they recorded the data on various maternal and neonatal symptoms and signs and these data were checked by a physician who visited each neonate in the field once in 15 days. A parallel recording of data on neonatal variables in a sample of 119 neonates revealed 92% agreement between the data recorded by the VHWs and the physician.[5,9,10] The neonatal births and deaths were recorded by the VHWs, as well as by an independent vital statistics surveillance system. We have earlier described the methods of clinical data collection, definitions, frequencies and percent fatality in various morbidities, and the surveillance of vital statistics.[5,8,9]

To identify the neonates at risk of death, we first searched for a set of clinical predictors present on the day of birth. Using univariate analysis, we evaluated 25 clinical variables on which data were collected in 1995 to 1996. Those with significant or near-significant association with neonatal death were further analyzed by logistic regression. Although all three birth weight categories showed significant association, we selected only one, <2000 g, for entering in the logistic regression model because it had the highest relative risk, and because other category, <2500 g, would have included a very large proportion (42%) of neonates. In the gestational age categories, <37 weeks was entered, which included other two categories of preterm birth. Thus, total 14 variables were entered in the regression model.

[Strong correlations between independent variables in a logistic regression model may sometimes cause multicollinearity, which may even result in incorrect conclusions (Kleinbaum DG. *Logistic Regression*. New York: Springer-Verlag; 1994). We assessed for the presence of multicollinearity among the selected 14 variables, using SAS Macro. A condition index (CI) of ≥ 20 indicates presence of collinearity in the model, and variance decomposition proportion (VDP) of ≥ 0.5 identifies the specific variables involved in collinearity (1. Kleinbaum DG. *Epidemiologic Modeling. Course Material for the Course Epi 740*. Rollins School of Public Health, Emory University, Atlanta; 2. David Garson. *Quantitative Research in Public Administration. Course Material for the Course PA 765*. North Carolina State University, Raleigh, North Carolina). We found multicollinearity between ''chest indrawing'' and ''grunt'' (highest CI 27.60 and highest VDP 0.97). After removing the chest-indrawing variable from the model, there was no multicollinearity among the remaining 13 variables. (Highest CI 6.5 and VDP as 0.22.)]

By backward elimination from the 13 remaining noncollinear variables in the regression model, we identified a smaller set, in which each clinical variable had a significant association with death. The presence of any one clinical feature in the set was evaluated[6] for its ability to predict neonatal death by estimating sensitivity, specificity, positive predictive value and yield. We then attempted to improve the predictors by eliminating one clinical variable at a time and estimating the resultant performance of the remaining predictors as well as the resultant yield. We selected a set of three clinical variables. We then evaluated this set against the other cohort of neonates from the same 39 villages on which data were collected during the intervention phase (1996 to 1998) of the trial.

To further improve the sensitivity of the criteria present on the day of birth, we explored the danger signs that mothers could identify/report on the remaining days of the neonatal period (days 2 to 28). We evaluated 13 maternally reported symptoms for their ability to identify additional neonatal deaths that the clinical features on the first day had missed. We evaluated the three symptoms that identified maximum additional deaths during the entire neonatal period. The best performing symptom among these was added to the three earlier identified high-risk criteria present on the day of birth. The performance of this combined set of four criteria was evaluated first on the cohort of 1995 to 1996, and then in the intervention years (1996 to 1998). We assessed the lead time, that is, days prior to death that would allow these criteria to identify the neonates as high risk. In those neonatal deaths that were missed (false negative) by this final set of criteria, we also looked into the causes of death[11] and the antemortem clinical features to explore whether we could have identified these deaths by any other clinical predictor.

We used SPSS PC+, version 5 for data analysis. This study is based on the analysis of data collected in another study,[5,8,9] which also reported on the consent and the ethical aspects.

RESULTS

The neonatal cohort in 1995 to 1996 included 763 neonates, of whom 40 died during neonatal period. The frequency of different

clinical features present on the day of birth among the neonates who subsequently died and among those who survived; and the association with neonatal death represented by the relative risk are presented in Table 1. The 18 clinical variables showed significant or near-significant association. The nonsignificant variables are listed in the footnote of Table 1.

When the 13 significant clinical variables were put into the logistic regression model and backward elimination applied, five showed significant association. Table 2 shows these five: birth weight <2000 g, preterm birth (<37 weeks completed), skin color pale or yellow, baby not taking feeds and baby's skin temperature <95°F.

Table 3 presents the performance of ''presence of any one of this set of five clinical variables'' as a screening test, and the effect of eliminating the variable ''color of the skin pale or yellow'' and ''baby's skin temperature <95°F''. Removing these two variables caused little loss of sensitivity, but improved specificity, and thereby reduced the yield from 26.5% to 18.5%. Thus, only the remaining three, that is, birth weight <2000 g, preterm birth or baby not taking feeds on the first day, were selected as the clinical predictors of a high-risk neonate. When this set was evaluated on the cohort of 1598 neonates and 38 neonatal deaths during the 1996 to 1998 intervention phase (Table 3), the performance level was less. The resultant sensitivity was 68.4%; specificity, 83.4%; positive predictive value, 9.1% and yield, 17.8%.

Among maternally recognized symptoms, Table 4 shows the performance of the three selected symptoms in neonates during days 1 to 28 that identified the largest number of deaths. The ''reduced or stopped sucking'' present in 137 neonates of whom 31 died gives the highest sensitivity (77.5%) as well as the longest lead time: 4.9 days. It identifies three deaths missed by the earlier criteria on the day of birth.

Since ''not taking feeds'' was also one of the three selected clinical criteria on the day of birth, the symptom of reduced/stopped sucking on days 2 to 28, reported by mother, was added to the three criteria on the day of birth. The performance of the combined set is presented in Table 5. The combined set (any one of the three on day of birth or reduced/stopped sucking on days 2 to

Table 1 Association of Selected* Clinical Features Present on the Day of Birth with Eventual Neonatal Death (1995 to 1996, $n = 763$ and Neonatal Deaths = 40)

Clinical features	Present in deaths (40)		Present in survivors (723)		Relative risk	p
	No.	%	No.	%		
Weak cry/respiration at 1 minute	16	40.0	100	13.8	3.7	<0.001
Weak cry/respiration at 5 minutes	15	37.5	74	10.2	4.5	<0.001
Birth weight (g)						
<1500	9	22.5	4	0.6	16.8	<0.001
<2000	27	67.5	47	6.5	19.3	<0.001
<2500	36	90.0	284	39.3	12.5	<0.001
Gestation period (weeks)						
<35	15	37.5	9	1.2	18.5	<0.001
<36	19	47.5	32	4.4	12.6	<0.001
<37	25	62.5	50	6.9	15.3	<0.001
Drowsy or unconscious	3	7.5	1	0.1	15.4	<0.001
Cry weak or no cry on 1st day	9	22.5	9	1.2	12.0	<0.001
Breast problems	4	10.0	24	3.3	3.0	<0.08
Baby not taking feeds	9	22.5	30	4.1	5.4	<0.001
Skin color; pale or yellow[a]	8	21.6	6	0.8	14.5	<0.001
Chest indrawing[b]	4	10.8	1	0.1	18.2	<0.001
Grunt[c]	3	8.1	4	0.6	9.4	<0.001
Baby skin temperature <95°F[d]	11	31.4	68	9.9	3.7	<0.001
One limb unable to move[e]	2	5.7	6	0.8	5.7	<0.001
Less tone of limbs	5	12.5	4	0.6	12.0	<0.001

*Other seven signs and symptoms evaluated showed nonsignificant association with death. They are: mother had fever 7 days prior to delivery, prolonged rupture of membrane, prolonged labor, neonatal respiratory rate ≥60, blue color of tongue, stops breathing intermittently, abnormal head size.
Corresponding denominators among dead and survivors respectively; a: 37 and 714, b: 37 and 719, c: 37 and 718, d: 35 and 684, e: 35 and 720.

Table 2 Clinical Features* Present on the Day of Birth, Selected by Logistic Regression for their Significant Association with Neonatal Death

Variable	Beta	Odds ratio	95% CI	*p*
Birth weight <2000 g	2.4151	11.2	4.7–26.6	<0.000
Gestation period <37 weeks	1.9837	7.3	3.1–17.3	<0.000
Color of skin pale or yellow	1.7280	5.6	1.4–22.8	<0.016
Baby not taking feeds	1.5191	4.6	1.5–14.2	<0.009
Baby's skin temperature <95°F	1.2024	3.3	1.2–9.0	<0.019

*The logistic regression model tested included following other variables: weak cry/respiration at 1 minute, weak cry/respiration at 5 minutes, drowsy or unconscious, cry weak or no cry, breast problems, grunt, one limb unable to move, loose strength of limbs. These nine clinical features were rejected after backward elimination.

28) gave, in 1995 to 1996, a sensitivity of 95.0%; specificity, 77.3%; predictive value, 18.8% and yield of 26.5%; in 1996 to 1998 these values were 86.8, 78.0, 8.8 and 23.5%.

The mean lead time gained by different criteria in the preintervention year and the intervention years is presented in Table 6. The mean lead time was 6.6 days in 1995 to 1996 and 3.4 days in 1996 to 1998.

The number of deaths missed by the final set was only two in 1995 to 1996 and five in 1996 to 1998. Review of their antemortem records did not reveal any clinical feature that could have predicted the risk of death. The cause of death assigned by the neonatologist[11] showed that no cause could be assigned in five out of these seven deaths. In the remaining two (both during 1996 to

Table 3 Evaluation of the Sets of Clinical Criteria on the Day of Birth to Predict Neonatal Death

Set of Clinical criteria (presence of any one or more on the day of birth)	True positive	False negative	False positive	True negative	% Sensitivity	% Specificity	% PPV*	% NPV†	% Yield
In 1995 to 1996									
A. Selected by logistic regression: Birth weight <2000 g; Gestation period <37 weeks; Color of skin pale or yellow; Baby not taking feeds; Baby's temperature <95°F	37	3	165	558	92.5	77.2	18.3	99.5	26.5
B. After removing "color of skin" from A	37	3	165	558	92.5	77.2	18.3	99.5	26.5
C. After removing "baby's temperature <95°F" from B	35	5	106	617	87.5	85.3	24.8	99.2	18.5
Performance of the selected set in 1996 to 1998									
Birth weight <2000 g; Gestation period <37 weeks; Baby not taking feeds	26	12	259	1301	68.4	83.4	9.1	99.1	17.8

*Positive predictive value.
†Negative predictive value.

Table 4 Performance of Maternally Reported Symptoms during 1 to 28 Days as Predictors of Neonatal Death

	Neonates	Deaths	Additional deaths*	% Sensitivity	% Specificity	% PPV†	% Yield	Mean day of diagnosis	Mean day of death	Lead time available
In 1995 to 1996 (n = 763, deaths = 40)										
Cry weak/different	90	23	3	57.5	90.7	25.6	11.8	4.1	8.1	4.0
Sucking reduced or stopped	137	31	3	77.5	85.3	22.6	18.0	4.3	9.2	4.9
Drowsy or unconscious	46	23	2	57.5	96.8	50.0	6.0	5.1	9.0	3.9
In 1996 to 1998 (n = 1598, deaths = 38)										
Cry weak/different	150	21	4	55.3	91.7	14.0	9.4	2.8	5.8	3.0
Sucking reduced or stopped	207	31	7	81.6	88.7	15.0	13.0	2.5	4.9	2.4
Drowsy or unconscious	72	16	4	42.1	96.4	22.2	4.5	4.3	6.8	2.5

*Over and above those identified by the three criteria on the day of birth (Table 3).
†Positive predictive value.

Table 5 Final Set of Clinical Criteria to Predict Neonatal Death

Clinical criteria (presence of any one or more)	True positive	False negative	False positive	True negative	% Sensitivity	% Specificity	% PPV*	% NPV†	% Yield
Presence of any one on the day of birth	In the preintervention year (1995 to 1996, $n = 763$, neonatal deaths = 40)								
Birth weight <2000 g	38	2	164	559	95.0	77.3	18.8	99.6	26.5
Gestation period <37 weeks	In the intervention period (1996 to 1998, $n = 1598$, neonatal deaths = 38)								
Baby not taking feeds	33	5	343	1217	86.8	78.0	8.8	99.6	23.5
Or, mother reports that sucking reduced/stopped during 2 to 28 days									

*Positive predictive value.
†Negative predictive value.

Table 6 Lead Time with High-Risk Criteria Selected

Period of observation	No. of deaths identified	Mean day of diagnosis	Mean day of death	Lead time available (days)
1995 to 1996 (n = 763, deaths = 40)				
Any one of the three high-risk criteria on first day	35	1.0	7.9	6.9
Any one of the three high-risk criteria on first day or sucking reduced or stopped 2 to 28 days	38	1.5	8.1	6.6
1996 to 1998 (n = 1598, deaths = 38)				
Any one of the three high-risk criteria on first day	26	1.0	4.6	3.6
Any one of the three high-risk criteria on first day or sucking reduced or stopped 2 to 28 days	33	2.1	5.5	3.4

1998), cause could not be assigned from the data recorded by the VHWs, but sepsis was assigned as the most probable cause, based on the additional information retrospectively collected by the supervisor.

DISCUSSION

This inquiry into clinical predictors that can identify neonates in community at risk of death used prospectively observed data on the cohorts of neonates in 39 villages during 1 year of minimum interventions and 2 years of full interventions. It yields two clinical sets as the possible predictors of high-risk neonates, which can be used in different settings:

(1) Where a visit by health workers to neonates on the day of birth is possible, these three criteria on the first day of life: birth weight <2000 g, preterm birth (<37 weeks) or baby not taking feeds; and mother's report that baby's feeding has decreased or stopped at any time during days 2 to 28 together make a good combination. Presence of any one of these four criteria predicted eventual neonatal death with high sensitivity (87 to 95%) and moderately high specificity (77 to 78%), identifying nearly a quarter of neonates in community as high-risk neonates, 3.4 to 6.6 days ahead of death.

(2) Where a visit or evaluation on the day of birth is not possible, the mother's report about feeding alone on days 1 to 28 can be used as the danger signal. This will give 77% sensitivity and 85% specificity and will identify 18% of neonates as high-risk, an average 4.9 days ahead of death. However, such maternal reports were elicited in this field trial only when a health worker made eight home visits to inquire about symptoms. In the absence of home visits, the frequency of maternal reporting and hence sensitivity may decline steeply.

There are a few limitations of this study. In the first year of observation, 75% of neonates born in the 39 study villages were observed, while 268 neonates and 12 neonatal deaths were not observed.[5] The two groups may not be completely similar. However, the stillbirth and the neonatal mortality rates in the observed and unobserved births were similar. Moreover, in the subsequent years the proportion of neonates not observed decreased. Thus, in 1997 to

1998, only seven percent of neonates were not observed.[8] Since the predictors were evaluated on these data from later years as well, the effect of selection bias in the observed group, if any, is expected to be small.

The quality of data collection was highly satisfactory, showing 92% agreement with the data collected by a physician on a subsample.[5,8,10] The birth and child death recording by the vital statistics surveillance system was high, at 98%.[8]

The decreased sensitivity of the clinical predictors in the intervention years, as compared to the minimum intervention year as seen in Table 3, is probably due to the fact that, during the intervention phase many neonates with clinical features were treated, and deaths averted. Hence, the neonatal mortality rate decreased from 52 in 1995 to 1996 to 25 in 1997 to 1998.[8] This probably resulted in selectively difficult-to-detect high-risk neonates in the cohort in 1996 to 1998. That may also explain why the mean lead time declined from 6.6 to 3.4 days.

LBW (<2500 g) is often used to mark high-risk neonates. It is true that the LBW neonates are at a higher risk of death and between 40 and 80% deaths globally occur in LBW neonates.[1] Used alone, it may identify between 40 and 80% neonates at the risk of death, that is, it has only a moderate sensitivity. Moreover, in South Asia, where nearly a third of the babies are born LBW,[1] it is somewhat less specific. In this cohort, 42% neonates were born LBW,[5,10] hence the yield would be 42%. In comparison, our criteria are more specific, since they identify approximately 25% of the neonates in community as high risk. They are more sensitive as well, giving a sensitivity of 85 to 95%.

Many investigators have evaluated different surrogates to birth weight. But these all were evaluated in neonates in hospitals.[12–14] No other clinical predictors of high risk in neonates have been evaluated on a cohort of neonates in community in developing country setting. Hence it is not possible to compare the performance of our criteria with others.

These criteria were developed in a field trial in rural Gadchiroli. Their generalizability in other areas and other developing countries needs to be tested. Their performance is conditional on using similar field methods. The prerequisites are:

1. Recording last date of menstrual period in pregnant women to assess the period of gestation at birth.
2. Presence of a trained health worker to measure birth weight on the day of birth or within a short time.
3. Repeated home visits to inquire about symptoms (''reduced or stopped taking feeds'') in neonates.

In the absence of a routine evaluation on the day of birth, the mother's history of the baby's ''reduced or stopped taking feeds'' may be used as it shows fairly high sensitivity in this study wherein VHWs made frequent home visits to inquire. Depending only on parents' ability to recognize and voluntarily report this symptom to a source of care may be insufficient, as low care-seeking has been observed for neonatal sicknesses.[4,5] Whether health education can improve the voluntary care seeking to high level is not known. Neonates who are born in hospitals are usually discharged within 24 to 48 hours, and most of them do not receive any postnatal visit.[15] In such situation, only the three high-risk predictors on the first day may be used, albeit with lower sensitivity.

SIGNIFICANCE

These high-risk criteria will identify nearly 25% of neonates in rural homes in India in whom 85 to 95% of neonatal deaths are expected to occur. The performance of these criteria will go a long way toward making the high-risk approach practicable.

Neonates are delicate and vulnerable human beings. They need care and attention. However, if the care and attention can be focused on those at higher risk, the returns in terms of lives saved will be much higher. These criteria allow a trained health worker and mother to identify neonates needing more attention. Such high-risk neonates should receive more visits by health workers and early treatment for any identified sickness. Alternatively, they can be referred to a medical facility where more evaluation and/or management can be provided.

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