Validation of community health workers' assessment of neonatal illness in rural Bangladesh

Gary L Darmstadt,[a] Abdullah H Baqui,[a] Yoonjoung Choi,[a] Sanwarul Bari,[b] Syed M Rahman,[b] Ishtiaq Mannan,[a] ASM Nawshad Uddin Ahmed,[c] Samir K Saha,[d] Radwanur Rahman,[b] Stephanie Chang,[a] Peter J Winch,[a] Robert E Black,[a] Mathuram Santosham[a] & Shams El Arifeen[b] for the Bangladesh Projahnmo-2 (Mirzapur) Study Group[e]

Objective To estimate the validity (sensitivity, specificity, and positive and negative predictive values) of a clinical algorithm as used by community health workers (CHWs) to detect and classify neonatal illness during routine household visits in rural Bangladesh.

Methods CHWs evaluated breastfeeding and symptoms and signs of illness in 395 neonates selected randomly from neonatal illness surveillance during household visits on postnatal days 0, 2, 5 and 8. Neonates classified with very severe disease (VSD) were referred to a community-based hospital. Within 12 hours of CHW assessments, physicians independently evaluated all neonates seen in a given day by one CHW, randomly chosen from among 36 project CHWs. Physicians recorded symptoms and signs of illness, classified the illness, and determined whether the newborn needed referral-level care at the hospital. Physicians' identification and classification were used as the gold standard in determining the validity of CHWs' identification of symptoms and signs of illness and its classification.

Findings CHWs' classification of VSD showed a sensitivity of 73%, a specificity of 98%, a positive predictive value of 57% and a negative predictive value of 99%. A maternal report of any feeding problem as ascertained by physician questioning was significantly associated ($P < 0.001$) with "not sucking at all" and "not attached at all" or "not well attached" as determined clinically by CHWs during feeding assessment.

Conclusion CHWs identified with high validity the neonates with severe illness needing referral-level care. Home-based illness recognition and management, including referral of neonates with severe illness by CHWs, is a promising strategy for improving neonatal health and survival in low-resource developing country settings.

Une traduction en français de ce résumé figure à la fin de l'article.   Al final del artículo se facilita una traducción al español.   .الترجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة

Introduction

Four million neonatal deaths occur globally every year, representing 38% of deaths in children under 5 years old.[1,2] Almost all of these deaths occur in low and middle-income countries, and more than half occur at home.[2,3] Improving neonatal health and survival requires cost-effective interventions at the community level, as well as linkages between the community and the health-care system within the continuum of care for the treatment of severe illness.[4–7] Trained community health workers (CHWs) can promote essential newborn care practices at home by educating parents on how to recognize the signs of illness and seek care, and by identifying danger signs through direct assessments at surveillance visits.[8,9] Once illness is identified, CHWs can refer sick infants to a facility[10] or manage illness at home if a referral is not complied with or is not feasible.[11–13] Successful management of neonatal illness requires accurate assessment, supported by an effective clinical guideline. Assessment by CHWs has been validated for older infants and children in facility settings,[14–21] but few studies have documented CHWs' accuracy in neonatal assess-

ment at the community level,[22] particularly in the first week of life, when 75% of neonatal deaths occur.[2]

The primary purpose of this study was to evaluate the performance of CHWs in recognizing signs and symptoms of neonatal illness during routine household surveillance in rural Bangladesh. Our main objectives were to estimate the validity of a clinical algorithm as used by CHWs to assess specific signs and symptoms and to classify neonatal illness, with physician assessment and classification used as the gold standard.

Methods

Study population and design

This prospective study was nested within Projahnmo-2, a cluster randomized controlled intervention trial of a maternal–neonatal health-care package in Mirzapur, Bangladesh. The neonatal mortality rate in the study area was 24 per 1000 live births in 2002. The area was served by Kumudini Hospital, a 750-bed, non-profit, private referral-level hospital. A population of about 292 000 resided in 12 rural unions, which were

Research
Gary L Darmstadt et al.
Neonates assessed by health workers in Bangladesh

randomly allocated to either an intervention (n = 6) or a control arm (n = 6).

In the intervention arm, we divided each union into 6 CHW areas, each having approximately 4000 people. CHWs identified pregnancies through routine bimonthly household surveillance. Pregnant women were visited at home twice during the antenatal period to promote preparedness for birth and newborn care. The mother and neonate were also scheduled for visits on the day of delivery (i.e. day 0) and on postnatal days 2, 5 and 8. During postnatal visits, CHWs assessed neonates for the presence of illness requiring referral to Kumudini Hospital, following the Mirzapur CHW clinical algorithm, adapted from the Bangladesh Young Infant Integrated Management of Childhood Illness (IMCI) protocol (Table 1, available at: http://www.who.int/bulletin/volumes/87/1/07-050666/en/index.html). CHWs ascertained 16 historical factors and 28 clinical signs, assessed breastfeeding and referred sick neonates to the hospital based on the algorithm. A total of 10 407 live births were reported between January 2004 and December 2006, and 7587 neonates were assessed by CHWs at least once (assessment rate 72.9%).

CHW recruitment and training

CHWs (n = 36) recruited through local advertisements were all female, 20–40 years old, and educated to secondary school certification or higher. To fill vacancies, 12 additional CHWs who met the requirements for initial CHW enrolment were recruited and trained, so that a total of 48 participated in the intervention study described above, hereafter referred to as the parent study. The average age of the 48 CHWs in the parent study was 27 years, 79% were married and the average schooling was 11 years.

We developed a manual for initial and refresher training in six areas: pregnancy surveillance and registration; antenatal counselling on preparedness for birth and newborn care; management of the neonate at birth, including resuscitation; continuing essential newborn care; routine neonatal assessment and illness classification; and management of illness according to the Mirzapur CHW clinical algorithm, including referral to the hospital. CHWs received initial training for 36 days (including 6 days of field practice) through didactic sessions, videos and practice on sick and healthy newborn babies in Kumudini Hospital. Their performance was monitored, evaluated and documented throughout the training, and their assessment of five neonates at the hospital was evaluated before they started field work.

Field supervisors used a standard checklist to monitor CHWs' neonatal assessment and management during field work, at scheduled and random evaluations. In each union, one field supervisor oversaw six CHWs by meeting with them for about 6 hours each fortnight to review all data collection forms and instructive case histories and to provide refresher training. Of the 36 CHWs recruited initially, 26 remained until the end of the project (attrition rate 27.8%). Of the 12 additional CHWs, 10 remained until the end (attrition rate 16.7%).

Mirzapur CHW clinical algorithm

Illness classification

The algorithm classified neonates with any of seven severe conditions requiring referral-level evaluation: very severe disease (VSD), possible very severe disease (PVSD), perinatal asphyxia, significant jaundice on the first day of life, possible gonococcal eye infection, bloody diarrhoea and diarrhoea with severe dehydration. A neonate was categorized as having VSD or PVSD if the CHW observed one or more of the signs and symptoms listed in Table 1. The algorithm also identified neonates with five minor conditions requiring management at home and a follow-up visit: fast breathing, oral thrush, localized bacterial infection, diarrhoea with dehydration and diarrhoea without dehydration (Table 1).

Feeding assessment

CHWs observed breastfeeding for at least 5 minutes to assess attachment, positioning and sucking. For attachment, CHWs assessed the four signs listed in Table 2 to categorize neonates as "well attached" (all four attachment observation points observed), "not well attached" (one or more of the points not observed) and "not attached at all" (neonate could not take the nipple into the mouth and keep it there to suck). For positioning, CHWs assessed the four signs listed in Table 2 to categorize neonates as "well positioned" (all four positioning observation points observed) or "not well positioned" (one or more points not observed). Finally, CHWs assessed sucking to categorize neonates as "sucking effectively" (slow, deep sucking with occasional pausing; apparently satisfied after feeding), "not sucking effectively" (only rapid and shallow sucks; apparently not satisfied after feeding) and "not sucking at all" (not able to suck breast milk into the mouth and swallow). A neonate was categorized as "having any feeding problem" if one or more of the feeding observation points was not confirmed. The complete inability to feed, attach or suck at all was categorized as a sign of VSD.

Management

For neonates recognized as having VSD, PVSD or any of the five specific severe conditions, CHWs recommended referral-level evaluation at Kumudini Hospital. CHWs facilitated transportation, if necessary, and all care at the hospital was free for referred neonates. If the family refused the referral, the CHW continued to encourage it but managed the neonate in the home according to the clinical algorithm.

CHW clinical algorithm validation study

A study was conducted between November 2005 and December 2006 to assess the validity of the clinical algorithm applied by the CHWs in the intervention arm. Study physicians from Kumudini Hospital randomly selected a CHW on each day and performed a complete history (including assessment of gestational age by maternal report of the first day of the last menstrual period) and physical examination of all the neonates who were enrolled in the parent study and were assessed by that CHW in a 24-hour period, except those being seen in follow-up by the CHW after a hospital visit. If a neonate was enrolled more than once for the validation study, we included only the first assessment in the analysis. A study physician completed the same newborn assessment form as the CHW, but male physicians did not assess breastfeeding due to cultural sensitivity. Neonates were assessed independently by a physician less than 12 hours after the CHW's assessment either at home (for well babies and referral failures) or at the hospital (for successfully referred neonates).

Data

A total of 4228 live births occurred in the intervention arm between November 2005 and December 2006, and 3038 neonates were assessed by CHWs at least once (assessment rate 71.9%), resulting in 10 957 CHW assessments. The study sample comprised 395 randomly selected neonates from the 3038 neonates. Both a CHW and a physician took a complete history and undertook a physical examination; in 317 (80%) cases, a CHW also undertook a complete breastfeeding assessment. A total of 8 study physicians and 36 CHWs participated in the validation study.

Statistical analysis

The unit of analysis was a CHW–physician assessment pair. We examined the association between the assessment by physicians and CHWs at two levels: assessment of individual signs and symptoms, and classification of neonates according to the presence of seven severe illnesses requiring referral to a hospital and of five minor illnesses requiring follow-up observations. The physicians' assessment and classification were considered the gold standard for calculating sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). Kappa statistics (K) were calculated to determine agreement between CHWs and physicians: poor (K < 0), slight (K = 0.0–0.20), fair (K = 0.21–0.40), moderate (K = 0.41–0.60), substantial (K = 0.61–0.80) and almost perfect (K = 0.81–1.00).[23]

We also examined associations between specific feeding problems observed by CHWs and generic feeding problems reported by mothers (as ascertained by physicians). Physicians asked mothers whether the baby had a feeding problem or not without seeking to define the problem. No gold standard was defined, and Pearson χ^2 tests were conducted to detect associations between each of the specific feeding problems observed by a CHW and each nonspecific feeding problem reported by the mother.

For χ^2 tests and K, a P-value of 0.05 was considered statistically significant. We used STATA 9.0 statistical software (Stata Corporation, College Station, TX, United States of America) for all analyses.

Table 2. **Frequency (%) of feeding problems classified by CHWs during breastfeeding assessments and χ^2 for association between CHW classification and physicians' ascertainment of a history of a feeding problem[a] in 317 neonates, Mirzapur, Bangladesh, 2005–2006**

Feeding problems	Frequency		Association	
	%	95% CI	χ^2 (DF = 1)	P-value
Feeding observation by CHWs				
Sign of improper attachment				
Chin not touching breast	5.4	3.2–8.4	6.2	0.013
Lower lip not turned outward	10.7	7.5–14.7	6.1	0.013
More areola below than above mouth	9.1	6.2–12.9	7.9	0.005
Mouth not wide open	5.4	3.2–8.4	16.7	0.000
Sign of improper positioning				
Head and body not straight	9.1	6.2–12.9	0.8	0.363
Body not close to mother	10.1	7.0–14.0	0.1	0.819
Entire body not fully supported	10.1	7.0–14.0	0.1	0.819
Not facing breast, nose not opposite nipple	1.9	0.7–4.1	5.0	0.026
Classification of feeding problems				
Attachment problem				
Not attached[b]	1.6	0.5–3.6	29.0	0.000
Not well attached[c]	11.0	7.8–15.0	0.0	0.894
Not attached or not well attached	12.6	9.2–16.8	4.6	0.032
Positioning problem				
Not well positioned[d]	16.4	12.5–20.9	0.1	0.763
Sucking problem				
Not sucking at all	0.9	0.2–2.7	117.0	0.000
Not sucking effectively[e]	5.0	2.9–8.1	1.0	0.329
Not sucking at all or not sucking effectively[e]	6.0	3.6–9.2	28.2	0.000
Any attachment, positioning or sucking problem	20.2	16.2–25.4	4.4	0.036

CHW, community health worker; CI, confidence interval; DF, degree of freedom (Pearson's χ^2 test for associations).

[a] Of 317 mothers, 8 (2.5%, 95% CI: 1.1–4.9%) reported that the baby "had a feeding problem" when asked by a physician.

[b] Neonate unable to take the nipple into the mouth and keep it there to suck.

[c] Neonate with one or more of the four signs of improper attachment listed above.

[d] Neonate with one or more of the four signs of improper positioning listed above.

[e] Effective sucking was defined as slow, deep sucking with occasional pausing.

The study was approved by the Committee on Human Research at the Johns Hopkins Bloomberg School of Public Health, and by the Ethical Review Committee and the Research Review Committee at the International Centre for Diarrhoeal Disease Research, Bangladesh, and was registered at clinicaltrials.gov (No. NCT00198627).

Results

Subjects

Of the 395 study neonates, 15.7% were born before 37 weeks' gestational age, and 88.1% were born at home (Table 3, available at: http://www.who. int/bulletin/volumes/87/1/07-050666/ en/index.html). About 70% and nearly all (97.8%) were assessed during the first 7 and 9 days of life, respectively.

Assessment of illness

Historical problems were reported rarely by mothers, but included yellow colour of body (3.8%), feeding problems (2.5%) and skin problems (1.8%) (Table 4). The most frequent signs were a respiratory rate of 60–69 breaths per minute (7.1%); jaundiced palms and soles after the day of birth (3.5%); and moderate hypothermia (2.5%). The frequency of VSD was 2.8%, and that of PVSD was 6.8%. No neonate presented

Research
Gary L Darmstadt et al.
Neonates assessed by health workers in Bangladesh

Table 4. Frequency (%) and validity of historical factors reported by mothers, clinical signs observed and classification of illness,[a] and Kappa statistics for agreement between assessments by CHWs and by physicians (gold standard) in Mirzapur, Bangladesh, 2005–2006

Historical factor or clinical sign	Frequency		TN	FN	FP	TP	Sensitivity		Specificity		PPV		NPV		K	P-value
	%	SE					%	SE	%	SE	%	SE	%	SE		
Historical factor																
Yellow body colour	3.8	1.0	379	15	1	0	0.0	0.0	99.7	0.3	0.0	0.0	96.2	1.0	0.00	0.58
Mother feels baby is hot	1.3	0.6	389	4	1	1	20.0	17.9	99.7	0.3	50.0	35.4	99.0	0.5	0.28	0.00
Any skin problems	1.8	0.7	387	6	1	1	14.3	13.2	99.7	0.3	50.0	35.4	98.5	0.6	0.22	0.00
Umbilical pus or redness, or foul smell	0.8	0.4	391	3	1	0	0.0	0.0	99.7	0.3	0.0	0.0	99.2	0.4	0.00	0.53
Clinical sign																
Respiratory rate ≥ 70 bpm	1.0	0.5	390	3	1	1	25.0	21.7	99.7	0.3	50.0	35.4	99.2	0.4	0.33	0.00
Respiratory rate 60–69 bpm	7.1	1.3	361	26	6	2	7.1	4.9	98.4	0.7	25.0	15.3	93.3	1.3	0.08	0.02
Severe fever: temperature > 101 °F (38.3 °C)	0.5	0.4	393	1	0	1	50.0	35.4	100.0	0.0	100.0	0.0	99.7	0.3	0.67	0.00
Moderate fever: temperature 100.0–101 °F (37.8–38.3 °C)	1.5	0.6	387	4	2	2	33.3	19.2	99.5	0.4	50.0	25.0	99.0	0.5	0.39	0.00
Severe hypothermia: temperature < 95.5 °F (35.3 °C)	0.8	0.4	389	0	3	3	100.0	0.0	99.2	0.4	50.0	20.4	100.0	0.0	0.66	0.00
Moderate hypothermia: temperature 95.5–97.5 °F (35.3–36.4 °C)	2.5	0.8	375	8	10	2	20.0	12.6	97.4	0.8	16.7	10.8	97.9	0.7	0.16	0.00
Weak, abnormal or absent cry	0.5	0.4	391	2	2	0	0.0	0.0	99.5	0.4	0.0	0.0	99.5	0.4	−0.01	0.54
Lethargic or less than normal movement	1.0	0.5	388	3	3	1	25.0	21.7	99.2	0.4	25.0	21.7	99.2	0.4	0.24	0.00
Unable to feed or suck, or not attached[b]	0.5	0.4	389	0	4	2	100.0	0.0	99.0	0.5	33.3	19.2	100.0	0.0	0.50	0.00
Skin pustules	2.0	0.7	381	6	6	2	25.0	15.3	98.4	0.6	25.0	15.3	98.4	0.6	0.23	0.00
Umbilicus discharging pus	2.0	0.7	384	5	3	3	37.5	17.1	99.2	0.4	50.0	20.4	98.7	0.6	0.42	0.00
Umbilical redness not extending to skin	0.8	0.4	388	3	4	0	0.0	0.0	99.0	0.5	0.0	0.0	99.2	0.4	−0.01	0.57
Jaundiced palms and soles after the day of birth	3.5	0.9	380	11	1	3	21.4	11.0	99.7	0.3	75.0	21.7	97.2	0.8	0.32	0.00
Ulcer or white patches inside the oral cavity	0.3	0.3	391	0	3	1	100.0	0.0	99.2	0.4	25.0	21.7	100.0	0.0	0.40	0.00
Classification of illness																
Very severe disease	2.8	0.8	378	3	6	8	72.7	13.4	98.4	0.6	57.1	13.2	99.2	0.5	0.63	0.00
Possible very severe disease	6.8	1.3	355	18	13	9	33.3	9.1	96.5	1.0	40.9	10.5	95.2	1.1	0.33	0.00
Local infection	4.3	1.0	369	11	9	6	35.3	11.6	97.6	0.8	40.0	12.6	97.1	0.9	0.35	0.00
Oral thrush	0.3	0.3	391	0	3	1	100.0	0.0	99.2	0.4	25.0	21.7	100.0	0.0	0.40	0.00

bpm, breaths per minute; FN, false negative; FP, false positive; K, Kappa statistics; TN, true negative; TP, true positive; NPV, negative predictive value; PPV, positive predictive value; SE, standard error; VSD, very severe disease.

[a] Validity (sensitivity, specificity, positive predictive value, negative predictive value) was not estimated for 5 historical factors, 12 clinical signs and 7 illness classifications whose frequency was 0%. The 5 historical factors were: no breathing immediately after birth; unconscious; persistent vomiting; blood in stool*; and vomiting everything. The 12 clinical signs were: convulsion; severe chest in-drawing; bulging fontanelle; unconsciousness; many or severe skin pustules; umbilical redness extending to abdominal skin; unable to drink or drinks poorly*; lethargic or unconscious*; slow skin pinch retraction (> 2 seconds)*; drinks eagerly*; restless or irritable*; and skin pinch retraction time > 2 seconds*. The 7 illness classifications were: perinatal asphyxia; significant jaundice on the first day of life; possible gonococcal eye infection; diarrhoea with blood; diarrhoea with severe dehydration; diarrhoea with some dehydration; and diarrhoea without dehydration. Since the classification of "fast breathing" is based on one clinical sign ("respiratory rate 60–69 per minute") that is presented under "observation of individual signs", validity estimates of the classification are not repeated. In addition, validity was not estimated for 7 historical factors and 2 clinical signs whose frequency was > 0% but for which no false positive or true positive results were obtained. The 7 historical factors and their frequencies (in parentheses) were: no cry immediately after birth (0.5%); convulsion (0.3%); difficult breathing (1.3%); mother feels baby is cold (1.0%); weak, abnormal or absent cry (0.3%); baby lethargic or less active than normal (0.5%); and feeding problem (2.5%). The 2 clinical signs were jaundice anywhere in the body within 24 hours after birth (0.3%) and eye discharging pus (0.3%).

* Assessed only if a mother reported the neonate had diarrhoea.

[b] Assessed by female physicians and nurses.

with 5 of the 16 historical factors, 12 of the 28 clinical signs and 7 of the 12 illness classifications in the clinical algorithm (Table 4).

Sensitivity and PPV varied greatly across individual historical factors and clinical signs; standard errors were large due to low prevalence. Severe fever and severe hypothermia had higher sensitivity (50% and 100%, respectively) and better agreement (K = 0.67 and 0.66, respectively) than moderate fever (sensitivity 33%; K = 0.39) and moderate hypothermia (sensitivity 20%; K = 0.16). Sensitivity for fast breathing was fairly low: 25% for a respiratory rate ≥ 70 breaths per minute, and 7% for a respiratory rate of 60–69 breaths per minute. K also indicated fair (0.33) agreement for a respiratory rate ≥ 70 breaths per minute and slight agreement (0.08) for a rate of 60–69 breaths per minute. Specificity was better than 97% and NPVs were higher than 93% across all historical factors and clinical signs.

Sensitivity for VSD classification was 73%, specificity was 98%, PPV was 57% and NPV was 99%. Classification of PVSD had lower validity (sensitivity 33%, specificity 97%, PPV 41% and NPV 95%). K was 0.63 for VSD and 0.33 for PVSD.

Assessment of feeding

CHWs observed at least one feeding problem in 20% of neonates (Table 2). About 13%, 16% and 6% had at least one sign of an attachment, positioning or sucking problem, respectively; 1.6% were not attached at all and 0.9% were not able to suck at all. Eight neonates (2.5%) were reported to have a feeding problem by their mothers, as ascertained by physicians. Maternal report of any feeding problem was significantly associated with "not sucking at all" and "not attached" as classified by CHWs, as well as with all individual signs of attachment problems observed on the feeding assessment (Table 2). Only one positioning sign (not facing the breast, nose not opposite nipple) was associated with a reported feeding problem.

Discussion

We assessed the validity of a clinical algorithm used by CHWs to assess clinical signs and symptoms of illness and to classify such illness, particularly

VSD, in a community-based sample of neonates largely younger than 7 days. Close links between the community and Kumudini Hospital facilitated physician evaluations of neonates at home.[10] Classification of VSD by CHWs – based on identification of one or more of 11 signs and symptoms – showed substantial agreement with that of physicians, as well as high sensitivity and high specificity.

Few studies have evaluated the validity of CHW assessment of clinical signs or symptoms or classification of illness in neonates. Kalter et al. included 234 infants aged 1 week to 2 months in their IMCI referral algorithm validation study (26% of their total sample), but the results were not reported separately for the young infants and did not include neonates in the first week of life.[24] Mullany et al. evaluated the validity of village-based workers' assessment of signs of neonatal umbilical cord infection but used physician evaluation of photographs of umbilical cords rather than direct examinations.[22] The validity of VSD classification by CHWs compared to physicians' assessment in our study was similar to that of pneumonia classification reported for children aged 2 months to 5 years in other IMCI studies in hospital settings: sensitivity of 76% in Uganda,[18] sensitivity of 81% and specificity of 89% in the Gambia,[14] sensitivity of 88% and specificity of 87% in Ethiopia[17] and sensitivity of 97% and specificity of 49% in Kenya.[21] In the United Republic of Tanzania, significantly higher interobserver variation was reported, even between physicians, in assessments of oedema and unarousable coma in infants compared to children 1–4 years of age.[16]

Among individual clinical signs, fast breathing (both respiratory rate ≥ 70 and 60–69 breaths per minute) had low validity, which suggests difficulties in measuring respiratory rate in young neonates or variability over time (or both). The sign "weak, abnormal or absent cry" also had low validity, perhaps due to its subjective nature (as suggested by Mullany et al. as an explanation for the low validity of umbilical cord swelling compared to other more objective signs of cord infection).[22] In infants aged 2 months to 5 years, Simoes et al. also found that chest in-drawing had lower sensitivity than tachypnoea, a more objective sign,

resulting in most of the false negative classifications recorded for severe pneumonia.[17] In another study in the United Republic of Tanzania, assessment of chest in-drawing in children aged 4 months to 6 years showed only fair agreement, even between physicians (K = 0.338).[16] The prevalence of severe chest in-drawing in our cohort was too low to assess validity.

In addition to clinical signs, our CHWs gathered historical information on neonatal illness. A history of a feeding problem, as reported by the mother to a physician, was significantly associated with the presence of a severe feeding problem (particularly a lack of ability to suck) as assessed by CHWs. The sign "unable to feed, or unable to suck at all, or not attached at all" was included in the VSD algorithm. However, assessing breastfeeding is complex, time-consuming and difficult for male physicians due to cultural sensitivity. Given these limitations, a reported history may substitute for an observed feeding problem in the algorithm, substantially simplifying the assessment. Other historical factors in neonatal illness were of limited use in the algorithm, being either too low in prevalence to assess validity or having high specificity but unacceptably low sensitivity. A larger sample is needed for definitive assessment of their validity.

Our study population had a relatively low burden of severe neonatal illness (VSD prevalence 2.8%) compared, for example, to the neonatal sepsis incidence of 10.5% reported in Maharashtra, India.[12] For many of the individual signs and symptoms, the frequencies of true positive, false positive and false negative results were too low to estimate validity. Our study population also had relatively low mortality and prevalence of HIV infection and malaria.[25,26] Further validation of CHW performance in assessing neonatal illness in other settings with different rates and types of illness (e.g. high HIV and malaria prevalence) is warranted. The agreement possible between CHW and physician assessments was limited by the average lag time of 3.0 hours, during which volatile signs may have changed. The performance of a group of CHWs may also be affected by attrition, as relatively inexperienced workers enter the pool of CHWs. The implications of this issue for programmes will be addressed in a separate report.

Conclusion

We found that CHWs were able to identify a constellation of key clinical signs and symptoms of severe illness with a high level of validity in the context of routine, population-based household surveillance. The use of CHWs to identify and refer neonates with severe illness in the home using an IMCI algorithm is a promising strategy for improving neonatal health and survival in low-resource developing country settings.[10] In certain settings with poor facility-based health care, CHWs can also manage neonates.[11,12,27]

CHWs' assessments showed high validity for recognizing neonates with severe illness needing referral-level care.

Home-based recognition and management – including referral of neonates with severe illness by CHWs – show promise as a strategy for improving neonatal health and survival in low-resource developing country settings. ■

Résumé

Validation de l'évaluation par les agents de santé communautaires des maladies néonatales dans le Bangladesh rural

Objectif Estimer la validité (c'est-à-dire la sensibilité, la spécificité et les valeurs prédictives positive et négative) d'un algorithme clinique tel qu'utilisé par les agents de santé communautaires pour détecter et catégoriser les maladies néonatales lors des visites systématiques dans les foyers, dans le Bangladesh rural.

Méthodes Les agents de santé ont évalué l'allaitement et les symptômes et signes de maladie chez 395 nouveau-nés sélectionnés au hasard, dans le cadre de la surveillance des maladies néonatales, lors des visites à domicile effectuées le jour de la naissance et les 2e, 5 et 8e jours après la naissance. Les nouveau-nés classés comme atteints d'une maladie très grave ont été orientés vers un hôpital communautaire. Dans les 12 jours suivant les évaluations par les agents de santé, des médecins ont évalué indépendamment tous les nouveau-nés vus au cours d'une journée par un agent de santé sélectionné au hasard parmi 36 agents de santé participant au projet. Les médecins ont enregistré les symptômes et les signes de maladie, catégorisé l'éventuelle maladie et déterminé si le nouveau-né nécessitait des soins spécialisés dans un hôpital. L'identification et la classification effectuées par les médecins ont servi de référence pour évaluer la validité de l'identification des symptômes et des signes de maladie et de la catégorisation des cas par les agents de santé.

Résultats L'identification par les agents de santé des maladies très graves présentait une sensibilité de 73 %, une spécificité de 98 %, une valeur prédictive positive de 57 % et une valeur prédictive négative de 99 %. Le signalement par la mère d'un problème d'allaitement lors de l'interrogatoire mené par le médecin était associé de manière significative (p < 0,001) aux observations cliniques « absence totale de succion » et « ne prend pas le sein » ou « prend mal le sein », faites par les agents de santé pendant l'évaluation de l'allaitement.

Conclusion L'identification par les agents de santé des nouveau-nés atteints d'une maladie grave et nécessitant des soins spécialisés présentait un haut niveau de validité. La reconnaissance à domicile des maladies et leur prise en charge, y compris l'aiguillage des nouveau-nés gravement malades vers des soins spécialisés, par des agents de santé représente une stratégie prometteuse pour l'amélioration de la santé et de la survie des nouveau-nés dans les pays en développement disposant de peu de ressources.

Resumen

Validación de la evaluación de las enfermedades neonatales por agentes de salud comunitarios en el Bangladesh rural

Objetivo Estimar la validez (sensibilidad, especificidad y valores predictivos positivo y negativo) de un algoritmo clínico en la forma en que lo usaban agentes de salud comunitarios (ASC) para detectar y clasificar las enfermedades neonatales en las visitas domiciliarias sistemáticas en zonas rurales de Bangladesh.

Métodos Los ASC evaluaron las prácticas de lactancia materna y los signos y síntomas de enfermedad en 395 recién nacidos seleccionados aleatoriamente mediante los sistemas de vigilancia de la morbilidad neonatal con ocasión de visitas domiciliarias realizadas a los 0, 2, 5 y 8 días del nacimiento. Los recién nacidos clasificados con enfermedades muy graves (EMG) fueron derivados a un hospital comunitario. En el término de las 12 horas siguientes a esos exámenes realizados por los ASC, los médicos exploraron de forma independiente a todos los recién nacidos examinados en un determinado día por un ASC, elegido al azar entre los 36 ASC participantes en el proyecto. Los médicos registraban los signos y síntomas de la enfermedad, clasificaban la enfermedad y determinaban si el recién nacido necesitaba atención de referencia

en el hospital. La identificación y la clasificación que realizaron los médicos se utilizaron como criterio de referencia para determinar la validez de la identificación de los signos y síntomas y la clasificación de la enfermedad realizadas por los ASC.

Resultados La clasificación de las EMG realizada por los ASC mostró una sensibilidad del 73%, una especificidad del 98%, un valor predictivo positivo del 57% y un valor predictivo negativo del 99%. Las referencias de las madres a cualquier problema de lactancia en sus respuestas a los médicos se asociaron de forma significativa (*p* < 0,001) a la observación por parte de los ASC, en

su evaluación de ese aspecto, de que el lactante no succionaba en absoluto o bien no prendía el pezón o lo prendía mal.

Conclusión Los ASC identificaron con una alta fiabilidad a los recién nacidos con enfermedades graves que necesitaban atención de referencia. El diagnóstico y manejo domiciliario de las enfermedades, incluida la derivación de los recién nacidos con enfermedades graves por los ASC, constituye una estrategia prometedora para mejorar la salud y la supervivencia de los recién nacidos en los entornos con pocos recursos de los países en desarrollo.

ملخص

صحة تقييم العاملين الصحيين المحليين لأمراض الولدان في أرياف بنغلاديش

الهدف: تقييم صحة الخوارزمية السريرية (الإكلينيكية) كما يستخدمها العاملون الصحيون المحليون عند زياراتهم الروتينية للأسر في أرياف بنغلاديش (من حيث الحساسية، والنوعية، والقيم الإرشادية الموجبة والسالبة).

الطريقة: قام العاملون الصحيون المحليون بتقييم الإرضاع من الثدي وأعراض وعلامات المرض لدى 395 وليداً اختيروا عشوائياً عن طريق ترصُّد الحالات خلال زيارات تمت للأسر في يوم الولادة، وبعدها بيومين، ثم بخمسة أيام، ثم بثمانية أيام. وأحيل الولدان الذين صُنفت حالاتهم بالإصابة بمرض وخيم جداً إلى مستشفى محلي. وقام الأطباء، في غضون 12 ساعة من تقييم العاملين الصحيين المحليين، بإجراء تقييم مستقل لجميع الولدان الذين فحصوا من قِبَل أحد العاملين الصحيين، في يوم معين، يختار عشوائيا من بين الـ 36 عاملاً صحياً المشاركين في هذا المشروع. وسجل الأطباء الأعراض والعلامات المرضية، وصنفوا المرض، وحددوا ما إذا كان الوليد يحتاج إلى الإحالة لتلقي مستوى رعاية أعلى في المستشفى. واستُخدم تحديد وتصنيف الأطباء كمعيار مرجعي لتقرير مدى صحة الأعراض والعلامات المرضية المحددة والمصنفة من قِبَل العاملين الصحيين المحليين.

الموجودات: جاءت معدلات التصنيفات التي حددها العاملون الصحيون للأمراض الوخيمة جداً لدى الولدان بنسبة 73% من حيث الحساسية، و98% من حيث النوعية، و57% للقيمة الإرشادية الموجبة، و99% للقيمة الإرشادية السالبة. وبالنسبة لإفادات الأمهات في ما يختص بمشاكل الإرضاع على النحو الذي تأكد من خلال أسئلة الأطباء، فقد جاءت مرتبطة ارتباطاً يعتد به إحصائياً (نسبة الاحتمال أقل من 0.001) بعبارات "لا يمصّ مطلقاً"،أو "لا يلتصق بالثدي مطلقاً" أو "لا يلتصق بالثدي جيداً"، وذلك على النحو الذي تقرر سريرياً (إكلينيكياً) من قِبَل العاملين الصحيين عند تقييمهم للإرضاع.

الاستنتاج: أمكن للعاملين الصحيين المحليين التعرُّف بدرجة عالية من الصحة على الولدان المصابين بأمراض وخيمة تستوجب الإحالة لتلقّي الرعاية في مرافق الإحالة. وإن تعرُّف العاملين الصحيين المحليين على الأمراض وتدبيرها في منازل المرضى، بما في ذلك إحالة الولدان المصابين بأمراض وخيمة، يُعَدُّ استراتيجية واعدة لتحسين صحة الولدان وبقائهم على قيد الحياة في مختلف مناطق البلدان النامية الشحيحة الموارد.

References

1. Black RE, Morris SS, Bryce J. Where and why are 10 million children dying every year? *Lancet* 2003;361:2226–34. PMID:12842379 doi:10.1016/S0140-6736(03)13779-8
2. Lawn JE, Cousens S, Zupan J, Lancet Neonatal Survival Steering Team. Four million neonatal deaths: When? Where? Why? *Lancet* 2005;365:891–900. PMID:15752534 doi:10.1016/S0140-6736(05)71048-5
3. *Saving Newborn Lives. State of the world's newborns.* Washington, DC: Save the Children; 2001.
4. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L. Lancet Neonatal Survival Steering Team. Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet* 2005;365:977–88. PMID:15767001 doi:10.1016/S0140-6736(05)71088-6 [accessed on 27 October 2008].
5. Darmstadt GL, Black R, Santosham M. Research priorities and postpartum care strategies for the prevention and optimal management of neonatal infections in less developed countries. *Pediatr Infect Dis J* 2000;19:739–50. PMID:10959744
6. Darmstadt GL, Walker N, Lawn JE, Bhutta ZA, Haws RA, Cousens S. Saving newborn lives in Asia and Africa: cost and impact of phased scale-up of interventions within the continuum of care. *Health Policy Plan* 2008; 23:101–17. PMID:18267961 doi:10.1093/heapol/czn001
7. Kerber KJ, de Graft-Johnson JE, Bhutta ZA, Okong P, Starrs A, Lawn JE. Continuum of care for maternal, newborn, and child health: from slogan to service delivery. *Lancet* 2007;370:1358–69. PMID:17933651 doi:10.1016/S0140-6736(07)61578-5
8. Osrin D, Mesko N, Shrestha BP, Shrestha D, Tamang S, Thapa S, et al. Implementing a community-based participatory intervention to improve essential newborn care in rural Nepal. *Trans R Soc Trop Med Hyg* 2003;97:18–21. PMID:12886798 doi:10.1016/S0035-9203(03)90008-3
9. Darmstadt GL, Kumar V, Yadav R, Singh V, Singh P, Mohanty S, et al. Introduction of community-based skin-to-skin care in rural Uttar Pradesh, India. *J Perinatol* 2006;26:597–604. PMID:16915302 doi:10.1038/sj.jp.7211569
10. Bari S, Mannan I, Rahman MA, Darmstadt GL, Serajil MH, Baqui AH, et al. Trends in use of referral hospital services for care of sick newborns in a community-based intervention in Tangail District, Bangladesh. *J Health Popul Nutr* 2006;24:519–29. PMID:17591349
11. Bang AT, Bang RA, Baitule SB, Reddy HM, Deshmukh MD. Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. *Lancet* 1999;354:1955–61. PMID:10622298 doi:10.1016/S0140-6736(99)03046-9
12. Bang AT, Bang RA, Stoll BJ, Baitule SB, Reddy HM, Deshmukh MD. Is home-based diagnosis and treatment of neonatal sepsis feasible and effective? Seven years of intervention in the Gadchiroli field trial (1996 to 2003). *J Perinatol* 2005;25:S62–71. PMID:15791280 doi:10.1038/sj.jp.7211273
13. Baqui AH, Darmstadt GL, Williams EK, Kumar V, Kiran TU, Panwar D, et al. Rates, timing and causes of neonatal deaths in rural India: implications for neonatal health programmes. *Bull World Health Organ* 2006;84:706–13. PMID:17128340 doi:10.2471/BLT.05.026443

14. Weber MW, Mulholland EK, Jaffar S, Troedsson H, Gove S, Greenwood BM. Evaluation of an algorithm for the integrated management of childhood illness in an area with seasonal malaria in the Gambia. *Bull World Health Organ* 1997;75 Suppl 1;25–32. PMID:9529715

15. Young Infants Clinical Signs Study Group. Clinical signs that predict severe illness in children under age 2 months: a multicentre study. *Lancet* 2008;371:135–42. PMID:18191685 doi:10.1016/S0140-6736(08)60106-3

16. Kahigwa E, Schellenberg D, Schellenberg JA, Aponte JJ, Alonso PL, Menendez C. Inter-observer variation in the assessment of clinical signs in sick Tanzanian children. *Trans R Soc Trop Med Hyg* 2002;96:162–6. PMID:12055806 doi:10.1016/S0035-9203(02)90290-7

17. Simoes EA, Desta T, Tessema T, Gerbresellassie T, Dagnew M, Gove S. Performance of health workers after training in integrated management of childhood illness in Gondar, Ethiopia. *Bull World Health Organ* 1997;75 Suppl 1;43–53. PMID:9529717

18. Kolstad PR, Burnham G, Kalter HD, Kenya-Mugisha N, Black RE. The integrated management of childhood illness in western Uganda. *Bull World Health Organ* 1997;75 Suppl 1;77–85. PMID:9529720

19. Kalter HD, Burnham G, Kolstad PR, Hossain M, Schillinger JA, Khan NZ, et al. Evaluation of clinical signs to diagnose anaemia in Uganda and Bangladesh, in areas with and without malaria. *Bull World Health Organ* 1997;75 Suppl 1;103–11. PMID:9529723

20. Gove S. Integrated management of childhood illness by outpatient health workers: technical basis and overview. The WHO Working Group on Guidelines for Integrated Management of the Sick Child. *Bull World Health Organ* 1997;75 Suppl 1;7–24. PMID:9529714

21. Perkins BA, Zucker JR, Otieno J, Jafari HS, Paxton L, Redd SC, et al. Evaluation of an algorithm for integrated management of childhood illness in an area of Kenya with high malaria transmission. *Bull World Health Organ* 1997;75 Suppl 1;33–42. PMID:9529716

22. Mullany LC, Darmstadt GL, Katz J, Khatry SK, LeClerq SC, Adhikari RK, et al. Development of clinical sign-based algorithms for community-based assessment of omphalitis. *Arch Dis Child Fetal Neonatal Ed* 2006; 91:F99–104. PMID:16223755 doi:10.1136/adc.2005.080093

23. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;33:159–74. PMID:843571 doi:10.2307/2529310

24. Kalter HD, Schillinger JA, Hossain M, Burnham G, Saha S, de Wit V, et al. Identifying sick children requiring referral to hospital in Bangladesh. *Bull World Health Organ* 1997;75 Suppl 1;65–75. PMID:9529719

25. National AIDS/STD Programme and Ministry of Health and Family Welfare. *2008 UNGASS country progress report: Bangladesh, reporting period: January 2006 – December 2007*. Geneva: Joint United Nations Programme on HIV/AIDS; 2008. Available from: http://data.unaids.org/pub/Report/2008/bangladesh_2008_country_progress_report_en.pdf [accessed on 29 October 2008].

26. *Districtwise distribution of API in Bangladesh, 2000*. New Delhi: World Health Organization, Southeast Asia Regional Office. Available from: http://www.searo.who.int/LinkFiles/Malaria_banmalmapc.pdf [accessed on 29 October 2008].

27. Baqui AH, El-Arifeen S, Darmstadt GL, Ahmed S, Williams EK, Seraji HR, et al. Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial. *Lancet* 2008; 371:1936–1944. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0140-6736(08)60835-1 [accessed on 28 October 2008].

Table 1. **Clinical algorithm for neonatal assessment applied in CHW validation study, Mirzapur, Bangladesh, 2005–2006**

Signs observed by CHW or history reported by mother	Classification[a]	Management guideline
Any one of the following signs, at 1 minute: - no cry, no breathing - gasping - slow breathing (< 30 bpm)	Perinatal asphyxia	To resuscitate baby, dry and wrap, position, stimulate, give mouth-to-mouth breathing. Resuscitate until breathing normally but not more than 20 minutes. If breathing normally after 20 minutes, observe for another hour, apply algorithm. If not breathing normally after 20 minutes, refer urgently to the hospital. If not breathing at all after 20 minutes, stop; baby is dead.
Observed convulsions Unconscious Fast breathing (≥ 70 bpm) Severe chest in-drawing Fever (> 101 °F or 38.3 °C) Low body temperature (< 95.5 °F or 35.3 °C) Many or severe skin pustules or blisters, or single large area of pus or redness with swelling Umbilical redness extending to skin Weak, abnormal or absent cry[b] Lethargic or less than normal movement[b] Unable to feed, or unable to suck at all, or not attached at all (based on feeding assessment)[b]	Very severe disease (VSD)	If one or more signs present, refer urgently to hospital, showing mother how to keep baby warm on the way and ensuring proper feeding to prevent low blood sugar. If referral fails, inform supervisors and start oral co-trimoxazole, 1.25 ml twice daily for 5 days, at home. (Avoid antibiotics in jaundiced or very small neonates.)
History of convulsion Bulging fontanelle Mother reports vomits everything Fever (100.0–101.0 °F or 37.8–38.3 °C) Low body temperature (95.5–97.5 °F or 35.3–36.4 °C) Jaundiced palms and soles after 24 hours	Possible very severe disease (PVSD)	If one or more signs present, refer urgently to hospital, showing mother how to keep baby warm on the way and ensuring proper feeding to prevent low blood sugar. If referral fails, inform supervisors and reassess baby again later in the day. If one or more signs present, counsel family for referral again. If referral fails and two or more signs present, start oral co-trimoxazole, 1.25 ml twice daily for 5 days, at home. (Avoid antibiotics in jaundiced or very small neonates.)
Jaundice anywhere in the body within 24 hours of birth	Significant jaundice	Refer urgently to hospital, showing mother how to keep baby warm on the way. Encourage breastfeeding.
Eyes discharging pus	Possible gonococcal eye infection	Refer urgently to hospital, showing mother how to keep baby warm on the way. If referral fails, contact supervisor immediately to ensure treatment.
History of diarrhoea (unusually loose, watery or frequent) and of blood in stool	Bloody diarrhoea	Refer urgently to the hospital, showing mother how to keep baby warm on the way. Encourage breastfeeding.
History of diarrhoea (unusually loose, watery or frequent) and any one of the following signs: - not able to drink or drinks poorly - lethargic or unconscious - skin pinch retracts in > 2 seconds	Diarrhoea with severe dehydration	Refer urgently to hospital, showing mother how to keep baby warm and give frequent sips of oral rehydration solution on the way. Encourage breastfeeding. If baby also has VSD, treat as above for VSD.
History of diarrhoea (stools unusually loose, watery or frequent) and any one of the following signs: - drinks eagerly - is restless or irritable - skin pinch retracts in > 2 seconds	Diarrhoea with some dehydration	Refer to hospital, showing mother how to keep baby warm and give frequent sips of oral rehydration solution on the way. Advise mother to continue breastfeeding.

(Table 1, cont.)

Signs observed by CHW or history reported by mother	Classification[a]	Management guideline
History of diarrhoea (unusually loose, watery or frequent) without signs of dehydration	Diarrhoea without dehydration	Breastfeed more often and for longer periods at each feeding. If required, give oral rehydration solution after every loose stool.
Respiratory rate 60–69 bpm	Fast breathing	Observe every day for 2 days. If no improvement after 2 days, refer baby to hospital.
Umbilicus discharging pus Umbilical redness, but not extending to skin Some skin pustules	Local infection	Teach mother to treat at home with half-strength gentian violet (0.5%) and follow up every day for 2 days. If no improvement after 2 days, refer baby to hospital.
Ulcers or white patches inside the oral cavity (tongue, and inside cheek or lips, or both)	Oral thrush	Teach mother to treat thrush at home with half-strength gentian violet (0.5%) and follow up after 2 days.

bpm, breaths per minute; CHW, community health worker.
[a] Neonates were classified into a relevant illness group if one or more of the listed historical factors or clinical signs (or both) was present.
[b] Sign of possible very severe disease in the original algorithm for the Projahnmo-2 study.

Table 3. **Characteristics of neonates (n = 395) included in CHW clinical algorithm validation study in Mirzapur, Bangladesh, 2005–2006**

Characteristics	No.	%
Sex		
Female	193	48.9
Male	202	51.1
Gestational age (weeks)[a]		
< 33	12	3.0
33–36	50	12.7
37–41	292	73.9
≥ 42	24	6.1
NA	17	4.3
Age of newborn at CHW assessment (complete days)		
0	73	18.5
1	6	1.5
2	75	19.0
3	4	1.0
4	5	1.3
5	114	28.9
6	4	1.0
7	2	0.5
8	103	26.1
9	3	0.8
11	2	0.5
14–27	4	1.2
Birthplace		
Own home	201	50.9
Maternal grandparents' home	147	37.2
Hospital	47	11.9

CHW, community health worker; NA, not available.
[a] Gestational age was determined by maternal report of the first day of the last menstrual period.