Bulletin of the World Health Organization, 65 (3): 309-316 (1987)

Measurement of mortality from neonatal tetanus in Burma

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Surveys to determine mortality from neonatal tetanus were conducted in March and April 1985 in accessible areas of Burma, where pregnant women had been immunized with tetanus toxoid and, for comparison, also in areas where such immunization had not been given. Neonatal mortality rates were three times greater in areas where tetanus toxoid immunization had only recently or had not yet been introduced by the national expanded programme on immunization. Analysis of the data indicates that the impact on reduction of neonatal mortality from tetanus of three interventions (immunization of pregnant women with tetanus toxoid; delivery in hospital; or birth at home attended by a trained health worker) was greatest for immunization.

In 1978, an expanded programme on immunization (EPI) was initiated in Burma in 27 townships in the Rangoon Division. By March 1985, the programme had been extended to all 14 states and divisions and covered 158 of the 314 townships of the country. Cold-chain constraints have continually limited expansion of the programme, and the more heat-sensitive vaccines have not been administered in areas where local health authorities lack reliable refrigerators or the ability to procure sufficient ice for field operations. Thus, oral polio vaccine has only been used in townships in Rangoon and Mandalay Divisions, and diphtheria-tetanus (DT) antigens were substituted for diphtheria-pertussis-tetanus triple vaccine (DPT) in rural areas with unreliable cold-chain capabilities. However, all EPI townships immunize with BCG, DT, and tetanus toxoid, the more heat stable of the vaccines used in the programme.

Evidence for the effectiveness of the programme in reducing morbidity and mortality has been difficult to document in Burma. Disease surveillance data are routinely reported by hospitals, but the information obtained has frequently been untimely and not particularly representative. The data most amenable to analysis for assessment of any EPI impact are admission records at the Rangoon Children's Hospital and the paediatric ward of Mandalay General Hospital. A recent review of poliomyelitis and neonatal tetanus immunization records in these hospitals showed acceptable efficacies for vaccines against these diseases, incipient evidence of decreasing mortality from neonatal tetanus, as well as an expected shift in the age-specific incidence of poliomyelitis (*1*). These data essentially applied to only the two major urban areas of Burma where EPI has been operational for several years.

In collaboration with WHO, the Burmese Ministry of Health therefore conducted a rapid assessment of neonatal tetanus in order to determine whether EPI has had a measurable impact in all the operational areas of the country. Neonatal tetanus was selected since, of the target diseases, it is the easiest to monitor for the early effects of programme impact (*2*): tetanus toxoid has good heat stability, is highly efficacious (exceeding 95% when properly administered), and is included in the immunization schedule in all areas of the country where EPI operates. The target group for immunization against neonatal tetanus in Burma is pregnant women, and the occurrence of the disease in infants in the first month of life enables data to be collected over a narrow time frame. A presumptive diagnosis of neonatal tetanus can be made from a history of the signs associated with the disease, and the relevant information can be obtained from mothers in surveys conducted by trained health staff. Finally, the incidence of the disease was expected to be high enough to allow surveys to be conducted within a short period of time

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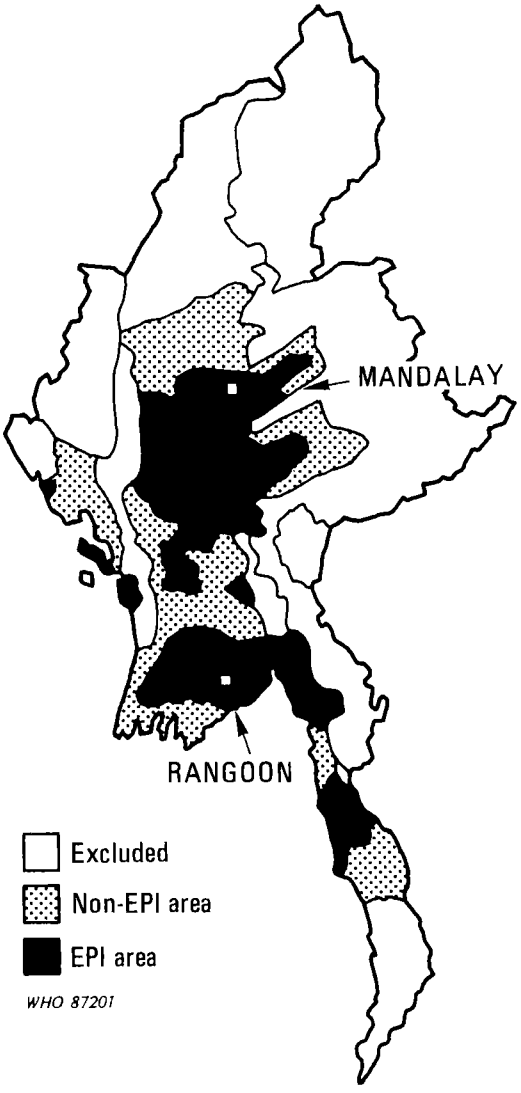

Fig. 1. Survey areas covered in the study.

on samples of sufficient size.

The three major objectives of the surveys were:

—to obtain baseline estimates of mortality from neonatal tetanus in those areas where EPI had been operational for at least 1 year and in areas where the programme had not been or had only recently been introduced;

—to compare the mortality rates and other characteristics from the two survey areas to evaluate the impact of tetanus toxoid immunizations on neonatal tetanus; and

—to train health staff how to manage and conduct future surveys.

MATERIALS AND METHODS

Surveys were conducted over a 4-week period between 18 March and 12 April 1985. The first week was used to determine the scope of and plan the surveys; to develop and reproduce questionnaires and other forms; and to train central, state, and divisional EPI staff. The second week was principally allocated to training local medical officers and health authority staff in those townships selected for the survey. The third week was allocated to data collection, while the fourth week was used to translate the findings from Burmese into English, to review, compile, and analyse the data, and to present the preliminary results to the Ministry of Health.

The primary sampling frames (EPI and non-EPI townships) were restricted to townships within 2 days' travelling time from either Rangoon or Mandalay. Of the 314 townships in the country, 191 (61%) met this criterion (approximately 74% of the total population of Burma resides in the latter townships). The townships selected were partitioned into those that had initiated EPI prior to May 1984 (114) and those that had not (77); these were designated EPI and non-EPI, respectively (see Table 1 and Fig. 1).

The 30-cluster sample survey method devised by WHO for rapid programme assessment was used in the study (*3*, *4*).[a] Thirty points were chosen in each sampling frame in three stages. Townships were first selected systematically in proportion to their population using a random start procedure and addition of an interval equal to 1/30th of the total population in each frame. Within each township picked in the first stage, a village, ward, or hamlet was selected in proportion to its population. In the third stage, a randomly selected household was chosen as the initial listing unit in each cluster. Clusters were completed by taking a census of neighbouring households until information was obtained on the number of live births needed from the cluster. Mothers who had had live births between 1 March 1984 and 28 February 1985 were surveyed. In this way, all infants delivered during this period who were at risk of neonatal tetanus and other causes of neonatal death were covered. However, the risk of infant mortality could not be completely quantified, since the average exposure to such death was expected to be 6 months.

[a] *Manual for the planning and evaluation of national diarrhoeal disease control programmes.* Unpublished document (WHO/CDD/SER/81.5).

Table 1. Distribution of townships covered in the surveys of neonatal tetanus in Burma, 1985

State/Division	No. of townships					
	Total	Excluded from survey	In sampling frames		Selected for survey	
			EPI area	Non-EPI area	EPI area	Non-EPI area
Sagaing	38	19	9	10	2	4
Pegu	28	4	8	16	2	6
Tenasserim	10	6	2	2	1	0
Mon	10	1	5	4	2	2
Magwe	25	5	15	5	4	1
Mandalay	29	0	20	9	6	4
Shan	52	39	7	6	2	1
Rakhine	17	8	3	6	0	2
Rangoon	39	1	35	3	7	1
Irrawaddy	26	0	10	16	4	9
Kachin	18	18	0	0	0	0
Chin	9	9	0	0	0	0
Kayah	6	6	0	0	0	0
Karen	7	7	0	0	0	0
Total	314	123	114	77	30	30

Sample sizes were calculated using assumed mortality rates for neonatal tetanus of 12 per 1000 live births in non-EPI and 4 per 1000 in EPI townships. An 80% probability of detecting such a difference in mortality rate at the 95% confidence level was chosen, and a factor of 2 for the design effects of the study was used in the calculations. For both the EPI and non-EPI areas the surveys collected data on 3000 live births. These births were distributed equally among the 30 clusters of the survey areas, i.e., data were collected until information on 100 live births was obtained for each cluster.

As far as possible, data were recorded on questionnaires using check-marks to record positive responses. This approach substantially reduced the time and resources required for the development and reproduction of survey forms as well as facilitated translation of the replies from Burmese into English. Case histories on neonatal deaths were initially reviewed by local medical officers and subsequently by a team of four medical officers and a WHO consultant before arriving at a presumptive diagnosis of neonatal tetanus.

Preliminary analysis of the results was performed on unweighted data (*5*). Weighted estimates for each survey were then obtained by summing the products of the unweighted cluster estimates and the cluster weights. Combined estimates were weighted by the population in each sampling frame. Differences between survey estimates were then evaluated using Student's t test, with weighted estimates and sample sizes corrected for the survey design effects.

RESULTS

Information on 6000 live births was collected by more than 250 health staff from approximately 33 000 households comprising roughly 178 000 residents (Table 2). In rural areas, surveys of complete clusters were conducted over 2–5 days by teams of two persons, while in urban areas, several clusters were completed in 1–2 days. In each cluster, local medical officers trained and assigned more than one interview team, and several clusters were completed by five two-person teams.

The data obtained in the surveys from households where live births occurred are also shown in Table 2. In general, the differences between non-EPI and EPI areas were as expected but were statistically significant only for levels of tetanus-toxoid coverage, for the proportion of deliveries in hospital, and for the proportion of neonates with potentially infectious material on umbilical stumps.

The number of deaths and weighted mortality rates are shown in Table 3. A threefold higher mortality rate from neonatal tetanus was found in the non-EPI area ($P < 0.05$), and 21% and 41% of neonatal deaths

Table 2. Information collected on neonatal tetanus in the 114 townships surveyed in Burma, 1985

	Survey		
	Combined areas	EPI area	Non-EPI area
General characteristics			
Population in sampling frames	26 782 000	16 640 000	10 142 000
No. of households surveyed	33 571	16 679	16 892
No. of residents in households	177 660	90 206	87 454
Average household size	5.5	5.5	5.4
Crude birth rate (per 1000)	34.0	33.6	34.7
Characteristics associated with live births			
Average age of mothers (years):			
At time of survey	28.7	28.8	28.5
At time of marriage	19.6	20.9	19.5
Average number of deliveries per mother	3.4	3.3	3.6
Average length of schooling (years):			
Of mothers	4.5	4.7	4.1
Of fathers	3.6	3.8	3.4
Percentage of mothers immunized with 2TT during pregnancy[b]	44.2	66.2[a]	8.1[a]
Percentage of male births	49.9	50.2	49.4
Percentage of births delivered in hospital	14.3	19.9[a]	5.0[a]
Percentage delivered at home by trained attendant	51.1	52.3	49.2
Percentage of deliveries with potentially infectious material on umbilical stump	21.5	15.9[a]	30.6[a]

[a] Statistically significant at the $P<0.05$ level.
[b] 2TT = 2 doses of tetanus toxoid.

Table 3. Summary of data for mortality from neonatal tetanus associated with live births in the surveys in Burma, 1985

	Mortality rate (per 1000 live births)		
Mortality group	Combined areas	EPI area	Non-EPI area
Maternal	2.1 (8)[a]	2.7 (5)	1.1 (3)
Neonatal	17.8(113)	14.9 (48)	22.7 (65)
Tetanus	5.4 (41)	3.1[b](11)	9.3[b](30)
Other	12.4 (72)	11.8 (37)	13.4 (35)
Post-neonatal[c]	5.2 (37)	2.8 (9)	9.1 (28)
Neonatal + post-neonatal	23.0(150)	17.7[b](57)	31.8[b](93)
Infant mortality[d]	38.8	32.4	49.3

[a] Figures in parentheses are the numbers of deaths.
[b] Statistically significant at the $P<0.05$ level.
[c] See text for a description of the limitation on full exposure to risk of infant death.
[d] Estimated assuming neonatal deaths represent 46% of all infant deaths.

Table 4. Characteristics of deaths from neonatal tetanus in the surveys in Burma, 1985

Characteristic	Survey[a]		
	Combined areas	EPI area	Non-EPI area
No. of deaths	41	11	30
Percentage of males	58.5	81.8	50
Average age at onset (days)	6.0	6.7	5.8
Average age at death (days)	8.8	8.8	8.8
Percentage of mothers that identified tetanus as cause of death	14.6	9	16.7
Percentage of neonates treated	41.5	54.5	36.7
Percentage treated by indigenous medical practitioners	60.0	50.0	63.6
Percentage of mothers who received 2TT during pregnancy[b]	9.7	27.3	3.3
Percentage of births in hospital	2.4	0.0	3.3
Percentage of births at home with trained attendant	41.5	27.3	46.7
Percentage of infants with potentially infectious material on umbilical stump	34.1	36.4	33.3

[a] Percentages and averages are based on unweighted data.
[b] 2TT = 2 doses tetanus toxoid.

in the EPI and non-EPI areas, respectively, were from tetanus. The proportion of neonatal deaths from causes other than tetanus was similar in both areas (11.8% and 13.4%, respectively, in the EPI and non-EPI areas). In the non-EPI area the post-neonatal mortality rate was approximately three times higher than in the EPI area; however, this difference was not significant ($0.10 > P > 0.05$). Combined neonatal and partial post-neonatal mortality rates were significantly different ($P < 0.05$), and an estimate of the infant mortality rate, calculated on the assumption that approximately 46% of infant deaths occur in the neonatal period, is also shown (*6*).

Table 4 shows the characteristics of the neonatal deaths obtained in the surveys. Differences between the EPI and non-EPI areas were generally not marked, except for the proportion of mothers who received two doses of tetanus toxoid during pregnancy (approximately 27% and 3%, respectively, for deaths in the EPI and non-EPI areas; $P = 0.052$, Fischer's exact test).[b]

Fig. 2 shows the ranges and average durations from birth to onset of signs of neonatal tetanus and from birth to death. The distribution is similar to those reported in previous surveys in other developing countries (*7*).

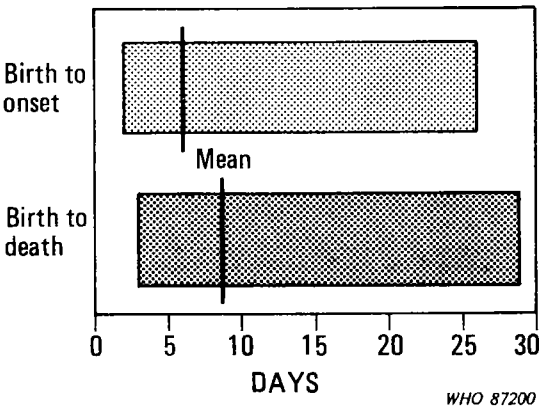

Fig. 2. Range of duration of neonatal tetanus from birth to onset and from birth to death in the surveys.

DISCUSSION

The major purposes of the surveys were to measure the extent of neonatal tetanus and, on this basis, determine whether EPI had been effective in Burma. Only two characteristics were determined for all households: the crude birth rate and average household size. The crude birth rate for the combined surveys was 34 per 1000 (95% confidence interval, ±6), which was not significantly different from the latest available estimate (1982) of the crude birth rate of 28.5 ($Z = 1.17$, Student's t test) for the entire country. The estimated average number of inhabitants per household in the surveys (5.5) did not differ

[b] Calculated using unweighted mortality data for neonatal tetanus.

significantly from the latest national census estimate.[c]

Since the survey focused on neonatal mortality, data collected on other characteristics of live births were expected to vary in precision. The absence of statistically significant differences between EPI and non-EPI areas for some of the data collected is probably due to the relatively small sample size. Several of the differences in the characteristics of parents recorded in EPI and non-EPI areas, although broadly as expected, were not particularly pronounced; for example, although the proportion of deliveries at home by a trained birth attendant was expected to be higher in the EPI area, it was essentially the same as in the non-EPI area.

As expected, in the EPI area a significantly higher proportion of women were immunized with tetanus toxoid during pregnancy, a greater use was made of hospitals for delivery, and the use of potentially infectious dressings on umbilical stumps (primarily saffron, sesame oil, and "indigenous medicine") was lower. The 15% higher rate of use of such dressings in non-EPI areas may be directly associated with deliveries by trained medical care providers in hospital or at home—72.2% in the EPI compared with 54.2% in the non-EPI area ($P > 0.05$, $Z = 1.85$, Student's t test).

The proportion of male neonatal deaths (58.5%) was not significant. Stanfield & Galazka comment on the possible causes of higher rates of neonatal tetanus among males (*7*). Nevertheless, in our surveys no attempt was made to collect information about sexual differences in exposure to risk of neonatal tetanus.

Of the 150 infants who died from all causes in the surveys, only 40 (27%) received any medical care; however, if the 62 infants who died on the first day of life are excluded, the proportion that received medical care increased to 45%. Of infants whose deaths were attributed to neonatal tetanus, 42% received medical care, i.e., essentially the same proportion as those who died on the first day of life from other causes. Interestingly, 60% of cases of neonatal tetanus that received medical care were attended by an indigenous medical practitioner. This reduced the proportion of cases that received potentially effective care to about 17%.

Only 15% of the mothers whose infants' deaths were attributed to neonatal tetanus identified this as the cause of death. This pattern was common also for all other causes of infant death: 16% of mothers stated an "unknown" cause of death, 17% that the cause of death was a "childhood disease", while the remaining 67% described signs associated with the terminal illness—30% of the last-mentioned specified signs that could be attributed to a probable specific cause.

To evaluate the impact of tetanus toxoid immunizations, the efficacies of three of the identified interventions (immunization of mothers with tetanus toxoid, birth in hospital, and delivery by a trained attendant if birth was at home) were determined (*8*). The attack rate of neonatal tetanus for all births recorded in the combined surveys was calculated, in turn, for each intervention category and then for births where there had been no

[c] Provided by Dr Daw Khin May Kyi, Central Epidemiologic Unit, Ministry of Health, Rangoon, Burma.

Table 5. Effect of the three interventions on mortality from neonatal tetanus in the surveys, Burma 1985, not corrected for multiple interventions

Characteristic	Survey area and intervention								
	EPI area			Non-EPI area			Combined areas		
	2TT[a]	Hospital delivery	Trained birth attendant	2TT	Hospital delivery	Trained birth attendant	2TT	Hospital delivery	Trained birth attendant
Efficacy[b]	0.81	1.0	0.66	0.60	0.33	0.10	0.91	0.85	0.33
Coverage	0.66	0.20	0.52	0.08	0.05	0.49	0.44	0.14	0.51
Efficacy × coverage	0.53	0.20	0.34	0.05	0.02	0.05	0.40	0.12	0.17
Contribution to reduced neonatal mortality (%)[c]	50	19	32	42	17	42	58	17	25

[a] 2TT = 2 doses of tetanus toxoid.

[b] Expressed as (attack rate$_{(\text{no intervention})}$ − attack rate $_{(\text{intervention})}$)/attack rate$_{(\text{no intervention})}$.

[c] Expressed as ((efficacy$_i$ × coverage$_i$) × 100)/Σ(efficacy$_i$ × coverage$_i$). Totals do not necessarily sum to 100% because of rounding.

Table 6. Effect of the three interventions on mortality from neonatal tetanus for the combined surveys in Burma, 1985, corrected for multiple interventions

Characteristic	Intervention			
	None	2TT[a]	Hospital delivery	Trained birth attendant
No. of live births	1722	486	276	1773
No. of neonatal deaths from tetanus (per 1000 live births)	0.0122	0.0041	0.0036	0.0073
Efficacy[b]	NA[d]	0.664	0.705	0.402
Coverage	NA	0.442	0.143	0.511
Efficacy × coverage	NA	0.293	0.101	0.205
Contribution to reduced mortality (%)[c]	NA	49	17	32

[a] 2TT = 2 doses of tetanus toxoid.
[b] Expressed as (attack rate $_{\text{(no intervention)}}$ − attack rate $_{\text{(intervention)}}$)/attack rate $_{\text{(no intervention)}}$.
[c] Expressed as $((\text{efficacy}_i \times \text{coverage}) \times 100)/\Sigma(\text{efficacy}_i \times \text{coverage}_i)$.
[d] NA = not available.

intervention. In this way the efficacy of two doses of tetanus toxoid was found to be 91.4%, while that of birth in hospital was 84.6%. Delivery at home by a trained attendant had the lowest efficacy (32.8%). The products of the efficacies and coverages for each intervention were then calculated for each separate survey and for the combined surveys. The proportional contribution of each intervention was then evaluated by dividing the product for each intervention by the sum of the products of the efficacies for the three interventions. The results obtained (Table 5) suggest that immunization with tetanus toxoid produced the greatest reduction in mortality from neonatal tetanus. This was particularly noticeable for the non-EPI area, where immunization coverage was only 8% and efficacy was relatively low (60%), but contributed 45% to the reduction of neonatal mortality in this area.

Because many births recorded in the surveys had been associated with two or all three interventions, efficacies were determined for those that had involved only one intervention by using the attack rate for each intervention group and that for births with no intervention. Because the number of births involved in each group was small, and the differences between the EPI and non-EPI areas were not significant, data for the combined areas were used; results are shown in Table 6. When corrected for multiple intervention, hospital delivery had the highest efficacy (71%), immunization with tetanus toxoid was intermediate (66%), and delivery at home by a trained attendant was lowest (40%). However, the proportional distribution of the products of efficacy and coverage were similar to those obtained when no correction was made for multiple interventions: two doses of tetanus toxoid contributed 49%; home delivery by a trained health attendant, 34%; but, because of the low proportion of those in this category, the contribution made by births in hospital was only 17%, although its efficacy was the highest.

CONCLUSIONS

The mortality levels for neonatal tetanus estimated in the surveys provide rough baselines for assessing future progress in combating the disease in Burma. The threefold higher mortality level from neonatal tetanus in non-EPI areas probably reflects the impact of immunizing pregnant women with tetanus toxoid, although other factors undoubtedly contributed to the lower incidence in the EPI areas. Comparison of the coverage and efficacy of the three interventions suggests that immunization contributed about 50% to the reduction in mortality from the disease. A programme to educate mothers and indigenous medical practitioners on neonatal tetanus might increase recognition and referral of cases to health facilities, where more effective care would be available. However, the major emphasis of such a programme should focus on efficacious preventive measures — care of the umbilical stump at delivery, avoidance of potentially infectious dressings, as well as timely and adequate immunization of pregnant women with tetanus toxoid.

ACKNOWLEDGEMENTS

The authors acknowledge the invaluable assistance of Dr U Soe Myint, Dr U La Win Maung, and Dr U Kyaw Thein during the training, field work, and review of data in the Central EPI unit in Rangoon. The numerous state, divisional, and township medical officers, as well as more than 250 local health workers and clerical staff who supervised the field work and collected and translated the information are also thanked. Finally, the help of Dr Robert Cook, Dr Arthur Galazka, and Dr Ralph Henderson, who reviewed the manuscript and offered useful comments and suggestions, is acknowledged.

RÉSUMÉ

MESURE DE LA MORTALITÉ PAR TÉTANOS NÉONATAL EN BIRMANIE

En 1978, la Birmanie lançait un Programme élargi de vaccination (PEV) dans 27 localités dépendant de la division administrative de Rangoon. En mars 1985, le Programme était élargi aux 14 Etats et divisions administratives birmanes pour couvrir 158 des 314 municipalités de l'Union. Les vaccins les plus thermosensibles n'ont pas été introduits partout dans le programme de vaccination; néanmoins, dans toutes les localités couvertes par le PEV, les enfants ont été vaccinés par le BCG, par le vaccin antidiphtérique-antitétanique et par l'anatoxine tétanique.

Faute de données suffisantes, l'efficacité du PEV pour la réduction de la morbidité et de la mortalité dues aux maladies cibles du programme a été difficile à établir. En mars et avril 1985, le Gouvernement birman a donc effectué, en collaboration avec l'OMS, une enquête destinée à mesurer les premiers résultats du programme et a choisi à cette fin le tétanos néonatal qui est une des maladies cibles les plus faciles à surveiller. Des enquêtes ont été réalisées dans 191 localités situées au maximum à deux jours de voyage de Mandalay ou de Rangoon; 114 étaient situées dans une région où le PEV avait été mis en place depuis au moins un an, alors que les 77 autres n'étaient pas encore dotées d'un PEV. Au moyen de la méthode de sondage par 30 grappes, on a recueilli des données sur plus de 6000 naissances vivantes.

L'analyse des données a indiqué que les différences entre les zones PEV et les zones non PEV étaient statistiquement significatives en ce qui concerne le niveau de couverture par l'anatoxine tétanique, le pourcentage d'accouchements pratiqués à l'hôpital et le pourcentage de cas où des matières potentiellement infectieuses avaient été appliquées sur le cordon. Une comparaison de la couverture par trois interventions (vaccination des mères au moyen de l'anatoxine tétanique, accouchement à l'hôpital ou en présence d'une personne qualifiée si l'accouchement a lieu à domicile) et de leur efficacité en ce qui concerne le taux de mortalité néonatale imputable au tétanos indique que la vaccination a contribué à réduire de près de 50% cette mortalité.

Les résultats montrent qu'il faudrait éduquer à la fois les mères et les praticiens traditionnels birmans en ce qui concerne le tétanos du nouveau-né afin d'améliorer le diagnostic et l'orientation des cas vers les centres de santé susceptibles de dispenser des soins plus efficaces; un tel programme d'éducation devrait être essentiellement axé sur des mesures de prévention efficaces.

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