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Completeness of reporting and case ascertainment for neonatal tetanus in rural Pakistan

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SUMMARY

Objectives: The objectives of this study were to assess the case ascertainment and completeness of neonatal tetanus (NT) reporting and to estimate the incidence of NT in Dadu District, Pakistan.
Methods: We conducted active surveillance and hospital record reviews for suspected NT cases. We compared the cases of NT reported to the routine surveillance system with the cases identified through the hospital record reviews for 1993 through 2003. The two-source capture–recapture method was used to evaluate case ascertainment in the routine surveillance system and to estimate the incidence of cases of NT.
Results: Active surveillance and hospital record reviews identified 134 cases in addition to 274 cases in the routine surveillance system. The two-source capture–recapture method indicated that there would have been 463 cases during this period (95% confidence interval (CI) = 418–508), representing an average annual incidence of 0.62 per 1000 live-births. The overall completeness of routine reporting was 59.2%. The proportions of cases reported were 68.1% for government hospitals and 53.8% for private reporting sites.
Conclusions: Reporting of NT cases is incomplete. Active promotion of private sector participation, community involvement, and strengthening of the government sector as a way of improving NT reporting and surveillance is strongly suggested.
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1. Introduction

The success of an immunization program in reducing the morbidity and mortality from vaccine-preventable diseases can be measured only if there is a reliable disease surveillance system.[1] Neonatal tetanus (NT) is the second leading cause of death from childhood vaccine-preventable diseases worldwide[2] and one of the most underreported diseases.[3] Underreporting of NT cases is of major public health concern to the global elimination of neonatal tetanus. Concerns about the underreporting of NT in developing countries have limited the impact of surveillance on disease control strategies, yet little consideration has been given to ways of improving the reporting system.

Completeness of reporting depends primarily on three elements.[1] First, the public must have access to health services, and second, must use them. Third, the health services must report cases accurately and regularly to the appropriate health authorities.[1] Community-based NT mortality surveys indicate that current surveillance systems as used in developing countries detect only 2–8% of cases.[1,3–6] The World Health Organization (WHO) received reports of only 9318 cases of NT in 2004,[7] compared to an estimated 128 000 NT deaths.[8]

NT is a highly fatal infection of the neonatal period, usually occurring in rural settings where there is poor access to health facilities and most deaths occur at home, with birth and death not being reported.[9] The development of effective surveillance through correct and accurate reporting will not only help to target and evaluate interventions,[9] but will also replace the survey method for obtaining data on the morbidity and mortality of NT.[4] Integration and expansion of acute flaccid paralysis (AFP) surveillance with measles and NT reporting,[9–11] building on the experience of polio surveillance and community-based NT reporting,[12] are some of the WHO recommendations for improving NT surveillance.

As at December 2010, Pakistan is one of the 39 countries that have not achieved maternal and neonatal tetanus (MNT) eradication.[13] WHO recommends that surveillance systems should be sufficiently sensitive to detect an annual rate of less than 1 NT case/1000 live-births at the district level as a target for global elimination; maternal tetanus is considered eliminated when NT

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is eliminated.[9] The main elimination strategies are: promotion of clean delivery services, immunization of women with a tetanus toxoid (TT)-containing vaccine, and effective surveillance.[8,9]

Dadu District (area 7866 square km, population 1.5 million; capital Dadu Town) is in the northern part of Sindh Province. Surveillance for NT began in the district in 1992, and beginning in 2004, NT was actively integrated into AFP surveillance and the district began to include suspected NT and measles cases in the monthly reports. We perceived a need to have baseline information prior to the change; however, our emphasis is on the evaluation of the surveillance prior to the change.

2. Methods

2.1. Active surveillance and retrospective record reviews

This work was carried out as part of the surveillance program for the country and ethical review was not required. To evaluate completeness of reporting and identify cases that were not previously reported, active surveillance for suspected NT cases was conducted in 2005 during reviews of hospital case records – surveillance records and registers of seven government hospitals and five private reporting sites (i.e., pediatricians in private clinics). In addition, the medical records of the five private reporting sites and of five tertiary referral hospitals in the areas adjacent to the district were reviewed for diagnoses relating to NT after administrative consents were obtained.

We also checked for the presence of vital events registries, inpatient registers, outpatient registers, Health Management Information System (HMIS), and standard case definitions for NT, AFP, and measles[14] in the seven government hospitals and the five private reporting sites. These records included both admission and discharge records. Each case had been diagnosed by a physician and classified as NT according to the WHO recommended case definition as follows: a case was defined as a neonate with normal ability to suck and cry during the first 2 days of life and who, between 3 and 28 days of age cannot suck normally and becomes stiff or has spasms.[14] Admission and discharge diagnoses of the cases were then reviewed and those cases for which the diagnosis was consistent with NT as defined by WHO were placed into a separate file (hospital case records/registers). NT case reports that were line listed in the surveillance register during 1993–2003 were checked for double-reporting and placed in a separate file (NT line list).

2.2. Neonatal tetanus case reporting

We compared the NT reporting from the 12 hospitals with the five private reporting sites. In exploratory analyses, notified cases were compared to the non-notified with respect to gender, age at onset of symptoms, age at admission, delay in presentation, residence, reporting sites, and final outcome for the child (dead or alive). All exploratory analyses were done at alpha = 0.05 for descriptive purposes.

2.3. Case ascertainment and data sources

For this study, the primary ascertainment source was the NT line list. The secondary ascertainment source comprised the hospital case records/registers. The two databases were then compared to each in order to identify cases common to both sources. The comparison was done using defined variables such as names, age, sex, date of birth, place of residence, and admitting hospital as identifiers.

2.4. Estimating the incidence of NT

The average annual incidence of NT was based on the total number of NT cases obtained by summing the number found only in the NT list and the number found in the hospital case records/registers. We used the two-source capture–recapture method to estimate the incidence of NT cases and to evaluate the case ascertainment during the period 1993–2003. The model used in this study has been described previously for the estimation of the incidence of AFP and for AFP case ascertainment.[15] The model is based on the comparison of cases from two sources for the estimation of the total number of cases, N, given by the expression: $N = ab/c$, where a is the total number of cases from the primary source, b is the total number ascertained from the secondary source, and c is the number of cases common to both sources.[15]

An estimate was made for the 11-year period. Data were entered into Excel spreadsheet and analyzed with SPSS version 12.0 for Windows (SPSS Inc., Chicago, IL, USA).

3. Results

A total of 408 NT cases were identified, comprising 274 reported cases (NT line list) and 134 cases that were found by active surveillance. The NT line list did not capture the 134 cases that should have been reported by the physicians in hospitals and at private reporting sites. Based on the 274 reported cases, this was equivalent to an average annual incidence of 0.37 per 1000 live-births. Active surveillance identified an additional 134 NT (32.8%) that had not been reported. Thus the average annual incidence in routine surveillance based on a total of 408 cases was 0.55 per 1000 live-births.

The primary and secondary sources identified 274 and 328 cases, respectively, and 194 cases that were common to both. The 328 NT cases included 194 cases detected in both the NT line list and the hospital case records/registers, 32 cases found only in the hospital registers, and 102 cases ascertained only by the hospital case records that met the case definition after review. Forty-eight cases in the NT line list could not be ascertained by the secondary source. The estimated crude total number of expected NT reports was 463 (95% CI = 418–508) (Table 1). The average annual incidence of NT was estimated to be 0.62 per 1000 live-births (capture–recapture method).

Case ascertainment based on routine surveillance was estimated to be 59.2% (274/463) complete. Based on the estimated crude total number of expected NT reports of 348 (95% CI = 298–398) for males and 115 (95% CI = 57–173) for females, the overall completeness of routine reporting was 60.6% (211/348) for males and 54.8% (63/115) for females (capture–recapture method). Figure 1 shows the trend in estimated completeness. The trends in reporting completeness show that after an initial increase to 81% in 1994, completeness fluctuated between 63% and 74% during 1995–1999 and then decreased from 35% in 2000 to 19% in 2002, concurrent with an increase in the number of unreported cases.

Further analysis showed that of the 134 cases that were identified through active surveillance, 122 (91.0%) were found in government hospitals and 12 (9.0%) at private reporting sites. Records of 105 cases (78.4%) that were not previously reported were found in registers in government hospitals, emphasizing the significance of actively searching for suspected NT cases during routine reviews (Table 2). Routine reviews of registers in the seven hospitals and in the five private reporting sites showed that none of the hospitals and private reporting sites had birth registers, and only two out five private reporting sites (40%) had standard case definitions of AFP, measles, and neonatal tetanus (Table 3). The government hospitals sent 260 (94.9%) routine NT reports, while the private reporting sites accounted for 14 (5.1%) reports. Overall,

Table 1
Crude and stratified analysis of neonatal tetanus ascertainment: cases ascertained and estimated total cases, 1993–2003

	Total from active search	Total from NT line list (primary source) (*a*)	Total from hospital case records/registers (secondary source) (*b*)	Total from both sources (*c*)	Estimated total number of cases *N*	95% CI for *N*
Crude analysis		274	328	194	463	418–508
Stratified by year:						
1993	12	16	27	15	29	13–46
1994	10	43	51	41	53	39–66
1995	14	31	41	27	47	33–61
1996	7	35	27	20	47	33–61
1997	12	31	33	21	49	35–63
1998	8	34	28	20	48	34–62
1999	8	30	29	21	41	26–41
2000	18	17	28	10	48	34–62
2001	20	15	28	8	53	39–66
2002	21	12	26	5	62	50–74
2003	4	10	10	6	17	–
Total cases, 1993–2003	134	274	328	194	494	450–538

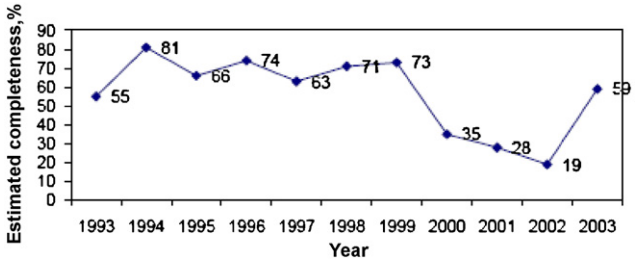

Figure 1. Estimated completeness of case ascertainment for neonatal tetanus, Dadu District, Pakistan, 1993–2003.

Table 2
Distribution of neonatal tetanus cases identified through active surveillance, 1993–2003 (*n* = 134)

Source	No.	%
Outpatient registers	15	11.2
Inpatient registers	77	57.5
Surveillance registers	13	9.7
Private reporting sites	12	8.9
Immediate notification form	13	9.7
Case records	4	3.0
Total	134	100

the proportions of cases reported were 68.1% (260/382) for government hospitals and 53.8% (14/26) for private reporting sites (Table 4).

Out of a total of 408 NT cases, the percentages of male and female cases routinely notified were 69.9% (211/302) and 59.4% (63/106), respectively ($p = 0.049$). Cases reported to the routine surveillance did not differ significantly from those identified by active surveillance and hospital record and register reviews with regard to age at onset of symptoms (i.e., incubation period), age at admission, delay in presentation, residence (rural or urban), reporting site (government or private), and final outcome for the child (dead or alive) (Table 4).

Table 3
Routine reviews of registers at government hospitals and private reporting sites

Variable	Government hospitals (*n* = 7), *n* (%)	Private reporting sites (*n* = 5), *n* (%)
Had an outpatient register	7 (100)	0
Had an inpatient register	6 (86)	5 (100)
Had a birth register	0	0
Had standard case definitions for AFP, measles, and neonatal tetanus	7 (100)	2 (40)
Had zero reporting	7 (100)	5 (100)
Submitted all four previously required reports	7 (100)	5 (100)
Had a functioning HMIS	7 (100)	NA

AFP, acute flaccid paralysis; HMIS, health management information system; NA, not applicable.

4. Discussion

Both the average annual incidence in routine surveillance and the average annual incidence by capture–recapture method of 0.55 and 0.62 per 1000 live-births, respectively, are below the WHO target of 1 case per 1000 live-births, the global elimination goal. The surveillance data indicated that we may be missing cases and this was the reason for the active surveillance for suspected cases.

Completeness of reporting for NT depends on access to health services, health seeking behavior, utilization of health services, conscientious notification,[1] and a sensitive surveillance system.[7,9] In our study, the overall completeness of routine reporting under passive surveillance was 59%. Reporting may also have changed over time since the onset of active surveillance in 2005. An assessment of the completeness of ascertainment of disease reporting systems for NT is difficult for several reasons. First, most NT deaths occur at home, with birth and death not reported.[9] Second, we do not know the proportion of NT cases for whom health care is sought, and third, despite underreporting, the true number of NT cases in the community is not known. Although the incidence rates in this study are below the global elimination goal, the surveillance data suggest substantial underreporting, as the number of cases and NT incidence rates vary from one geographical area of the district to another (data not shown).

The finding of 134 (33%) cases that were not routinely reported suggests that healthcare professionals, having correctly made the diagnosis of NT, did not report the cases, particularly in areas where most of the NT cases resided. Thus underreporting of NT cases may be due to the failure of healthcare professionals to report diagnosed NT cases. Although we did not explore the reasons for failure to report, it has been hypothesized that workers may still fear the consequences of reporting.[16] However, the finding relating to the limited availability and use of registers and case definitions in private reporting sites suggests that the availability and widespread use of birth attendant logs, vital events registries, and standard case definitions in hospitals and private reporting sites may impact on NT reporting and surveillance.

Our results suggest an active promotion of private sector participation and strengthening of the government sector as a way

Table 4
Comparison of the characteristics of reported and unreported neonatal tetanus cases, Dadu District, Pakistan

Variable	Reported cases	Unreported cases	*p*-Value
Number, *N*	274	134	
Reporting sources/location of cases,[a] *n* (%)			
Hospitals	244 (89)	83 (62)	
Private pediatrician clinics	14 (5)	12 (9)	
Tertiary referral hospitals outside district	16 (6)	39 (29)	
Gender, *n* (%)			0.049
Male	211 (77)	91 (68)	
Female	63 (23)	43 (32)	
Male:female ratio	3.3:1	2.1:1	
Residence, *n* (%)			0.323[b]
Rural	239 (87)	116 (87)	
Urban	35 (13)	12 (9)	
Unknown	–	6 (4)	
Rural:urban ratio	6.8:1	9.6:1	
Age at onset of symptoms (days), mean ± SD	6.3 ± 2.7	6.6 ± 2.8	0.609
Age on admission (days), mean ± SD	8.1 ± 3.1	8.3 ± 4.1	0.659
Delay in presentation (days), mean ± SD	1.7 ± 1.5	2.0 ± 2.1	0.268
Final outcome of child's health, *n* (%)			0.308[c]
Discharged alive	97 (35)	56 (42)	
Dead	89 (33)	34 (25)	
Discharged against medical advice	41 (15)	12 (9)	
Unknown	47 (17)	32 (24)	
Case fatality ratio, %	47.8	37.8	
Reporting sites, *n* (%)			
Government	260 (95)	122 (91)	0.135
Private	14 (5)	12 (9)	

SD, standard deviation.
[a] Location of cases for unreported cases.
[b] Excluding the six unreported cases for whom residence was unknown.
[c] Excluding the 79 cases for whom the outcome was unknown.

of improving NT reporting and surveillance, as others have previously suggested.[16] Such promotion should include adequate supply of resources for reporting, provision of regular feedback from the health authority to health workers, and training and retraining, not only of all health personnel involved in maternal and child health activities, but also community informants, traditional birth attendants, and primary healthcare workers (known in Pakistan as lady health workers) and their sensitization to enquire about and report cases of neonatal death and NT. One study on community involvement in surveillance in Cambodia in which lay people were trained as village health volunteers to detect suspected outbreaks, reported a sensitivity of reporting of communicable disease ranging from 65% for malaria to 93% for measles.[17]

We believe that the decline in the reporting rate in 2000–2002 may be attributed to the implementation of TT supplementary immunization activities (SIAs) in Dadu District during 2001–2003, for two reasons. First, the decline occurred before and during the TT SIAs campaign. Second, the decline correlated with a decrease in the number of reported cases and with an increase in the number of unreported cases from eight in 1999 to 18 in 2000 and 21 in 2002. A TT SIAs campaign is a time to increase community awareness of NT and to increase demand for TT vaccine among women of childbearing age. Our study shows that the highest numbers of unreported cases were detected during this time, suggesting that the TT SIAs campaign may not have led to increased community awareness and to increased reporting behavior. It appears that the degree of underreporting may be a reflection of both the inadequate knowledge of reporting requirements by health professionals and low community awareness.

Accurate and prompt reporting and active surveillance for suspected cases in high-risk districts, especially in 'silent' areas where routine surveillance is unreliable or not taking place at all, are essential surveillance activities.[18] We did not identify any factors associated with reporting completeness, as reporting completeness appears to be most strongly related to the disease or condition being reported and geographical location appears to be less important in determining disease-reporting completeness.[19] The differential reporting of male cases in our study might reflect gender bias in care seeking and to cultural practices giving preference to the survival of male children in this area. More complete reporting of cases including female cases is needed, and surveillance data should be corrected for gender bias.[3]

Similar studies have examined the incidence of NT[20] and the sensitivity of the surveillance system and reporting. Singh et al. (1997) estimated a sensitivity of 8–13% for the NT surveillance system in India by comparing the number of cases routinely reported with that estimated by survey.[6] Although community-based NT mortality surveys have shown the magnitude and distribution of NT in the population,[5,21,22] these surveys are not cost-effective for the routine monitoring of NT mortality.[5] Our study is different in that it compares the observed incidence with that of the estimate from the two-source capture–recapture method.

Our study is beset with several limitations, most importantly the assumptions that are inherent in the capture–recapture methods for the estimation of incidence. The assumptions underlying these methods are that the data sources are independent, that the probability of being present or 'captured' in one data source is unrelated to the probability of being present in the other data sources, and that cases are correctly identified, i.e., diagnosed and linked.[19,23] Therefore, data validation is an important aspect of accurately applying capture–recapture methods.[19]

The routine surveillance data, which relies on reporting by pediatricians and physicians, is the responsibility of the district health office, while the hospital discharge data are the responsibility of the hospital information staff. The consistency of the estimates across the crude and stratified data further lends credence to the independence of the two sources. However our study was not able to ascertain whether cases had the same probability of being captured by either of the two sources.

The two sources had recruited cases from the same closed population with cross-notifications from the five tertiary referral hospitals across the district's boundary. We are confident in the validation of the cases common to both sources given the high discriminatory combination of the identifying variables. However, given the possibility that the clinical presentations of the causes of early neonatal death may be indistinguishable from NT, and due to delays in diagnosis, we cannot completely exclude the probability that clinicians may have missed some NT cases that were not notified. Surveillance figures miss those NT deaths that occur at home with birth and death not being reported and those who do not seek medical care at the hospital.[9,24] In spite of the potential for both underreporting and misclassification of cases, our risk estimates are relatively insensitive to either of these biases.

Another limitation of our study was the biased estimates of reporting. Bias can occur when the data collection/reporting system excludes part of the population.[7] This present study did not report any neonatal deaths or NT cases from the community, and a significant proportion of NT reporting was missing from the private sector, which was not reported to the routine surveillance system.

Since 1999, the completeness of NT surveillance (i.e., the number and proportions of health facilities reporting at least one case of NT) in the district has increased substantially (>80%) due to ongoing improvements in the HMIS. However, more efficient and accurate NT surveillance might result from the linkage of the data from the HMIS and the Expanded Programme on Immunization (EPI) reporting systems into the active surveillance system. The data may then be subjected to a 'capture–recapture' analysis to calculate a new estimate of the overall incidence of NT cases.[25] Evaluation of the impact of the integration and expansion of AFP surveillance on NT and on the community-based reporting of NT is urgently needed.

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