# NEONATAL TETANUS ELIMINATION FIELD GUIDE

Expanded Program on Immunization
Special Program *on* Maternal and Child Health and Population

Technical Paper No. 35

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# FOREWORD

The primary aim of the *Neonatal Tetanus Elimination Field Guide* is to provide medical officers and other health personnel involved in neonatal tetanus elimination efforts at national, state, and local levels with a step-by-step guide for setting up and carrying out control and elimination activities. This guide particularly emphasizes enhanced surveillance for the identification and monitoring of high-risk areas and the conduct of special immunization activities targeted to women of childbearing age in those areas. Such measures are meant to supplement routine procedures such as providing diphtheria-pertussis-tetanus (DPT) vaccine for infants and children, tetanus toxoid (TT) for school-aged children, and TT for pregnant women. Detailed information on clean delivery and postdelivery practices will not be given, as these topics are well covered in other documents of the World Health Organization (WHO).

Much of the information contained in this manual was taken directly from technical papers previously prepared by the Pan American Health Organization and other WHO Regional Offices. In addition, several textbooks and a number of other publications were consulted. Some of these works are listed at the end of this guide. Sample forms are included in the appendices and may be copied or modified to meet specific program needs.

# 1. BACKGROUND

## 1.1. Introduction

In many countries neonatal tetanus (NNT) is responsible for half of all neonatal deaths and for a quarter of all infant mortality. Over 10,000 newborns are estimated to die annually from neonatal tetanus in the Americas. *Neonatal tetanus is preventable by immunization and/or assuring clean delivery and postdelivery practices.*

In 1989 the World Health Assembly adopted a resolution calling for the elimination of neonatal tetanus from the world by 1995. This resolution has been endorsed by the Directing Council of the Pan American Health Organization (PAHO). In order to achieve the goal of neonatal tetanus elimination, Ministers of Health of PAHO Member Countries, with support from PAHO and a variety of international agencies, are beginning specific program activities. The intensification of neonatal tetanus activities should take place within the wider context of accelerated Expanded Program on Immunization (EPI) and existing maternal and child health (MCH) activities, and it should take advantage of recent accomplishments of the polio eradication program. It is recognized that the NNT elimination program is different from other eradication programs, such as those for smallpox and polio, in that even after the goal of zero cases is reached, the potential for return of the disease is always present. Therefore, the issue of sustainability is of paramount importance.

## 1.2. Program Strategy

Neonatal tetanus control can be achieved faster if efforts and resources are concentrated in geographic areas of high risk. The identification of these high-risk counties/municipalities will permit health authorities to know where to implement the main strategy of the program, that is, the vaccination of all women of childbearing age with at least two doses of tetanus toxoid.

To meet the goal of elimination of neonatal tetanus, it will be necessary to intensify all principal components of the EPI and MCH strategies; therefore, all countries should do the following:

- Establish a tetanus surveillance system to record neonatal and non-neonatal tetanus cases separately.
- investigate all neonatal tetanus cases and institute active search for cases in areas which are thought to be "silent" for neonatal tetanus. A "silent" area is one that has or is likely to have neonatal tetanus cases occurring which are not reported.
- Concentrate vaccination efforts among women of childbearing age who live in high-risk areas, assuring that every contact with such women is an opportunity to provide vaccination and that they keep a permanent immunization record.
- Ensure that traditional birth attendants are involved in tetanus toxoid vaccinations and surveillance activities for neonatal tetanus.
- Utilize newer simple injection technologies, which can be used easily by lay personnel and introduced for routine use by national programs.
- Improve clean delivery and postdelivery practices.

After reading this manual, health workers should be able to accomplish the following tasks necessary for the success of this program:

- Establish and/or expand active surveillance at sites where neonatal tetanus cases are most likely to be heard about or seen (such as hospitals, clinics, and churches), and begin educational and promotional activities to improve detection and reporting of suspected neonatal tetanus cases.
- Determine whether a suspected case is neonatal tetanus.
- Conduct an ongoing assessment of case data, including the thorough investigation of the circumstances surrounding each case, and identify risk factors.
- Develop special vaccination programs in areas at highest risk of neonatal tetanus (based on disease surveillance, population, and coverage data).
- Conduct selected reviews of birth practices to promote educational campaigns targeted at high-risk and problem communities.

### 1.3. Program Management

In order for a program of this magnitude to succeed, a well coordinated and managed approach is necessary. This usually requires both centralized responsibility for all surveillance and control activities and decentralization, so that health workers have enough authority and flexibility at the local level to conduct program activities. The program manager needs to use the epidemiologic investigation data to direct the program and to supervise and evaluate activities. The manager must *see* to it that resources are directed toward high-risk areas. All activities should be detailed in a national plan of action, which should form the basis for local plans of action (Appendix A).

Direct functional links need to be established between epidemiology and management. Such links require exchanges of reports and definition of tasks and duties related to the elimination program. A close collaboration should be maintained at every level between staff engaged in maternal and child health care and staff involved in the Expanded Program on Immunization. A national Interagency Coordinating Committee (ICC) should be established so that all involved agencies, both public and private, will have a clear idea of what each agency's commitments are to the program.

Training and management seminars play an integral role in the implementation of the neonatal tetanus elimination strategy. Development of workshops both for surveillance and for evaluating high-risk areas is a priority.

### 1.4. Information Systems

An important aspect of a successful program is a well-developed information system, which provides program managers and health workers with the necessary information for taking appropriate actions (see Appendix B). Information from the disease surveillance system must also be summarized into regular useful reports and provided to all responsible health staff as well as management.

*Certain minimum information* needs to be collected, analyzed, and reported at the country level. These data include the following:

- Current listings of all suspected, confirmed, and discarded cases.
- Listings of municipalities at high risk for NNT.
- Population of women of childbearing age by municipality.
- Number of doses of TT1, TT2, and TT3 delivered to women 15–45 years of age.
- Listings of types of deliveries by municipality.
- Listings of reporting sites and weekly compliance.

In addition, summary information on disease occurrence and control activities should be kept up-to-date, so that the current neonatal tetanus situation within a country can be evaluated at any given time (see Appendix C for sample form).

# 2. EPIDEMIOLOGY OF NEONATAL TETANUS

## 2.1. Occurrence

Records dating from the fifth century B.C. mention clinical illness which is consistent with tetanus. Even today, NNT remains an important cause of avoidable morbidity and mortality in developing countries. *Clostridium tetani,* the organism which causes neonatal tetanus, is ubiquitous, but it is most frequently found in densely populated regions with hot, damp climates where the soil is rich in organic matter. Neonatal tetanus is most common in developing countries and rarely occurs in developed countries where improvements in delivery practices and nearly universal tetanus immunization have been achieved. In developing countries, the disease usually occurs among the poor in the urban periphery and in certain rural areas.

The results of community-based surveys show that neonatal tetanus mortality rates range from less than 5 to more than 60 per 1,000 live births; these deaths represent between 23% and 72% of all neonatal deaths. The estimate of yearly deaths worldwide due to neonatal tetanus is now placed at over half a million. Tetanus cases remain substantially underreported in most countries, and it is estimated by WHO that routine reporting systems identify only 2%–5% of the actual number. In the American Region, PAHO estimates that 10% of the true number of cases is detected by routine reporting systems.

## 2.2. Epidemiologic Characteristics

**Sex:** Worldwide reports indicate that the ratio of male to female NNT cases usually ranges from 1:1 to 1:3, in both hospital and community-based surveys. One possible explanation for this predominance of female over male victims is that males may receive preferential care after birth. In the Americas, however, the ratio is generally close to 1:1.

**Mother's age:** The average age of mothers usually ranges between 20 and 30 years, the same as the period of highest frequency of pregnancy.

**Seasonality:** Seasonality has been observed in several countries; however, no plausible explanation for it has yet been put forward.

**Delivery location:** Approximately 90% of NNT cases are home births. In the Americas, 7% of NNT babies were born in a health service facility, usually a hospital. A review of cases whose birthplace was a health facility reveals that the mother and baby were typically discharged within 6 to 12 hours after delivery. When such early discharges occur, the mother or other persons may be more likely to handle the cord stump improperly.

## 2.3. infectious Agent

The tetanus bacillus *(Clostridium tetani)* is a gram-positive anaerobic rod that can develop a terminal spore. The disease is caused by the exotoxin produced by the vegetative form. *Clostridium tetani* multiplies quickly in decaying tissue. The vegetative form is sensitive to heat and a number of antibiotics, and it cannot survive in the presence of oxygen. However, the spore form is very resistant to heat and common antiseptics. Spores can survive autoclaving at 121 °C for 10–15 minutes and are relatively resistant to

phenol and other chemical agents. The germination of spores requires anaerobic conditions. If not exposed to sunlight, the spores may persist in soil for months to years.

### 2.4. Reservoir

The bacilli are widely distributed in the environment and in feces of certain animals and human populations; therefore, soil fertilized with manure may be highly infectious. In agricultural areas a significant number of normal human adults may harbor the organism in their stools. The spores are densely present in soil contaminated by feces and can also be found in street dust and on skin surfaces.

### 2.5. Transmission

Transmission usually occurs through infection during unhygienic cutting of the cord or improper handling of the cord stump, particularly when the umbilical cord is "treated" or "dressed" with contaminated substances which may contain tetanus spores, for example, animal dung.

### 2.6. Incubation

For neonatal tetanus, the incubation period is the time between the start of infection and the occurrence of the first symptom, usually trismus (lockjaw). In neonates the start of infection occurs soon after birth. The incubation period is commonly 6 days, but ranges from 3 to 28 days.

### 2.7. Communicability

Tetanus is *not* directly transmitted from person to person.

### 2.8. Susceptibility and Immunity

Infants born to immune mothers acquire temporary immunity for about 5 months. However, if an infant is born less than 15 days after the mother's second or subsequent dose, the infant will not be protected because the vaccine will not have had time to stimulate the production of antibodies. A significant level of immunity can be obtained from vaccination with two doses of adsorbed tetanus toxoid given at least 4 weeks apart. The primary series of two doses should be reinforced by a third dose given 6–12 months later. The duration of immunity after three doses of tetanus toxoid is thought to be at least 5 years, with a total of five doses producing lifelong immunity.

At present the most specific test available for determining tetanus immunity is the neutralization test *in vivo.* This test is expensive, time consuming, and requires a large number of animals. *In vitro* techniques — including passive hemagglutination, enzyme-linked immunosorbent assay (ELISA), and radioimmunoassay — are simple, sensitive, and rapid; however, they are less specific than the neutralization test. Although the results of these tests, which measure antitoxin levels, are not entirely comparable, a serum level of >0.01 international units per milliliter (IU/ml) is generally considered protective.

### 2.9. Control

The primary focus of the Neonatal Tetanus Elimination Program is the *immunization of women of childbearing age* with tetanus toxoid. This strategy prevents neonatal tetanus and also tetanus in the mother. In addition, *general improvements in delivery practices and postdelivery practices* can also be effective in preventing tetanus.

# 3. CLINICAL ASPECTS

### 3.1. Pathogenesis

In a neonate, the portal of entry of the bacilli is almost always the site at which the umbilical cord is cut. In the presence of dead tissue and possibly other organisms, the spores germinate and the bacilli multiply at the site of primary inoculation, producing the toxin tetanospasmin, which causes the symptoms and signs. The toxin disseminates by means of the bloodstream and lymphatics. It appears that the toxin progresses up the motor nerve trunks first and then up the spinal cord. The typical clinical manifestations of tetanus are caused by the effect of tetanospasmin on the central nervous system. Spasms such as lockjaw occur because the toxin allows the nerve cells for many muscle groups to fire at one time. Seizures may occur and the autonomic nervous system may be affected.

### 3.2. Clinical Features

There are three essentially different clinical forms of tetanus: (1) local, (2) cephalic, (3) generalized. Neonatal tetanus is one form of generalized tetanus and is dealt with in detail in this manual; the other two forms, which are most common in older children and adults, will not be discussed.

Failure to suck is often a first sign in the neonate, and typically occurs between the 3rd and 10th day of life. In spite of efforts by the infant, spasms of the superior and inferior masseter muscle (upper and lower jaw) impede feeding. Trismus (a spasm of the masticatory muscles) apparently disturbs the proper movement of the lips that helps control sucking. The newborn becomes irritable and cries constantly. The mother may still manage to squeeze milk into the mouth or to spoon-feed the infant; however, the jaw's rapidly increasing rigidity impedes swallowing. The cry of the affected newborn varies in intensity from a short hoarse sound to a gurgle. Exhaustion brings about cessation of audible crying.

As a rule, neonatal tetanus follows a descending pattern of nerve involvement. The first sign is usually trismus or lockjaw, followed by difficulty in swallowing, stiffness of the neck, rigidity of abdominal muscles, and a temperature rise of 2–4 °C above normal. Spasms may occur frequently and last for several minutes.

In the hours following the appearance of the first symptoms, generalized rigidity often occurs at the same time as the initiation of spasms. The jaws are contracted and the lips stretched laterally in an upward direction. The eyebrows are frequently arched, and the facial expression is that of a sardonic smile (risus sardonicus). Sometimes the lips are rounded as if to whistle.

The time between the first symptoms, usually cessation of suckling or trismus, and the occurrence of spasms is called the period *of* onset. In NNT this period has important prognostic value; the shorter the period of onset, the higher the case fatality rate.

The tetanic spasms become more frequent and are often initiated by light or noise. Such spasms can last from a few seconds to more than a minute. Respiration is affected; infants can become pale or cyanotic, and some may die during the attack. The arms are usually flexed at the elbow, and the hands may be drawn to the chest during the spasm. When the fist is tightly clenched the thumb often interlocks within the fingers. The feet are in a dorsiflexed position with the toes tightly gripped. This hyperflexion of the toes is very characteristic of the level of rigidity and of the hypertonia of the

**Failure to suck, owing to spasms of the jaw muscles, is often the first sign of neonatal tetanus.**

**Baby showing first symptoms of generalized rigidity and trimus. Note puckered lips and arched eyebrows.**

small muscle of the sole of the foot. The neck is somewhat arched toward the back, and the abdominal muscles become markedly rigid. Spasms of the spinal muscles bow the back.

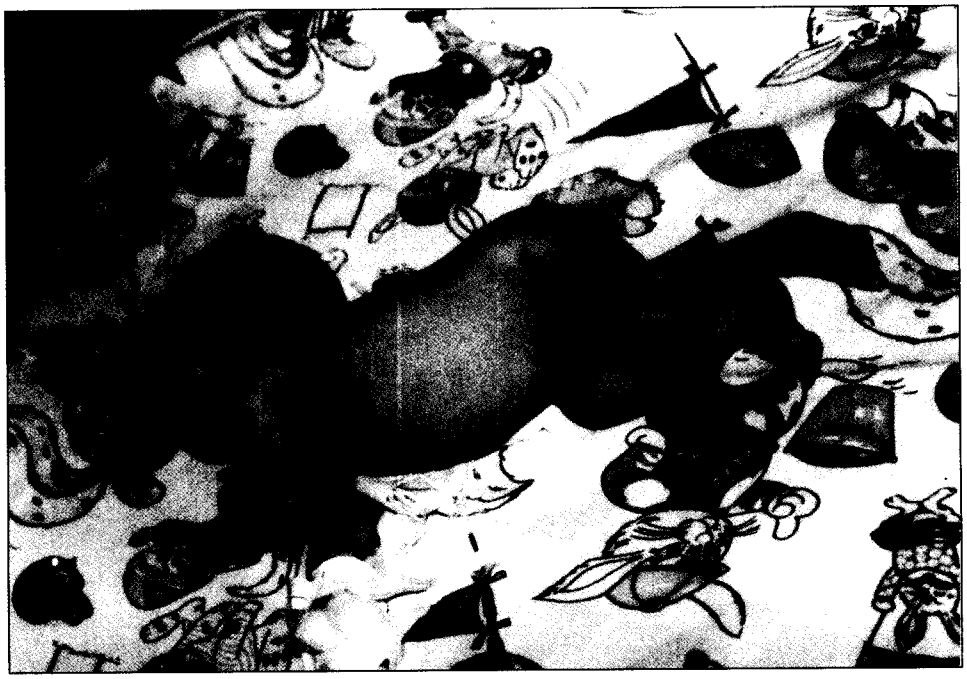
In half of the cases of NNT, infection of the umbilicus is not apparent. Extensive involvement may include a diffuse inflammation of all the anterior abdominal muscles.

The infant may die from either apnea or severe anoxia during the spasms, or after 2 to 4 days from acute gastroenteritis or complications of the swallowing defect leading to pneumonia.

### *3.2.1. Case Presentations*

CASE 1. A 7-day-old baby was brought in the morning to the hospital because he stopped suckling the night before. The day before hospitalization the baby had become irritable and had cried constantly, after which he had stopped suckling. The mother had managed to squeeze milk into his mouth, but he could not swallow. During the medical examination the convulsions started. As a consequence of the action of stronger muscle groups overwhelming weaker groups, the following signs were observed: the spasms of the spinal muscle bowed the back of the newborn (opisthotonos); the arms flexed at the elbow; and the feet became dorsiflexed.

The birth had occurred at home and the delivery had been assisted by the grandmother. The umbilical cord had been cut with a shaving blade. The mother had attended prenatal care twice, but these visits had occurred in the 3 weeks prior to delivery, as had the prenatal visits in her three previous pregnancies. At none of those opportunities was tetanus toxoid vaccine administered, as the health providers felt that the timing of the visits was not consistent with the recommended schedule.



**Opisthotonos (bowed back), caused by spasms of the spinal muscles. Spasms become more frequent as the disease progresses.**

CASE 2. A 13-day-old male infant was brought to Children's Hospital of Los Angeles (California, U.S.A.) with respiratory arrest. He had been born 2 weeks earlier at another hospital in an uneventful vaginal delivery; the patient was the fifth child of the mother. On the second day of life the patient was discharged from the hospital. On the 10th day of life, the umbilical stump fell off, and purulent drainage was observed at the site. On the 13th day of life, the infant had trismus, was irritable, and refused feedings. On the morning of the 14th day (the day of hospital admission), the infant was febrile, his body was rigid, his respirations were noisy, and he was drooling. The infant had frequent spasms of the extremities and the body triggered by external stimuli. The mouth was locked in an open position. Respirations were shallow, and an inspiratory rattle was heard that was suggestive of laryngospasm.

Treatment included the use of tetanus antitoxin (human), surgical debridement of the umbilical stump, tracheostomy, reduction of environmental stimuli, and the use of diazepam (Valium), meprobamate, phenobarbital, chlorpromazine (Thorazine), and penicillin. The infant received feedings by gavage, and the bladder was emptied by Credé's method.

The patient's condition improved steadily. Spasms decreased in frequency and stopped altogether after 4 weeks. The use of medications was also discontinued then, without return *of* spasms, and the patient was well when discharged after 48 days in the hospital.

*3.2.2. Discussion*

Case #1 is hypothetical and based on the typical case presentation of neonatal tetanus in the Americas. Case #2 is a case described by Krugman and Katz (1981); it is important because it occurred in Los Angeles in a patient who had been born in a hospital. important points illustrated by these cases include: (1) risk factors for NNT (birthplace, vaccination status of the mother, method of cutting the cord, etc.), (2) "missed opportunities" for immunization of the mother in case #1 (clearly, she had several opportunities during her previous pregnancies to be immunized, but there had been a failure to do so because she had presented so late for prenatal care each time), and (3) incubation period (which is associated with prognosis, since the shorter the incubation period the higher the case fatality rate). Perhaps the contamination of case #2 occurred during improper dressing or treatment of the umbilicus after discharge from the hospital. This case points out that no place is entirely free of the risk of NNT.

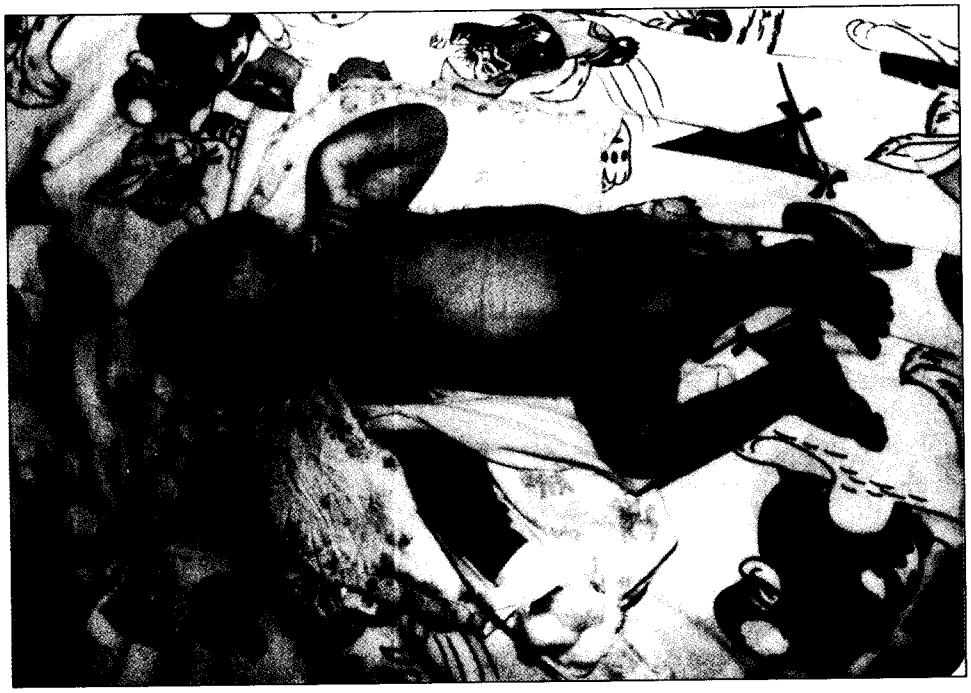
### 3.3. Differential Diagnosis

While no other disease clinically resembles full-blown neonatal tetanus, there are a number of medical conditions that can display one or more of the clinical findings observed in NNT. The differential diagnosis should include consideration of causes of neonatal convulsions. In general, there are three etiologic categories of neonatal convulsions:

- congenital (cerebral anomalies);
- perinatal (complicated labor, perinatal trauma and anoxia, or intracranial hemorrhage);
- postnatal (infections and metabolic disorders).

Brain damage due to the first two categories may lead to spasticity, bizarre or jerky body movements, and convulsions. Infants with brain damage are often stuporous or in coma, and seizures usually develop late on the first postnatal day. Cerebral contusion, usually a secondary trauma associated with breech delivery or other obstetric difficulties, occurs particularly in large, full-term infants. Brain damage syndromes may often produce a laxness of mouth and tongue, the

**After treatment, mouth muscles relax and child is able to suckle (above). Spasms gradually cease and generalized rigidity disappears (below). With prompt and appropriate treatment, full recovery is possible.**



sucking reflex may be absent, and swallowing may be lost from the first day of life. None of these conditions produce trismus as tetanus does.

The most important infection during the neonatal period is meningitis, often associated with septicemia. Neonatal meningitis may be the result of infections with group B streptococci, *Escherichia coli, Listeria monocytogenes*, or *Klebsiella-Enterobacter-Serratia* organisms. The first two infections account for 70% of systemic neonatal bacterial infections. Infants with neonatal meningitis may develop lethargy, seizures, apneic episodes, poor feeding, hypo- or hyperthermia, and sometimes respiratory distress in the first week of life or later. A frequent symptom is a bulging fontanelle.

Group B streptococcal infections can affect low-birthweight infants born to mothers who have obstetric complications. Onset of symptoms may be early, in the first 48 hours of life, or late, between 10 days and 4 months. Apnea is often the first sign, and pneumonia with respiratory failure may be present.

In all these conditions trismus is absent and the seizures differ from those of tetanus, tending to occur with shorter, less rapid jerks and often affecting only a portion of the body. In NNT there is no bulging fontanelle.

Metabolic disorders include hypoglycemia, which is particularly frequent in small babies or in infants of mothers who are diabetic, and hypocalcemia, which has two major peaks of incidence in the neonatal period: the first in the first 2 or 3 days of life (in low-birth-weight infants and often following obstetric trauma), and the second later in the first week or early in the second week of life. These babies are usually large, full-term infants who voraciously consume milk with a suboptimal calcium-phosphorus ratio, such as cow's milk. Hypocalcemic tetany of the newborn may produce seizures and sometimes laryngospasm, but the seizures are of a different character from those of tetanus, and usually there are also tremors or muscle twitchings. It does not produce trismus or the generalized rigidity seen in tetanus. Infants with tetany appear well between convulsive episodes.

**Field investigations:** During investigations, especially of unhospitalized cases, diagnoses must be made retrospectively, based on information provided by mothers. The validity of the information obtained in such a way will be influenced by the ability and willingness of a respondent to answer, as well as by the tact, knowledge, and skill of the interviewer.

The basic questions posed to the mother concern the following features of the infant's history:

- Was the infant born alive and did it develop normally during the first days of life?
- Was the infant able to suckle during that period?
- Did the infant stop suckling or develop any other feeding problem between the 3rd and 15th day of life, or when the illness began?
- Did the child develop generalized stiffness, trismus, or risus sardonicus?
- Did the child develop spasms/convulsions which increased in frequency and in intensity?
- What reason does the mother give for the child's death?

### 3.4. Laboratory

Laboratory confirmation is difficult. Isolation of the organism may be attempted by inoculation of the stump material into an adequate culture medium. More often than not, the organism cannot be recovered from the site of infection. For the patient there are no specific laboratory tests that show abnormalities characteristic of tetanus. *The diagnosis is clinical and does not depend upon bacteriologic confirmation.*

### 3.5. Complications

(1) *Laryngospasm*—spasm of the vocal cords and/or spasm of the muscles of respiration leading to interference with breathing.
(2) *Fractures* of the spine or long bones as a result of sustained contractions and convulsions.
(3) *Hyperactivity of the autonomic nervous system* leading to hypertension and/or an abnormal heart rhythm.
(4) *Coma.*
(5) *Generalized infection* from indwelling catheters.
(6) *Pulmonary embolism.*
(7) *Aspiration pneumonia*—a common late complication of tetanus.
(8) *Death*—Without good supportive care, case fatality rates can exceed 90%. The largest number of deaths from NNT occur during the first week of the disease.

### 3.6. Treatment

Treatment generally includes tetanus antitoxin, muscle relaxants, and intravenous feeding.

**Control of muscular spasms:** The patient should be admitted to a quiet, darkened room where all auditory, visual, tactile, or other stimuli are reduced to a minimum. The first priority in spasm management should be the administration of appropriate drugs to reduce the number and severity of spasms. Diazepam (Valium) has proved to effectively control spasms and hypertonicity without depressing the cortical centers. The recommended dose for infants is 8 mg per kilogram of body weight per day.

**Antitoxin therapy:** After adequate sedation has been achieved, human tetanus immunoglobulin should be given in a single dose, 3,000 to 6,000 IU, intramuscularly. If human immune serum globulin is unavailable, tetanus antitoxin should be given if sensitivity reactions to horse serum are negative. The antitoxin is given intravenously and intramuscularly, half the dose via each route.

**Antimicrobial therapy:** Although antimicrobial therapy has no effect on the toxin itself, it is important in eliminating the organism which produces the toxin. It is recommended that aqueous penicillin G be given in a dose of 1 million IU intravenously every 6 hours, or 1.2 million IU of procaine penicillin once daily.

**Wound treatment:** After the patient has been sedated and received antitoxin, the wound should be thoroughly cleansed and debrided.

**Supportive treatment:** Oxygen should be available. During early stages, oral feeding should be avoided because of the danger of aspiration. A continuous intravenous infusion can provide water, electrolytes, glucose, and amino acids.

**Tracheostomy:** The combination of heavy sedation, difficulty in swallowing, laryngospasm, and accumulation of secretions may lead to obstruction of the airway. A tracheostomy can be lifesaving if performed when appropriately indicated.

# 4. CASE DEFINITIONS

For reporting purposes, *a standard clinical case definition should be adopted at the national level.* The category "suspected case" is particularly useful for those cases which are based upon reports by traditional birth attendants. Reports based upon hospital review are considered essentially confirmed.

### 4.1. Suspected Case

- Any infant with a history of tetanus-compatible illness during the first month of life that fed and cried normally for the first 2 days of life;

OR

- Any neonatal death in a child who could suck and cry normally during the first 48 hours of life.

### 4.2. Confirmed Case

A confirmed case of neonatal tetanus is defined as a child with a history of all three of the following:

- Normal feeding and cry for the first 2 days of life.
- Onset of illness between 3 and 28 days of life.
- Inability to suck (trismus), followed by stiffness (generalized muscle rigidity) and/or convulsions (muscle spasms).

### 4.3. Discarded Case

A discarded case is one which has been investigated and does not fit the case definition. The diagnosis should be specified. A summary of diagnoses for discarded cases should be made routinely (see Appendix D for sample form).

# 5. SURVEILLANCE

Simultaneously with an increase in control measures, it is critical that an epidemiologic surveillance system be established or improved. The most basic form of surveillance can be carried out by review of death records; however, as such records may be incomplete, this activity should only supplement more active surveillance and reporting mechanisms. For those areas initially classified as at low risk for NNT, improved surveillance will either confirm that status or provide additional information on the disease occurrence that will lead to the area being reclassified as high risk. For those areas already classified as high risk, the system allows measurement of the impact of NNT control measures.

Health facilities that report tetanus cases should distinguish between neonatal and non-neonatal tetanus. Reports should categorize these cases separately. It may be possible to conduct sentinel surveillance in selected high-risk areas. Periodic visits can be made to such areas by someone from the national EPI. Based upon the origin of neonatal patients in a given region, hospital catchment areas can be set up (see section 5.2). This is very important in helping to define high-risk areas and improving surveillance.

### 5.1. Identification of High-risk Areas

The primary focus for surveillance should be areas of high risk. A study in 11 South American countries found that only 191 of 2,212 counties (9%) were at high risk for neonatal tetanus, and that they contributed 79% of the total cases reported in those countries. The distribution of reported cases by urban or rural location in this study showed that 58% of the reported cases occurred in urban areas, where the population has access to both preventive services and prenatal and delivery care.

The utilization of data on NNT that are available routinely through national morbidity and mortality information systems should, in many instances, provide enough information for the identification of high-risk areas. Where possible, high-risk areas should be identified at the subdistrict level, i.e., the level of municipality. These *high-risk areas should be given priority.* In particular, campaigns should be initiated to cover all women with at least two doses of TT in the shortest time possible. It is necessary to document cases that are not being reported through the routine national surveillance system. Several criteria have been used to define high-risk municipalities/counties, including the following:

- one or more cases of NNT reported in each of the last 3 years;
- a higher incidence of NNT morbidity or mortality than the national average in any one of the 3 previous years;
- areas with unreliable data on incidence;
- areas with unreliable data on TT vaccination coverage.

In addition, in the future any municipality or county which has not previously been identified as high risk will become classified as high risk if it reports one or more cases.

**Silent areas:** Municipalities/counties for which there are unreliable data regarding either incidence or coverage of women of childbearing age, or where delivery is largely done outside of the hospital setting, should be suspected as being "silent" for neonatal tetanus. It is in these municipalities/counties that active search for cases will be needed. These active searches will consist of hospital record reviews, house-to-house interviews, community surveys, etc.

### 5.2. Reporting from Sites

In addition to all health facilities in the high-risk areas, an entire network of community reporters needs to be organized to report suspected cases. The network may include traditional birth attendants (TBAs), village leaders, guards at clandestine cemeteries, school workers, pharmacists, and anyone else likely to come in contact with such illnesses.

- Each health facility should identify one individual (and one or two alternates) who will be responsible for keeping track of suspected cases and reporting such cases to health authorities responsible for surveillance (this may be the same person who reports acute flaccid paralysis, malaria, and other infectious diseases).
- In hospitals, the assigned doctor or nurse must visually check pediatric and infectious disease wards in addition to conducting monthly record reviews.
- In addition to health and allied health personnel, the monitoring system must include at least one reporting source identified in each "village/township" (or comparable small geopolitical unit), and he or she should report a minimum of once a month, whether suspected cases have been seen or not.
- At each level of the health system, some sort of record must be maintained to keep track of all suspected case reports and the outcome of any review or investigation. A line listing, as presented in Appendix E or other similar form, may be used.
- Each health facility should be directed to report suspected neonatal tetanus cases to local and/or state surveillance coordinators immediately. State officials should report on a regular basis

(weekly or monthly) to the national level, and national authorities should report to PAHO's EPI office every semester (6 months).

- Repeated visits by the program surveillance officers will be required to establish and monitor all levels of the reporting system.
- All suspected cases should be investigated by an epidemiologist or other specially trained staff in an attempt to confirm the diagnosis and to detect possible sources of infection. (For example, if delivery was done by a TBA, the TBA should be visited and a determination should be made as to whether the TBA is appropriately trained, performs clean deliveries, etc.)
- Each suspected case should be given a unique identification number, which should be used whenever reference is made to the case. This unique number should be included in the report. The identification number should contain certain identifiers, such as a T for tetanus, the country or state code, and the year (e.g., T ELS 92–001).

### 5.3. Active Case-Finding

An enhanced surveillance system should incorporate periodic case-finding, particularly in those areas which have not been consistent in reporting, or which have been reporting zero cases for a long period of time. In order to find cases, community leaders and pediatric associations should be contacted and their assistance obtained. Churches, hospitals, and clinics should also be visited. Door-to-door searches might be used in those areas where patients are unlikely to seek medical care and when there is a "rumor" of a neonatal death compatible with tetanus. All health workers should be instructed to ask patients about tetanus-like illnesses occurring in their villages/towns. Health workers who make visits outside their health centers should be instructed to submit a form indicating the areas they visited and how many persons they asked about neonatal tetanus.

### 5.4. Feedback

Feedback includes providing surveillance participants with the following: (1) information about the number and location of cases reported, (2) assessment of the level of promptness and accuracy of their surveillance reports, (3) data on the effectiveness of vaccination and control activities, (4) specific recommendations on how to solve a common problem, and (5) commendation of personnel doing excellent jobs. Feedback can be effectively provided by sending newsletters to the reporting sites, health professionals, and other interested parties.

# 6. CASE INVESTIGATIONS

### 6.1. Introduction

All reported cases should be investigated, whenever possible, by specially trained staff from the province/state or national level. It is necessary to confirm a diagnosis of NNT that was made by untrained people. Hospitalized cases should be investigated, as information may be obtained from the patient's medical record at the hospital or in the hospital archives. Efforts should be made to determine why the case occurred:

- Was the mother unvaccinated?
- Was the delivery unattended?

- Were improper techniques used during or after delivery?

### 6.2. Investigation of the Case

Each reported case should be investigated no later than a month after it is reported. The shorter the period before the mother and others in attendance at the birth are visited, the more likely they are to remember details about the delivery. In addition to investigating the suspected case, inquiries should be made as to whether any other cases have occurred in the area. The state or neonatal tetanus surveillance coordinator should be contacted as early as possible in the course of the investigation. Case definitions given in this guide should be strictly followed. It is important to immunize the mother of the infant whose case is being investigated.

### 6.3. Using the Case Investigation Form (Appendix F)

**General information:** If the baby has not been given a name, write "baby" followed by the parents' names. Be specific when giving the address so that the location can be found by others if a follow-up visit is necessary. The "date reported" is the date when the case was first reported to any level of the health system. For example, if a private doctor notified the health center on 3 March that he had seen a case of NNT on 1 March, then the report date would be 3 March. And in this case "reported by" would be the doctor's name, and his "position" would be PMD (private medical doctor).

**Clinical data:** Date of onset of illness is when the mother first noticed something wrong: difficulty in opening the mouth or in swallowing or sucking. *Trismus* refers to difficulty in opening the mouth. *Body rigidity* is when the body is stiff. *Convulsions* are usually defined as episodes of violent body shaking.

**Maternal and delivery data:** The immunization status of the mother is very important, and therefore every effort should be made to document by inspection of a record any report of TT immunizations received, as well as any other prenatal care. If the mother received such care, it is important to identify the health center that provided it. The child's birth order and mother's total number of pregnancies and deliveries are indirect indicators of lost opportunities for vaccination. The characteristics of the person who delivered the child are also important. If possible, find out and record whether or not the person who delivered was trained and whether the place of delivery was appropriate. If health personnel were involved, take down their names, no matter whether they are medical personnel or trained midwives. If the delivery took place in a health center, also take note of the facility's name and address. This information will make it possible to take corrective measures.

# 7. DATA ANALYSIS

## 7.1. Data Elements

Data from case investigation forms and line listings should be analyzed in order to provide a descriptive picture of the cases and to determine whether standards for case reporting and investigation are being met. Such reviews assist in the identification of system failures. In selected areas clinical and epidemiologic data may be collected retrospectively from hospital records, a procedure that may help evaluate diagnostic capability as well as the national information system's efficiency in identifying all cases of the disease. The diagnostic quality would be evaluated according to the data contained in the clinical record. Data to be collected should include the following information:

- Case identification, place of residence, age, and sex.
- Dates of birth, onset of trismus, hospitalization, and release from hospital (depending on the clinical evolution of the disease).
- Information on the mother: age, vaccination history, prenatal care, number of previous births (Appendix F).
- Data related to the birth: place of birth and level of training of birth assistant (Appendix F).
- Source of notification.

## 7.2. Reports

In order to benefit from control activities, it is necessary to organize and report on data related to cases. All reports should include the following sections: 1. Introduction, 2. Description of the cases, 3. Analysis of the data, 4. Methods of surveillance, 5. Control activities, 6. Problems, 7. Conclusions and recommendations.

The following information should be included in periodic summary reports:

- Possible sources of infection.
- Description of persons attending the deliveries.
- Description of deliveries.
- Places where vaccination with TT was available in affected areas.
- District(s) with neonatal tetanus cases (include map).
- Date of onset of trismus of the most recent case.
- Immunization status of mothers of cases.
- Estimated coverage (two or more doses in females 15–45 years of age in affected area).
- Immunization efforts after identification of case(s).
- Demographics (population size, age breakdown, geography of affected areas).
- How first case and other cases were found (source of reports).
- Special surveillance efforts.
- Graph of cases by date of onset.
- Table showing age and sex distribution of cases.
- Summary of clinical presentation of cases.
- Hospitalizations and deaths.
- Reason(s) why mothers of case(s) had not been previously vaccinated.
- Evaluation of the accuracy of estimate of existing coverage (record review, house-to-house, etc.).
- Vaccination methods used to improve coverage (house-to-house, central collection points, etc.).
- Staff utilized, including involvement of local health staff and community leaders.
- Problems in investigation, supervision.

# 8. CONTROL IN HIGH-RISK AREAS

## 8.1. Introduction

There are two principal avenues open for the control and eventual elimination of neonatal tetanus: first, immunization, and second, improved delivery and postdelivery practices. It has been clearly demonstrated that immunizing women with TT substantially reduces deaths from neonatal tetanus—even more than training traditional birth attendants in safe delivery practices. However, training TBAs also helps to reduce neonatal deaths due to tetanus, as well as to lower overall neonatal death rates. Both are important to child survival.

When planning neonatal tetanus elimination activities, it is reasonable to focus attention first on known areas of high risk, or areas where because of lack of data the risk is undefined ("silent areas").

## 8.2. Program Priority Areas

In developing program activities and priorities, it is useful to write up a plan of action at both the national and local level (see Appendix A). Each national plan should have a detailed budget. It should also contain a method for increasing surveillance and for identifying the "silent" areas for NNT. Plans of action in the high-risk areas should identify localities at highest risk and the activities that will be carried out. In particular, the plan should detail ways to augment coverage and to improve clean delivery and postdelivery practices.

## 8.3. Measuring TT Coverage

There are problems in determining valid TT coverage rates based upon routine service statistics. Since multiple doses of TT are administered within varying intervals over a 30–year reproductive span, and women enter and leave the eligible age range continuously, for practical reasons only the second doses applied during every 3–year period should be considered in determining coverage. When a new year is reached, the doses of TT2 applied during the first year of the previous period must no longer be counted, being replaced by the doses applied during the new year. After achieving coverage of 100% of women of childbearing age with TT2 the goal ought to be coverage with TT3.

## 8.4. Immunization Activities

*The primary targets for immunization are women in the childbearing age range (15–45 years of age).* The immunization of women of childbearing age provides TT to the population group with the most immediate need. The vaccination of these women with TT has been shown to markedly reduce the incidence of NNT. Where resources exist, immunization of young schoolgirls in the early grades should be considered.

### *8.4.1. Immunization of Women*

Immunization of women of childbearing age is the most rapid means of controlling neonatal tetanus. For women with no prior history of immunization, it is necessary to begin a series of two doses of TT not less than 4 weeks apart, with a booster dose

6–12 months later. For those with a documented history of prior immunization, including DPT or DT vaccination at an early age, a booster dose is sufficient. When a woman becomes pregnant, the first dose should be given as early as possible during pregnancy, and the second dose should be given no later than 3 weeks before the expected date of delivery. Women who have received two doses of TT during a previous pregnancy should be given a booster dose of TT in the new pregnancy. The third dose will protect for up to 5 years, during which time an additional booster dose is not required, even during a new pregnancy.

Every immunization given during a pregnancy should be recorded, and the record compared with the number of women who attend either prenatal or antenatal clinics (Appendix G).

Areas considered at high risk for NNT generally have low coverage rates and should be considered a priority for immunization efforts. Of particular concern are poorly served rural populations and the urban poor, including migrants and slum dwellers. Special efforts are needed in these areas to reduce the level of drop-outs. This can usually be achieved through careful monitoring by health workers and community leaders.

*8.4.2. Mass Campaigns*

In addition to improved delivery of immunization, there may be a need to conduct periodic campaigns aimed at special target groups. Such vaccination rounds or vaccination days are used to accelerate the immunization activities and can be carried out at either the local level or nationally, where many resources can be committed and mass media attention focused on the event.

**National level:** When national vaccination days are conducted for other EPI antigens, TT should also be included and given to women 15–45 years of age.

**Local level:** Intensified immunization efforts for short periods can be used to supplement routine daily vaccination programs (such efforts are generally referred to as "mop-up vaccination campaigns"). This technique is particularly useful in areas with deficient health services or low coverage.

The mass campaign approach aims at coverage of 100% of the target population with two doses of TT in a single designated period of time. Every effort should be made to include immunizing women 15–45 years of age with TT during campaigns for other EPI antigens.

*8.4.3. Outreach Programs*

A community outreach program can have dramatic success reaching populations that were once considered "unreachable." Key elements of a good outreach program include marketplace immunization programs; utilization of local institutions—churches, schools, and local leaders—to assist in the program; and follow-up activities to complete coverage through rural health posts, preceded by door-to-door enrollment of families using resident home visitors, community social workers, and TBAs.

*8.4.4. Missed Opportunities*

In studies conducted in the Andean Region (Bolivia, Colombia, Ecuador, Peru, and Venezuela) of the Americas, 78% of reported cases occurred in children born to women who had already had at least two previous pregnancies, and therefore may have had a prior opportunity to have been vaccinated. Many approaches to reducing missed opportunities are available to health workers, some of which are outlined in Table 1.

In addition, health care providers should evaluate their own behavior, as it may be responsible for many missed opportunities for immunization. For example, some health staff, as well as the

Table 1. Approaches to reduce missed opportunites for immunization.

| Approach | Advantages |
|---|---|
| Immunization of pregnant women attending maternity wards | • Few additional resources needed<br>• Potentially rapid impact on future pregnancies |
| Immunization of women of childbearing age through regular health services | • Any contact of women with health worker can be used to immunize<br>• Better chance of reaching high-risk women (who may not come for preventive care, but would come for care of their child) |
| Immunization of women coming with a child to an immunization session | • Few additional resources needed<br>• Women with children are likely to become pregnant again |
| Immunization of women coming with or without children to the immunization session | • Few additional resources needed<br>• Some women reached prior to first pregnancy |
| Immunization of women during mass campaigns | • Large numbers immunized in a relatively short period of time<br>• Areas without usual access to health care are reached |
| Improved follow-up of pregnant women for second TT dose | • Reduces rate of failure to receive TT2 |

population they serve, may erroneously believe that TT immunizations should not be given at anytime during pregnancy or during specific months of pregnancy. Some health workers show reluctance to immunize children with a low-grade fever or to give multiple antigens. There are many ways health providers can promote demand for TT immunization, including:

- expanding the number of immunization sites;
- modifying the days and hours when immunizations are available;
- modifying the way the mothers are treated within the service delivery system;
- ensuring that mothers know why they are being immunized;
- improving communication on side-effects and follow-up immunization.

*8.4.5. Lifetime Immunization Record*

All women should be provided with a durable lifetime immunization record or an integrated health care card, which records all TT doses received, including any DPT vaccinations received in childhood (which can count for up to two TT doses in the five dose series).

*8.4.6. Role of the Traditional Birth Attendant in Immunization*

The training of TBAs is one way through which improved delivery of TT to pregnant women, and other women of childbearing age, can take place. The improved heat stability of the vaccine allows it to be out of a refrigerator for up to 42 days without losing potency.

*8.4.7. Hospital Vaccination Programs*

Hospitals can help achieve dramatic improvements in the immunization coverage of women of childbearing age. Hospitals should set up routine daily immunization points to provide TT to their clients and to other women accompanying patients to such facilities. Contact needs to be established with hospitals in order to review their immunization policies and to adopt specific immunization programs where none exist. Routine monitoring and reporting from hospitals on number of doses provided must be implemented.

## 8.5. Delivery and Postdelivery Practices

For purposes of the NNT elimination program, a clean delivery is defined as a delivery attended by health staff in a medical institution or by a trained birth attendant at home using hygienic practices (i.e., assuring the cleanliness of hands, cord, and perineum, as well as any substances applied). Hygienic delivery practices can reduce other causes of perinatal mortality such as meningitis. The training of traditional midwives, though important, will not be covered in this manual, since many other texts deal with it extensively.

**Postdelivery practices:** Inappropriate cord care may place the infant at risk. Special education programs for new mothers, birth workers, and health attendants should be conducted. Any case of neonatal tetanus occurring in a newborn delivered by a trained person is an indicator of a failure of aseptic techniques at either delivery or postdelivery, and a lack of adequate protection by TT.

**Community-based delivery kits:** Introduction of a simple community-based delivery kit, assembled from local materials and distributed with the assistance of women's groups, is one means of achieving clean delivery. The kit should remain in the mother's home. Explanations on its use should be given by health care workers and reinforced with simply drawn illustrations.

## 8.6. Social Mobilization

The community should be aware that tetanus is a major killer of newborns and that it can be prevented by (1) immunizing the mother prior to delivery, (2) assuring that the delivery is carried out and the cord cut under clean conditions, and (3) ensuring that no unclean dressings are placed on the cord while it is healing. Community programs stressing the "three cleans" (clean hands, clean delivery surface, and clean cut) need to be developed in high-risk areas.

**Refusal to be immunized:** In studies of reasons why women refuse immunization during pregnancy, responses include: objections by husbands and mothers-in-law, fear of harming the fetus, and village rumors related to the vaccine. In one West African country, a survey revealed that in some areas it was a common belief that TT could cause women to be infertile. Confusion may also be created by differences between the name used for the vaccine and local names used for neonatal tetanus disease. The correct local terminology for NNT should be carefully researched.

**The role of the health educator:** The health educator plays an important role in gaining public acceptance for immunization and encouraging clean delivery practices. Health educators can be useful in contacting the media, schools (both public and private), and religious organizations. Problems of inadequate coordination at local levels can be addressed by local seminars, with special seminars conducted in areas with large numbers of cases or low coverage rates. Other health education efforts can focus on determining why some women and children do not come to clinics, as well as other barriers to participation. A commonly reported explanation for lack of immunization is that the person was too ill to take the immunization on the day of the clinic visit. Both families and health workers should be made aware that *minor illness is not a contraindication for vaccination.*

**Changing health behavior:** Promoting health behavior change is a difficult task requiring an open-minded and consistent effort from a multidisciplinary team. Therefore, a person knowledgeable in health education should be included in the early planning stages. Such a person may be helpful in providing information on mothers' knowledge, attitudes, and practices regarding immunization. Based upon such information the program staff can better communicate with and motivate high-risk mothers so that they will be predisposed to come in for immunization and prenatal care, and to report illness if it does occur. The development of specific posters regarding disease reporting and the need for immunization and clean delivery is an important element in efforts to change behavior.

Health messages need to be culture-specific and address the decision makers within families; they should therefore be directed at affecting the attitudes of not only the women themselves, but also of mothers-in-law, husbands, and other men. Women should understand that they need immunization for their own sake, as well as for their newborns. This concept of passing on protection to their unborn children can be a very strong motivational message.

# 9. PROGRAM MONITORING

### 9.1. Introduction

Program monitoring should be an ongoing process, with on-site reviews conducted frequently by internal staff and less frequent reviews by external experts. The development of standards and indicators is an important mechanism to help quantify the level of program performance (see Appendix H).

### 9.2. Program Review

Periodic review of EPI program elements is conducted to document progress toward achievement of objectives and targets and to identify and solve problems preventing achievement of such goals. Managers at each level should regularly monitor progress in a number of important areas for other targeted EPI diseases as well as NNT (Table 2).

### 9.3. Surveillance Indicators

(1) Reporting completeness—90% of sites should report each week/month, even in the absence of cases, and should be monitored using the chart in Appendix I.
(2) Punctuality—90% of reporting units should report on time (based upon a previously designated time limit).
(3) Interval between case onset and notification—90% of all suspected cases should come to the attention of health/medical care workers within 3 months from time of onset. This indicates whether health education efforts are successful in informing both the population and the medical/health community of the importance of early reporting.

### 9.4. Investigation Indicators

(1) Time frame—interval between case notification and investigation should be no greater than 30 days.
(2) Percentage of reported cases investigated—100% of nonhospitalized cases should be investigated. This indicates whether reports are being actively followed up.
(3) Proportion of cases with critical information—the name, address, age of mother, type of

Table 2. Outline of program review elements and schedule.

| Area for Monitoring | Frequency |
|---|---|
| Training | |
| Plan | Annually |
| Conduct | Quarterly |
| Evaluate | Semi-annually |
| Plan of Action | |
| Update Plan | Semi-annually |
| Monitor Plan | Quarterly |
| Surveillance System | |
| Reporting | Quarterly |
| Hospitals | Semi-annually |
| Vaccine Supply | Quarterly |
| Needles & Syringes | Quarterly |
| Coverage | |
| Available Data | Semi-annually |
| Supervision | |
| Plan | Semi-annually |
| Evaluate | Semi-annually |
| MCH Program | |
| Immunization Activities | Quarterly |
| Delivery Programs | Semi-annually |
| Summary Reports | Annually |

delivery, and vaccine history of mother should be recorded for 100% of suspected cases. These data form the basis for analysis.

(4) Final classification—100% of suspected cases should be classified as either "discarded" or "confirmed" within 7 days of the investigation by health staff.

### 9.5. Immunization Indicators

(1) 100% of health services should provide TT to pregnant women and women of childbearing age on a routine basis.
(2) 100% of health jurisdictions should keep records that monitor coverage at the municipality or county level.
(3) 90% TT2 vaccination coverage should be achieved among women 15–45 years of age in high-risk areas.

### 9.6. Clean Delivery Indicators

(1) 100% of births should be delivered by medical personnel or trained birth attendants.
(2) 90% of mothers in rural areas should have received a clean delivery kit prior to the birth of their infant.

# 10. TETANUS VACCINES

### 10.1. Introduction

Adequate immunization of women with tetanus toxoid has been shown to prevent neonatal tetanus and maternally acquired tetanus. *The newborn is protected* in utero *through the transfer of maternal antibody across the placenta into fetal circulation.* The maternal antitoxin antibody transported into fetal circulation is gamma-type immunoglobulin (IgG). The currently available adsorbed vaccines are extremely effective and safe, giving protection after at least two doses. In order to reach the neonatal tetanus elimination target, the strategy of vaccinating all women of childbearing age in high-risk areas (with at least two doses of TT) is being implemented. Already in the first 2–3 years, the program has had a great impact on the incidence of NNT. In the areas that were identified as being

high risk in 1988–1989 in the Region of the Americas, and in which the program strategy had been initiated, there has been a 70% decrease in reported cases of neonatal tetanus between 1989 and 1991.

Experimental single-dose high-potency TT preparations have been shown to produce protective antitoxin antibody levels in 36%–100% of first-time vaccine recipients. Both the efficacy and safety of the high-potency TT preparations remain to be established.

### 10.2. Schedule, Contraindications, and Adverse Reactions

Table 3 gives the recommended immunization schedule for women of childbearing age, including pregnant women. Other live and inactivated bacterial and viral vaccines can be administered simultaneously without problem. The intervals shown in the table are the minimum acceptable time between doses. There is no maximum interval.

Table 3. Recommended immunization schedule for women of childbearing age.

| Dose | Schedule |
|---|---|
| TT1 | At first contact, or as early as possible during pregnancy |
| TT2 | Four weeks after TT1 |
| TT3 | Six to 12 months after TT2, or during subsequent pregnancy |
| TT4 | One to 3 years after TT3, or during subsequent pregnancy |
| TT5 | One to 5 years after TT4, or during subsequent pregnancy |

Table 4 shows the recommended immunization schedule for children. Other live and inactivated bacterial and viral vaccines can be administered simultaneously without problem.

Table 4. Recommended immunization schedules for children.

| Dose | Schedule |
|---|---|
| DPT1 | At 6 weeks of age |
| DPT2 | At 10 weeks of age |
| DPT3 | At 14 weeks of age |
| DT | At 5 years of age |

Vaccine can be safely and effectively administered to persons with mild acute illnesses. There is no evidence for contraindications in pregnant women.

In countries where human immunodeficiency virus (HIV) infection is widespread, individuals should be immunized with the EPI antigens according to standard schedules. This recommendation also applies to individuals with asymptomatic HIV infection and individuals with clinical (symptomatic) AIDS. (However, those with symptomatic HIV infection should not receive BCG vaccination.)

Currently available adsorbed vaccines are extremely effective and safe, causing only minor local reactions which are usually self-limiting and require no therapy. Although acute anaphylatic reactions were reported in the 1940s, it is believed that they were due to the presence of sensitizing agents from the culture media. The improvement of manufacturing techniques decreased the risk of untoward reactions. Local reactions in the form of erythema, pain, and swelling usually last less than 1 day and only rarely more than 3 days. Several reports indicate that the incidence of such reactions may increase somewhat as the number of doses increases. A nodule may be palpable at the injection site. Abscess may occur at the injection site due to either contaminated vaccine or secondary contamination.

**NOTE:** *The benefit of using the vaccine clearly outweighs the costs associated with contracting the disease, in both human and monetary terms.*

### 10.3. Vaccine Efficacy

**Seroconversion rates:** After two doses, between 80%–90% efficacy is achieved for a minimum of 3 years. Three properly spaced doses of tetanus toxoid will produce antitoxin antibody levels considerably greater than the minimal protective level of 0.01 IU/ml for at least 5 years in 95% of recipients. A series of five doses is thought to confer virtually 100% protection (Table 5). Seroconversion efficacy is highly correlated with clinical efficacy.

**Duration of immunity:** The first immunization with the conventional adsorbed tetanus toxoid induces a low and nonprotective level of antibodies but leaves a lifelong imprint on the individual's immune system, so that a second immunization anytime after 4 weeks later will rapidly produce a protective antitoxin antibody level.

Table 5. TT vaccine efficacy, by dose.

| Dose | Minimum interval between doses | Percent protected | Duration of protection |
|---|---|---|---|
| TT1 | — | — | — |
| TT2 | 4 weeks | 80 | 3 years |
| TT3 | 6 months | 95 | 5 years |
| TT4 | 1 year | 99 | 10 years |
| TT5 | 1 year | 99 | likely life-long |

### 10.4. Vaccine Storage

Tetanus toxoid vaccine is extremely stable even at temperatures as high as 18 °C. The vaccine should not be frozen, since freezing irreparably damages it. DPT, DT, Td, and tetanus toxoid should be stored continuously at 2–8 °C (35–46 °F). Although the vaccine is heat stable, it should be refrigerated immediately when received.

If there is doubt about whether any vaccine was stored under the proper conditions, it should not be used and the situation should be reported. If a decision is made to test the vaccine, it should be packed in appropriate transport containers and sent to the central level for potency testing. When used in the field, it should be transported on wet ice in isothermic containers.

In areas where the cold chain cannot be maintained, a detailed and precise program to vaccinate the target population within a 42–day period without relying on a cold chain should be developed. Since TT vaccines are highly stable at 37 °C for at least 42 days, the cold chain can be eliminated for short-term programs. Nevertheless, when the vaccine is not in use, it should be maintained under the proper storage conditions outlined above so as to maintain potency.

### 10.5. Vaccine Supply

Effective distribution of viable vaccine in sufficient quantities is critical to the success of the program. Efficient distribution systems will be essential to ensure that vaccines are available at the delivery points on the scheduled days. To guarantee that immunization activities will not be interrupted, a stockpile of vaccines should be maintained at the country or regional level for use when needed.

*No expired vaccine should be kept.* Recent monthly usage rates should be compared with the amount of vaccine remaining to determine if the vaccine on hand can be used up prior to its expiration date.

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# APPENDIX A

## PLAN OF ACTION
## OUTLINE FOR NEONATAL TETANUS

### INTRODUCTION

This section should include a brief explanation of why the NNT control program is being accelerated.

### BACKGROUND INFORMATION

Geographic description of the area (country, state, districts).

Vital statistics of the population, including women of childbearing age, general population, number of live births, fertility rate, urban and rural population distribution.

Health indicators: infant and maternal mortality rates, delivery practices, prenatal care and vaccination coverage (specify coverage for pregnant women if figure available); number of traditional birth attendants (TBAs); percentages of births delivered at home and births attended by trained TBAs; calculation of health services demand through DPT and polio vaccine first and third doses coverage.

Magnitude of the problem: number of cases, rate per thousand live births; proportion of mortality due to NNT in the neonatal period; estimate of the cost of treating NNT cases.

Epidemiologic description of NNT cases investigated, including geographic distribution; place of delivery and by whom birth was attended; prenatal care, vaccination status, and age of mother; number of previous deliveries and pregnancies.

Current NNT control policy: target population, immunization schedule, and vaccination strategies.

Social mobilization: educational material related to NNT, type of media involvement and communication.

### JUSTIFICATION OF PLAN OF ACTION

Main problems identified and priorities outlined.

### OBJECTIVES OF THE PLAN

Precise target groups and planned achievements.

## ACCELERATED ACTIVITIES TO BE UNDERTAKEN AND/OR CONSIDERED

Various activities should be presented. A short description and explanation should be given for each activity proposed. The following activities should be considered: (1) new surveillance activities (surveys, sentinel systems, strengthening routine reporting systems); (2) alternative control activities (justify any change proposed or describe plans for studies on strategies, target population, immunization schedules, safe delivery, social mobilization, intensification and improvement of communication messages dispelling misconceptions and rumors).

## TRAINING NEEDS

Describe plans for training medical staff and TBAs.

## BUDGET

Personnel (salaries for health workers assigned to specific jobs), vaccine and syringes (take into account waste and transport), supervision (vehicles and maintenance costs) and per diem for supervisors; epidemiologic surveillance (information system, special campaigns in high-risk areas); training activities, social communication; special research and evaluation.

APPENDIX B

# NEONATAL TETANUS INFORMATION SYSTEM FLOW DIAGRAM

| | FORM | TIMING | ACTION | DATA ENTRY AND ANALYSIS |
|---|---|---|---|---|
| *LOCAL* | LINE LISTINGS | WEEKLY | MAINTAIN LISTS OF NEONATAL TETANUS CASES. INITIAL DATA ENTERED IN LINE LISTING AND UPDATED AS DATA BECOME AVAILABLE. | LISTINGS UPDATED MANUALLY. SUMMARY STATISTICS FROM LISTS. |
| | CASE INVESTIGATION FORM | WHEN CASE SEEN | CASE INVESTIGATED BY HEALTH STAFF. FORM REMAINS WITH LOCAL HEALTH STAFF UNTIL INVESTIGATION IS COMPLETE. | FORMS REVIEWED BY HEALTH STAFF. |
| *NATIONAL* | LINE LISTINGS | MONTHLY/ AS NEEDED | INITIAL AND FOLLOW-UP REPORTS OF ANY SUSPECTED CASES RECEIVED. | LISTINGS REVIEWED, LARGER AREAS MAY ENTER DATA INTO COMPUTER. |
| | REPORT FROM REPORTING UNITS | MONTHLY | REPORTS BY REPORTING UNITS, INCLUDING NEGATIVE REPORTING. | UNITS TRACKED BY HAND; PERCENT REPORTING ON TIME. |
| | CASE INVESTIGATION FORMS | END OF INVESTIGATION | COPIES OF FORMS RECEIVED AFTER END OF INVESTIGATION. | REVIEWED BY EPIDEMIOLOGIST, ANALYZED AS NEEDED. |
| *REGIONAL* | SUSPECTED NNT LINE LISTING | MONTHLY/ AS NEEDED | UPDATE AS NEEDED. | SELECTED DATA ENTERED INTO COMPUTER SYSTEM AND ANALYZED. |
| | WEEKLY REPORT FROM COUNTRIES | MONTHLY | WEEKLY REPORTS BY COUNTRY, INCLUDING NEGATIVE REPORTS. | REPORTS ENTERED INTO COMPUTER SYSTEM AND ANALYZED. |
| | CASE INVESTIGATION FORMS | AS REQUESTED | COPIES OF INVESTIGATION FORM MADE AVAILABLE ON REQUEST. | ANALYZED WHEN NEEDED . |

APPENDIX C

# CURRENT STATUS OF TETANUS CASES

BY COUNTY/MUNICIPALITY

*TIME PERIOD COVERED:* _____ *TO* _____

*JURISDICTION:* _____

| COUNTY/ MUNICIPALITY | TETANUS CASES TOTAL NEONATAL | TETANUS CASES TOTAL >28 DAYS | BREAKDOWN FOR NEONATAL TETANUS SUSPECTED # | SUSPECTED % | CONFIRMED # | CONFIRMED % | DISCARDED # | DISCARDED % |
|---|---|---|---|---|---|---|---|---|
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| TOTAL # OF AFFECTED COUNTIES | % OF AFFECTED COUNTIES |
|---|---|
| | |

APPENDIX D

## DIAGNOSES FOR DISCARDED CASES OF SUSPECTED NEONATAL TETANUS

*JURISDICTION:* _____

| DIAGNOSIS | 19__ | | 19__ | | 19__ | |
|---|---|---|---|---|---|---|
| | # | % | # | % | # | % |
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| TOTALS | | | | | | |

APPENDIX E

COUNTRY _____ WEEK ENDING:____/____/____

JURISDICTION _____

AREA _____ PAGE # ____

# NEONATAL TETANUS LINE LISTING

## (Including Confirmed and Suspected Cases)

| ID #/ MED # | NAME OF CASE AND ADDRESS | DR'S NAME/ NURSE'S NAME/ CLINIC | SEX/ AGE | DATE ONSET TRISMUS | DATE REPORTED/ INVESTI-GATED | SOURCE OF REPORT* | SYMPTOMS | MOTHER VACCINE STATUS (# DOSES or UNK) | DATE OF LAST DOSE | TYPE OF DELIVERY (ATTENDED BY:) | # OF PRENATAL VISITS | FINAL DIAGNOSIS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
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*SOURCE OF REPORT: R = ROUTINE, A = ACTIVE SEARCH, D = DOCTOR (PRIVATE), H = HOSPITAL (PUBLIC OR PRIVATE), Y = PHARMACY, P = PUBLIC, O = OTHER

APPENDIX F

CASE ID _____
MEDICAL RECORD #_____
HEALTH CENTER _____

# NEONATAL TETANUS CASE INVESTIGATION FORM

INSTRUCTIONS: Complete this form for all reported suspected cases and for each confirmed case of neonatal tetanus. The definition of a "suspected case" is:

*Any infant with a history of tetanus-compatible illness during the first month of life that fed and cried normally for the first two days of life; OR*
*Any neonatal death in a child who could suck and cry normally during the first 48 hours of life.*

**GENERAL INFORMATION** ----------

Name of infant _____

Sex M__F__ Date of Birth ___/___/___

Father's name _____

Mother's name _____

Address _____

Village/City _____ County/Municipality _____

State/Province _____ Country _____

Date reported ___/___/___ Reported by _____ Position _____

**CLINICAL DATA** ----------

Weight at birth _____ or at hospitalization _____

Date onset of illness ___/___/___ Normal suck and cry during first 2 days of life? YES ___ NO ___

Was the umbilicus infected? YES ___ NO ___ Omphalitis? YES ___ NO ___

Fever at hospitalization _____°C Fever range during hospitalization: from _____°C to _____°C

| | YES | NO | UNK | |
|---|---|---|---|---|
| Trismus | __ | __ | __ | Date of trismus ___/___/___ |
| Body rigidity | __ | __ | __ | Date of onset ___/___/___ |
| Convulsions | __ | __ | __ | Date of 1st convulsion ___/___/___ |
| Muscle spasms | __ | __ | __ | Date of 1st spasms ___/___/___ |
| Jaundice | __ | __ | __ | Date of fever ___/___/___ |
| Seen by a doctor | __ | __ | __ | Name of doctor _____ |

Was infant treated in a hospital/health facility? YES ___ NO ___

Name of 1st clinic or hospital _____

Date admitted ___/___/___ Discharge status _____ Date ___/___/___

If death, date ___/___/___

Name of 2nd (reference) hospital/health unit _____

Date admitted ___/___/___ Discharge status _____ Date ___/___/___

If death, date ___/___/___

APPENDIX F (cont.)

CASE ID _____
MEDICAL RECORD #_____
HEALTH CENTER _____

## NEONATAL TETANUS CASE INVESTIGATION FORM - PART II

**MATERNAL DATA**----------

Mother's age __ # Previous births ____ # Children living ____

# TT doses ___ Date last dose ___/___/___ Documented? Yes __ No __

Number of prenatal visits ____ Place prenatal care received _____

Was baby born in: Hospital __ Home __ Other _____

Address _____

Was baby delivery attended by: Doctor __ Nurse __ Midwife __ Traditional birth attendant __

Untrained attendant __ Family __ Other _____

Name _____ Address _____

Describe hygienic conditions and instruments used to cut the cord: _____

_____

_____

How was the cord stump treated or dressed? _____

_____

_____

**ADMINISTRATIVE INFORMATION**----------

Final classification of case: CONFIRMED_____ DISCARDED _____ Date ___/___/___

A confirmed case is defined as a child with all the following:

*Normal feeding and cry for first 2 days of life.*
*Onset of illness between 3 and 28 days of life.*
*Inability to suck (trismus) followed by stiffness (generalized muscle rigidity) and/or convulsions (muscle spasms).*

If case was discarded give discard diagnosis: _____

Person completing the form _____ Position _____

Tel # _____ Date of investigation ___/___/___ Date Ministry notified ___/___/___

COMMENTS (e.g., Reasons for mother not being immunized, surface baby was delivered on, etc.)

_____

_____

_____

APPENDIX G

## TETANUS PROTECTION CARD

Family name _____

First name _____

Year of birth _____

Address _____
_____
_____

District _____

State/ Province _____ _____

Childhood DPT/DT Immunizations

Number of doses _____
Date of last dose ___/___/___

If unknown ____

Adult tetanus toxoid (TT)

| | Day | Month | Year |
|---|---|---|---|
| 1st dose | _____ | _____ | _____ |
| 2nd dose | _____ | _____ | _____ |
| 3rd dose | _____ | _____ | _____ |
| 4th dose | _____ | _____ | _____ |
| 5th dose | _____ | _____ | _____ |

APPENDIX H

SELECTED INDICATORS

*JURISDICTION* _____

| CRITERIA | TIME PERIOD | | |
|---|---|---|---|
| % OF SURVEILLANCE UNITS WHICH NOTIFY MONTHLY | | | |
| % SUSPECTED CASES WITH INTERVAL BETWEEN DATE OF DEATH AND NOTIFICATION BETWEEN 0 AND 14 DAYS | | | |
| % SUSPECTED CASES WITH INTERVAL BETWEEN NOTIFICATION AND START OF INVESTIGATION WITHIN 72 HOURS | | | |
| % OF SUSPECTED CASES WITH FINAL CLASSIFICATION OCCURRING WITHIN 7 DAYS | | | |
| % OF HIGH-RISK AREAS WITH SPECIFIC CONTROL PROGRAMS FOR PREGNANT WOMEN | | | |
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APPENDIX I

# ACTIVE MONTHLY SURVEILLANCE REPORT

Instructions: Indicate the number of new suspected (S) and confirmed (C) NNT cases reported each month under # column; indicate with a check if report is On Time, or write "L" if late

| REPORTING UNITS | MONTHS 1 | | 2 | | 3 | | 4 | | 5 | | 6 | | 7 | | 8 | | 9 | | 10 | | 11 | | 12 | | TOTALS | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME | # | ON TIME |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| TOTALS | | | | | | | | | | | | | | | | | | | | | | | | | | |