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Neonatal Tetanus Elimination

Field Guide

Second edition

Pan American Health Organization

Regional Office of the World Health Organization

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ABOUT THE IMMUNIZATION FIELD GUIDES

The Expanded Program on Immunization is viewed as one of the most successful public health experiences in the Americas because it has played a pivotal role in reducing infant mortality from vaccine-preventable diseases in the Region. In fact, since the program was launched, our countries stopped the transmission of wild poliovirus in the Region in 1991 and interrupted indigenous measles transmission in November 2002; they also are making significant gains in the battle to eliminate rubella and congenital rubella syndrome. In addition, national immunization programs are undertaking extraordinary efforts to identify at-risk populations and overcome inequities in vaccination. To maintain these advances and to cope with new challenges, such as the introduction of new vaccines, partnerships will have to be strengthened among governments, donor agencies, the private sector, scientific associations, and society as a whole.

To this end, PAHO is promoting the best technical quality by issuing these practical Field Guides that have been prepared by the Immunization Unit in the Family and Community Health Area. The most recent techniques presented in the Field Guides, coupled with useful illustrations, will help health workers in their efforts to control, eliminate, or eradicate diseases such as poliomyelitis, neonatal tetanus, yellow fever, diphtheria, pertussis, tetanus, *Haemophilus influenzae* type b infections, hepatitis B, measles, and rubella. The Field Guides also include standardized methods and procedures for conducting epidemiologic surveillance and maintaining an up-to-date information system that makes it possible to take timely and effective decisions.

These Field Guides are based on the latest scientific information and they bring together the experience of prominent health professionals in the field. As a result, they are particularly suitable for promoting strategies that have already proven to be effective. The strengthening of prevention activities, the reduction of health inequities, and the promotion of technical expertise in vaccination services were the principles that guided the preparation of the guides.

The Expanded Program on Immunization, a joint effort of all the countries of the Americas, effectively contributes to the attainment of the Millennium Development Goals.

Dr. Mirta Roses Periago
Director
Pan American Health Organization

PREFACE

The primary aim of the *Neonatal Tetanus Elimination Field Guide* is to provide those who already have managed to reduce the incidence of this disease to zero, as well as 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 emphasizes the progress made by surveillance systems in the identification and monitoring of high-risk areas and the conduct of special immunization activities targeting women of childbearing age who live in those areas. Such measures are meant to complement routine procedures such as providing diphtheria-pertussis-tetanus (DPT) vaccine for infants and children and tetanus and diphtheria toxoid (DT/Td) for school-aged children and pregnant women. Detailed information on clean delivery and post-delivery practices will not be given, as these topics are thoroughly covered in other documents of the World Health Organization (WHO).

Much of the information contained in this manual, the first edition of which was published in 1993, was taken directly from technical papers prepared by the Pan American Health Organization (PAHO) and other WHO Regional Offices. In addition, a number of other publications were consulted, and the field experience of those who have made advances in eliminating the disease was used. Several of these works are listed in the Bibliography. Sample forms are included in the Annexes and may be copied or adapted to meet specific program needs.

1. INTRODUCTION

1.1 Background

In many countries neonatal tetanus is responsible for half of all neonatal deaths due to vaccine-preventable diseases and for almost 14% of all infant deaths. It is estimated that in the 1970s more than 10,000 newborns died annually from neonatal tetanus in the Americas. Neonatal tetanus is prevented by immunization and/or assuring clean delivery and post-delivery practices.

In 1989, the World Health Assembly adopted a resolution calling for the elimination of neonatal tetanus throughout the world by 1995 and the resolution was endorsed by the Directing Council of PAHO. Ministers of Health of PAHO Member Countries initiated specific program activities to eliminate neonatal tetanus with support from PAHO and a variety of international agencies. These activities take place within the wider context of the Expanded Program on Immunization (EPI) and existing programs on family and community health and benefit from knowledge acquired in polio and measles eradication programs. It is recognized that the program to eliminate neonatal tetanus as a public health problem differs 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 high-risk geographic areas. The identification of these high-risk municipalities/districts allows 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 and diphtheria toxoid (Td). It should be noted that although tetanus toxoid (TT) alone provides immunity against tetanus and is mentioned in this report, the administration of tetanus and diphtheria toxoid (Td) is recommended because it provides the opportunity to maintain immunity to both diphtheria and tetanus in adults. To meet the goal of elimination of neonatal tetanus, it will be necessary to intensify all principal components of the EPI and programs for family and community health.

For operational purposes, neonatal tetanus is considered to be eliminated as a public health problem when all municipalities of a country have annual neonatal tetanus rates of less than 1 per 1,000 live births. However, this criterion should be analyzed carefully before applying it in the field, since, for example, if a municipality of one million inhabitants with about 30,000 annual births reports 29 cases of tetanus per year, it would meet the criterion for elimination, but in practice this level

of tetanus would be unacceptable. In municipalities with very low population density, the opposite situation could occur. For this reason, although the criterion for elimination has been defined, it is advisable to evaluate achievement of the goal or progress made in this regard in relation to the specific characteristics of each country and municipality.

To meet the goal of elimination of neonatal tetanus, it is recommended that all countries do the following:

- Establish or intensify a tetanus surveillance system to record neonatal and non-neonatal tetanus cases separately.
- Investigate all neonatal tetanus cases and institute active searches 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 unreported neonatal tetanus cases.
- Concentrate vaccination efforts among women of childbearing age who live in high-risk areas, ensuring that every contact with these women provides the opportunity for vaccination. At the same time, it should be ascertained that women are keeping a permanent immunization record.
- Ensure that traditional birth attendants participate in tetanus toxoid vaccination activities and surveillance for neonatal tetanus.
- Utilize newer and simpler injection technologies, which can be used easily by lay personnel and introduced for routine use in national immunization programs.
- Improve clean delivery and post-delivery 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 of neonatal tetanus meets clinical criteria for confirming the diagnosis;
- Conduct an ongoing assessment of case data on newborns with tetanus, including a 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

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 must use the epidemiologic investigation data to direct the program and to supervise and evaluate activities, and ensure that resources are assigned to high-risk areas. All activities should be detailed in a national plan of action, which should form the basis for local plans of action (Annex 1).

Direct functional links must be established between the epidemiology and management components of the program and will require the exchange of reports and definition of tasks and duties related to the elimination program. 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 that provides program managers and health workers with the necessary information for taking appropriate actions (see Annex 2). Information from the disease surveillance system must be summarized into regular, useful reports and provided to all responsible health staff and to program managers.

Certain basic 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 of neonatal tetanus;
- Population of women of childbearing age by municipality;
- Number of doses of Td1, Td2, Td3, Td4, and Td5 (i.e., first, second, third, fourth, and fifth doses of adult tetanus diphtheria toxoid) delivered to women of childbearing age. Each country should define the group of women of child-

bearing age. In general, this group includes 15–45-year-old women, but in many places the first pregnancy occurs at a very early age (starting at 12 years) and in others the reproductive age extends to 49 years;

- Listings of types of deliveries by municipality/district;
- Listings of reporting sites and records of compliance with required weekly reporting.

In addition, summarized 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 Annex 3 for a sample form).

2. EPIDEMIOLOGY OF NEONATAL TETANUS

2.1 Occurrence

Records dating from the fifth century B.C. mention clinical illness that is consistent with tetanus. Even today, neonatal tetanus remains an important cause of preventable morbidity and mortality in developing countries. *Clostridium tetani*, the microorganism that 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 industrialized countries where improvements in delivery practices have been made and nearly universal tetanus immunization has been achieved. In developing countries, the disease usually occurs among marginalized populations living in peripheral urban and certain rural areas.

The results of community studies performed at the beginning of the 1970s and 1980s in Latin America and other developing countries show that the mortality rate from neonatal tetanus ranged from less than 5 to more than 60 cases per 1,000 live births. In some developing countries these deaths represented 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. WHO estimates that in some countries with deficient surveillance procedures, the regular notification systems only detect about 5% of the actual number of cases. In the Region of the Americas, PAHO estimates that in the 1970s regular reporting systems detected only 10% of the true number of cases.

2.2 Epidemiologic Characteristics

Sex. Reports gathered from both hospital and community-based surveys indicate that the ratio of male to female neonatal tetanus cases worldwide usually ranges from 1:1 to 1:3. 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 of infected newborns usually ranges between 20 and 30 years, during the period of highest frequency of pregnancy. In some countries, this group also includes late adolescence (15 to 19 years).

Seasonality. Seasonality of cases has been observed in several countries but no plausible explanation for this factor has been advanced.

Location of the delivery. In the Americas in the 1970s, close to 3% of infants with neonatal tetanus were born in a health service facility, usually a hospital. Between 2000 and 2003, 5.5% of the cases of neonatal tetanus were infants born in health facilities. This change could be due to both an increase in the number of institutional deliveries and to better practices during home deliveries. An examination of newborns with tetanus born in health facilities revealed that the mother and the child were discharged 6 to 12 hours after delivery. In such cases, the probability that the mother or another person would handle the umbilical stump incorrectly is greater.

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 of the bacillus. *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 to 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 can persist in soil for months to years.

2.4 Reservoir

Tetanus bacilli are widely distributed in the environment and in feces of certain animals and humans; therefore, soil fertilized with manure may be highly infectious. In agricultural areas, a significant number of healthy human adults may harbor the organism in stool. Soil contaminated with feces presents a high spore concentration. Spores may also be found in street dust and on the skin surface.

2.5 Transmission

Transmission usually occurs through infection during unhygienic cutting of the umbilical cord or improper handling of the cord stump, particularly when the cord is "treated" or "dressed" with materials that may be contaminated with tetanus spores, for example, with 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, infection starts 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 five months. However, if an infant is born less than 15 days after the mother's second or subsequent dose of tetanus toxoid, 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 in mothers (and in infants after 6 weeks of age) can be achieved from vaccination with two doses of adsorbed tetanus toxoid given at least four weeks apart. The primary series of two doses should be reinforced by a third dose given 6 to 12 months later. The duration of immunity after three doses of tetanus toxoid is thought to be at least five years, with a total of five doses providing lifelong immunity.

At present the most specific test available for determining tetanus immunity is the *in vivo* neutralization test. This test is expensive, time-consuming, and requires a large number of animals. The *in vitro* techniques, including passive hemoagglutination, ELISA, and radioimmunoassay, are simple, sensitive, and fast. 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 tetanus in both the newborn and the mother. *In addition, general improvements in delivery and postdelivery practices can be effective in preventing tetanus.*

3. CLINICAL ASPECTS

3.1 Pathogenesis

In a newborn, 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 microorganisms, the spores germinate and the bacilli multiply at the site of primary inoculation,

producing the toxin tetanospasmin, which causes the symptoms and signs of tetanus. 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 simultaneously. 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, and 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, are not addressed here.

Failure to suckle is often the first sign of infection in the neonate, and typically occurs between the third and tenth day of life. In spite of efforts by the infant, spasms of the masseter muscle (upper and lower jaw) impede feeding (see Figure 1). 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 spoon-feed the infant, but the jaw's 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.

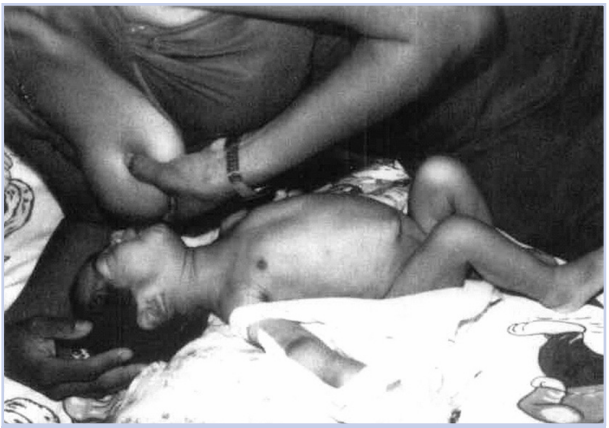

Figure 1. Difficulty sucking due to spasms of the oral (masticating) muscles is often the first sign of neonatal tetanus.

As a rule, neonatal tetanus follows a descending pattern of nerve involvement. The first sign is usually trismus or lockjaw, followed by difficulty swallowing, stiffness in the neck, rigidity of abdominal muscles, and a temperature rise of 2°C – 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 jaw contracts and the lips stretch 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 pursed as if to whistle (see Figure 2).

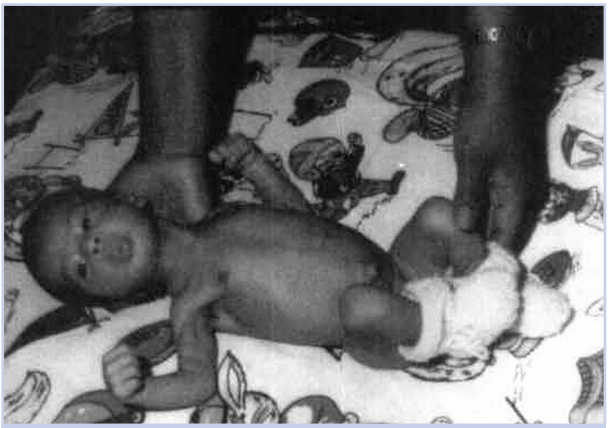

Figure 2. The child shows the first symptoms of widespread rigidity and trismus. Lips are pursed and the eyebrows are arched.

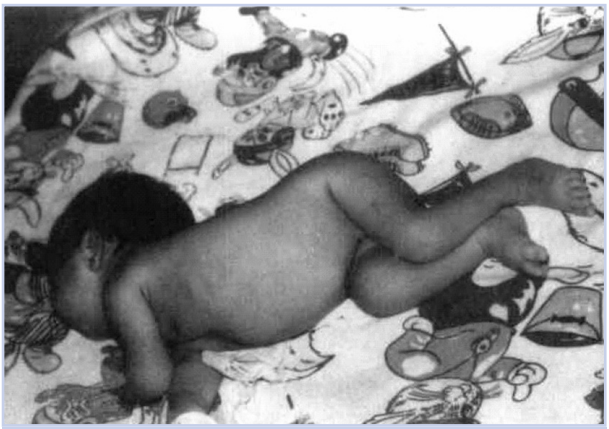

Figure 3. Opisthotonos (arched back) caused by spasms of the spinal muscles. Spasms become more frequent as the disease advances.

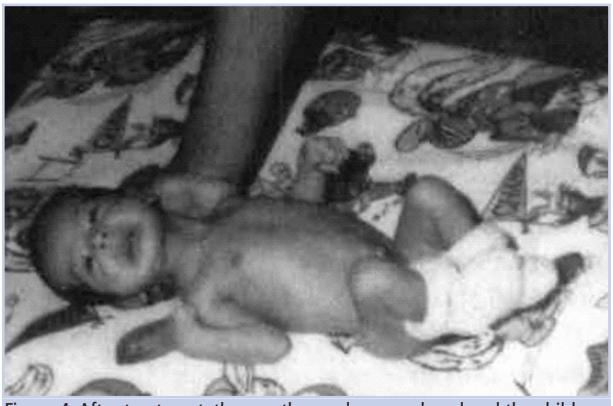

Figure 4. After treatment, the mouth muscles are relaxed and the child can suckle.

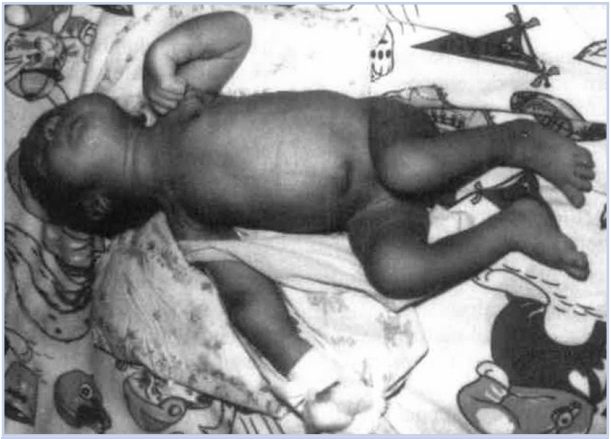

Figure 5. Spasms gradually cease and generalized rigidity disappears. With appropriate and timely treatment, total recovery is possible.

The interval between the first symptoms, usually cessation of suckling or trismus, and the occurrence of spasms is called the period of onset. In neonatal tetanus this period is important for the prognosis: the shorter the period of onset, the higher the fatality rate.

The tetanic spasms become more frequent and often are 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 with the fingers. The feet are in dorsiflexion with the toes tightly gripped. This hyperflexion of the toes is very characteristic of the level of rigidity and hypertonia of the plantar muscle. The neck is arched backwards slightly and the abdominal and dorsal muscles are very rigid. Due to spasms of the back muscles, the back is arched (see Figure 3). After treatment, spasms gradually subside and eventually disappear (see Figures 4 and 5).

In half of the newborns with tetanus, infection of the navel (omphalitis) is not evident. Extensive infection may cause diffuse inflammation of all the anterior abdominal muscles.

The child can die of apnea or serious anoxia during the spasms, or two to four days later due to acute gastroenteritis or complications from difficulty in swallowing that lead to pneumonia.

Cases

The following two cases highlight significant aspects of neonatal tetanus. The first is hypothetical and based on the typical presentation of tetanus in the Americas. The second case, reported by Krugman and Katz in 1981, is significant because it occurred in a child delivered in a Los Angeles hospital.

Case 1. A 7-day-old infant was brought to the hospital in the morning because it had stopped breast-feeding the previous night. The day before hospitalization, the child

had become irritable and cried constantly. The mother managed to place drops of milk in the infant's mouth, but the child could not swallow. Convulsions occurred during the medical examination. As a consequence of the predominance of stronger muscle groups over weaker ones, the following signs were observed: due to the vertebral muscle spasm the back of the newborn was arched (opisthotonos), arms were flexed at the elbow, and feet were in dorsiflexion.

The child had been delivered at home by the grandmother. The umbilical cord was cut with a straight-edge razor. The mother had two prenatal consultations, both taking place three weeks before delivery, as she had done in her three previous pregnancies. Tetanus toxoid was not given on any of those occasions because the health workers believed that the dates of the visits did not coincide with immunization recommendations.

Case 2. A 13-day-old male infant was brought to Children's Hospital of Los Angeles (California, U.S.A.) with respiratory arrest. The fifth pregnancy of his mother, he was born two weeks earlier at another hospital during a normal delivery. He was discharged the day after delivery. On day 10, the umbilical stump fell off and purulent discharge of the navel was observed. On day 13, the child had trismus, was irritable, and refused to eat. On the morning of day 14 (when he was hospitalized), the infant had fever, a rigid body, noisy breathing, and drooling. External stimuli triggered frequent spasms of the limbs and body, and his mouth was stuck open. The infant's breathing was superficial and he emitted an inspiratory noise indicative of laryngospasm.

Treatment consisted of administration of tetanus antitoxin (human), surgical debridement of the umbilical stump, tracheotomy, and reduction of environmental stimuli. He also was given diazepam (Valium), meprobamate, phenobarbital, chlorpromazine (Thorazine), and penicillin. The infant was fed by gastric tube and his bladder was emptied using the Crede method. The child improved; spasms became less frequent and ceased after four weeks. At that time the medication was discontinued, the spasms did not recur, and the patient was discharged in good condition after 48 days of hospitalization.

Case analysis

Significant points about these cases are: 1) risk factors for neonatal tetanus (birth site, maternal immunization, method for severing the umbilical cord, etc.); 2) immunization opportunities lost in the case of the first mother (there had clearly been several opportunities for vaccination during previous pregnancies, but she was not vaccinated because she always began her prenatal visits late); and 3) the incubation period (which is related to prognosis: the shorter it is, the greater the case-fatality rate). In the second case, contamination may have occurred due to incorrect use of dressings or to improper navel care after the child was discharged from the hospital.

This shows that no infant is completely free of the risk of contracting neonatal tetanus.

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 similar clinical characteristics. The differential diagnosis should take into account causes of neonatal convulsions. In general, there are three etiologic categories of neonatal convulsions:

- Congenital (cerebral anomalies);
- Perinatal (complicated delivery, perinatal trauma and anoxia, or intracranial hemorrhage); and
- Postnatal (infections and metabolic disorders).

Brain damage due to congenital or perinatal disturbances 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 often produce laxness of the mouth and tongue; the sucking reflex may be absent, and the infant may not be able to swallow 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 by group B streptococci, *Escherichia coli*, *Lysteria monocytogenes*, or *Klebsiella-Enterobacter-Serratia* microorganisms. The first two infections account for 70% of all systemic neonatal bacterial infections. Infants with neonatal meningitis may develop lethargy, seizures, apneic episodes, poor feeding, hypothermia 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 four months. Apnea is often the first sign and pneumonia with respiratory failure may be present.

Trismus is absent in the illnesses mentioned above, and the seizures differ from those caused by tetanus, tending to occur with shorter, less rapid jerks and often affecting only part of the body. In neonatal tetanus, there is no bulging of the fontanelle.

Metabolic disorders include hypoglycemia—which is especially frequent in low-weight babies or in infants of mothers with diabetes—and hypocalcemia. There are

two major peaks of incidence of hypocalcemia in the neonatal period: the first in the first 2 or 3 days of life (seen in low-birthweight infants and often following obstetric trauma), and the second at the end of the first week of life or early in the second. The later onset of hypocalcemia is usually seen in large, full-term infants who voraciously consume milk with suboptimal calcium-phosphorus relation, such as cow's milk. Hypocalcemic tetany of the newborn may produce seizures and sometimes laryngospasm. The seizures differ from those caused by tetanus, and usually there are also tremors and muscle twitching, but hypocalcemia does not produce trismus or the generalized rigidity seen in tetanus. Infants with hypocalcemic tetany appear normal between convulsive episodes.

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

The basic questions asked of mothers concern the following features of the infant's history:

- Was the infant born alive?
- Where was the infant born (at home or in a health center)?
- Who assisted during the delivery (a trained or untrained person)?
- Has the mother had other children who died in similar circumstances?
- Did the child develop normally during the first days of life?
- Was it able to suckle during that period?
- Did the infant stop suckling?
- Did it develop any other feeding problems between age 3 and 15 days, or when the illness began?
- Did the child develop generalized stiffness, trismus, or risus sardonicus?
- Did the child develop spasms or convulsions that increased in frequency and in intensity?
- What reason does the mother give for the child's death?

3.4 Laboratory Confirmation

Laboratory confirmation of neonatal tetanus is difficult. Isolation of the microorganisms can be attempted by inoculation of the umbilical stump material onto a suitable culture medium. In most cases, the microorganisms cannot be recovered from the site of infection. There are no specific laboratory tests that show abnor-

malities characteristic of tetanus. *The diagnosis is clinical and does not depend on bacteriologic confirmation.*

3.5 Complications

1) *Laryngospasm:* spasm of the vocal cords and/or of the respiratory muscles 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, abnormal heart rate, or both;
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%. Most deaths from neonatal tetanus occur during the first week of the disease.

3.6 Treatment

Treatment for neonatal tetanus generally includes administration of tetanus antitoxin and muscle relaxants and parenteral feeding.

Control of muscle spasms. The patient should be admitted to a quiet, darkened room where all possible auditory, visual, tactile, or other stimuli are minimized. The first priority in spasm management should be the administration of appropriate drugs to reduce the number and the severity of spasms. Diazepam (Valium) has proved to effectively control spasms and hypertonicity without depressing the cortical centers.

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

Antimicrobial therapy. The antimicrobial drug of choice is oral (or intravenous) metronidazole (30 mg/kg/day, given at six hour intervals; maximum 4 g/day), which is used to eliminate vegetative forms of *C. tetani*. Parenteral penicillin G (100,000 U/kg/day) is an alternative. Treatment for 10 to 14 days is recommended.

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 intra-

venous infusion can provide fluid (such as water and plasma), electrolytes, glucose, and amino acids.

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

4. CASE DEFINITIONS

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

4.1 Suspected Case

The following cases are regarded as suspected:

- Any infant with a history of tetanus-compatible illness during the first month of life who fed and cried normally for the first 2 days of life;
- 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 crying during the first two days of life;
- Onset of illness between age 3 and 28 days;
- Inability to suckle (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 satisfy the clinical criteria for confirmation. In these circumstances, the diagnosis should be specified. Furthermore, a summary of diagnoses for discarded cases should be made routinely (see Annex 4 for a 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 complement more active surveillance and reporting mechanisms. For those areas initially classified as low-risk for neonatal tetanus, improved surveillance will either confirm that status or provide additional information on 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 neonatal tetanus control measures.

Health care 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. A representative from the national EPI should inspect such areas periodically. Based on the origin of neonatal patients in a given region, service areas or hospital catchment areas can be established (see Section 5.2), as well as those areas of the country that do not report cases ("silent" areas). In an adequately functioning surveillance system the ideal is to have both weekly positive and negative reports, that is, the presence or absence of cases should be reported each week. This is very important in helping to define high-risk areas and improve surveillance.

5.1 Identification of High-Risk Areas

The primary focus for surveillance should be high-risk areas, that is, regions of the country with an annual incidence of neonatal tetanus of more than 1 case per 1,000 live births. The classification of a municipality or district as high- or low-risk is not permanent: it is done to guide prevention and surveillance actions and may be modified in relation to the new findings. Thus, for example, if the annual national incidence is 0.5 cases per 1,000 live births, all municipalities with an incidence higher than the national rate become high-risk municipalities, even though the annual rate is lower than 1 case per 1,000 live births.

A study in 11 South American countries in 1992 found that only 191 of 2,212 localities (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 had access to both preventive services and prenatal and delivery care.

The data on neonatal tetanus obtained routinely through national morbidity and mortality information systems usually provide enough information for the identification of high-risk areas. Where possible, high-risk should be identified at the district or municipality level. *These high-risk areas should be given priority and be classified as municipalities in the attack phase*, that is, municipalities that should have a good epidemiologic surveillance system and where intensive immunization campaigns should be carried out to achieve Td2 coverage of more than 90% as soon as possible. In par-

ticular, campaigns should be initiated to cover all women with at least two doses of tetanus and diphtheria toxoid (Td2) in the shortest time possible, and to continue with the five-dose schedule when there is no history of vaccination through a regular program. 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/localities, including the following:

- One or more cases of neonatal tetanus reported in each of the last three years;
- Incidence of neonatal tetanus morbidity or mortality that is above the national average in any one of the three previous years;
- Areas with unreliable data on incidence of neonatal tetanus;
- Areas with unreliable data on vaccination coverage with DPT, Td, or both.

In addition, any municipality or locality that has not previously been identified as high-risk will be classified as such in the future if it reports one or more cases. When a high-risk municipality has achieved Td2 vaccination coverage above 90% and the incidence of neonatal tetanus has been confirmed as lower than 1 per 1,000 live births by means of a good surveillance system, the municipality will be classified as in the maintenance phase, that is, a municipality with adequate epidemiologic surveillance and where measures are taken to maintain high vaccination coverage. The classification of municipalities as in the attack or maintenance phases is not a definitive but operative classification and is designed to guide disease elimination efforts. The municipality can be reclassified into any phase depending on epidemiologic findings.

Silent areas. Municipalities or localities for which there are unreliable data regarding either incidence or coverage of women of childbearing age, or where delivery takes place largely outside the hospital setting, and where cases have never been reported should be suspected as being "silent" for neonatal tetanus. Active search for cases should be intensified in these localities by examining hospital records and conducting door-to-door interviews, community surveys, etc.

5.2 Reporting from Sites

In addition to the health facilities in high-risk areas, a community network needs to be organized to report suspected cases. The network may include traditional birth attendants, community leaders, caretakers at cemeteries, school workers, pharmacists, and anyone else likely to have knowledge about cases. The following points should be taken into account when establishing or reviewing the efficacy of a reporting system:

- Each health facility should identify one individual (and one or two alternates) who will be responsible for keeping records of suspected cases and reporting such cases to health authorities responsible for surveillance (this may be the same person who reports other vaccine-preventable diseases, infectious illnesses, or both).
- In hospitals, the assigned doctor or nurse must visually inspect pediatric and infectious disease wards, in addition to conducting monthly reviews of hospital records.
- The monitoring system should include at least one reporting source or designated reporting unit identified in each municipality or locality (or comparable small geopolitical unit). At least every week, these sources should report on the presence or absence of suspected cases of neonatal tetanus.
- 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 examination or investigation. A line-listing, as presented in Annex 5, or other similar form may be used.
- Each health facility should be instructed to immediately report suspected neonatal tetanus cases to local and/or state surveillance coordinators. State officials should report on a regular basis (weekly) to the national level, and national authorities should report to PAHO's EPI office every six 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 assisted by a traditional birth attendant, the birth attendant should be visited and a determination should be made as to whether the birth attendant 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. 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 05-001).

5.3 Active Case-Finding

An enhanced surveillance system should incorporate active or periodic case-finding of newborns with tetanus, particularly in those areas that have not been consistent in reporting or that have reported zero cases for a long period of time. These active

case-findings should preferably be carried out for several diseases, thereby using the opportunity to investigate if there are cases of flaccid paralysis, suspicions of neonatal tetanus, or cases of rash with fever. In order to find cases, community leaders, pediatric associations, churches, hospitals, and clinics should be asked to assist in identifying possible cases. Door-to-door visits might be used in areas where patients are unlikely to seek medical care and when there are rumors of a neonatal death compatible with tetanus.

Verbal autopsies of cases of neonatal deaths can be made. In general, a verbal autopsy should determine: (a) if the newborn looked healthy at birth and if in the first 7 days of life it became ill and died; (b) if delivery occurred in a residence and what material was used to treat the umbilical stump; and (c) if the signs and symptoms of the disease included difficulty in suckling and rigidity. If those responses are positive, the verbal autopsy can conclude that the death was probably caused by neonatal tetanus. All health workers should be instructed to ask patients about tetanus-like illnesses occurring in their villages or towns. Health workers who make visits outside their health centers should be instructed to submit a form indicating the areas they visited and the numbers of persons interviewed about neonatal tetanus.

5.4 Feedback

Feedback includes providing those participating in surveillance activities with the following: information about the number and location of cases reported; assessment of the level of promptness and accuracy of their surveillance reports; and data on the effectiveness of vaccination and control activities. Specific recommendations on how to solve a common problem and commendations for personnel doing excellent work can also be included. Information 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 municipal, provincial, state, or national level since it is necessary to confirm diagnoses of neonatal tetanus made by untrained people. All suspected cases recorded in hospitals should be investigated, as information may be obtained from the patient's medical records at the hospital or in the hospital archives. All questions relevant to case investigations in health services should also be made in cases found in the community. Every effort should be made to determine why the newborn contracted tetanus. With this aim, the following questions should be answered:

- Was the mother vaccinated?
- Was the delivery assisted?
- Were improper techniques used during or after delivery?

6.2 Investigation of Cases

Each reported case should be investigated no later than a week after it is reported. The sooner the mother and others in attendance at the birth are visited, the more likely they are to remember relevant details. 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 to protect her and her future children.

6.3 Using the Case Investigation Form (Annex 6)

General information. If the baby has not been given a name, write "baby" followed by the parents' names. Be specific when taking down the address so that the family can be located 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 care center on 3 March that he or she had seen a case of neonatal tetanus on 1 March, then the report date would be 3 March. In this case, "reported by" would be the doctor's name, and "position" would be "private medical doctor."

Clinical data. The date of onset of the disease is when the mother first noticed that the infant had difficulties opening its mouth, swallowing, or sucking. *Trismus* refers to difficulty in opening the mouth. *Body rigidity* means that the body is stiff. *Convulsions* are usually defined as episodes of violent body shaking.

Data on mother and the delivery. The immunization status of the mother is very important and, therefore, every effort should be made to review medical records to document immunization with tetanus and diphtheria toxoid, as well as any other prenatal care. If the mother received prenatal care, it is important to identify the health center that provided it. The child's birth order and the mother's total number of pregnancies and deliveries are indirect indicators of lost opportunities for vaccination. What happened in the mother's previous deliveries and whether her children died in the neonatal period should be documented. The person who attended the birth and place of delivery also are key data; whether or not the person who assisted the delivery was trained and the place of delivery was appropriate should be recorded. The names of health personnel, if involved, should be recorded whether they are medical personnel or trained birth attendants. If the delivery took place in

a health center, take note of the facility's name and address so that corrective measures can be taken, if necessary. The instructions that the mother received for umbilical stump care should be specified, as well as whether she followed them and what she used to treat the stump.

Information regarding the age of the mother, urban or rural residence, ethnic group, and place of origin is also fundamental for guiding prevention efforts. Any mother (of a child with neonatal tetanus) who has lived less than one year in the locality where the delivery took place is considered a migrant. In such cases the place of origin of the mother should be recorded because migrations into a community often occur from the same places and from areas with worse sanitary conditions. This information should be sent to health officials in the place of origin of the migrant. This definition of migrant is used only for the mothers of newborns with tetanus, because it is assumed that if she has lived at least one year in the community where delivery occurred she has had time to contact health services.

7. DATA ANALYSIS

7.1 Necessary Data

Data from case investigation forms and line-listings should be analyzed to provide a description 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 some areas, clinical and epidemiologic data may be collected retrospectively from hospital records; this may help evaluate diagnostic capacity as well as the national information system's efficiency in identifying all cases of the disease. Diagnostic quality is evaluated on the basis of data contained in the medical record. Data to be collected should include the following:

- Name, address, age, and sex of patient;
- Dates of birth, of trismus onset, of hospitalization, and of discharge (depending on the clinical evolution of the disease);
- Information about the mother: exact address, age, vaccination history (including number of doses received), prenatal care, number of previous deliveries, migrant status, and ethnic group (Annex 6);
- Data related to the birth: place of birth and level of training of birth attendant (Annex 6);
- Time that the mother has lived in the municipality or district where the delivery took place (to determine migrant status);
- Source of notification;
- Name and address of the birth attendant.

7.2 Reports

In order to benefit from control activities, it is necessary to organize and report case data. All reports should include the following: 1) introduction, 2) case description, 3) data analysis, 4) methods of surveillance, 5) control activities, 6) problems observed, and 7) conclusions and recommendations.

The following information should be included in periodic summary reports:

- Possible sources of infection;
- Description of persons attending the deliveries (trained or untrained personnel);
- Description of delivery sites (institutions, home);
- Places where vaccination with tetanus and diphtheria toxoid is available in affected areas;
- District(s) with neonatal tetanus cases (include map);
- Date of onset of trismus in the most recent case;
- Immunization status of mothers of newborns with tetanus;
- Estimated vaccination coverage (two or more doses in women 12 or 15 to 45 years of age in the affected area);
- Immunization efforts after identification of case(s);
- Demographics (population size, age groups, 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;
- Reasons why mothers of newborns with tetanus had not been vaccinated;
- Evaluation of the accuracy of data on existing coverage (record review, door-to-door interviews, etc.);
- Vaccination methods used to improve coverage (door-to-door, central vaccination points, etc.);
- Staff utilized, including involvement of local health staff and community leaders;
- Problems in investigation and supervision.

8. CONTROL IN HIGH-RISK AREAS

8.1 Introduction

There are two principal approaches to the fight against and eventual defeat of neonatal tetanus: immunization and improved delivery and post-delivery practices. It has been clearly demonstrated that immunizing women with tetanus toxoid substantially reduces deaths from neonatal tetanus. Training traditional birth attendants also helps to reduce neonatal deaths from tetanus and neonatal mortality in general. Both approaches are important to child survival.

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

8.2 Program Priority Areas

In developing program activities and priorities, it is useful to prepare a plan of action at both the national and local level (see Annex 1). Each national plan should have a detailed budget. It should include the plan for increasing surveillance and for identifying the "silent" areas for neonatal tetanus. 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 vaccination coverage and to improve clean delivery and post-delivery practices.

8.3 Measuring Coverage with Tetanus Toxoid

There are problems determining a valid coverage rate with tetanus and diphtheria toxoid using statistics from routine health services. Since multiple doses of tetanus and diphtheria toxoid are administered at different intervals over the 30-year reproductive span of women, and women enter and leave this eligible age range continuously, for practical reasons only the second dose administered during every three-year period should be considered in determining coverage. At the end of a year, the second dose of tetanus and diphtheria toxoid administered during the first year of the previous three-year period should no longer be counted, being replaced by the doses given during the year just ending. After the second dose of tetanus and diphtheria toxoid has been administered to all women of childbearing age, the goal should be coverage with the third, fourth, and fifth doses.

8.4 Immunization Activities

The primary targets for immunization are women in the childbearing age range (usually women 12 or 15 years to 45 years of age). Administration of tetanus toxoid to women of childbearing age provides protection for the population group with the

most immediate need. The vaccination of women of childbearing age (pregnant or not) has been shown to markedly reduce the incidence of neonatal tetanus.

Immunization of women

Immunization of women of childbearing age is the simplest means of controlling neonatal tetanus. Women with no prior history of immunization should begin with a series of two doses of tetanus toxoid no less than four weeks apart, a third dose 6 to 12 months later, a fourth dose one year after the third, and a fifth dose one year after the fourth.

For women with a documented history of having completed the first series of vaccination with DPT or Td, a booster dose every 10 years is sufficient. Pregnant women who lack documentation showing that they have received adequate doses should be given the first dose as soon as possible during the pregnancy, and the second dose no later than three weeks before the expected date of childbirth. Women who have received two doses of tetanus and diphtheria toxoid during a previous pregnancy should be given a third dose in the new pregnancy. The third dose provides protection for up to five years.

Every immunization given during a pregnancy should be recorded, and the record compared with the number of women who attend prenatal clinics (Annex 7). Areas considered at high risk for neonatal tetanus generally have low coverage rates and should be considered a priority for immunization efforts. Poorly served rural populations and the urban poor, including migrants and slum dwellers, are of particular concern within this category. Special efforts are needed in these areas to reduce the number of dropouts. This can usually be achieved through careful monitoring by health workers and community leaders.

Mass campaigns

In addition to improving routine vaccinations, there may be a need to conduct periodic campaigns for special target groups. These vaccination rounds or vaccination days are used to intensify immunization activities. They can be carried out at either the local level or nationally, where many resources can be committed and mass media attention can be focused on the promotion of campaigns.

National campaigns. When national vaccination days are conducted for other EPI antigens, tetanus and diphtheria toxoid should be included for women 12 or 15 to 45 years of age.

Local campaigns. Intensified immunization efforts for short periods can be used to reinforce routine daily vaccination programs. These programs are generally referred to as "mop-up vaccination campaigns" and are particularly useful in areas with deficient health services. This approach aims at 100% coverage of the target population with two doses of tetanus and diphtheria toxoid in a designated period of time.

Every effort should be made to vaccinate women 12 or 15 to 45 years of age with tetanus and diphtheria toxoid during campaigns for other EPI antigens.

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, collaboration of local institutions (churches, schools) and local leaders to assist in the program, and follow-up activities to complete coverage through rural health posts. Before starting these activities, home visitors, community social workers, and traditional birth attendants should carry out door-to-door campaigns to ensure that all families participate in the program.

Missed opportunities

In studies conducted in Bolivia, Colombia, Ecuador, Peru, and Venezuela, 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 procedures as they may be responsible for many missed opportunities for immunization. For example, some health staff, as well as the population they serve, may erroneously believe that tetanus and diphtheria toxoid should not be given at any time during pregnancy or during specific months of pregnancy. Some health workers are reluctant to immunize children presenting a low-grade fever or to give multiple antigens simultaneously. To promote demand for tetanus and diphtheria toxoid immunization, health providers can do the following:

Table 1. Approaches to reduce missed opportunities for immunization

Method	Advantages
Immunization of pregnant women attending maternity wards	• Few additional resources needed • Potentially rapid impact on future pregnancies
Immunization of women of childbearing age through regular health services	• Any contact of women with health workers provides the opportunity for immunization • Better chance of reaching high-risk women (who may not come for preventive care, but would come for care of their children)
Immunization of women who bring children for immunizations	• Few additional resources needed • Women with children may become pregnant again
Immunization of women coming with or without children to an immunization session	• Few additional resources needed • Possible to vaccinate some women before their first pregnancy
Immunization of women during mass immunization campaigns	• Large numbers immunized in a relatively short period of time • Areas without regular access to health services are reached
Improved follow-up of pregnant women so that they receive second dose of tetanus and diphtheria toxoid	• Reduces number of people failing to receive the second dose of tetanus and diphtheria toxoid

- Increase the number of sites where vaccinations can be administered;
- Modify the days and hours when immunizations are available to accommodate the times when members of the community can go to health facilities;
- Improve the way mothers are treated in the service delivery system;
- Ensure that mothers know why they are being immunized.
- Improve communication on side effects and the need for follow-up immunizations to complete the five-dose schedule.
- Determine the vaccination status of every patient or companion seen in health facilities and offer them the vaccines needed to complete the series.

Lifetime immunization record

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

Role of traditional birth attendants in immunization

Training traditional birth attendants to administer vaccine is one way to improve the delivery of tetanus and diphtheria toxoid to pregnant women and to other women of childbearing age. The increased heat stability of the vaccine allows it to be unrefrigerated for up to 42 days without losing potency, thus making it easier for birth attendants to transport and administer the vaccine safely and effectively. This information is given to illustrate a feature of the vaccine, but it should not lead to neglect of the cold chain by birth attendants or other health workers.

Vaccination programs in hospitals

Hospitals can help achieve dramatic improvements in the immunization coverage of women of childbearing age. Hospitals should set up routine daily immunization centers to provide tetanus toxoid 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 the number of doses provided must be implemented.

8.5 Delivery and Post-Delivery Practices

For purposes of the neonatal tetanus 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 and neonatal sepsis. The training of traditional birth attendants, though important, is not covered in this manual, since there are numerous other publications that deal with this topic in depth.

Post-delivery practices. Inappropriate cord care may place the infant at risk. Special education programs for new mothers, birth attendants, and health workers should be offered. 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 post-delivery, and the lack of adequate protection by tetanus toxoid.

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 immunizing the mother prior to delivery, by ensuring that the delivery is carried out and the cord cut under clean conditions, and ensuring that no unclean dressings are placed on the cord while it is healing. Community programs stressing the "three cleans" need to be developed in high-risk areas, that is: clean hands, clean delivery surface, and clean instruments to cut the umbilical cord.

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 rumors related to the vaccine. In one West African country, a survey revealed that in some areas it was a common belief that tetanus toxoid could leave women sterile. Confusion may also be created by differences between the name used for the vaccine and local names used for neonatal tetanus disease. Accurate local terminology for neonatal tetanus 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, religious organizations, and leaders in rural areas. Problems of inadequate coordination at the community level can be assessed during seminars conducted locally, particularly 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 in the programs. A commonly reported expla-

nation for lack of immunization is that the person was too ill to be vaccinated on the day of the visit to the clinic. Both families and health workers should be made aware that *minor illness is not a contraindication for vaccination.*

Changing health behavior. Promoting changes in health behavior is a difficult task requiring an open-minded and consistent effort from a multidisciplinary team. Therefore, health educators should be included in the early planning stages since they may be helpful in providing information on the knowledge, attitudes, and practices of mothers regarding immunization. Using this information, program staff can better communicate with high-risk mothers and motivate them to attend clinics for immunization and prenatal care, and to report illness if it does occur. The development of specific posters about reporting disease 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 not only of the women themselves, but also of mothers-in-law, husbands, and other family members. Women should understand that they need immunization for their own sake, as well as for that of their newborns. This concept of passing on protection to unborn children can be a very strong motivational message.

9. PROGRAM MONITORING

9.1 Introduction

Program monitoring should be an ongoing process, with regular on-site reviews by institutional staff and, less often, by outside experts. The standards and indicators outlined in the following sections are important mechanisms to help quantify the level of program performance (see Annex 8).

9.2 Program Review

Periodic review of the elements of the immunization and surveillance program takes place in order to document progress toward achievement of objectives and targets and to identify and to solve problems preventing achievement of such goals. Managers at each level should regularly monitor progress in a number of important areas for neonatal tetanus as well as other diseases included in the EPI (see Table 2).

9.3 Surveillance Indicators

1) *Completeness of reporting.* At least 80% of sites should report each week/month, even in the absence of cases, and should be monitored using the chart in Annex 9.
2) *Timeliness of reports.* At least 80% of suspected cases should be reported within 24 hours of detection.

3) *Investigation.* At least 80% of all suspected cases should be thoroughly investigated within 7 days of the initial report.

9.4 Investigation Indicators

1) *Percentage of cases with complete information.* For all suspected cases, the name, address, origin, ethnic group, age of mother, type of delivery, and mother's immunization history should be recorded. These data form the basis for analysis.
2) *Final classification.* All suspected cases should be classified as either discarded or confirmed within 7 days of the initial investigation.

9.5 Immunization Indicators

1) All health services should routinely provide tetanus and diphtheria toxoid to pregnant women and women of childbearing age. For this purpose, daily immunization services should be offered in health centers and, if necessary, community campaigns should be undertaken.
2) All health jurisdictions should maintain records that monitor coverage at the municipality or locality level.
3) In high-risk areas, vaccination coverage with Td2 to Td5 should reach 90% or more for women 12 or 15 to 45 years of age.

Table 2. Outline of program review elements

Area to be reviewed	Frequency of review
Training Plan Implementation Evaluation	 Annually Quarterly Semi-annually
Plan of action Update plan Monitor plan	 Semi-annually Quarterly
Surveillance system Reporting Hospitals	 Immediately, if there are cases Weekly, whether or not there are cases
Vaccine supply	Quarterly
Needle and syringe supply	Quarterly
Coverage Available data	 Weekly Monthly
Supervision Planning Evaluation	 Monthly Semi-annually
Maternal and child health program Immunization activities Delivery programs	 Monthly Quarterly
Summary reports	Semi-annually

The exact calculation of vaccination coverage with tetanus toxoid in women of childbearing age is complex, so coverage estimates have been used to guide the actions of countries and municipalities. In the group of women of reproductive age, which is the target group of the immunization program, 12-year-olds enter and 46-year-olds leave the group every year. It is thus recommended that an annual record

be kept of women 12 to 45 years old who receive Td1, Td2, Td3, Td4, or Td5. This makes it possible to estimate coverage by adding the doses given in previous years and dividing the total by the number in the target group; more complex calculations take into account the women entering and leaving the group. For the purpose of neonatal tetanus control and elimination programs, experience shows that it is enough to estimate coverage, using the total number of women vaccinated since beginning activities as the numerator and the number of women in the target group living in the area as the denominator.

9.6 Clean Delivery Indicators

All deliveries should be attended by medical personnel or trained birth attendants. The percentage of deliveries assisted in these conditions should be reported.

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 fetus is protected* in utero *through the transfer of maternal antibodies 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. 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 tetanus toxoid) is being implemented. Within two or three years of initiating the program there has been a significant impact on the incidence of neonatal tetanus. 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 was initiated, there was a 70% decrease in reported cases of neonatal tetanus between 1989 and 1991 and a 98% decrease between 1989 and 2003.

10.2 Schedule, Contraindications, and Adverse Reactions

Table 3 gives the recommended immunization schedule with TT or Td for women of childbearing age, including pregnant women. Other live and inactivated bacterial and viral vaccines can be administered simultaneously without problem. The table shows the minimum acceptable interval between doses; there is no maximum interval.

Table 4 shows the WHO recommended schedule for immunization with DPT and DT for children at 6, 10, and 14 weeks of age. However, in the majority of countries of the Americas, infants are vaccinated with DPT at 2, 4, and 6 months of age. Other

live and inactivated bacterial and viral vaccines can be administered simultaneously without problem. A minimum interval of four weeks should be observed between the first doses.

The vaccine is safe and effective, even for people who suffer from an acute mild illness. There are no signs that it is contraindicated 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 applies to individuals with asymptomatic HIV infection and individuals with clinical (symptomatic) AIDS. (However, those with symptomatic HIV infection should not receive BCG vaccination.)

Table 3. Recommended tetanus toxoid (TT) and tetanus and diphtheria toxoid (Td) immunization schedule for previously unvaccinated women of childbearing age

Dose	Schedule
TT1 or Td1	At first contact or as early as possible during pregnancy
TT2 or Td2	At least four weeks after the first dose
TT3 or Td3	6 to 12 months after second dose or during subsequent pregnancy
TT4 or Td4	One to five years after third dose or during a subsequent pregnancy
TT5 or Td5	1 to 10 years after fourth dose or during a subsequent pregnancy

Currently available adsorbed vaccines are extremely effective and safe, causing only minor local reactions that are usually self-limiting and require no therapy. Although acute anaphylactic reactions were reported in the 1940s, it is believed that they were due to the presence of sensitizing agents from the culture media. Improvements in manufacturing techniques decreased the risk of adverse reactions. Local reactions in the form of erythema, pain, and swelling usually last less than one day and only rarely more than three 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.

The benefits of using the vaccine clearly outweigh the costs associated with contracting the disease, in both human and monetary terms.

Table 4. WHO-recommended schedule for diphtheria-pertussis-tetanus (DPT) and diphtheria-tetanus (DT) immunization 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

10.3 Vaccine Efficacy

Seroconversion rates. After two doses, 80%–90% efficacy is achieved for a minimum of three years. In 95% of recipients, 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 five years. A series of five doses is thought to con-

Table 5. Tetanus toxoid 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%	Probably for life

fer virtually 100% protection (Table 5). Seroconversion efficacy is highly correlated with clinical efficacy.

Duration of immunity. The first vaccination 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. Accordingly, a second vaccination administered any time after four weeks will rapidly produce a protective antibody antitoxin level.

10.4 Vaccine Storage

Tetanus toxoid vaccine is extremely stable, even at temperatures as high as 18°C, and can go without refrigeration for up to six weeks without losing potency. While this is an important feature of the vaccine, it should not lead to neglect of the cold chain. DTP, DT, Td, and TT vaccines should be refrigerated immediately when received and stored continuously at 2°C to 8°C (35–46°F). The vaccine should not be frozen, since freezing irreparably damages it.

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 immediately to supervisors. When vaccines are used outside health care centers, they should be packed on ice in insulated containers.

In areas where the cold chain cannot be maintained, a detailed and precise program should be developed to vaccinate the target population within a 30-day period without relying on the cold chain. Since tetanus toxoid is highly stable at 37°C for three to four weeks, the cold chain can be eliminated for short-term programs. Nevertheless, when the vaccine is not in use it should be stored in the 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 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 supply on hand can be used up prior to its expiration date.

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ANNEXES

ANNEX 1. OUTLINE OF A PLAN OF ACTION FOR NEONATAL TETANUS ELIMINATION

Introduction

This section should include a brief explanation of why the neonatal tetanus control program is being strengthened.

Background Information

Geographic description of the area: Country, state, districts.

Vital statistics: Women of childbearing age, general population, number of live births, fertility rate, distribution of urban and rural population.

Health indicators: Infant and maternal mortality rates; delivery practices; coverage for prenatal care and for vaccination (specify coverage for pregnant women separately, if figures are available); number of traditional birth attendants; percentage of births delivered at home and births assisted by traditional birth attendants; calculation of health service demand based on immunization coverage with the first and third doses of DPT and with BCG vaccine.

Magnitude of the problem: Number of neonatal cases; rate per 1,000 live births; proportion of mortality due to neonatal tetanus in live births; estimated cost of treating neonatal tetanus cases.

Epidemiologic description of neonatal tetanus cases investigated: Geographic distribution; description of delivery location (location of delivery and who assisted delivery); prenatal care; vaccination status and age of mother; number of mother's previous deliveries and pregnancies.

Current neonatal tetanus control policy: Target population; immunization schedule; vaccination strategies.

Social mobilization: Educational material related to neonatal tetanus; type of participation by the communications media.

Justification of Plan of Action

Main problems identified and priorities outlined.

Objectives of the Plan

Precise target groups and planned achievements.

Priority Activities to Consider and/or Initiate

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 proposed change; describe plans for studies on strategies, target populations, immunization schedules, safe delivery, social mobilization, and intensification and improvement of messages to dispel misconceptions and rumors).

Goals

Monitoring and Review Indicators

Training Needs

Describe plans for training medical staff and traditional birth attendants.

Budget

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

ANNEX 2. FLOW CHART FOR NEONATAL TETANUS INFORMATION SYSTEM

Form	Timing	Action	Data entry and analysis
Line-listing of reported cases	At first detection of a case	Initial data on reported cases are entered in a line-listing of variables of interest and updated as data from the investigation become available.	Line-listings updated manually. Summary statistics based on line-listings.
Case investigation form	When suspected case is reported	Case investigated by health workers. Forms/files remain with local health workers until investigation is concluded and data are sent to higher level.	Forms/files reviewed, cleaned, and completed by health workers at local level. Database systematized at national level with complete information on each reported case.
Report from reporting units	Weekly	Each reporting unit should report weekly on presence or absence of neonatal tetanus cases.	Database systematized with listings from reporting units and respective dates of weekly reports to confirm if they satisfy reporting requirements and detection of silent areas.
Detailed line-listings of cases of neonatal tetanus in the Region			
Weekly report from countries			
Database of confirmed cases of neonatal tetanus in the Region			

ANNEX 3. CURRENT STATUS OF TETANUS CASES IN COUNTRY, BY MUNICIPALITY OR DISTRICT (FORM)

Time period covered: _____ **to** _____

Jurisdiction: _____

Municipality or district	Tetanus cases		Classification of neonatal tetanus cases					
	Total neonatal	Total cases	Suspected		Confirmed		Discarded	
			No.	%	No.	%	No.	%
TOTAL								

Total number of affected municipalities: Number of municipalities in the country:	Percentage of municipalities affected:
Total number of women of childbearing age living in high-risk areas of country:	Percentage of women of childbearing age living in high-risk areas in municipalities affected:

ANNEX 4. DIAGNOSES FOR DISCARDED NEONATAL TETANUS CASES (FORM)

Country _____

Final diagnoses	20___		20___		20___	
	No.	%	No.	%	No.	%
TOTALS						

ANNEX 5. LINE-LISTING FOR NEONATAL TETANUS (FORM)

Country: _____ Week ending ___/___/_____

Jurisdiction: _____

Area: _____ Page: _____

NEONATAL TETANUS LINE-LISTING
(including confirmed and suspected cases)

Case no.	Address: municipality, neighborhood, or district where case occurred	Migrant mother[a] (yes–no)	Mother's ethnic group[b]	Birth date of infant	Date of trismus onset	Date case reported and investigated	Source of report[c]	Symptoms	Mother's vaccination status (no. of doses or unknown)	Date of last dose	Type of delivery (attended by)	No. of prenatal visits	Final diagnosis

[a] Mother of a neonatal tetanus case who has lived less than 1 year in the district where delivery occurs is considered a migrant.
[b] If not applicable, insert "NA."
[c] Source of report: R = routine, A = active search, D = doctor (private), H = hospital (public or private), Y = pharmacy, P = general public, O = other.

ANNEX 6. NEONATAL TETANUS CASE INVESTIGATION FORM

INSTRUCTIONS:
Complete this form for all suspected cases reported 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 who 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.

CASE ID No. _____

MEDICAL RECORD No. _____

HEALTH CENTER
_____
_____
_____

GENERAL INFORMATION

Name of infant _____ Sex: ☐ Male ☐ Female

Date of birth ____/____/_____

Father's name _____

Mother's name _____

Address _____

Village/City _____ District/Municipality _____ ☐ Urban ☐ Rural

State/Province _____ Country _____

Date reported ____/____/_____ Reported by _____ Position _____

CLINICAL DATA

Weight at birth _____ or at time of hospitalization _____

Date of onset of illness ____/____/_____

Normal suckling and crying during first 2 days of life? ☐ Yes ☐ No

Was umbilicus infected? ☐ Yes ☐ No Omphalitis? ☐ Yes ☐ No

Fever at hospitalization _____ °C

Maximum and minimum fever during hospitalization From _____ °C to _____°C

Trismus	☐ Yes	☐ No	☐ Not known	Date of onset ____/____/_____
Body rigidity	☐ Yes	☐ No	☐ Not known	Date of onset ____/____/_____
Convulsions	☐ Yes	☐ No	☐ Not known	Date of first convulsion ____/____/_____
Muscle spasms	☐ Yes	☐ No	☐ Not known	Date of first spasm ____/____/_____
Jaundice	☐ Yes	☐ No	☐ Not known	Date of onset ____/____/_____
Seen by a doctor	☐ Yes	☐ No	☐ Not known	Name of doctor _____

Was infant treated in a hospital/health facility? ☐ Yes ☐ No ☐ Not known

Name of first clinic or hospital _____

Date admitted ____/____/_____

Discharge status _____ Date ____/____/_____

If death, date ____/____/_____

Name of second hospital/health unit _____

Date admitted ____/____/_____

Discharge status _____ Date ____/____/_____

If death, date ____/____/_____

(ANNEX 6, CONTINUED)

MATERNAL DATA

Mother's age _____ No. of previous pregnancies _____ No. children living _____ No. children dead _____

No. of TT or Td doses _____ Date of last dose ____/____/_____ Documented? ☐ Yes ☐ No

Number of prenatal visits _____ Place prenatal care received _____

Migrant? (less than 1 year of residency in case site) ☐ Yes ☐ No

If yes, indicate municipality or district of origin _____

Ethnic group _____ or NA

Infant born in: ☐ Hospital ☐ Home ☐ Other _____

Name _____ Address _____

Delivery attended by: ☐ Doctor ☐ Nurse ☐ Trained birth attendant

☐ Untrained attendant ☐ Family ☐ Other _____

Name _____ Address _____

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

_____

_____

Describe the treatment or dressing used on cord stump _____

_____

_____

RESULTS OF INVESTIGATION AT SITE OF CASE

Women of childbearing age, according to census _____

Number of pregnant women _____

Number of women who are not pregnant _____

Percentage of women of childbearing age with three or more doses of TT or Td _____

Percentage of women of childbearing age with zero doses of TT or Td _____

Percentage of women of childbearing age with vaccination card _____

Classification of risk for neonatal tetanus _____

Number of women of childbearing age vaccinated with some dose of Td _____

Percentage of women of childbearing age vaccinated with three or more doses of Td following investigation _____

(ANNEX 6, CONTINUED)

ADMINISTRATIVE INFORMATION

Final classification of case: ☐ CONFIRMED ☐ DISCARDED Date ____/____/_____

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

- *Normal feeding and crying during the first 2 days of life;*
- *Onset of illness between 3rd and 28th day 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 form _____ Position _____

Telephone _____

Date of investigation ____/____/_____ Date of report to Ministry ____/____/_____

COMMENTS (e.g., reasons mother was not immunized, surface infant was delivered on, etc.)

_____

_____

_____

_____

ANNEX 7. TETANUS VACCINATION CARD

Family names:
First name:
Year of birth:
Address:
District:
State/province:
Childhood DPT/DT immunizations Number of doses: _____ Date of last dose: ____/____/_____ Unknown: _____
Adult tetanus toxoid (Td) Date of application ____/____/_____ First dose: ____/____/_____ Second dose: ____/____/_____ Third dose: ____/____/_____ Fourth dose: ____/____/_____ Fifth dose: ____/____/_____

ANNEX 8. SELECTED INDICATORS FOR PROGRAM EVALUATION

JURISDICTION:	
CRITERIA	**PERIOD**
Percentage of surveillance units reporting weekly on the presence or absence of neonatal tetanus	
Percentage of suspected cases with less than 3 days between symptom onset and notification	
Percentage of suspected cases with less than 48 hours between notification and start of investigation	
Percentage of suspected cases given definitive classification within 7 days	
Percentage of high-risk areas with specific programs for neonatal tetanus elimination	
Percentage of municipalities with cumulative Td coverage of less than 90%	
Number of municipalities with neonatal tetanus rates of 1 or more per 1,000 live births	
Percentage of neonates with tetanus born in hospitals	

ANNEX 9. MONTHLY REPORTS OF ACTIVE SURVEILLANCE

Instructions: Enter the number of new, suspected (S), and confirmed (C) neonatal tetanus cases reported each month in number (No.) column; indicate with a check mark if report is "On Time," or write "L" if report is late.

UNITS REPORTING	Months																									
	1		2		3		4		5		6		7		8		9		10		11		12		TOTALS	
	No.	On time	No.	On time	No.	On time	No.	On time	No.	On time	No.	On time	No.	On time	No.	On time	No.	On time	No.	On time	No.	On time	No.	On time	No.	On time
TOTAL																										

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