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SEP 03

U.S. DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF PRISONS

INFORMATION ON VACCINATION (CONSENT, DECLINATION)FOR TETANUS VACCINE

The Disease

Tetanus is often a fatal disease caused by a bacteria known as Clostridium tetani. The bacteria is found in soil, street dust, intestines and feces (stool) of dogs, cats, horses, sheep, cattle, rats, guinea pigs, and chickens. Manure-treated soil may be highly infectious. The bacteria is spread as it enters into humans through open wounds like punctures, cuts, scratches, and pinpricks that are most apt to be on the hands, feet, and lower extremities of the body. One of the first signs is often trismus, otherwise known as "lockjaw," and stiffness of the neck. Persons may experience difficulty in swallowing and muscle tightness with spasms. The spasms may occur frequently or become continuous over a few weeks. The disease can become fatal when the respiratory and abdominal muscles are affected and complications occur. It can lead to seizures, coma, and even death. Approximately 30% of the cases reported are fatal.

Tetanus is not transmitted from person to person. It is spread when the bacteria gains entry into an open area of the body. Cases of tetanus have been associated with animal injuries, wounds or injuries, wound infections, contaminated equipment used for invasive purposes.

Tetanus is an infectious disease that can be prevented through use of a vaccine. Tetanus infection does not mean lifelong immunity. Although cases are rare in the United States, cases still exist throughout the world and more frequently in populated areas where it is hot with damp climates, ie. Southeast countries; and areas with rich soil.

The Vaccine

Tetanus Toxoid Vaccine is a formalin-treated toxoid that is highly effective and is supplied in two types. Tetanus toxoid is made as an adsorbed (aluminum precipitated) toxoid and a fluid toxoid. In clinical studies, the adsorbed toxoids have been found to be more effective than the fluid toxoid, based on the level of titer and the length of protection which is obtained. The vaccine is stored continuously in the refrigerator (not frozen).

Currently the toxoid is recommended as a routine vaccination given every ten years for all ages, and is appropriate to consider an update of the vaccination when there is a lapse of five years or more and the person has experienced an acute injury or has a wound. The next booster is not given for ten years thereafter.

As with any vaccine, persons with impaired immunity or with kidney failure on dialysis may have a poorer antibody response to vaccination.

Dosing Schedules

Tetanus toxoid is generally given as a primary series of three doses and one booster injection every ten years. The primary series is given at four to eight weeks apart for the first two doses followed by a third dose at six to twelve months after the second dose. It is administered (0.5ml) intramuscularly in either the anterolateral aspect of the upper thigh or the deltoid muscle of the arm. Individuals who have not completed the primary vaccine series should receive an initial booster and be considered for IG, in the event of an acute injury. Measures should be taken to complete the primary vaccination series. There is no need to restart the vaccination for persons who have had interruption of the recommended schedule. Post vaccination testing is not routinely indicated because of the known high rate of vaccine response.

Adverse Reactions

Tetanus toxoid has been associated with reported adverse reactions including redness, swelling, pain at the injection site, fever, chills, aches, and headache. As with any vaccine, however, it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions not observed in clinical studies. More serious neurologic reactions have been reported and allergic reactions are infrequent.

If you have any questions about Tetanus Toxoid vaccination, please ask.

Name:	
Reg.No:	SSN:
Institution:	

Contraindications

Hypersensitivity or neurologic symptoms to any component of the vaccine is a contraindication for use of the vaccine.

Warnings

Patients experiencing hypersensitivity after a Tetanus Toxoid Vaccine injection should not receive further injections. Tetanus infection has an average incubation period of eight days and generally occurs anywhere from three days to three weeks. The shorter the incubation period, the greater the risk. Tetanus Toxoid Vaccination may not prevent tetanus infection in persons with unrecognized tetanus infection at the time of vaccine administration.

Pregnancy

Based on limited data, tetanus toxoid vaccine contains no components that have been shown to pose a risk to the fetus or newborn. Pregnancy should not be considered a contraindication to vaccination for women at high risk of acquiring tetanus infection, since tetanus poses a risk to the fetus or newborn. Pregnant women or women or childbearing age who may be pregnant should discuss the risks and benefits of tetanus toxoid vaccination with their physician.

Approval from Physician

____Yes, approved for vaccination ____No, not approved for vaccination

________________________________ ________________

Physician's Signature Date

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CONSENT FORM

I,___________________________________, have read the above statement about Tetanus and the Tetanus Toxoid Vaccine. I have been provided with updated information and have had the opportunity to ask questions about the benefits and risks of Tetanus Toxoid Vaccination. I understand that there is no guarantee that I will become immune to future tetanus infection, and that there is a possibility that I will experience an adverse side effect from the vaccine.

FOR WOMEN

Based on limited data, Tetanus Toxoid Vaccine contains no components that have been shown to pose a risk to the fetus or newborn. Pregnancy should not be considered a contraindication to vaccination for women at high risk of acquiring tetanus infection, since tetanus poses a risk to the fetus or newborn. I have been advised, however, to review the risks and benefits of vaccination with my physician, if I am pregnant or am of childbearing age and have reason to believe that I may be pregnant.

____ ____

Signature of Recipient Date Signature of Witness

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Tetanus Toxoid Declination (MANDATORY WHEN APPLICABLE)

I understand that due to my potential risk of injury and chance of contracting the bacteria through an open injury/wound, I may be at risk of acquiring tetanus infection. I have been given the opportunity to be vaccinated with tetanus toxoid vaccine, at no charge to myself. However, I decline tetanus toxoid vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring tetanus toxoid and severe complication.

____ ____

Signature of Patient Date Signature of Witness

(This form may be replicated via WP)