

# 21 Tetanus

Vaccine introduced in 1930s (DT)/ 1952/53 (DTP)/ 1996 (DTaP)

NOTIFIABLE

In some circumstances, advice in these guidelines may differ from that in the product Summary of Product Characteristics (SmPC). When this occurs, NIAC advises that the recommendations in these guidelines, which are based on current expert advice from NIAC, are followed.

## Key changes

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Key changes

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### 21.1 Introduction

Tetanus is an acute potentially fatal disease characterised by muscular rigidity and intermittent spasms. It is the only vaccine preventable disease which is non communicable. It is caused by the neurotoxin produced by *Clostridium tetani* which grows anaerobically in a contaminated wound. The toxin is taken up by nerves, and blocks inhibitory synapses. Effective protection is provided in 90-95% of those who are fully vaccinated. Protection declines with time since vaccination and with age; up to 50% of 20 year olds and up to 70% of 70 year olds who have not received boosters within 10 years may be unprotected. Naturally acquired immunity does not occur.

### 21.2 Epidemiology

Tetanus spores are present in the soil, and in the intestine and faeces of cattle, sheep, horses, chicken, dogs, cats, rats, guinea pigs, and chickens. The spores are very resistant and remain viable for years. Thus, technically it is not possible to eradicate tetanus. In agricultural areas a significant number of adult humans may harbour the organism in their gut. Spores may also be found in contaminated heroin. The spores may be introduced into the body during injury, often through a puncture wound but also through burns or occasionally trivial wounds and the neonatal umbilical stump. Tetanus is not transmitted from person to person.

Internationally, there has been a dramatic decline in tetanus in recent years following improvements in tetanus vaccination coverage. In the 1980s, over 1 million deaths every year were attributable to tetanus, with an estimated 787,000 deaths in 1988 from neonatal tetanus alone.

Worldwide, it is estimated that over 73,000 total tetanus cases, including over 27,000 neonatal tetanus infections, occurred in 2019. An estimated 34,700 tetanus deaths occurred, most in South Asia and Sub-Saharan Africa. Maternal and neonatal tetanus remains a major public health problem globally.

There is an 80%–100% case fatality rate among infants, especially in areas with poor immunisation coverage and limited access to clean deliveries and umbilical cord care. In countries with no intensive care, almost 100% of persons who get infected with tetanus die.

The WHO has reported an increasing incidence of tetanus in adult men, especially in countries that do not provide tetanus booster doses.

Those most at risk of developing tetanus are young children and people over 60 years of age, many of whom have not had appropriate vaccination.

In Ireland there have been five cases reported since 2012, four probable and one confirmed. Ages ranged from 11 to 39 years. There was a death in a 63 year-old reported in 2001.

The incubation period ranges from 2 days to months but most cases develop in less than 14 days. The shorter the incubation period, the greater the likelihood of death. Spores germinate in anaerobic conditions, producing toxins that spread via blood and lymphatics.

### 21.3 Effects of tetanus

Tetanus is a medical emergency requiring hospitalisation and immediate treatment (see [Section 21.4](#))

**Local tetanus**, unusual in humans, is manifested by muscle spasms in areas contiguous to the wound. The spasms may continue for several weeks. Local tetanus may precede generalised tetanus but is usually much milder, about 1% of cases being fatal.

**Generalised tetanus** is the most common form, accounting for more than 80% of cases. The most common initial sign is spasm of the muscles of the jaw (“lockjaw”). Severity of disease varies, as shown in Table 22.1.

**Table 22.1.** Grading and symptoms of generalised tetanus

Grading	Symptoms
<b>Mild</b>	Mild trismus* and/or generalised spasticity
<b>Moderate</b>	Moderate trismus*, generalised spasticity, dysphagia, some respiratory distress
<b>Severe</b>	Severe trismus* and generalised spasticity, severe prolonged muscle spasms, severe dysphagia, severe respiratory distress, autonomic dysfunction with arrhythmias, hypertension and profuse sweating

\*Painful contractions of the masseter and neck muscles

Pulmonary embolism may occur in drug users and the elderly. Mortality rates in recent years are 10-90%, being highest in infants, the elderly, and those who are unvaccinated or have not received a booster within the previous 10-20 years.

The disease remains severe for 3-4 weeks and gradually subsides over months.

### Diagnosis

Diagnosis is primarily clinical, when other causes of muscle spasms such as phenothiazine toxicity, hypocalcaemic tetany and hysteria are outruled. Attempts to culture the organism are seldom successful.

### Tetanus-prone wounds include:

- puncture type injuries acquired in a contaminated environment and therefore likely to contain tetanus spores e.g., gardening injuries
- wounds containing foreign bodies
- compound fractures
- wounds or burns with systemic sepsis
- some animal bites and scratches – saliva of domestic pets is unlikely to contain tetanus spores unless the animal has been rooting in soil or lives in an agricultural setting.

Note: this list is not exhaustive; e.g., a wound from a discarded needle found in a park may be tetanus-prone.

### High-risk tetanus-prone wounds include: Any of the above with:

- heavy contamination with material likely to contain tetanus spores, e.g., soil, manure
- wounds or burns with extensive devitalised tissue
- wounds or burns requiring surgical intervention which is delayed for more than six hours are high risk, even if the contamination was not heavy.

Clean wounds are very unlikely to contain tetanus spores, and immediate post exposure treatment is not indicated. However, for those who are incompletely immunised, further tetanus toxoid doses should be given to complete the recommended schedule and protect against future exposures (Table 21.2).

## 21.4 Treatment and Prophylaxis

### 21.4.1 Human tetanus immunoglobulin (TIG)

Each vial (100IU/ml) contains at least 250 IU of human tetanus immunoglobulin. It is bioavailable in the circulation 2 - 3 days following IM administration.

#### Licensed indications

##### *a) Post exposure prophylaxis*

Immediate prophylaxis after tetanus prone injuries in patients

- not adequately vaccinated
- whose immunisation status is not known with certainty
- with severe deficiency in antibody production

##### *b) Treatment of clinically manifest tetanus*

Tetanus immunoglobulin should always be administered along with tetanus vaccination unless there are contraindications or confirmation of adequate vaccination.

#### Recommendations

##### *a) Post exposure prophylaxis*

##### *Dose and route of administration*

Children and adults: 250 IU, intramuscularly into the anterolateral thigh.

The dose may be increased to 500 IU if the risk is thought to be extremely high e.g.,

- infected wounds where surgically appropriate treatment cannot be achieved within 24 hours
- deep or contaminated wounds with tissue damage and reduced oxygen supply, as well as foreign-body injury (e.g., bites, stings) burns
- tissue necrosis
- septicaemic abortion
- adults weighing more than the average.

In case of extensive burns, it is advisable to administer a second injection of 250 IU after the exudative phase of the burn has subsided (about 36 hours after onset of the burn).

If TIG and tetanus vaccine are required they should be given at different sites

### ***b) Treatment of clinically manifest tetanus***

As the recommended volume of TIG is 12-24 mls HNIG should be used

#### **21.4.2 Human normal immunoglobulin (HNIG)**

The following HNIG preparations for IV use are authorised in Ireland and have been shown to contain reasonable levels of tetanus antibody by the National Institute for Biological Standards and Control in the UK. None are authorised for post exposure prophylaxis of tetanus. In addition, anti-tetanus antibody content varies from lot to lot.

Flebogamma 5% and 10%

Intratect 5% and 10%

Privigen 5% and 10%

#### **Recommendations**

##### ***a) Post exposure prophylaxis***

HNIG should be used for post exposure prophylaxis in the following situations:

- after tetanus prone injuries in patients not adequately vaccinated
- in patients whose immunisation status is not known with certainty
- in patients with severe deficiency in antibody production
- in vaccinated patients with high risk wounds
- if TIG is not available

##### ***b) Treatment of clinically manifest tetanus***

HNIG is the preferred treatment for clinically manifest tetanus, as the volume of TIG required to reach therapeutic levels is too large for IM administration.

#### **Dose and route of administration**

200-400 milligrams/kg. infused intravenously at an initial rate of 0.01 - 0.02 ml/kg/min for the first thirty minutes. If well tolerated, the rate of administration may gradually be increased to a maximum of 0.1 ml/kg/min.

For more information see the SmPC.

**Table 21.2** Risk assessment of wounds for use of vaccination and tetanus immunoglobulin (TIG)

Vaccination status	Clean wound	Tetanus prone wound	
Fully immunised (5 doses of tetanus vaccine at appropriate intervals)	Nil	Tetanus vaccine if more than 10 years since previous tetanus vaccine	Consider TIG*
Primary immunisation and age appropriate boosters complete	Nil	Nil	Consider TIG*
Primary immunisation or age appropriate boosters incomplete	Age appropriate tetanus vaccine and complete vaccine schedule	Age appropriate tetanus vaccine and complete vaccine schedule	TIG
Unimmunised or unknown vaccine status	Age appropriate tetanus vaccine and complete vaccine schedule	Age appropriate tetanus vaccine and complete vaccine schedule	TIG

\*TIG for fully vaccinated patients who are immunocompromised

Refer to GP for follow-up vaccines.

If both TIG and vaccine are required, administer at separate sites.

## 21.5 Tetanus vaccine

This is a toxoid, prepared by inactivating tetanus toxin with formaldehyde and adsorbing it onto aluminium as an adjuvant, to increase immunogenicity. Clinical efficacy after a complete series of vaccines is almost 100%. However immunity wanes and after 10 years may be insufficient to provide protection. The currently licensed tetanus vaccine are combination vaccines.

Tetanus (T) containing vaccines in combination with high dose diphtheria (D) and acellular pertussis (aP) (DTaP/IPV/Hep B/Hib or DTaP/IPV) are recommended for children up to 10 years of age. In the event of a temporary shortage of DTaP/IPV, Tdap/IPV may be used.

Tetanus (T) containing vaccines in combination with low dose diphtheria (d) and acellular pertussis (ap) (Td, Tdap, Td/IPV or Tdap/IPV) are recommended for those aged 10 years and older (see [Table 2.4a in Chapter 2](#)).

An up-to-date list of licensed vaccines can be accessed on the HPRA website [www.hpra.ie](http://www.hpra.ie)

A list of the currently available vaccines from the National Cold Chain Service can be found at [www.immunisation.ie](http://www.immunisation.ie)

Tetanus vaccines should be stored at +2 to +8°C. If a tetanus vaccine has been frozen it should not be used.

### **Dose and route of administration**

The dose is 0.5 ml, given by intramuscular injection into the anterolateral thigh or the deltoid area.

### **Recommendations**

#### **1. Primary vaccination**

Three doses at 2, 4 and 6 months of age as part of a 6 in 1 vaccine (DTaP/IPV/Hib/Hep B).

When 6 in 1 vaccine is given concurrently with PCV, it should be given first as it is less painful.

If the primary course is interrupted it should be resumed but not repeated, allowing appropriate intervals between the remaining doses (see catch-up schedule in [Chapter 2](#)).

#### **2. Booster vaccination**

A first booster dose is recommended at 4-5 years of age as DTaP/IPV (4 in 1) vaccine. In the event of a temporary shortage of DTaP/IPV, Tdap/IPV may be used.

Some countries give a fourth dose of tetanus containing vaccine at approximately 18 months of age. An additional dose should be given from the age of four years, usually in junior infants. If a fourth dose has been given at age  $\geq 3$  years and 4 months, a fifth dose is not required until age 12-13 years.

A second booster dose is recommended at 12-13 years as Tdap vaccine **regardless of the interval from a previous tetanus containing vaccine.**

#### **3. Tetanus prone wounds**

See Table 21.2



#### 4. Adults

Unvaccinated adults should be given a tetanus containing vaccine as shown in [Table 2.4a in Chapter 2](#).

For vaccinated persons who have received 5 doses of tetanus vaccine, booster doses should be considered every 10 years. This is based on concern regarding the decline of antibody levels with age and potential failure of single booster doses to produce protective levels in older individuals.

**Children under 10 years should receive tetanus vaccine as DTaP/IPV/Hib/ Hep B or DTaP/IPV (or Tdap/IPV in the event of a temporary shortage)**

**All aged 10 years and over should receive tetanus vaccine as Td, Tdap, Td/IPV or Tdap/IPV depending on other vaccine requirements (see [Table 2.4a in Chapter 2](#)).**

**If tetanus vaccine is indicated for those aged <10 years**

- Wait at least 6 months between booster doses of DTaP and the completion of a primary course of DTaP containing vaccines.
- DTaP containing vaccines can be given at any interval following (an inappropriately administered) Td.

**for those aged 10 years and older**

- Tdap or Tdap/IPV can be given at any interval following a Td containing vaccine.

#### Contraindications

Anaphylaxis to any of the vaccine constituents

#### Precautions

Acute severe febrile illness, defer until recovery.

Type III (Arthus) hypersensitivity reaction to a previous dose (see Adverse reactions). Persons experiencing these reactions usually have very high serum diphtheria or tetanus antitoxin levels; they should not be given further routine or emergency booster doses of tetanus or diphtheria containing vaccines more frequently than every 10 years.

### **Adverse reactions**

Local: Pain, palpable lump, swelling and erythema at the injection site occur in up to 20% of recipients. They are more frequent with subsequent doses. Most of these reactions resolve with no treatment. A cold pack or ice wrapped in a cloth applied to the site for 20 minutes per hour as necessary may be required. On occasions paracetamol or ibuprofen may be needed. Antibiotics are very rarely indicated.

Very rarely a Type III (Arthus) hypersensitivity reaction occurs, involving swelling and erythema of most of the diameter of the limb from the shoulder to the elbow or the hip to the knee. This usually begins 2-8 hours after vaccination and is more common in adults. This resolves without sequelae.

General: Malaise, transient fever and headache are uncommon. Temperature over 40°C is rare. Dyspnoea, urticaria, angioedema, and neurological reactions are very rare.

Anaphylaxis is extremely rare (0.6-3 per million doses).

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