

## **Td Booster Dose in 6<sup>th</sup> Class Frequently Asked Questions**

### **1. Question**

**A child has come to Ireland from another country, e.g. US, and has had 4 primary doses of Diphtheria and Tetanus + 1 preschool booster, so already has had 5 doses. Should they have a 6<sup>th</sup> dose?**

### **Answer**

The US still recommends a dT at 11-12 years, i.e. the US recommend 6 doses by 12 years. This is also the recommended in other countries. The Irish Guidelines recommend a minimum of 5 doses, not a maximum of 5 doses. Also the 18 month dose is really part of the US primary immunization, rather than a booster.

Therefore, the recommendation is that they have the dT (Tdap once implemented) booster. Five years should be left between dose 5 and dose 6, i.e. between the preschool and 6<sup>th</sup> class boosters

### **2. Question**

**A child has had 3 primary doses of diphtheria and tetanus, no preschool booster, but 1 dose of tetanus following injury. What vaccine should be given?**

### **Answer**

Monovalent tetanus has not been available since mid 2002, more that five year ago. If children now aged 11-12 years had tetanus in A+E/GP in the last 5 years they may have had either dT, DT, dT/IPV or DTaP/IPV.

Whatever presentation of tetanus was given he/she has only had 4 doses of tetanus.

Therefore, the recommendation is that they have a fifth tetanus as dT (Tdap once implemented). Five years should be left between dose 4 and 5, i.e. between the post-injury and 6<sup>th</sup> class booster.

If the child has not had a fourth dose of IPV this can be given either as IPV or in combination vaccine, dT/IPV, if these are available.

Check also that child has had 2<sup>nd</sup> MMR. If not, will need MMR.

### **3. Question**

**A child has had 3 primary immunizations and 1 preschool booster and has also had 1 dose of tetanus following injury. What vaccine should be given?**

#### **Answer**

Presuming the child had a preschool booster at 4-5 years no tetanus booster should be needed until aged 9-10 years when attending at A+E or GP with injury. However, booster may have been given if immunization history unclear.

Monovalent tetanus has not been available since mid 2002, more that five year ago. If children now aged 11-12 years had tetanus booster in A+E/GP in the last 5 years they most likely had dT or else DT.

Therefore, in most cases the child should not require dT, as he/she already had 2 booster doses. However, if >5 years have elapsed since the last dose dT should be given, as in that case the 2<sup>nd</sup> booster would have been given inappropriately, within 2-3 years of the preschool booster.

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#### Question 4

**What are the reported adverse effects following dT vaccine?**

#### Answer

The following information is found in the SPC for the diTeBooster.

“In relation to the administration of diTeBooster, the most common adverse reactions are redness and swelling at the injection site and fever. The reactions most commonly start within 48 hours from the day of vaccination.

Frequency of ADR Organ class	Common (>1/100 and <1/10)	Uncommon (>1/1,000 and <1/100)	Rare (>1/10,000 and <1/1,000)
Immune system			Anaphylactoid reactions
Skin and sub- cutaneous tissue		Eczema and dermatitis	Urticarial reactions
General disorders and administration site conditions	Malaise Fever > or = 38 <sup>0</sup> C Redness/swelling at injection site	Redness/swelling >or = 6cm at the injection site	High fever >40 <sup>0</sup> C Granuloma or sterile abscess at the injection site”

The following information is found in the SPC for Revaxis (dT/IPV) which has similar dose of tetanus and diphtheria toxoid.

“The adverse events are ranked under headings of frequency using the following convention:

Very common:  $\geq 10\%$

Common:  $\geq 1\%$  and <10%

Uncommon:  $\geq 0.1\%$  and < 1%

Rare:  $\geq 0.01\%$  and  $< 0.1\%$

Very rare:  $< 0.01\%$ , including isolated reports

In clinical studies, the most common events occurring after vaccine administration were local injection site reactions (pain, erythema, induration and oedema) reported by 65 to 80% of subjects in each trial. These usually had their onset within the 48 hours following vaccination and persisted for 1 to 2 days. These reactions are sometimes accompanied by injection site nodules.

Blood and lymphatic system disorders:

*Uncommon:* lymphadenopathy

Ear and labyrinth disorders:

*Common:* vertigo

Gastro-intestinal system disorders:

*Common:* nausea / vomiting

General disorders and administration site conditions:

*Very common:* local reactions (injection site pain, injection site erythema, injection site induration, injection site oedema and injection site nodule)

*Common:* pyrexia

*Uncommon:* malaise

Musculo-skeletal and connective tissue disorders:

*Uncommon:* myalgia

*Rare:* arthralgia

Nervous system disorders:

*Common:* headache

### **Data from post-marketing surveillance:**

Based on spontaneous reporting, the following additional adverse events have been reported during the commercial use of REVAXIS®.

These events have been very rarely reported, however exact incidence rates cannot precisely be calculated.

#### General disorders and administration site conditions:

asthenia, usually occurring and resolving within a few days

influenza-like symptoms, mostly the same day as the vaccination

#### Immune system disorders:

systemic allergic / anaphylactic reactions

#### Skin and subcutaneous tissue disorders:

allergic-type reactions such as urticaria, various types of rash, and face oedema

### **Potential adverse events:**

Guillain-Barré-Syndrome has been reported after vaccination with tetanus-toxoid containing vaccines. “

### **Question 5**

**What advice should be given to parents regarding the need for further booster doses?**

### **Answer**

The advice given will depend on the vaccine status of the particular child. If after the dT booster the child is fully vaccinated against tetanus, i.e. has had at least 5 doses, then he/she should not need a further booster for at least 10 years. The most important message should be to keep the immunization records safely and remember to bring them to South Doc or A+E if have to attend with an injury. The main problems arise when the assessing doctor does not have access to records and parents/patient cannot remember date of vaccination.