Ministry of Health & Family Welfare Government of India



# **Tetanus and adult diphtheria (Td)**

**Operational Guidelines** 

## Introduction of Td vaccine in Universal Immunization Programme of India

### Replacement of TT with Td vaccine

Since 1998, WHO has recommended that TT should be replaced by Td vaccine. This is reiterated in the WHO tetanus vaccine position paper of 2017 and deliberations of Strategic Advisory Group of Experts in 2002 and 2016. National Technical Advisory Group on Immunization (NTAGI), Ministry of Health & Family Welfare has also recommended the replacement of TT vaccine with Td vaccine in India's immunization programme for all age groups, including pregnant women.



Countries that have replaced TT with Td vaccine 🛛 Countries still using TT vaccine

## Rational for TT to Td replacement

As per the lab supported vaccine preventable diseases surveillance data in India, majority of the cases of Diphtheria are occurring in age group 5 years and above (77% and 69% respectively in 2017 and 2018) mostly in unvaccinated (~ 2/3rd). In 2016 diphtheria outbreak in Kerala, nearly 79% cases occurred in >10 years age group. Since 1999, there have been more than 80% reduction in tetanus mortality, however diphtheria outbreaks are increasing which reflect gaps in diphtheria protection. Diphtheria epidemics in Eastern Europe and South America revealed that immunity to diphtheria subsides following the primary series of DTP infant immunization. After experiencing outbreaks, these regions changed to Td vaccine for women of reproductive age, and provided Td booster doses for older children and adolescents. This strategy resulted in marked decrease of diphtheria cases in Eastern Europe and South America. It is now well established that immunity to diphtheria subsides following the primary series of DTP infant immunization and that booster doses of diphtheria toxoid containing vaccines are needed for continued protection.

The use of Td rather TT is recommended during pregnancy to protect against maternal and neonatal tetanus & diphtheria during prenatal care. Vaccination during pregnancy also serves to boost immunity and increase the duration of protection in those pregnant women who had not received the full set of recommended booster doses. Td also boost decreasing diphtheria immunity in addition to assuring tetanus protection, and help to curtail diphtheria outbreaks.

## Tetanus and Diphtheria disease burden

Tetanus is an acute infectious disease caused by toxigenic strains of the bacterium Clostridium tetani. The disease may occur at any age and case-fatality rates are high even where intensive care is available. In the absence of medical intervention, the case-fatality rate approaches 100%. Of all the tetanus cases reported in 2015, 35% were in neonates and 65% in older children and adults, with nearly half the cases from South Asian countries.

Diphtheria caused by Corynebacterium diphtheriae, has been one of the most feared infectious diseases globally, which causes devastating epidemics. South East Asia is the primary driver of global diphtheria incidence, especially since 2005. Reported cases of Diphtheria in India has a fluctuating trend. India contributes to nearly three-fourth of the cases in SEAR region.

### About Td vaccine

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Tetanus and adult diphtheria (Td) vaccine is a combination of tetanus and diphtheria with lower concentration of diphtheria antigen (d) as recommended for older children and adults.

	Ø	WHO prequalified
2-40		VVM 30
Diphtheria Tetanus Vaccino orbed) for Adults Adolescents I.P		Shelf life: 24-36 months
	I I MA	Preservative: Thiomersal

#### UIP schedule after introduction of Td vaccine

Age	Vaccination schedule after Td introduction		
At birth	BCG, OPV-zero dose, Hep B-birth dose		
6 weeks	OPV-1, Pentavalent-1, Rota-1*, fIPV-1, PCV-1*		
10 weeks	OPV-2, Pentavalent-2, Rota-2*		
14 weeks	OPV-3, Pentavalent-3, Rota-3*, fIPV-2, PCV-2*		
9 months	Measles-1/MR-1, Vit A, JE-1*, PCV-B*		
16-24 months	DPT first booster dose, OPV-booster dose, Measles-2/ MR-2, JE-2*		
5-6 years	DPT second booster dose		
10 & 16 years	Td		
For pregnant woman	Td-1 : early in pregnancy Td-2 : 4 weeks after Td-1 Td-B: if pregnancy occur within 3 years of last pregnancy and 2 Td doses were received		

# 🚀 Rollout of Td vaccine

#### Workshops:

» State & district level workshops will be organized to disseminate information regarding replacement of TT with Td vaccine

#### Trainings

» Block level trainings will be held to create awareness among ANMs.

#### Vaccine supply:

» Td vaccine will be supplied by Government of India as is done for other vaccines under UIP. Orders of Td have been placed and supplies are likely to commence from November 2018 onwards in phased manner.

#### Strategies to achieve maximum coverage of Td:

- For Children of 10 and 16 years (school going)
  - » Convergence with School Health and Adolescent Health programme will be used as a platform to generate awareness for pregnant women and adolescents.
  - » States may plan annual campaign with Td vaccine to target children at schools: rough idea is that to cover 5th standard (10 years) and 10-11th standard (16 years) children
  - » Health education sessions conducted under Rashtriya Kishor Swasthya Karyakram may be used to create awareness about Td
  - » States may use its experience and advocacy done during MR campaign

#### • For pregnant women

- » Convergence with Maternal Health programme at various forums
- » Other RI strengthening activities in general
- Involvement of private organizations, professional bodies etc. to be done at all levels

#### Cold chain and Stock management:

- The storage, package size, presentation, route of administration, wastage rate, doses required, transportation, heat and freeze sensitivity, cold chain maintenance is same as TT. No requirement for additional cold chain storage capacity to accommodate Td vaccine.
- » If remaining stock of TT vaccine still meets all validity requirements, it should to be used first and then begin using Td vaccine. There is no need to discard or recall stocks of available TT vaccine
- » Td vaccine can be given as a subsequent dose following TT, and all previous TT doses will remain valid. There is no need to re-start the series.

#### **Recording and reporting**

- » Revision of all recording and reporting formats (MCP card, due list, tally sheets, RCH registers, microplans, AEFI formats etc.) replacing TT with Td is to be done.
- » If the same has been revised to include Td doses, it should be recorded at appropriate columns (at 10 years & 16 years for children and Td-1, Td-2 and Td-B for pregnant women). If not done: Td doses should be recorded at the place of TT doses.

## $\gtrsim$ Key Messages for ANMs:

- » Tetanus Toxoid (TT) vaccine has been replaced with Tetanus and adult diphtheria (Td) vaccine.
- » Tetanus and diphtheria can lead to hospitalizations or even cause death.
- » There are increasing numbers of cases of diphtheria amongst older age group. Td vaccine in place of TT will help to decrease diphtheria outbreaks.
- » The use of Td rather TT is recommended during pregnancy to protect against maternal and neonatal tetanus & diphtheria during prenatal care.
- » Vaccination during pregnancy also serves to boost immunity and increase the duration of protection in those pregnant women who had not received the full set of recommended booster doses.
- » Available TT will be used first before starting use of Td.
- » Td is a safe vaccine; 133 countries are using Td vaccine and it is being introduced in India.



## Points to Remember:

- Td vaccine is a combination of tetanus and diphtheria with lower concentration of diphtheria antigen (d)
- The MoHFW recommends the replacement of TT vaccine with Td vaccine for all age groups, including pregnant women.
- » Td is freeze and heat sensitive.
- » Open vial policy is applicable to Td vaccine.
- » Shake test applicable
- » Available TT stock should be used first before using Td under UIP schedule. TT should not be recalled or discarded.
- » Td is a safe vaccine. Any minor, severe & serious AEFI event should be reported immediately.
- » Td will be reported in place of TT till the revision of reporting formats.



