



WHO/UNICEF JOINT COMMUNIQUE

Replacement of TT with Td vaccine for dual protection

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BACKGROUND

In 1998 the World Health Organization (WHO) recommended that the use of tetanus toxoid (TT) vaccine should be replaced with tetanus-diphtheria (Td) vaccine following huge outbreaks of diphtheria in the Soviet Union and other countries despite the high coverage of routine childhood vaccination. The outbreaks resulted from the accumulation of a susceptible population in older age groups following the waning of immunity to diphtheria toxoid. The recommendation to shift from using TT to Td vaccine was re-stated by the Strategic Advisory Group of Experts (SAGE) on Immunization in 2002 and 2016, and was published and disseminated again in the WHO position papers on tetanus vaccine in 2006¹ and 2017².

JUSTIFICATION

In this era with more than 80% reduction in tetanus mortality since 1999, the world has witnessed increasing diphtheria outbreaks. These outbreaks reflect gaps in diphtheria protection, resulting from a mix of low vaccination coverage and waning immunity, and could have been prevented with the use of Td vaccine in the immunization schedule. As surveillance for diphtheria is weak in many countries, often cases of diphtheria are not being identified and reported. However, large outbreaks have occurred in 2017 and 2018 in a growing number of countries including Bangladesh, Indonesia, Kenya, Philippines, South Africa, Venezuela, and Yemen, among others.

A 2017 global vaccine market study by WHO confirms sufficient supply to meet increased global demand for Td vaccines as well as minimal price differentials between TT and Td vaccines.³ WHO and United Nations Children's Fund (UNICEF) are therefore strongly urging countries that have not yet replaced the use of TT with Td vaccine to immediately initiate the process to avoid preventable morbidity and mortality, and complete the replacement by January 2020 to achieve global implementation of this very significant WHO policy recommendation.

The tetanus and diphtheria components of Td vaccine serve as booster doses to both vaccines, thus prolonging the duration of protection from both diseases. Td vaccine has been WHO prequalified and used in immunization programmes in countries supported through UNICEF since 1995.

The Td vaccine market is a healthy market, with ample capacity and five WHO pre-qualified suppliers of Td vaccine, four of which are actively supplying and have in-house production of tetanus and diphtheria bulk, with an estimated capacity of approximately 300 million doses per annum. The global demand for tetanus toxoid containing vaccine is approximately 250 million doses⁴, of which 160 million doses are supplied through UNICEF. There is sufficient supply of Td vaccines for all countries to replace TT with Td in their immunization schedule.

133 countries have already replaced TT with Td in their routine immunization programmes. From prior country experience, the process of replacement has been easily executed. As the route of administration, packaging size, targets and schedule are the same as for TT, the replacement with Td requires no change in cold chain storage capacity and no change in the logistics for vaccine delivery. The price differential between TT and Td vaccines is also very negligible, especially if the same vial size (10 or 20 dose vials) is maintained. Both tetanus and diphtheria toxoid

¹ WHO. Tetanus vaccine: WHO position paper. Weekly Epidemiological Record, No 20, 19 May, 2006.

² WHO Tetanus vaccine: WHO position paper. Weekly Epidemiological Record, 10 February 2017, vol. 92, 6 (pp. 53–76)

³ www.who.int/immunization/MI4A

⁴ http://www.who.int/immunization/programmes_systems/procurement/v3p/platform/WHO_DT_global_market_study.pdf

containing vaccines are considered safe for use in pregnancy. These vaccines have been used for decades and there is no evidence of adverse pregnancy outcomes or risk to the fetus from the vaccination during pregnancy. However, local reactions at the site of injection are common.

To this end, WHO and UNICEF highlight that:

- 1) replacement of TT with Td vaccine will boost waning diphtheria immunity in addition to assuring tetanus protection, and help to curtail diphtheria outbreaks;
- 2) there are no programmatic implications – as the formulations, storage, targets, schedule and mode of service delivery remain unchanged;
- 3) it is highly cost effective – a very nominal additional cost will save millions of dollars required for outbreak response;
- 4) Td vaccine is WHO prequalified since 1995 and is available from 4 active producers in the market.⁵

GUIDANCE NOTE

The guidance note accompanying this joint communique provides further details for country decision makers and programme managers on the considerations required to replace TT with Td vaccine. These include the WHO recommended schedule for tetanus toxoid containing vaccines, forecasting planning, and budgeting, training requirements for immunization providers, and regulatory considerations.

The accompanying guidance note clearly describes the need for and feasibility of this vaccine replacement, and provides an overview of financial implications, albeit minimal, for all countries including those supported by UNICEF. This is basically a product replacement with negligible programmatic changes – the target population and the vaccination schedule remain the same and the cold-chain requirement is unchanged.

WHO & UNICEF RECOMMENDATIONS ON REPLACING TT WITH Td

In light of the growing number of diphtheria outbreaks, WHO and UNICEF through this joint communique strongly urge countries to take the necessary steps and complete the TT to Td vaccine replacement process by January 2020 – a simple shift that will contribute to reduction in diphtheria morbidity and mortality, with negligible programmatic and financial implications.

As of January 2020, UNICEF will no longer fund TT vaccine, nor provide procurement services for supply of TT vaccine. UNICEF will continue to support Td vaccine only, in support of maternal immunization programmes.

For countries self-procuring TT vaccine, it is expected that this vaccine will remain available on the global market. However, as a result of decreased demand through UNICEF and market evolution toward production of Td vaccine, the cost and delivery lead-time of vaccine may increase.

FOR FURTHER INFORMATION

For further information see the attached guidance note and contact:

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⁵ For more information on product availability kindly consult the Market Information for Access website here www.who.int/immunization/MI4 Or contact MI4A@who.int . For UNICEF procuring countries, kindly consult UNICEF's website here: https://www.unicef.org/supply/index_67674.html