India is on the way forward to maternal and neonatal tetanus elimination!

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Tetanus is an acute, potentially fatal disease, caused by a bacterium, *Clostridium tetani*. The disease usually occurs in newborns through infection of the unhealed umbilical stump, particularly when the stump is cut with a non-sterile instrument. NT contributes to 5–7% of neonatal mortality worldwide. Several thousand mothers are also estimated to die annually of maternal tetanus. MNT elimination relies on promotion of maternal tetanus immunization along with safe delivery and avoidance of unsafe abortion and umbilical cord care practices. The Government of India (1983) introduced at least two doses of tetanus toxoid vaccine (TT) to all pregnant women during each pregnancy as a part of its nationwide immunization policy. To date, a total of 15 States including union territories of the India have achieved NT elimination. The remaining Indian States need to strengthen TT coverage to save the lives of neonates as well as mothers from tetanus.

Introduction

Tetanus is an acute, potentially fatal disease, caused by a gram-positive, obligate anaerobic spore-forming bacterium, *Clostridium tetani*. Clostridium spores are found in soil and in animal and human feces. The spores enter the body through breaks in the skin and germinate in the deep tissues. The disease usually occurs in newborns through infection of the unhealed umbilical stump, particularly when the stump is cut with a non-sterile instrument. *C. tetani* produces a

neurotoxin that is one of the most potent toxins ever identified, with a minimum lethal human dose of < 2.5 ng/kg.¹ This high potency is caused by the toxin's absolute neuro-specificity and enzymatic action. The disease manifests as muscle stiffness that usually starts in the jaw (lockjaw) and neck and later becomes generalized.²

MNT cases are clustered in poor, remote and disenfranchised communities where unhygienic obstetric and postnatal practices prevail and access to maternal tetanus toxoid immunization is poor. In 1980s more than 1 million deaths every year were attributable to tetanus.³ In very high-mortality settings (neonatal mortality rate > 45 per 1,000 live births), almost 50% of deaths are due to severe infection, tetanus and diarrhea. Tetanus accounts for 5–7% of worldwide neonatal mortality.⁴ Globally only 11,762 cases of neonatal tetanus (NT) were reported in 2002, of which 1,718 cases occurred in India. While WHO estimates that about 218,000 cases of NT occurred worldwide that year, of which approximately 180,000 resulted in death, given that surveillance for NT is poor in most developing countries.^{3,5} It is estimated that < 10% of NT cases and deaths are actually reported (out of total disease burden).² The South East Asia region contributed to an estimated 81,500 cases of NT in that year.⁵

In 2010, there were 4,797 reported NT cases globally with 373 cases from India.⁶ According to the Child Health Epidemiology Reference Group (CHERG) (2008), an estimated 60,000 newborns die of the disease each year.^{2,7} NT mortality approached 100% in community-based

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surveys in the 1980s, but is now 10–60% with hospital care, depending on the availability of intensive care facilities.⁸ Several thousand mothers are also estimated to die of maternal tetanus.⁹

How to Prevent MNT?

MNT prevention relies on the avoidance of unsafe delivery, abortion and umbilical cord care practices and promotion of maternal tetanus immunization. Hygiene of the puerperal and umbilical stump has a significant impact on prevention of NT, as is evident from the history of developed countries before the availability of TT (e.g., during the first half of the 20th century, NT in Denmark and the US steadily decreased to 0.05 and 0.02 cases per 1,000 live births, respectively). Even in rural regions of the developing world where home deliveries are common, concerted efforts to educate health workers and pregnant women about safe deliveries and care of neonates can result in substantial reductions in NT.³

Control and Elimination Strategies

TT vaccination of pregnant women to prevent NT was included in the Expanded Program on Immunization a few years after its inception in 1974.¹⁰ The Government of India (1983) introduced at least two doses of TT to all pregnant women during each pregnancy as a part of nationwide immunization policy. However, TT immunization of pregnant women was implemented in the state of Andhra Pradesh in 1979.⁵

Despite the notable gains in child immunization in the 1980s, only 27% of pregnant women were receiving ≥ 2 doses of TT by 1989.³ In recognition of the substantial burden of NT in developing countries, the World Health Assembly (1989) adopted a resolution to eliminate NT by 1995 through the increased availability of TT and clean deliveries and improved surveillance. The elimination of NT was defined as < 1 case per 1,000 live births in every district. This definition also has been adopted as a proxy for the elimination of maternal tetanus.^{2,7}

Since 57 countries had not achieved the elimination goal, UNICEF, WHO

and UNFPA re-launched the initiative in 1999 as “Maternal & Neonatal Tetanus Elimination Initiative” and set the year 2005 as the target date. It was decided to use a high-risk approach in countries where the elimination goal had not been achieved.^{3,11} In high-risk districts/areas where women had not been reached by immunization services, supplemental immunization activities would be conducted to vaccinate $\geq 80\%$ of all women of childbearing age with three properly spaced doses of TT vaccine and the promotion of antenatal care with clean delivery practices.¹² Once elimination is achieved, it is very important to sustain it by increasing: (1) Routine TT coverage for pregnant women, (2) routine DPT (diphtheria, tetanus, pertussis vaccine) coverage for children and (3) women’s access to and use of clean delivery services.

Once the countries claim that they have achieved NT elimination, validation for MNT elimination is done. A specific MNT elimination validation survey is conducted if a decision cannot be reached on the basis of the district routine data review (and field visits, when performed). The recommended community-based survey method uses a combination of lot quality assurance and cluster sampling (LQA-CS) techniques to judge whether the NT mortality rate (NTMR) is probably > 1 NT death/1,000 live births (elimination not achieved) or not (elimination achieved). The LQA-CS methodology sampled up to 3,000 live births in a two-staged approach (1,000 and 2,000 live births) in each district. If 1, 2 or 3 NT deaths were identified among the 1,000 live births in the first sample, the second sample of 2,000 live births would be surveyed. A conclusion can be made that NT is eliminated (i.e., pass status) if no NT deaths are found in the first sample of 1,000 LB. If there are > 3 NT deaths in the first sample or ≥ 4 NT deaths in the combined first and second samples, a fail status (i.e., NT is not eliminated) is assigned.⁵

Where does India Stand?

A mix of strategies has been implemented in India to facilitate clean deliveries by training auxiliary nurse-midwives

(ANMs) and other cadres of trained birth attendants who work at the village level, in addition to increase routine TT coverage. In the Rajasthan state, the high-risk approach was also used in 1998–1999.¹² In 2003, the Ministry of Health and Family Welfare (MoHFW), Government of India and the Department of Family Welfare in the state of Andhra Pradesh (AP) in collaboration with WHO, UNICEF, PATH and the Indian Council of Medical Research (ICMR) evaluated for the validation of NT elimination in the state of AP. Since the data regarding the routine reporting of NT was not considered reliable, a NT mortality survey (validation survey) using a lot quality assurance-cluster sampling (LQA-CS) methodology was conducted in each of the two highest risk districts, Kurnool and Mahbubnagar. Based on the validation survey, NT elimination was considered to have been achieved throughout the state of AP. The achievement of NT elimination in AP may be attributed to a number of programmatic factors, including high political commitment, effective village level promotional materials on vaccination, village level registration and TT vaccination of pregnant women, cash payments to families to cover costs associated with institutional deliveries and the provision of 24-h service at most primary health centers.⁵

Based on the available data for all the districts in Kerala state in 2005, the MoHFW, GoI concluded that reporting systems, immunization coverage, clean delivery rates and/or access to health care (TT2 coverage $> 80\%$ and $> 98\%$ institutional delivery) were such that it would be highly unlikely that NT rates would be > 1 per 1,000 live births. Therefore, Kerala state was considered to have been eliminated NT.¹³ In 2006, additional five states Haryana, Karnataka, Maharashtra, Tamil Nadu and West Bengal had eliminated NT (confirmed by the validation survey), thus increasing to seven the number of states who have eliminated NT.¹⁴ In 2007, Lakshadweep and Puducherry were considered to have eliminated NT on the basis of routine data review. On the other hand, Goa, Punjab, Sikkim and Chandigarh had been validated the NT elimination by LQA-CS method in the same year.¹⁵ As of 2012, 15 states have achieved NT

elimination with the addition of Gujarat and Himachal Pradesh (confirmed by the validation survey).¹⁶ Measures should now be strengthened to ensure to sustain elimination in these states.

What to do?

Although Government of India planned to eliminate MNT by 2009,¹⁷ a major part of India including some highly populous states, viz., Uttar Pradesh, Bihar, Madhya Pradesh, Rajasthan, have yet to achieve the elimination goal. It is time to improve the TT2/booster coverage among pregnant women and routine DPT vaccination coverage among children along with other measures to eliminate MNT from the country.

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