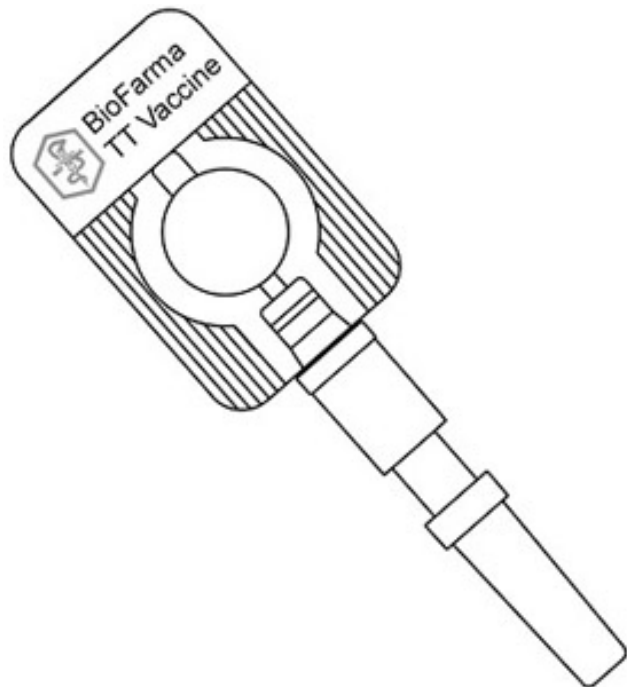


Introducing TT-Uniject™

**in Maternal and Neonatal Tetanus
Elimination**

A guide for program planners



Introducing TT-Uniject in Maternal and Neonatal Tetanus Elimination

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December 2003

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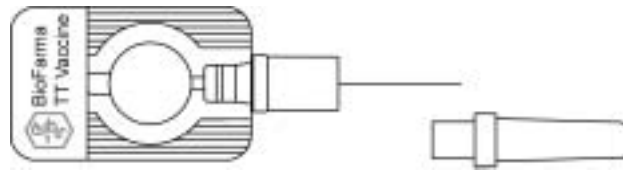
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INTRODUCTION

Efforts to eliminate maternal and neonatal tetanus have greatly reduced the number of neonatal deaths from tetanus over the last decade. However, neonatal tetanus is still responsible for up to 14 percent of neonatal deaths globally and up to 50 percent in selected high-risk districts (1998 WHO figures). Areas with limited access to health care services or education

account for the majority of neonatal tetanus cases. The primary factors contributing to the high incidence of neonatal tetanus in these areas include the following: underutilized or unavailable antenatal care (ANC) and immunization services, frequent home deliveries, illiteracy, low income, remote or migrant populations, and civil unrest.



TT-Uniject prefill injection device

The use of an auto-disable (AD), prefilled, single-dose injection device, called Uniject,^{TM*} has emerged as an important tool for increasing coverage of tetanus immunization and strengthening safe injection practices in underserved populations. The easy-to-use Uniject injection device is prefilled with a single dose of tetanus toxoid (TT) vaccine. It combines a dose of vaccine with a syringe and sterile needle. The Uniject device cannot be reused. It can be used safely and effectively to address some of the factors contributing to neonatal tetanus.

Tetanus toxoid in the Uniject device (TT-Uniject) is expected to enable innovative approaches to expand TT coverage, such as:

- Administration by traditional birth attendants (TBAs) or other lay providers.
- A more flexible cold chain for storage and transport.
- Use in areas with limited health facility infrastructure and/or health worker shortages.
- Capacity to overcome acceptability concerns such as fear of injections.
- Facilitating the logistics of in-house immunization strategies.

This document provides materials to assist health workers and program managers in the introduction, training and proper use of TT-Uniject.

*Uniject is a trademark of BD.

UNIJECT BACKGROUND

Uniject design features

The Uniject device was designed with the following features:

- **Single dose**—to minimize wastage and facilitate outreach to individual patients.
- **Prefilled**—to ensure that the correct dose is given, and to simplify procurement, logistics and administration of vaccine.
- **Nonreusable**—to minimize patient-to-patient transmission of bloodborne pathogens.
- **Easy to use**—to allow use by health workers who do not normally give injections.
- **Compact size**—for easy transport and less disposal volume.
- **Vaccine vial monitors (VVMs)**—on each package to monitor heat exposure.

Previous experience with TT-Uniject

The Uniject device has already been used by health workers for millions of clinical injections of hepatitis B and TT vaccines, utilizing strategies such as lay-provider delivery and house-to-house outreach. In field trials in Bolivia, the use of Uniject devices enabled TBAs who had never before given injections to visit remote homes and deliver TT during ANC visits.¹ The studies took advantage of the relative heat stability of TT. TT-Unijects were stored at ambient temperatures for up to one month in the homes of the TBAs and carried on extended outreach without cold boxes. This improved the timeliness of vaccine delivery and expanded the ANC services provided by TBAs.

A study was conducted in Mali in 2002 to evaluate TT in Uniject administered by community volunteers TBAs.² Results showed that TT-Uniject was correctly administered by TBAs, most of whom had no formal schooling and only half of whom had taken literacy courses. Not only was the injection correctly administered, but TBAs also applied safe injection practices, and they were well accepted socially. TBAs and health staff both felt that TBAs could administer TT-Uniject in routine vaccination programs, and that they would do so without being recompensed.

TT-Uniject was introduced in Afghanistan in 2003, with a target of immunizing women of childbearing age in Kabul.³ The restrictive atmosphere necessitated innovative methods to reach women, while still respecting the conservative Muslim culture. Four hundred illiterate women were paired with trained health workers (85% female) and together they moved from house to house and immunized 440,000 women. No major difference was observed in injection technique or refusal between literate and illiterate vaccinators. VVMs were relied upon to determine viability of vaccine, since the cold chain was not used.

TT-Uniject has been approved by WHO for UNICEF distribution.

¹ Quiroga R, et al. A prefilled injection device for outreach tetanus immunization by Bolivian traditional birth attendants. *Pan American Journal of Public Health*, 4(1), 20-25, 1998.

² D'Alois, L. Community Volunteer TBAs Using TT-Uniject in Mali. BASICS II draft report, 2003.

³ Islam, K. Maternal and Neonatal Tetanus Elimination Campaign Afghanistan, 2003. Presentation to Eliminating Maternal and Neonatal Tetanus Programme Committee, UNICEF, May 2003.

PROGRAM INNOVATIONS

TT-Uniject used by lay providers

In settings with insufficient health personnel or where health care providers are not accepted by part of the community, empowering nontraditional health providers to deliver TT could improve coverage. Such people could include TBAs, traditional healers, religious leaders, community volunteers, and others who may have better geographic or cultural access to underserved populations.

Although the use of lay providers to give injections may raise concerns about reuse, training difficulties, poor compliance, or supervisory limitations, the use of TT-Uniject overcomes these barriers because of its low training burden, acceptability, and simplicity. Since the Uniject device is easy to use, does not need to be filled, and cannot be reused, it is especially well suited for use by lay providers. Innovative program strategies involving the use of lay providers include:

- **Using TT-Uniject in low-infrastructure settings.** Limited health infrastructure, including insufficient health facilities and personnel shortages, can severely limit TT immunization coverage, especially in remote and isolated settings or areas of civil strife. Making use of community members to give TT immunizations could reduce dependence on static facilities or health personnel and improve coverage in these situations. Immunization outreach provides opportunities to reach pregnant women who are not able to visit a health center. For example, in an inaccessible mountainous setting, community leaders or TBAs could be trained to use TT-Uniject to give TT immunizations. They could store the TT-Uniject devices outside the cold chain in their homes. Every one to three months they could meet with a health supervisor to receive new TT-Unijects and report TT coverage.
- **Using TT-Uniject in culturally inaccessible populations.** Due to cultural, religious, ethnic, gender taboos, or other reasons, certain subpopulations may not accept TT immunization from the health staff and may only accept vaccination against tetanus during in-house immunization sessions. However, members of the underserved group, trained to deliver TT, could immunize these women. For example, if a minority religious group refuses services from health workers of the majority religion, volunteers or community leaders from the minority group could use TT-Uniject to immunize women during home visits.
- **Using TT-Uniject in multi-antigen campaigns.** Partnering TT immunization with campaigns for polio or other antigens could efficiently build upon existing programs to improve TT coverage. Concerns about slowing down the campaign, syringe reuse, personnel shortages, or logistic complexities may be overcome with TT-Uniject by allowing quick injection by lay providers, eliminating reuse, minimizing fear of injection, reducing dependence on the cold chain, and simplifying logistics. For example, village volunteers who organize an oral polio vaccine (OPV) campaign could be trained to give TT-Uniject injections to mothers while their children receive OPV. House-to-house immunization can easily be done in conjunction with other antigens, such as OPV. If the health center refrigerators cannot hold both the OPV and the TT for the campaign, the TT-Unijects could be dropped at the campaign stations and stored at ambient temperature during the week prior to the immunization day.

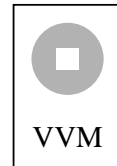
Taking Uniject out of the cold chain

Another innovative approach to distributing TT vaccine is to take advantage of its heat stability and remove it from the cold chain (see Flexible Cold Chain, page 4). This is especially helpful in countries that have a lack of equipment or a very centralized cold chain system with few

functioning refrigerators in peripheral or hard to reach areas and limited access to icepacks and icepack logistics. Care must be taken to avoid exposure to excessive heat or direct sunlight.

FLEXIBLE COLD CHAIN

Tetanus toxoid is one of the most heat-stable vaccines. It can be transported, stored, and used with less cold chain protection than the less-stable vaccines such as OPV or measles. To ensure that each TT-Uniject has not been damaged by heat, a vaccine vial monitor (VVM) is attached to each package of TT-Uniject. VVMs change color to show when the vaccine has been exposed to too much heat and should not be used (see VVM Training, page 15). The VVMs used with TT-Uniject change color at a rate that is based on the heat stability of TT.



WHO supports flexible cold chain strategies when vaccines are labeled with VVMs, health workers have been trained to use them correctly, and any vial bearing a VVM that has reached its endpoint is discarded.⁴ According to WHO, vaccine use outside the cold chain can be implemented either generally for all routine immunization activities or according to special circumstances, such as national immunization days, hard-to-reach geographical areas, immunizations provided in the home, cool seasons, and storage and transportation of freeze-sensitive vaccines (including TT) where the risk of freezing is greater than the risk of heat exposure.

Since tetanus toxoid is more than 20 times more heat stable than OPV, there are significant opportunities for taking TT-Uniject out of the cold chain to improve logistics and delivery. The length of time that TT-Uniject can be kept outside of the cold chain will depend on ambient temperatures and the quality of the cold chain.

The following table shows the number of days a TT-Uniject with a VVM can be exposed to various temperatures. This information can be compared to local temperatures and used to design a more flexible distribution system based on actual vaccine stability.

Days Until VVM Discard Point at Various Temperatures (for tetanus toxoid)

Temp °C	Days
50	3
45	8
40	17
35	35
30	73
25	154
20	337
15	756

For temperatures above 50°C. TT life is limited to a few hours. Care must be taken to always check the VVM before use.

A few possible examples of cold chain flexibility in TT-Uniject programs include:

- **Peripheral storage and delivery outside the cold chain.** In the Indonesian and Bolivian Uniject programs, midwives stored TT-Unijects in their homes for weeks and traveled directly to villages for home immunizations without ice or cold boxes.

⁴ “Getting Started with Vaccine Vial Monitors,” WHO/V&B/02.35, 2002, p.8-9.

- **Transportation outside the cold chain.**

Since transportation can be an expensive, but quick, segment of the cold chain, it may be feasible to transport TT-Unijects without refrigerated trucks, cold boxes, or ice.

- **Out of cold chain storage at delivery points.**

In situations such as campaign posts or health care centers without sufficient cold chain capacity, TT-Uniject could be stored without refrigeration prior to use.

- **Air-conditioned storage.**

At points in the cold chain where there are large volumes of vaccine (such as district stores), TT-Unijects could be stored in air-conditioned rooms rather than 2°-8°C cold chain refrigerators.

VVMs and the stability of TT vaccine create opportunities for reducing dependence on a 2°-8°C cold chain. While care must always be taken to avoid leaving unprotected vaccines in direct sunlight or in hot environments (such as a closed vehicle parked in the sun), there are tremendous opportunities for simplifying logistics and improving outreach through a more flexible cold chain for TT-Uniject.

Tetanus toxoid vaccine is inactivated by freezing. TT-Unijects must not be exposed to freezing temperatures.

SOCIAL MOBILIZATION

Introduction of a new immunization approach, such as TT-Uniject or immunization by lay workers can create significant opportunities to improve immunization coverage. However, care must be taken to make sure the new program is not misinterpreted, possibly leading to negative publicity and vaccination refusals.

Depending on local perceptions and conditions, the introduction of TT-Uniject should be actively promoted to public- and private-sector health personnel, communities, and the media. The promotional activities serve to improve community awareness and compliance, but also to forestall any negative rumors that may circulate.

Respected doctors, political figures, or religious authorities should be brought into the planning process for introduction of TT-Uniject and involved in community meetings, press conferences, radio advertisements, and other support-building activities. These experts should fully understand the impact of neonatal tetanus, TT-Uniject, and the program designed to use TT-Uniject to reduce neonatal tetanus. If rumors arise, respected authorities can be called upon to make statements to the press or community.

It is also important to include heads-of-households and community members in awareness-raising activities. Any person (for example, husband, father, in-laws) or group (for example, religious affiliation) who may forbid an injection be given to a woman must be educated about the benefits and importance of TT immunization.

Since tetanus toxoid is targeted specifically toward women of childbearing age, one rumor that occasionally arises is that the vaccine is actually a contraceptive intended to forcibly prevent births. This is a very sensitive issue, and accurate statements need to be made quickly to the community and press to prevent the rumor from causing a serious drop in TT vaccine coverage. Health authorities should anticipate these types of rumors, and a response plan should be agreed upon and ready prior to the start of immunization.

LOGISTICS

Cold chain

As described in the Technical Information section (page 20), TT-Uniject will occupy approximately eight times more cold chain space than 10-dose vials. Methods of reducing impact on the cold chain include transport without ice packs, ambient temperature or cool room storage, and more frequent distribution of smaller quantities per shipment. Local conditions dictate whether alternative methods of storage and transport are appropriate.

Comprehensive planning is necessary to ensure adequate refrigerated space exists at each level of the cold chain, especially at central levels with high concentrations of Uniject devices. Estimates of TT dose requirements and delivery schedules are necessary to prepare adequate refrigerators, cold boxes, and ice packs at each level of vaccine distribution. A cold chain plan, complete with capacity calculations and delivery schedules, should be created to assure adequate storage capacity is available before Uniject devices are ordered, transported, or received.

Wastage

A high percentage of vaccine is typically wasted in programs that use multi-dose vials. Since each Uniject is a single dose, wastage due to discarding partially used vials is eliminated. This should reduce the buffer stocks required to offset high wastage.

Stock management

The use of TT-Uniject may simplify ordering and inventory logistics since each Uniject device consists of a syringe and a dose of vaccine. Adequate buffer stocks should be allowed for, but as mentioned above, wastage will usually be lower with Uniject.

When ordering TT-Uniject supplies, it is important to include an adequate quantity for training purposes. Three to five Unijects per vaccinator should be sufficient for even inexperienced vaccinators to become skilled at delivering vaccine using Uniject. Extra Unijects should also be ordered for demonstrating to national and local administrators. (It is advisable that each staff person be allowed to try activating a Uniject, which helps reinforce the ease of use and build confidence that lay persons are able to use it.)

Disposal

Disposal containers should be supplied along with TT-Uniject. Since TT-Uniject is smaller than a conventional AD syringe, more Uniject devices can be placed in a disposal container. A standard 5-liter disposal box that holds 100 AD syringes will hold about 400 Uniject devices. Disposal containers must be regularly distributed and collected. Disposal systems and procedures should be well defined and managed. Incineration or other means of destruction will have requirements for transportation, fuel, labor, and monitoring.

DISPOSAL

Using a sharps container effectively

- **Do not recap TT-Unijects before disposal.**
Most needle sticks happen when workers recap used needles.
- **Place the TT-Uniject in the sharps container immediately after use.**
The more syringes are handled, the greater the risk of needle sticks.
- **Place the sharps container where the injections are given.**
Eliminate the need to carry used TT-Unijects before disposal by placing containers within reach of every vaccinator's workstation.
- **Do not put TT-Uniject foil wrapper in safety box.**
The foil wrapper takes up space and may block the opening, making it hazardous to place the TT-Unijects in the box. A plastic bag should be used to collect nonhazardous waste materials.
- **Do not overfill the sharps containers.**
A total of 400 TT-Unijects can fit into one standard safety box. Before containers are completely full, close and seal them shut.
- **Sharps containers should be filled only once and discarded immediately.**

Destruction of filled sharps containers

- **Incineration.** Incineration can completely destroy syringes by burning at temperatures above 800°C. The high temperatures kill microorganisms and reduce the volume of waste to a minimum. Properly functioning incinerators ensure the most complete destruction of syringes and produce less air pollution than burning at lower temperatures. Sharps containers can also be destroyed by commercial or public incinerators.
- **Burning in metal drum or protected hearth.** Burning in a metal drum or protected hearth is another way to dispose of used syringes. Sharps containers can be placed in a metal drum. When the drum is full, fuel can be poured in, the waste ignited, and the materials burned until the fire goes out. The remains should then be buried. Care must be taken that filled drums are not accessible to the public.
- **Burying debris after burning.** The remains of sharps containers should be buried after burning. Bury debris in a pit at least one meter deep in a controlled area for burying waste, where people do not have access and will not dig to plant crops or establish latrines.
- **Open burning.** Open burning in a pit is the least preferred option for contaminated sharps such as the Uniject device. However, if open burning must be done, health workers should:
 - Fence off and clear the area in which open burning takes place.
 - Warn people to stay away and avoid smoke and fumes from the fire.
 - Carry the waste to the site just before burning.
 - Burn the waste in small, designated areas.
 - Prevent animals or people from accessing the site.
 - Make sure the fire is completely out before leaving the site.
 - Prevent waste from scattering and littering the surrounding areas.
 - Bury the remains.

TRAINING

TT-Uniject is extremely easy to use. Experienced vaccinators are typically comfortable using it after just two to three practice injections.

The introduction of TT-Uniject is an excellent opportunity to review related immunization issues. Therefore, most training exercises will be more comprehensive than simply teaching people how to use TT-Uniject. Additional topics might include:

- Elimination of maternal and neonatal tetanus.
- Injection safety.
- Use of TT-Uniject out of the cold chain—vaccinators will need to understand the revised cold chain procedures and be trained in the use of VVMs.
- Use of nonmedical personnel as immunizers. For programs that will train lay people to give TT injections, more information will be required on injection technique and follow-up procedures. Additional practice and supervision will be required.

If all of these topics are included, training will typically take three to four hours. This includes time for demonstration as well as practicing injections.

The type of training required to introduce TT-Uniject will depend on local conditions and program design. Possible training formats that could be developed from these guidelines include:

- Classroom training.
- In-service training of individuals or small groups.
- Development of printed self-training materials.

Materials required for training

- TT-Unijects (three to five per trainee).
- Uniject instruction sheet (one per trainee—see page 14).
- Oranges for practice injections (one per trainee or group of two).
- Sharps disposal containers.
- All recording forms to be used during the campaign (registration, TT cards, tally sheets, log book, etc.).
- Large paper or writing board and marking pens.
- Tape, pins, or sticky clay to hang sheets.
- Snacks, tea, or lunch.



TT-Uniject Training

Explain neonatal tetanus

Tetanus is a disease of the nervous system and is caused by bacteria. Neonatal tetanus occurs as a result of unhygienic birth practices, most commonly when tetanus spores contaminate the umbilical cord at the time it is cut or dressed after delivery. Symptoms of neonatal tetanus usually appear on the third day after birth. An apparently healthy baby will stop nursing, become progressively more rigid, develop an arching of the whole body, and experience painful convulsions. Neonatal tetanus is one of the main causes of death for newborns (215,000 deaths in 1998, according to WHO). Mothers can be infected with tetanus at the same time as the baby through unclean delivery and cord-cutting practices.

Questions often arise concerning the exclusive vaccination of women for TT campaigns (people often wonder why men are not included). It is important to explain that an immunization campaign is a *public health* program, and the approach necessitates targeting activities to those segments of the population that are at the highest risk of contracting the disease. The birthing process puts women at an exceptionally high risk of exposure to tetanus spores, and this is why women of childbearing age are targeted for tetanus vaccination.

Discuss TT immunization

Neonatal and maternal tetanus are preventable through improved delivery practices and immunization of the mother with TT. Women and their babies are protected if the woman has received five doses of TT during her life, but fewer doses will provide protection for a shorter period of time. Women need at least two doses for any protection. (*Trainers: Add specifics of the TT campaign or program designed to immunize women in your country.*)

Explain Eligibility

Explain which women should receive TT-Uniject injections. Note that women **do not** have to be pregnant to receive TT. The UNICEF eligibility guidelines are:

Dose	Minimum Intervals Between Doses	Effectiveness	Protection Duration
First	At first contact or as early as possible in 2 nd trimester	Zero	Zero
Second	At least 4 weeks later	80%	3 years
Third	At least 6 months after TT2 (or subsequent pregnancy)	95%	5 years
Fourth	At least 1 year after TT3 (or subsequent pregnancy)	99%	10 years
Fifth	At least 1 year after TT4	99%	Life long



Introduce Uniject	<p>TT-Uniject is a new type of syringe that comes prefilled with a single dose of TT. It is very easy to use and gives fast and accurate injections of TT. TT-Uniject cannot be refilled or reused, so it prevents the dangers of syringe reuse. (<i>Trainer: Present and discuss injection safety here, if desired.</i>)</p> <p>Each TT-Uniject contains one dose of vaccine plus the syringe. The expiration date is on one end of the foil package and on the top of the TT-Uniject device.</p>
Discuss key techniques	<p>Key Points:</p> <ul style="list-style-type: none">• Shake foil package before opening.• Activate device fully.• Hold so as not to expel vaccine during activation (finger and thumb on neck of the device and not on blister).• Inject at downward angle (keep air bubble from being injected).• Squeeze firmly—some liquid will remain (this is extra).• Do not recap.• Place directly in sharps container.• Place foil wrapper in separate waste receptacle.
Demonstrate Uniject	<p>Demonstrate the use of TT-Uniject and show why it cannot be refilled.</p>
Review the issues of safe disposal	<p>Practice assembling safety boxes. Skilled health workers can assist, but lay providers should be the ones to actually assemble the boxes.</p> <p>Key Issues:</p> <ul style="list-style-type: none">• Always have a sharps disposal container available.• Do not recap before disposal.• Place the TT-Uniject in the sharps container immediately after use.• Sharps containers should be filled only once and discarded immediately.• Do not overfill the sharps containers.• Do not put foil wrapper in safety box or leave on ground.• Destroy sharps/safety box: burn and bury. <p>(More information is available in the <i>Disposal</i> section, page 8.)</p>
Practice injections together	<p>Hand out TT-Unijects, oranges, and instruction sheets to trainees—three Uniject devices, one orange per trainee, and one instruction sheet—and one sharps container per group. Lead the trainees, step by step, to lightly shake and open the TT-Uniject pouch, activate the TT-Uniject, inject an orange, and dispose of the TT-Uniject in a sharps container.</p> <p>Have extra Uniject devices available; allow those who are not yet comfortable to use as many as they need to feel confident.</p>



Discuss impressions of Uniject	<p>Discuss trainees' initial impressions of the Uniject device, and answer any questions.</p> <p>(One question likely to arise is about aspiration—the process of gently pulling back on the plunger to check for blood before injection. Although aspiration is a common procedure, no data exists to document the necessity of this procedure. WHO's "2000 General Recommendations on Immunization" does not recommend aspiration before injection.)</p>
Review procedures for human IM injection	<ul style="list-style-type: none">• Injection site: deltoid (left upper arm, outer side—<i>Trainer: Show the site</i>).• Angle, depth: straight in or slight downward angle and deep for an intramuscular (IM) injection (<i>Trainer: Show with drawing or pantomime</i>).• Withdraw the needle without touching site. Give the woman a piece of cotton to press onto the site if necessary to stop bleeding.
Discuss side effects	<p>The most common side effect of TT vaccination is a sore, red, and sometimes swollen arm at the place of injection. Slight fever may accompany redness and swelling. Women should be told that these side effects are normal.</p> <p>A system for dealing with more serious side effects should be articulated and vaccinators should be informed of how to react and who to contact if this arises.</p>
Review record keeping	<p>Review the TT record keeping procedures (tally sheets) and women's TT immunization cards. Use actual forms and cards for practice.</p> <p>Remind vaccinators that they should tally injections as they are administered (not wait until the end of a session to mark the tally sheets).</p> <p>Women should be strongly encouraged to keep their vaccination cards in a safe place and to bring them the next time they are vaccinated.</p>
Review eligibility	<p>Review which women should receive TT-Uniject injections. Discuss what to do in various eligibility situations:</p> <ul style="list-style-type: none">• Woman has no TT card, but is confident she has received two TT injections during her pregnancy within the last year.• Woman has TT card showing three TT immunizations in the last two years.• Woman has TT card showing five TT immunizations.• Other common but potentially confusing situations.



Uniject beyond the cold chain, VVM training

Describe changes, if any, to the cold chain that will be introduced with TT-Uniject. Train vaccinators in the use VVMs (these materials are available in the *VVM Training* section of this document, page 15).

Days Until VVM Discard Point at Various Temperatures (for tetanus toxoid)

Temp °C	Days
50	3
45	8
40	17
35	35
30	73
25	154
20	337
15	756

Note:

- Freezing inactivates TT vaccine.
- TT must be kept out of the sun.
- Expiration date takes precedence over VVM reading.

Role play

Set up a mock immunization session, complete with all stations, recording forms, registration forms, TT-Unijects, and sharps containers. Injectees should be role-playing mothers for other trainees, holding oranges to their arms for injections. Include:

- Registrating.
- Providing information to the woman.
- Selecting appropriate injection site.
- Checking the TT-Uniject for correct medication, expiry, VVM, and proper activating and injecting.
- Disposing of the TT-Uniject and foil wrapper.
- Providing other information for the woman (side effects, how many more TT injections she needs, and how to get them).
- Completing the TT card and other records.
- Reporting any problems to supervisors.
- Practicing what to do with remaining Unijects and filled sharps containers.
- Sending reports and records to proper place.

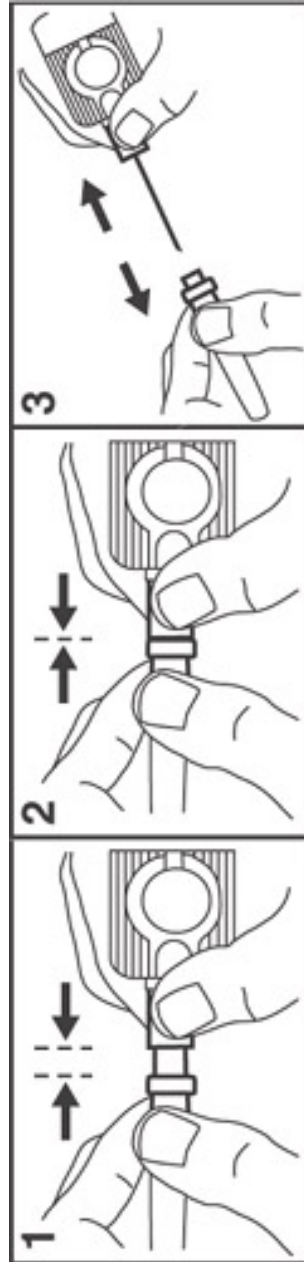
Practice human injections

Vaccinators should perform at least one human injection in the presence of a supervisor. This could be scheduled to occur either during or after the training session. The first human injection should occur prior to the start of the campaign, in a relaxed setting, to allow time for additional training, if necessary. Possible injectees include:

- Other trainees who have not received TT within the last year (one practice injection per person).
- Men (husbands, relatives, neighbors) who have not received TT within the last year.
- Women from the community who are eligible for TT immunization.



Activation Instructions





Vaccine Vial Monitor (VVM) Training

Trainer's notes

- Photocopy and distribute *VVM Instructions* (page 15) to participants before beginning training session.
- Present information on this page to the trainees. Use overheads, examples, discussions, etc. to convey these basic principles of VVM use.

NOTE: photocopying may change the appearance of VVMs. Before using photocopies, check to make sure that the top package has a VVM with the square lighter than the surrounding circle.

Describe VVM

A vaccine vial monitor is a label made of heat-sensitive material that is placed on a Uniject package to show cumulative heat exposure over time. VVMs have two important benefits:

- VVMs identify heat-damaged vaccine so that it can be discarded.
- VVMs reduce wastage of good vaccine.

VVMs show the cumulative, irreversible heat exposure to which a vaccine has been exposed. The VVM is tailored to the specific heat stability of the vaccine to which it is attached. As the vaccine is exposed to more heat, the square becomes darker and darker. Use only vaccines in which the inner square on the VVM is lighter than the outside circle.

By looking at the VVMs, health workers can determine which vaccines are still usable, and which have been exposed to more heat than others. TT-Unijects with VVMs where the inner square has begun to darken (but is still lighter than the outer circle) should be used before those with a lighter inner square. In this way, health workers can minimize the number of TT-Unijects that have to be discarded.

A VVM only measures exposure to heat. It does not indicate if the vaccine has been frozen or is beyond its expiration date.

The expiration date of the vaccine always takes precedence over the color of the VVM.

Explain how to use VVM

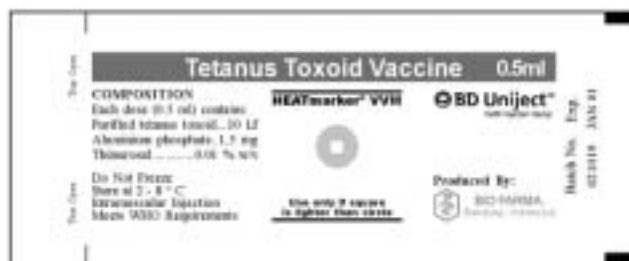
Use VVM Instructions sheet as a visual reference (page 16)

The VVM is attached to the Uniject package. It looks like a square inside a circle. Use VVMs to check that the vaccine has not been exposed to too much heat.

- Check to see if the inner square is lighter than outside circle.
- Discard the Uniject device if the inner square is the same color or darker than the outside circle.

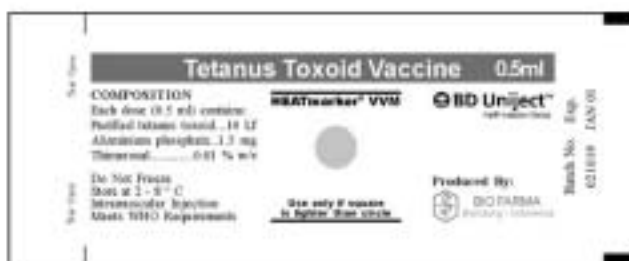


VVM Instructions



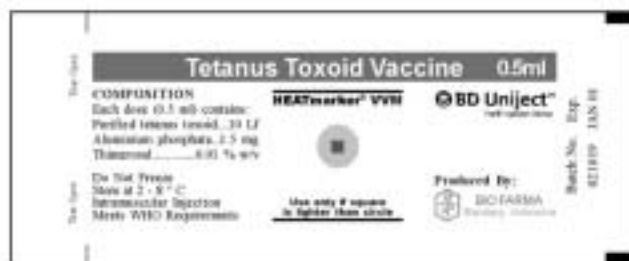
USE

Inner square is lighter than outer circle.



DON'T USE

Discard point!
Inner square matches color of outer circle.



DON'T USE

Beyond discard point!
Inner square is darker than outer circle.



Ask quiz questions

1. Why use vaccine vial monitors (VVMs)?
2. What should be done when the inner square of the VVM is the same color or darker than the outside circle?
3. True or false? “Uniject devices with VVMs that have just started to change color should be used before those with VVMs that have not changed color.”

Provide answers to VVM quiz

1. Why use vaccine vial monitors (VVMs)?
VVMs help health workers determine whether vaccines have been damaged by exposure to too much heat. If the Uniject packages have VVMs with an inner square that is the same color or darker than the outside circle, health workers should discard the Uniject devices.
In addition, VVMs can reduce vaccine wastage during cold chain breakdowns by identifying which vaccines can be saved and which must be discarded.
2. What should be done when the inner square of the VVM is the same color or darker than the outside circle?
The Uniject package should be discarded
3. Is the following statement true or false? “Uniject devices with VVMs that have just started to change color should be used before those with VVMs that have not changed color.”
True, if the inner square is still lighter than the outer circle.

Practical exercises on how to read VVMs

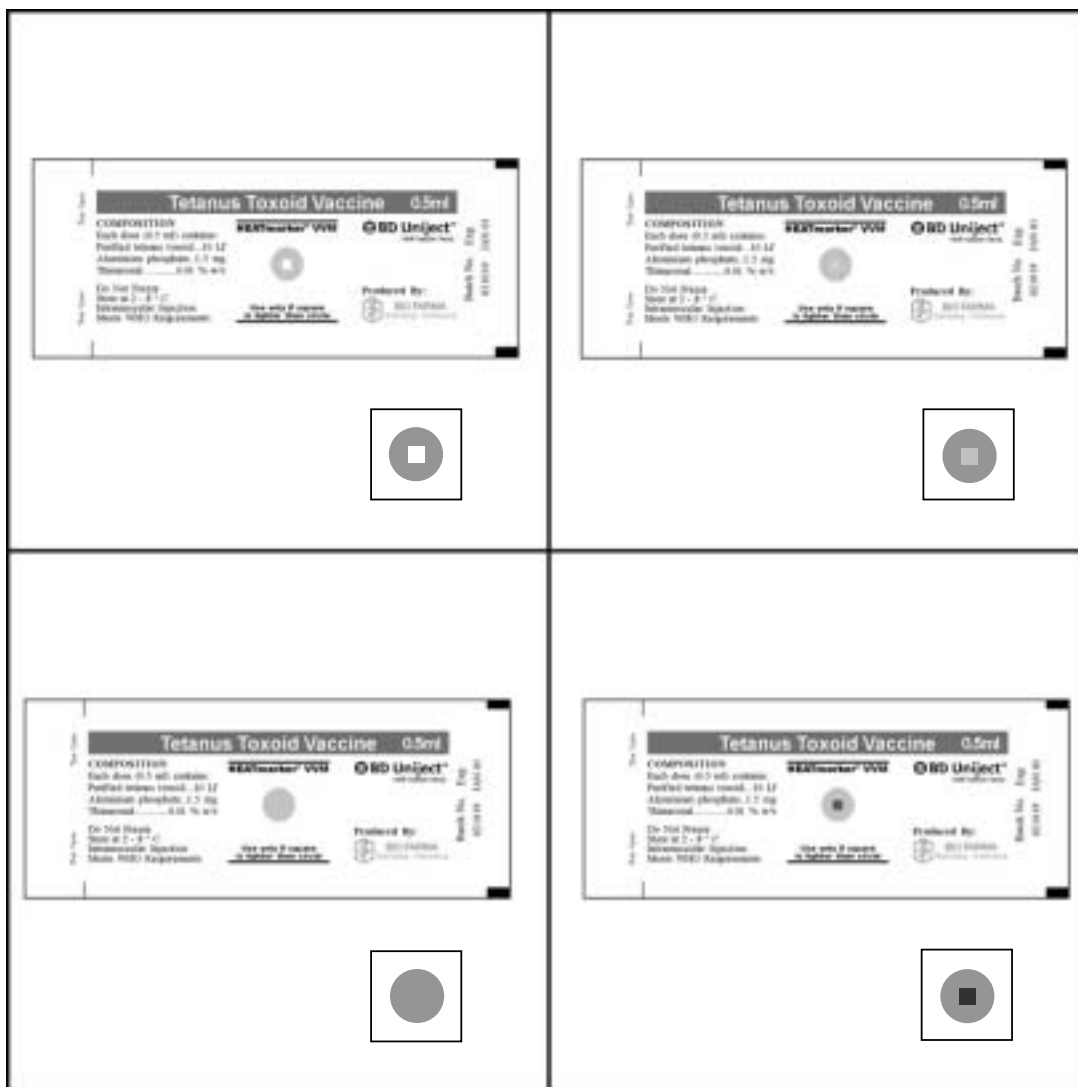
The trainer will show the illustration on page 18 to the group and ask the following questions (answers are provided on page 19):

1. Which package has been exposed to the most heat?
2. Which package has been exposed to the least heat?
3. Which package should be used first?
4. Which package(s) should be discarded?







VVM Illustration (Practical Exercise)

Four Unlabelled Illustrations of VVMs





Answers to Practical Exercise

<p>A</p>  <p>USE Inner square is lighter than outer circle.</p>	<p>B</p>  <p>USE FIRST As time passes, inner square is still lighter than outer circle</p>
<p>C</p>  <p>DON'T USE <u>Discard point!</u> Inner square matches color of outer circle.</p>	<p>D</p>  <p>DON'T USE <u>Beyond discard point!</u> Inner square is darker than outer circle.</p>

Questions	Answers
1. Which package has been exposed to the most heat?	D
2. Which package has been exposed to the least heat?	A
3. Which package should be used first?	B
4. Which package(s) should be discarded?	C and D

TECHNICAL INFORMATION

Needle

1 inch (25 mm)
23 gauge

Labeling

Device:

contents
lot number
expiry date
manufacturer

Pouch: (see illustrations at right)

contents/composition
batch number
expiry date
manufacturer
VVM
instructions for use



Packaging

Inner box:

125 TT-Unijects per box
width: 16.5 cm
depth: 15.5 cm
height: 12 cm

Shipping box:

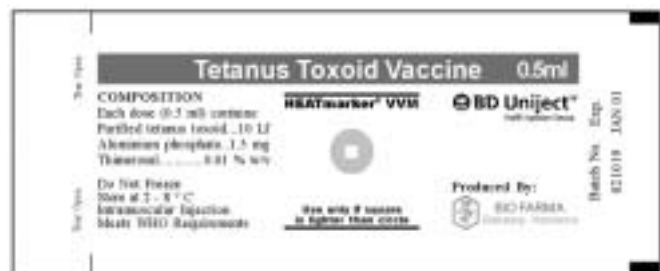
2,000 TT-Unijects (16 inner boxes)
including ice packs and insulation
per UNICEF specifications
width: 60 cm
depth: 50 cm
height: 50 cm

Contents

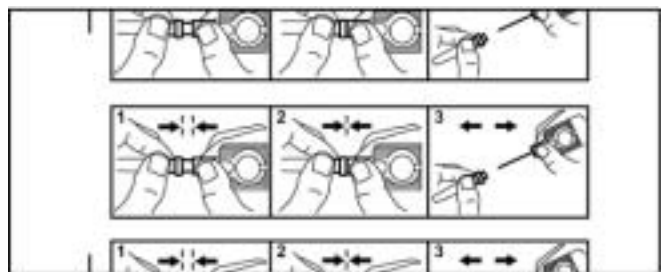
Tetanus Toxoid Vaccine
Delivered dose: 0.5 ml

Each 0.5ml dose contains:

Purified tetanus toxoid: 10 Lf
Aluminum phosphate: 1.5 mg
Thimerosal: 0.01 %w/v



TT-Uniject label front



TT-Uniject label back