

VACCINES: HANDLED WITH CARE



For every child
Health, Education, Equality, Protection
ADVANCE HUMANITY

unicef 



TWENTY MILLION LIVES SAVED

Vaccines are technological miracles, one of the success stories of medical history. They have saved more than 20 million lives over the last two decades – 2.5 million in 2003 alone – and prevented countless disabilities. They have wiped out smallpox, which once killed up to 5 million people a year and left others disfigured or blind. They have almost eradicated polio.

Immunization is one of the safest health interventions available today. Before they are given to children, all vaccines supplied by UNICEF go through rigorous reviews by manufacturers, national regulatory authorities and the World Health Organization (WHO) to ensure their quality, safety and effectiveness.

Vaccines now reach three quarters of the world's children. When the World Health Assembly launched the Expanded Programme on Immunization in 1974, less than 10 per cent of children in developing countries were protected by vaccines. Fifteen years later, immunization coverage rates approached 75 per cent, where they remain today. In total, nearly 100 million infants across the globe are vaccinated each year.

Millions more can be saved if all children get the vaccines they need.

Children living in the poorest countries and in countries in conflict are the least likely to be immunized. A quarter of all children born each year – about 33 million – are not immunized against common, preventable diseases during their first year of life. Most of them live in sub-Saharan Africa and South and South-East Asia.

Many partners are needed to ensure a reliable supply of safe vaccines.

The task of immunizing the world's children is enormous, and involves many important steps – from forecasting vaccine needs and monitoring safety to training and equipping health workers and mobilizing community support. UNICEF works closely with WHO and many other partners, such as ministries of health, vaccine manufacturers and communities, to perform these tasks and bring the protection of immunization to children everywhere.

“We used to bury two or three children every week during measles epidemics. This does not happen any more....”

Serigne Dame Leye, chief of Nguoye Diaraf village, Senegal



THE 'BIG SIX' CHILDHOOD DISEASES

Measles can spread rapidly among children who are not immunized. When it doesn't kill, measles can cause permanent disabilities, including blindness, deafness and brain damage.

Pertussis, or whooping cough, is also highly contagious. It sometimes results in death, but, more often, in prolonged and exhausting bouts of coughing that may continue for up to three months.

Tetanus is caused by naturally occurring bacteria that enter the body through open wounds. It is nearly always fatal.

Diphtheria is a bacterial infection that spreads through close contact. Even with treatment, one in ten infected people die from the disease. The infection can also damage the heart and nervous system and, in tropical environments, the skin.

Tuberculosis is one of the leading causes of adult deaths worldwide. The existing vaccine is effective in preventing some of the most dangerous forms of the disease in children.

Polio is a viral infection that can result in permanent paralysis.



WHY SHOULD ALL CHILDREN BE IMMUNIZED?

To prevent death or disability

Thanks to immunization, common childhood diseases are no longer a threat.

To open the door to other health services

Immunization reaches more children than any other health intervention. And where immunization goes, other life-saving health services follow. This is especially true for the children born in the world's poorest countries. Immunization is the primary – sometimes the only – path to realize their 'right to health'. Immunization is often the first health service for children to be restored after war – and perhaps the only health intervention that has inspired ceasefires (see page 19).

To protect the wider population

Infectious diseases, by definition, spread easily. But viruses and bacteria can be stopped if enough people are immunized. The more fully immunized children there are in a community, the safer everyone is.

In most developing countries, vaccines against polio, diphtheria, pertussis, tetanus, measles and childhood tuberculosis are provided to children through regular health services and special campaigns. Increasingly, countries are also providing immunization against hepatitis B, Hib disease (*Haemophilus influenzae* type b) and, where needed, yellow fever.

To prevent tetanus in mothers and their newborns, pregnant women are immunized with the tetanus toxoid vaccine. Vaccinations are provided to pregnant women through regular health services and to all women aged 15 to 49 through campaigns.

AN AMBITIOUS GOAL

By 2010, 80 per cent of children in all districts of all countries will receive the full course of vaccinations against diphtheria, pertussis and tetanus (DPT3) before their first birthday.

(Adopted at the United Nations General Assembly Special Session on Children, May 2002)

TWO MILLION STILL AT RISK

Annual deaths from vaccine-preventable diseases

Measles	610,000	Tetanus**	33,000
Hepatitis B	600,000	Yellow fever	30,000
Hib disease*	413,000	Diphtheria	5,000
Pertussis	294,000	Polio	214
Neonatal tetanus	180,000		

Estimated number of lives that could be saved each year through immunization **2,165,214**

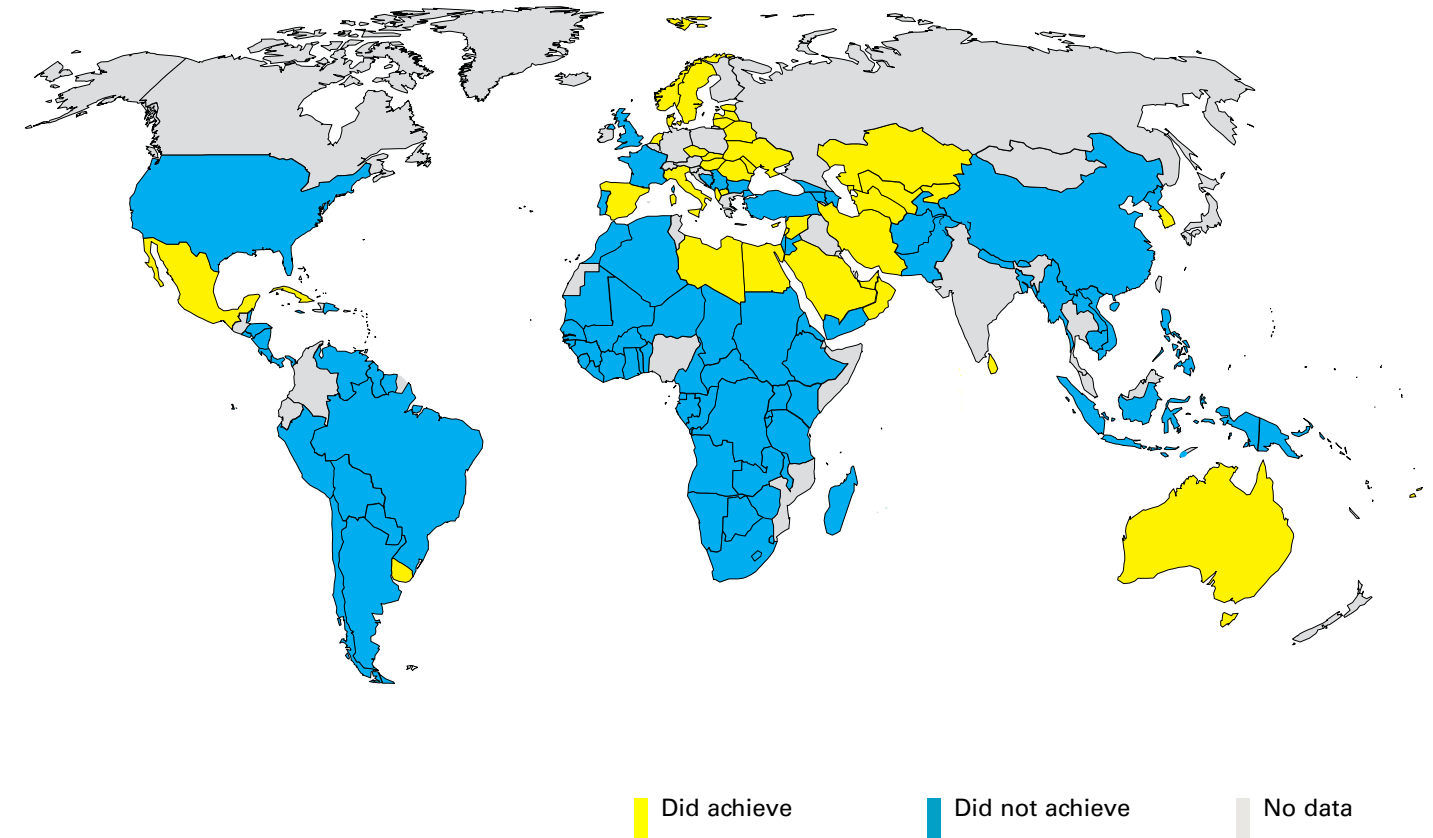
* *Haemophilus influenzae* type b

** Excluding neonatal tetanus

Source: WHO/UNICEF, 2002.

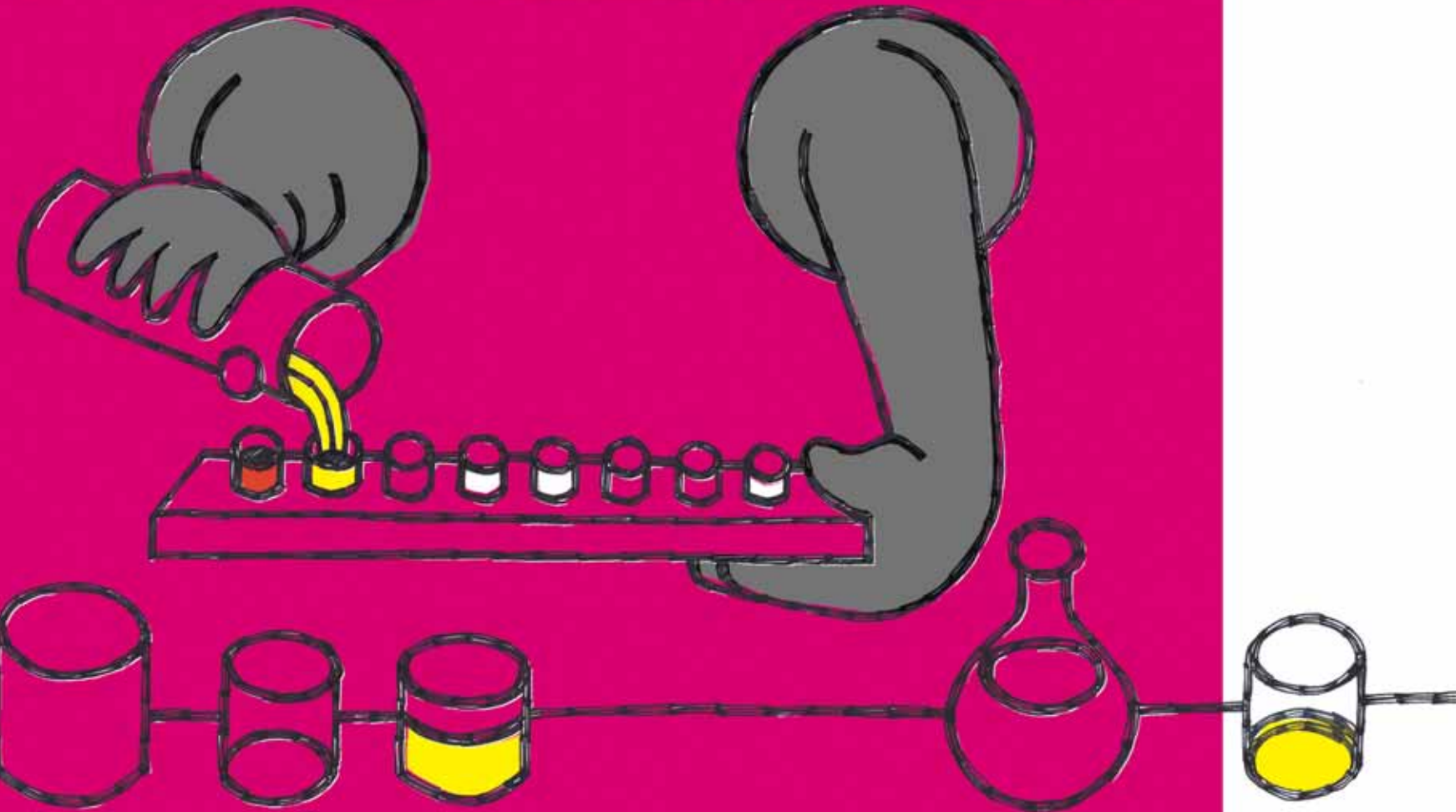
WHERE WE STAND NOW

Countries that achieved at least 80 per cent DPT3 coverage in all districts in 2002



Source: WHO/UNICEF, 2003.

The maps in this booklet do not reflect a position by UNICEF or WHO on the legal status of any country or territory or the delimitation of any frontiers. Dotted line represents approximately the Line of Control in Jammu and Kashmir agreed upon by India and Pakistan. The final status of Jammu and Kashmir has not yet been agreed upon by the parties.



HANDLED WITH CARE

Safety is the overriding concern in the long process of getting vaccines from manufacturers to those who need them. UNICEF supplies only vaccines pre-qualified by WHO. This involves the following checkpoints:

WHO experts assess the national regulatory authority of the producing country to establish that it effectively exercises all required regulatory oversight responsibilities. If the authority is functioning at an acceptable level, the manufacturer prepares a product summary file detailing production facilities and processes, staff, vaccine composition, packaging, labelling and quality control for each vaccine. Production must conform to international standards known as good manufacturing practices. The product summary file is reviewed by experts contracted by WHO.

Samples from three or more consecutive batches, or 'lots', of vaccines are tested by laboratories qualified by WHO, and WHO experts conduct a site visit to audit the manufacturer's operations.

In order to ensure consistency of production, WHO conducts random testing at six-month intervals and a full reassessment every two years. Inspections continue at every step to ensure vaccines are safe, effective and of assured quality.

Vaccines are produced in large batches, typically about 3 million doses. Each batch is given a number that appears on the label of every vial, and that can be used to trace its origin and identify other vaccines in the same batch in the event of a problem.

THE INNER SANCTUM: THE VACCINE LABORATORY

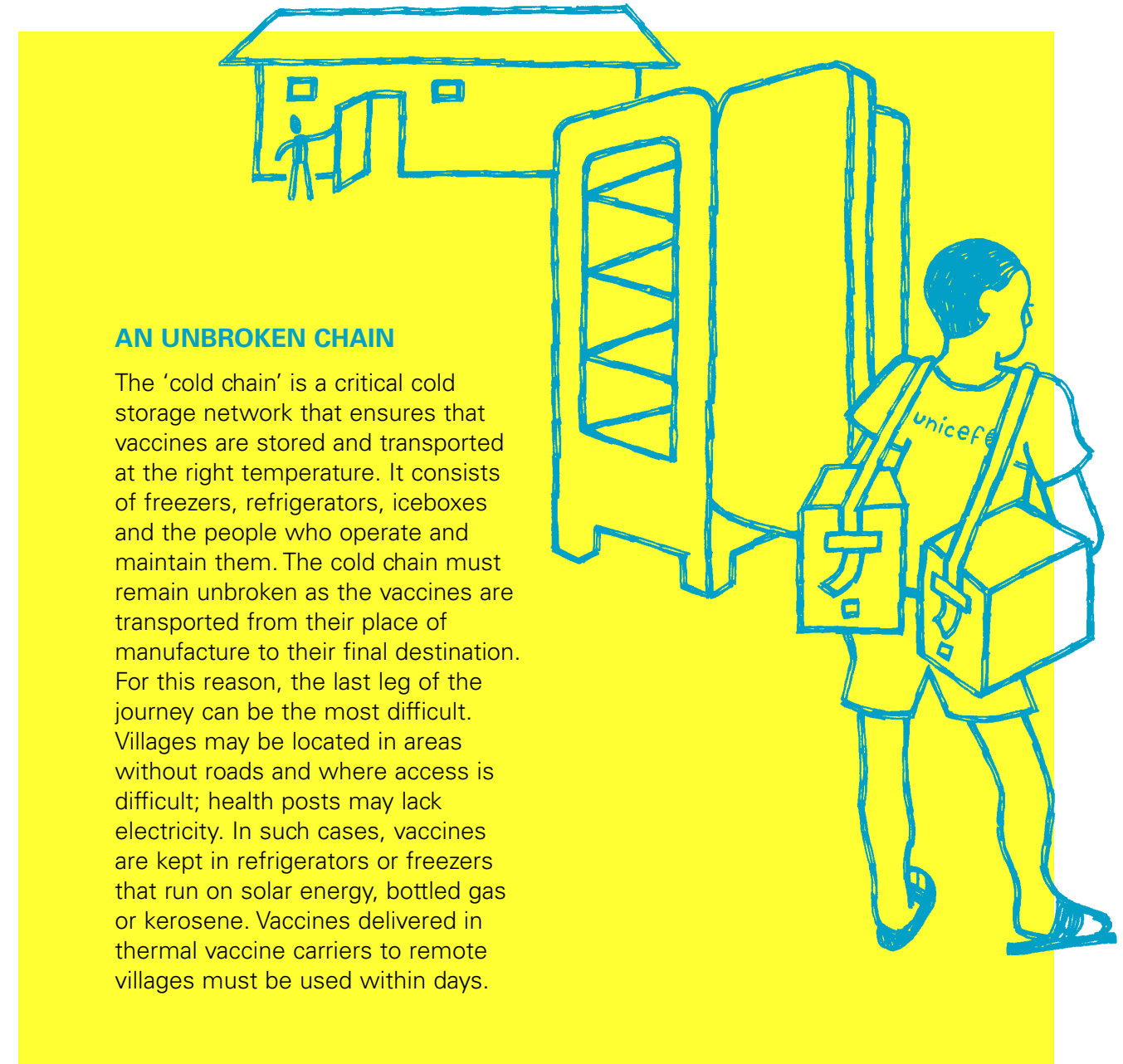
The workers wear sterile gowns, caps and special shoes. They wash their hands with disinfectant before passing through an airlocked compartment that leads into a 'clean room'. They enter a world that is sterile and silent, polished and precise, where a positive atmospheric pressure is maintained to keep dirt particles from entering.

Conditions inside this Biosafety Level 2 facility match those required of approved vaccine producers everywhere in the world. Host cells are grown, or propagated, in an array of flasks and growing cubes. They develop in cell incubators located in adjacent thermostatic rooms. They are manipulated exclusively by robotic hands.

In top safety areas – known as 'red zones' – host cell cultures are inoculated with live virus in large stainless steel harvest tanks. Control samples are taken after six days, refiltered and refrigerated for six weeks, and then tested again. The whole process takes several months.

The end product is re-tested, and only then is it labelled, packaged and put on the market. Wherever they are produced, all vaccines pre-qualified by WHO must meet the same high standards.

Handled with the utmost care throughout their creation, vaccines must now maintain their potency on the long road to immunization.



AN UNBROKEN CHAIN

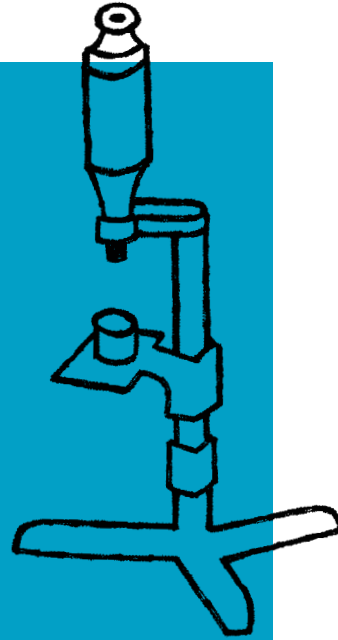
The 'cold chain' is a critical cold storage network that ensures that vaccines are stored and transported at the right temperature. It consists of freezers, refrigerators, iceboxes and the people who operate and maintain them. The cold chain must remain unbroken as the vaccines are transported from their place of manufacture to their final destination. For this reason, the last leg of the journey can be the most difficult. Villages may be located in areas without roads and where access is difficult; health posts may lack electricity. In such cases, vaccines are kept in refrigerators or freezers that run on solar energy, bottled gas or kerosene. Vaccines delivered in thermal vaccine carriers to remote villages must be used within days.

A 16TH CENTURY DISCOVERY COMES OF AGE

Smallpox, which is believed to have originated over 3,000 years ago in north-eastern Africa, is one of the most devastating diseases known to humanity. For centuries, repeated epidemics swept across continents, decimating populations.

In 16th century China, a process called 'variola' was discovered that prevented smallpox by exposing a healthy person to tissue from the lesions of an infected person. The technique spread across Asia and was observed in Turkey in 1717 by the wife of the British ambassador who introduced it to England. The first vaccination in Europe – against smallpox – was performed in England in 1798 by Dr. Edward Jenner, who inoculated a young boy with cowpox. Two hundred years later, smallpox became the first disease to be eradicated through immunization.

Though far more sophisticated today, vaccines still work on the same principle. Through immunization, healthy children and adults receive relatively harmless, weakened forms of specific germs. The body's immune system responds by producing protective antibodies. If those vaccinated are exposed to the actual disease at some later time, these antibodies are reactivated to fight off infection. Usually, several vaccinations are needed to provide immunity from the disease.



YEARS OF WORK

Research and development of new vaccines is a long, complex and expensive process. It costs \$500 million or more to bring a new vaccine to market and years of testing to ensure its safety.

It takes a minimum of one to two years to produce most vaccines. That is why producers cannot rapidly increase production to meet sudden demand and why accurate forecasting of needs is so important. In fact, stringent safety rules and strict requirements for vaccines pre-qualified by WHO mean that it takes about three years to expand existing production – and up to five years if a new facility has to be built.

THE SAFETY WATCHDOG

Independent oversight for safe vaccine production is the responsibility of the national regulatory authority, which is established in all exporting and many importing countries. Officials at the regulatory authorities publish national requirements for the licensing of vaccines, conduct surveillance of vaccine field performance, establish a system of releases for vaccines by lot (batch), select a control laboratory to perform testing, inspect production facilities to ensure compliance with good manufacturing practices, and evaluate clinical performance for safety and effectiveness.

DELIVERING THE GOODS: A 24-DAY JOURNEY

The safe delivery of vaccines requires insulation against heat, cold and light. Even under the best of circumstances it is a challenge, as can be seen in the following example from Sierra Leone, which at the time was in the midst of civil conflict.



Day 1: An Italian vaccine manufacturer fills an order for 1.5 million doses of oral polio vaccine: 75,000 vials are carefully placed into 28 containers that are packed with dry ice and transported for two hours by refrigerated truck before a 1.5-hour flight from Rome to Brussels. They are then kept for eight hours in an airport warehouse, ready for the next flight to West Africa – which is cancelled.

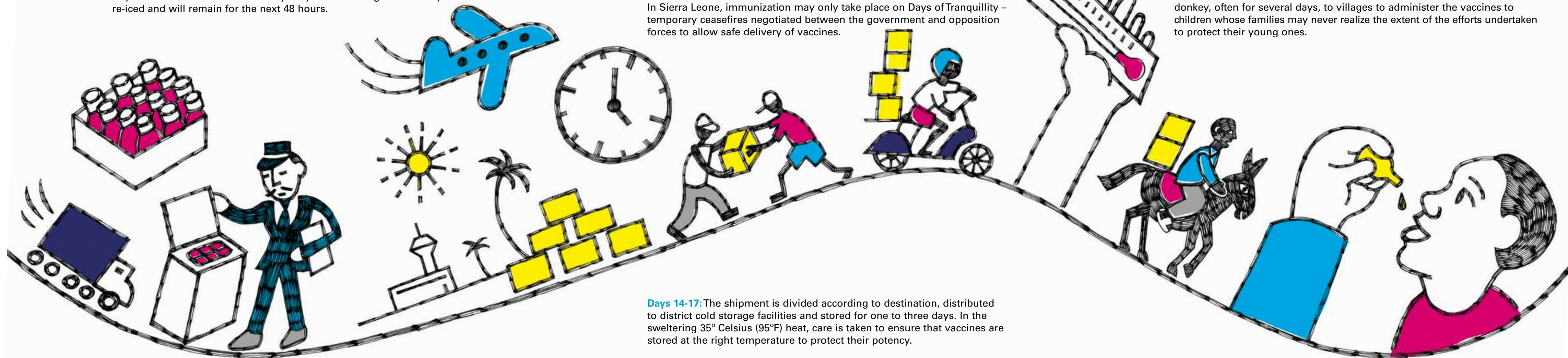
Days 2-3: The vaccines are moved quickly to cold storage where they are re-iced and will remain for the next 48 hours.

Days 4-7: The re-iced boxes are loaded onto a plane for the nine-hour flight to the transit point of Conakry, Guinea. Cleared by a UNICEF agent upon arrival, they are put in an airport cold storage room for three days to await helicopter transport to Freetown, Sierra Leone.

Day 7-14: A refrigerated truck meets the helicopter and delivers the vaccines to a central cold storage facility in Freetown where they remain for a week. In Sierra Leone, immunization may only take place on Days of Tranquillity – temporary ceasefires negotiated between the government and opposition forces to allow safe delivery of vaccines.

Days 17-23: Vaccine vials are placed in cold boxes for the two- to six-hour ride to rural health centres. Since the centres have no refrigeration, the vaccines are first placed in nearby cold storage.

Day 24: At last, vaccines are distributed to campaign health workers who place them in portable vaccine carriers lined with ice packs or cubes. These 'unsung heroes' then hit the trail, travelling by foot, by bicycle, even by donkey, often for several days, to villages to administer the vaccines to children whose families may never realize the extent of the efforts undertaken to protect their young ones.



Days 14-17: The shipment is divided according to destination, distributed to district cold storage facilities and stored for one to three days. In the sweltering 35° Celsius (95°F) heat, care is taken to ensure that vaccines are stored at the right temperature to protect their potency.

SAFETY FIRST

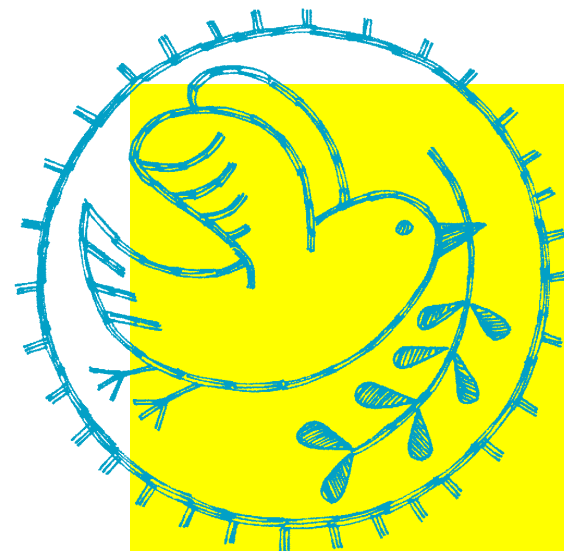
UNICEF, WHO and their partners continually introduce new equipment and practices to improve immunization safety. Some of the most important recent developments in this field are vaccine vial monitors, auto-disable syringes and safety boxes.

A vaccine vial monitor is a temperature-sensitive label that can be attached to vaccine vials. Through a gradual and irreversible colour change, the monitor warns health workers that vaccines have been exposed to heat and should be discarded.

Auto-disable syringes are single-shot injection devices designed to prevent reuse. Costing only \$.06 apiece, the syringes protect against blood-borne diseases such as hepatitis B or HIV/AIDS that can be transmitted when non-sterile needles are shared.

Safety boxes, or puncture-resistant containers holding up to 100 syringes each, were introduced in 1999 as part of a broad strategy put forward by WHO, UNICEF and the United Nations Population Fund to make injection and disposal practices safer. Costing only \$1 each, the boxes prevent environmental contamination by storing used syringes, needles and other injection materials. Safely disposing of materials in this way also guards against needle-stick accidents to health workers and others.

Minor adverse reactions to immunization do occur, but severe reactions are quite rare. Ministries of health, national regulatory authorities and WHO have surveillance mechanisms in place to monitor and respond swiftly to such incidents. Training and supervision of immunization programme staff is essential since a reaction may occur due to the way an immunization is given rather than a problem with the vaccine itself.



DAYS OF TRANQUILLITY

Immunization not only saves lives. On some occasions, it can also provide a respite from war.

In Afghanistan, Angola, the Democratic Republic of the Congo, Sri Lanka, Sudan and other countries, warring factions have been persuaded to lay down their arms for what have become known as 'Days of Tranquillity'. During these temporary cease-fires, usually negotiated by United Nations agencies, vaccination teams fan out to reach children who may otherwise be cut off completely from health services.

Ensuring the safety of vaccines under such conditions can present huge logistical challenges. With the regular cold chain damaged or non-existent, the vaccination teams often need to carry their own refrigeration equipment as well as vaccines, auto-disable syringes and safety boxes for disposal.

These specially arranged ceasefires have been crucial in the campaign to eradicate polio. They have also been used to administer emergency measles vaccinations and vitamin A supplements to children displaced by conflict.

Just as significantly, Days of Tranquillity remind combatants that there is an alternative to war and of the importance of child well-being.



REACHING CHILDREN EVERYWHERE

Elaborate step-by-step precautions are taken as vaccines journey across oceans, deserts and mountain ranges to reach children across the globe. If properly protected against light and heat, vaccines can maintain their quality, potency and safety for about two years.

Safe delivery depends on a whole team of players – technicians, shipping agents, customs officials, pilots and drivers, government officials, health workers, community leaders – and the support of UNICEF and WHO.

Careful advance planning

Guaranteeing safe transport begins before vaccines leave the warehouse. Shipments are monitored closely to ensure they follow WHO's comprehensive *Guidelines on the international packaging and shipping of vaccines*, which include the use of:

- Insulated packaging to ensure safe temperatures during transport
- Clear labelling showing packed volumes, weights, expiration dates and required storage temperatures
- Time-sensitive shipping procedures. Advance notice of arrival allows adequate preparations to be made at the receiving site.



Arriving at the final destination

The moment a shipment reaches its destination, a vaccine arrival report is completed to ensure that the type of vaccine, batch numbers, shipping boxes, vial size, quantity and expiration date all correspond to shipping papers. Temperature monitors and vaccine boxes are examined to ensure that the cold chain has been maintained. All documents are checked for compliance with shipping instructions and to ensure that relevant certificates and test protocols are included. Once this has been done, the vaccine arrival report is signed, and the recipient government assumes responsibility to maintain the vaccine in good condition.

Storing the precious cargo

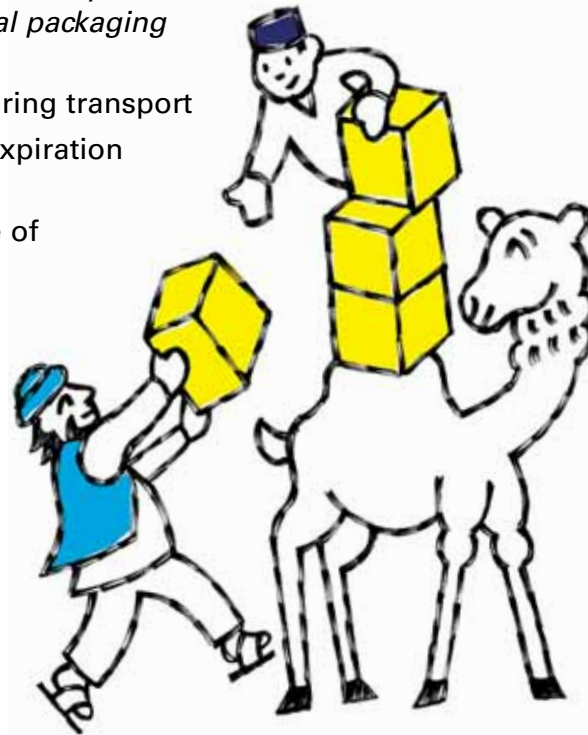
When the vaccines arrive at the national cold storage facility, details of their type, the number of doses, batch number and expiration date are recorded again. The vaccines are regularly checked while in storage and when they leave for distribution.

Newly arrived shipments are immediately stored in giant walk-in freezers or refrigerators where temperatures are monitored and recorded several times a day. Since different vaccines require different storage conditions, staff must ensure the optimal storage conditions for each vaccine. That means that exactly the right temperature range is maintained continuously, from manufacture until the moment of use.

All cold-storage equipment, such as cold rooms, refrigerators and freezers, and transport mechanisms, such as cold boxes and vaccine carriers, are regularly inspected for adherence to WHO and UNICEF standards.

Guarding against time

Since vaccines lose potency over time, each vial has a clearly marked expiration date. Loss of potency is quicker if the cold chain is broken. To ensure top quality, vaccines are arranged systematically so that those with the earliest expiration dates are the first to be distributed. Trained government staff are responsible for carrying out the 'first expiry, first out' stock management system.



LOCAL SUCCESSES

Nguoye Diaraf, Senegal. Women carrying their infants flock into the chief's compound. Health workers carry his table and set it under a massive tree. They lay out the paraphernalia of the outreach immunization session – the registration and new health cards for newborns, the cold boxes with vaccines, the new syringes still in their packets, and the safety boxes used for disposal. A local birth attendant, Mbathio Dioum, organizes the mothers as the chief, Serigne Dame Leye, looks on.

“Let me tell you,” says the chief to the people gathered around him, “if we don’t have polio or measles or whooping cough in this village any more it is due to the dedication of these health workers. During measles epidemics we used to bury two or three children every week. This does not happen any more because of these people. I include them in my prayers. I trust that they will be rewarded in heaven.”

Almost every woman carries yellow vaccination cards for her children. Most of the women have not been to school, few can read, few know exactly what immunizations their children have received. Yet they know the card is important.

One of the health workers completes a record card for a one-week-old baby about to receive her first shot of the BCG vaccine against childhood tuberculosis. As he hands the card to the mother he says, “This is your child’s identity card. You should always bring it for immunizations.”

Mbathio Dioum is not surprised by the enthusiastic turnout in the village. “Every immunization is a celebration,” she says, “because it is one burden less for the mother.”



“Every immunization is a celebration.”

Mbathio Dioum, a birth attendant in Nguoye Diaraf village, Senegal



GLOBAL COMMITMENT

Promises made by nearly every country in the world at the Millennium Summit and the United Nations General Assembly Special Session on Children:

By 2005: To rid the world of polio

- Certify the global eradication of polio
- Cut measles deaths in half from 1999 levels
- Eliminate maternal and neonatal tetanus

By 2010: To save the lives of more children under five

- Provide routine immunization to 80 per cent of children in all districts of all countries
- Reduce the death rates of infants and children under five by one third

By 2015: To achieve the Millennium Development Goal of reducing child deaths

- Immunization is essential to reach the goal of reducing by two thirds the number of deaths in children under five



UNICEF SUPPLIED VACCINES TO THE FOLLOWING COUNTRIES AND TERRITORIES IN 2003

Afghanistan	Democratic Republic of the Congo	Liberia	Serbia and Montenegro
Albania	Djibouti	Madagascar	Solomon Islands
Algeria	Egypt	Malawi	Somalia
Angola	Equatorial Guinea	Maldives	Sri Lanka
Armenia	Eritrea	Mali	Sudan
Azerbaijan	Ethiopia	Mauritania	Syrian Arab Republic
Bangladesh	Fiji	Mongolia	Tajikistan
Benin	Gabon	Morocco	The former Yugoslav Republic of Macedonia
Bhutan	Gambia	Mozambique	Timor-Leste
Bosnia and Herzegovina	Georgia	Myanmar	Togo
Burkina Faso	Ghana	Namibia	Turkey
Burundi	Guinea	Nepal	Turkmenistan
Cambodia	Guinea-Bissau	Niger	Uganda
Cameroon	Haiti	Nigeria	Ukraine
Cape Verde	India	Occupied Palestinian Territory	United Republic of Tanzania
Central African Republic	Indonesia	Pakistan	Uzbekistan
Chad	Iraq	Papua New Guinea	Viet Nam
Comoros	Kazakhstan	Philippines	Yemen
Congo	Kenya	Republic of Moldova	Zambia
Côte d'Ivoire	Kyrgyzstan	Rwanda	Zimbabwe
Cuba	Lao People's Democratic Republic	Samoa	
Democratic People's Republic of Korea	Lebanon	Sao Tome and Principe	
	Lesotho	Senegal	

UNICEF provides vaccines to 40 per cent of the world's children. In 2003 alone, that translated into 2.5 billion doses of vaccines, valued at \$348 million, to nearly 100 developing countries.

For more information please see the following:

Publications

State of the World's Vaccines and Immunization, published by WHO, UNICEF and the World Bank in 2002

The State of the World's Children 2004, published by UNICEF

The Case for Childhood Immunization, published by the Children's Vaccine Program at the Program for Appropriate Technology in Health (PATH) in 2002

Websites

UNICEF: <www.unicef.org/immunization> and <www.unicef.org/supply>

WHO: <www.who.int/vaccines/>

World Bank: <www.worldbank.org>

Global Alliance for Vaccines and Immunization (GAVI): <www.vaccinealliance.org>

Vaccine Fund: <www.vaccinefund.org>

Children's Vaccine Program at PATH: <www.childrensvaccine.org>

The Vaccine Page: <www.vaccines.org>

Safe Injection Global Network: <www.injectionsafety.org>



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Illustrations by Peter Linenthal

**"The world has made enormous strides in immunization....
Our goal now is to make routine immunization the norm
for all children. This goal is morally imperative, technically
doable and financially feasible."**

Carol Bellamy, UNICEF Executive Director



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