BCG

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

Typical immunization schedule for children (see Appendix 2.19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO recommended vaccine storage conditions (Appendix 17.3).

Immunization in practice: a practical resource guide for Health workers 2004 update Module 6: Holding an immunization session

See Appendix 6.19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

WHO recommends the following schedule for infants (Appendix 39.5).

Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81.1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15°C and -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2°C and +8°C. All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.
Ensuring the quality of vaccines at country level: Guidelines for health staff

At the higher levels of the cold chain, i.e. at the national (central) and regional or provincial levels, OPV must be kept frozen between -15°C and -25°C.

Freeze-dried vaccines, i.e. BCG, measles, MMR and yellow fever vaccines, may also be kept in this temperature range (-15°C and -25°C) if there is sufficient space in the cold chain, but this is neither essential nor recommended. At other levels of the cold chain these vaccines should be stored between +2°C and +8°C. All other national immunization service vaccines should be stored between +2°C and +8°C at all levels of the cold chain.

Cold Chain Equipment

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

VVMs have been in use with oral polio vaccine (OPV) since 1996. If adequate training is provided they are well accepted by health workers and managers. They have contributed to the success of national immunization days, particularly in areas with a weak cold-chain infrastructure, and they clearly help to reduce vaccine wastage.

DPT

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

Typical immunization schedule for children (see Appendix 2_19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO recommended vaccine storage conditions (Appendix 17_3).

Immunization in practice: a practical resource guide for Health workers 2004 update Module 6: Holding an immunization session

See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

WHO recommends the following schedule for infants (Appendix 39_5).
The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.

Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15°C and -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2°C and +8°C. All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

Wait at least four weeks between doses of OPV, DTP, Hib, and HepB vaccines.

Diphtheria

The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.

Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15°C and -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2°C and +8°C. All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.
GACVS

Global Advisory Committee on Vaccine Safety, 34 December 2003

GACVS was informed of the (poliomyelitis eradication) programmes decision to stop oral polio vaccine use after certification of eradication in light of the adverse effects associated with its long-term use. It acknowledged that there are four critical elements of work for the period following the global interruption of polio transmission: finalizing the strategy for discontinuing oral polio vaccine after certification; providing country-level guidance on decisions regarding future use of inactivated polio vaccine; ensuring the necessary laboratory capacity for continued surveillance; and mainstreaming (integrating into routine services) the highly experienced and competent polio eradication infrastructure and personnel that have been developed for the programme.

General

Proper handling and reconstitution of vaccines avoids programme errors

Oral polio vaccine (OPV) is the only vaccine that still needs to be kept deep-frozen at 20°C at central and at provincial store levels whenever possible. However, OPV may be stored at +2 to +8°C for up to 6 months. So, in any emergency or for polio national immunization days (NIDs), it may be possible to store OPV at this temperature relying on the vaccine vial monitors (VVMs) to warn of its condition.

Thermostability of vaccines

Oral poliomyelitis vaccine is unstable except when held at very low temperatures (frozen). When distribution is not imminent, it is advisable to store the vaccine at temperatures of -20°C or less, since this halts deterioration in vaccine potency.

Thermostability of vaccines

WHO management recommendation is that OPV should not be kept at refrigerator temperatures (0°C to 8°C) at health centres for more than one month, nor transported at these temperatures for more than one week.

Thermostability of vaccines

WHO requirements for thermostability for OPV: Each final lot of OPV must undergo the accelerated degradation test to confirm that its stability is satisfactory. Representative final containers of the vaccine have to be incubated at 37°C for 48 hours. The total virus content in both exposed and unexposed vials is determined concurrently with that of a trivalent reference preparation. The vaccine passes the test if the loss on exposure is not greater than a factor of 100.5 infectious units per human dose. The national control authorities are to specify the minimum virus titres per human dose.

WER 2004, vol. 79, 3, pp 16-20

V&B update 34

WHO/GPV/98.07
Thermostability of vaccines

Poliomyelitis vaccines were remarkably stable within the pH range 6.5-7.2. A vaccine can be maintained in this pH range by preventing the loss of carbon dioxide from a bicarbonate-containing vaccine, keeping the air space above the vaccine to a minimum, and packing the vaccine in tightly stoppered containers.

WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services

VVMs have been in use with oral polio vaccine (OPV) since 1996. If adequate training is provided they are well accepted by health workers and managers. They have contributed to the success of national immunization days, particularly in areas with a weak cold-chain infrastructure, and they clearly help to reduce vaccine wastage.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 1: Target diseases

All member states of WHO agreed in 1988 to eradicate polio, and WHO aims to certify the world as free of the disease by 2005.

There are four core strategies to stop transmission of the wild poliovirus and certify all WHO regions polio-free by the end of 2005 (page 15):
- high infant immunization coverage with four doses of oral polio vaccine in the first year of life;
- supplementary doses of oral polio vaccine to all children under five years of age during national immunization days (NIDS);
- surveillance for wild poliovirus through reporting and laboratory testing of all cases of acute flaccid paralysis (AFP) among children under fifteen years of age;
- targeted mop-up campaigns once wild poliovirus transmission is limited to a specific focal area.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 1: Target diseases

OPV is recommended for both routine immunization and supplementary campaigns for polio eradication. IPV is also an effective vaccine. But OPV is less expensive, safe, and easy for health workers and volunteers to administer.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

Administration summary: OPV (see Appendix 2_5)
Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

(Supplementary immunization with OPV) is usually conducted in large scale campaigns (National Immunization Days) where two doses of OPV, one month apart, are given to all children under five years of age regardless of how many doses they have received in the past. Many rounds of National immunization days maybe conducted in a country however there is no risk associated with receiving multiple doses of OPV.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

Typical immunization schedule for children (see Appendix 2_19.)

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

If a child has diarrhoea when you give OPV, administer an extra dose: that is, a fifth dose at least four weeks after he or she has received the last dose in the schedule.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO recommended vaccine storage conditions (Appendix 17_3).

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

At the higher levels of the cold chain, i.e., at primary, and regional intermediate stores oral polio vaccine (OPV) must be kept frozen between -15oC and -25oC.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO international shipping guidelines (WHO/V&B/01.05) do not require use of icepacks for freeze-sensitive vaccines, although current EPI policy continues to recommend that vaccines should be transported in-country with conditioned icepacks. Unfortunately, evidence from the field indicates a serious problem of compliance with the icepack conditioning recommendations. In order to overcome this problem, WHO has recently carried out tests using chilled water packs instead of icepacks for in-country vaccine transport. These tests have shown that it is quite safe to transport vaccines other than OPV in cold boxes containing chilled water packs at a temperature from +2C up to +8C. Transportation with chilled water packs can be repeated for the same vaccines up to four times, each not exceeding 48 hours of delivery time.

If the decision is taken to use chilled water packs for vaccine transport, OPV should be packed separately and should continue to be transported with icepacks (See also Monitoring vaccine wastage at country level, Annex 5 (WHO/V&B/03.18).)
Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

Vaccination against polio will need to continue (at least until poliovirus transmission has been interrupted globally) because of the threat of wild poliovirus importation. However, an increasing number of polio-free countries are determining that the risk of paralytic poliomyelitis associated with continued routine immunization using oral poliovirus vaccine (OPV) is greater than the risk of importation or laboratory handling of wild poliovirus. Some of these countries have introduced inactivated poliovirus vaccine (IPV) a safe and effective alternative for routine immunization using one of two approaches: replacement of OPV by IPV and introduction of a sequential IPV/OPV schedule (in which 13 doses of IPV would be followed by 23 doses of OPV.) Tropical developing countries pose a special challenge for policy formulation on IPV. In these countries, given the unresolved issues related to the immunogenicity of IPV when administered in the WHO/Expanded Programme on Immunization (EPI) vaccination schedule, the continued focal circulation of wild poliovirus on two continents, the relatively high cost of IPV and the operational complexities of introducing this vaccine, WHO does not as of July 2003 recommend the adoption of IPV alone or in a sequential schedule. It is expected that this position will be reviewed late 2004 and, if appropriate, revised according to the additional information that has become available on IPV effectiveness, logistic implications, and on further progress towards polio eradication. WHO is encouraging operational studies and introduction projects to evaluate these issues.

Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

In 1988 a global eradication target (was set) by the World Health Assembly (to be accomplished by 2000). The polio eradication initiative developed the following four strategies: (i) achieving and maintaining high routine infant vaccination coverage with OPV; (ii) establishing surveillance for poliomyelitis and poliovirus through acute flaccid paralysis (AFP) notifications and laboratory investigation; (iii) conducting mass OPV campaigns (i.e. national immunization days or NIDs) to eliminate widespread circulation of wild poliovirus; and (iv) carrying out house-to-house OPV mop-up campaigns to interrupt any remaining chains of transmission.
Countries considering a change in policy should conduct a thorough evaluation of the epidemiological, financial and operational implications before introducing IPV. At a minimum, the potential burden of OPV-related adverse events (i.e. VAPP) should be verified. Second, there should be a sound understanding of how political leaders and the general public perceive the importance of OPV-related adverse events and its possible impact on the acceptance of other vaccines. Third, the cost-effectiveness of introducing IPV should be analysed using a range of potential vaccine prices. Fourth, there should be the capacity for sustainable financing of IPV. Finally, the operational implications of introducing IPV should be studied, taking into consideration the current antigens offered in the routine immunization schedule, the existing or planned combinations of those antigens and other immunization policy decisions that may be taken in the medium term.

WHO recognizes that IPV may have an important role in the post-certification era and encourages operational studies and pilot projects to provide better understanding of the performance of this vaccine in different areas. WHO is particularly interested that opportunities for IPV introduction be fully exploited to study the effects on seroconversion and document its impact on VAPP and on the circulation of OPV-derived polioviruses.

Having reviewed the available scientific and operational data on both IPV and the global polio eradication effort, WHO recommends that IPV is not introduced alone or in a sequential schedule in any of the following circumstances: (i) in the tropical, developing country setting; (ii) in countries that were recently or are currently polio-endemic or have substantial contacts with such an area; (iii) in countries using the WHO/EPI routine vaccination schedule (i.e. doses administered at 6, 10, 14 weeks); and/or (iv) in countries where the routine vaccination coverage is <90% DTP3 coverage (3 doses of diphtheria-tetanus-pertussis vaccine.)

Poliomyelitis is targeted for eradication. Highly sensitive surveillance for acute flaccid paralysis (AFP), including immediate case investigation, and specimen collection are critical for the detection of wild poliovirus circulation with the ultimate objective of polio eradication. AFP surveillance is also critical for documenting the absence of poliovirus circulation for polio-free certification.
WHO recommended standards for surveillance of selected vaccine-preventable diseases

Recommended types of surveillance for polio:
1) Aggregated data on AFP cases should be included in routine monthly surveillance reports.
2) Designated reporting sites at all levels should report at a specified frequency (e.g., weekly or monthly) even if there are zero cases (often referred to as zero reporting).
3) All outbreaks should be investigated immediately.
4) All AFP cases under 15 years of age or with paralytic illness at an age where polio is suspected should be reported immediately and investigated within 48 hours, and two stool specimens should be collected 24-48 hours apart and within 14 days of the onset of paralysis.
5) Active surveillance: Regular weekly visits should be made to selected reporting sites that are most likely to admit acute flaccid paralysis patients (e.g., major hospitals, physiotherapy centers) to look for unreported AFP cases.

Guidelines on the international packaging and shipping of vaccines

For OPV, the following instruction should be stated in the AWB: Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15°C to -25°C (i.e., +5°F to -13°F).

Global Advisory Committee on Vaccine Safety, 34 December 2003

GACVS was informed of the (poliomyelitis eradication) programmes decision to stop oral polio vaccine use after certification of eradication in light of the adverse effects associated with its long-term use. It acknowledged that there are four critical elements of work for the period following the global interruption of polio transmission: finalizing the strategy for discontinuing oral polio vaccine after certification; providing country-level guidance on decisions regarding future use of inactivated polio vaccine; ensuring the necessary laboratory capacity for continued surveillance; and mainstreaming (integrating into routine services) the highly experienced and competent polio eradication infrastructure and personnel that have been developed for the programme.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

(SAGE) noted that any switch to inactivated poliovirus vaccine brings potential new challenges with diphtheriatetanuspertussis and combination vaccines; and strongly supported immunization activities in countries currently or recently endemic for polio. These could be through high-coverage routine service, good supplementary immunization activities, or a combination of both, stressing that by whatever means all children need to be protected from polio.

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

WHO recommends the following schedule for infants (Appendix 39_5).
Ensuring the quality of vaccines at country level: Guidelines for health staff

At the higher levels of the cold chain, i.e. at the national (central) and regional or provincial levels, OPV must be kept frozen between -15C and -25C.

The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.

Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or provincial level, OPV must be kept frozen between -15oC and -25oC. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15oC to -25oC if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2oC and +8oC. All other vaccines should be stored at between +2oC and +8oC at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Temperature sensitivity of vaccines

Current recommendations (for OPV) require that, for maintenance of potency, the vaccine must be stored and shipped at low temperatures (-20C).

Temperature sensitivity of vaccines

Each final lot of OPV must undergo the accelerated degradation test to confirm that its stability is satisfactory. Representative final containers of the vaccine have to be incubated at 37C for 48 hours. The total virus content in both exposed and unexposed vials is determined concurrently with that of a trivalent reference preparation. The vaccine passes the test if the loss on exposure is not greater than a factor of 100.5 infectious units per human dose. The national regulatory authorities are to specify the minimum virus titers per human dose.
Ensuring the quality of vaccines at country level: Guidelines for health staff

At the higher levels of the cold chain, i.e. at the national (central) and regional or provincial levels, OPV must be kept frozen between -15C and -25C.

Freeze-dried vaccines, i.e. BCG, measles, MMR and yellow fever vaccines, may also be kept in this temperature range (-15C and -25C) if there is sufficient space in the cold chain, but this is neither essential nor recommended. At other levels of the cold chain these vaccines should be stored between +2C and +8C. All other national immunization service vaccines should be stored between +2C and +8C at all levels of the cold chain.

Immunization in practice: a practical resource guide for Health workers 2004 updateModule 2: The vaccines

Wait at least four weeks between doses of OPV, DTP, Hib, and HepB vaccines.

WHO recommended standards for surveillance of selected vaccine-preventable diseases

For polio:
_ All outbreaks should be investigated immediately.
_ All AFP cases under 15 years of age or with paralytic illness at an age where polio is suspected should be reported immediately and investigated within 48 hours, and two stool specimens should be collected 24-48 hours apart and within 14 days of the onset of paralysis.

Immunization in practice: a practical resource guide for Health workers 2004 updateModule 2: The vaccines

WHO does not, as of July 2003, recommend the adoption of IPV, either alone or in a sequential schedule, in developing countries for the following reasons: unresolved issues related to the immunogenicity of IPV when administered at birth, six, ten and 14 weeks of age in the EPI vaccination schedule, the continued focal circulation of wild poliovirus on two continents, the relatively high cost of IPV and the operational complexities of introducing a vaccine which requires syringes and needles, while OPV is given orally.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The ACPE (Advisory Committee on Polio Eradication) recommended that the risk of importation from polio-infected areas should be reduced further by ensuring all travellers from such areas are immunized, regardless of their age or immunization status; it proposed that a standing recommendation be established to this effect under the International Health Regulations (IHR) (2005).
Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

SAGE reinforces the need to keep manufacturers, national regulatory authorities and other stakeholders fully apprised of developments in post-eradication planning through mechanisms such as the annual meeting of OPV and IPV manufacturers.

Weekly Epidemiological Record, No. 23 2010

OPV alone, including a birth dose is recommended in all polio-endemic countries and in countries at high risk for importation and subsequent spread. The birth dose should be administered at birth, or as soon as possible after birth.

Weekly Epidemiological Record, No. 23 2010

OPV alone, preferably with a birth dose, is also recommended in all countries with a moderate potential or high potential for WPV transmission.

Weekly Epidemiological Record, No. 23 2010

A birth dose of OPV is not considered necessary in countries where the risk of poliovirus transmission is low, even if the potential for importation is high or very high.

Weekly Epidemiological Record, No. 23 2010

Where the risk of WPV importation is high or very high, the transmission potential should be reduced to a low level before alternatives to OPV alone may be considered. Using routine immunization coverage with 3 doses of poliovirus vaccine as the main determinant of transmission potential, WHO suggests that in countries with a very high risk of WPV importation, a sequential IPVOPV schedule should not be introduced unless immunization coverage is approximately 95% or, where there is a lower importation risk, coverage should reach approximately 90%.

Weekly Epidemiological Record, No. 23 2010

Where a sequential IPV-OPV schedule is used, the initial administration of 1 or 2 doses of IPV should be followed by 2 doses of OPV to ensure both sufficient levels of protection in the intestinal mucosa and a decrease in the burden of VAPP.
IPV alone may be considered an alternative to OPV alone (or an IPV-OPV sequential schedule) only in countries that have the lowest risk of both WPV importation and WPV transmission. Switching from OPV to IPV for routine vaccination during the pre-eradication era is not cost-effective, as determined on the basis of existing economic analyses and current IPV costs.

The primary series of 3 OPV vaccinations should be administered according to the schedules of national immunization programmes, for example at 6 weeks, 10 weeks, and 14 weeks, or at 2 months, 4 months, and 6 months. In addition, a birth dose should be given as soon as possible after birth when the potential for poliovirus importation is very high or high and the transmission potential is high or moderate. The interval between doses of OPV or IPV should be 4 weeks.

IPV is given intramuscularly (preferably) or subcutaneously, and may be offered as a component of fixed combinations of vaccines. A primary series of 3 doses should be administered beginning at 2 months of age. If the primary series begins earlier (for example, with a 6-week, 10-week and 14-week schedule) then a booster dose should be administered after an interval of 6 months (for a 4-dose schedule). Where sequential IPV/OPV is used, WHO recommends that IPV be administered at 2 months of age (e.g. an IPV-OPV-OPV schedule) or at 2 months and 3-4 months of age (e.g. an IPV-IPV-OPV-OPV schedule); in both schedules IPV should be followed by at least 2 doses of OPV.

Each dose in the primary series, whether IPV or OPV, should be separated by 4-8 weeks, depending on the risk of exposure to polio in early childhood. Both IPV and OPV may be administered simultaneously with other vaccines in national childhood immunization programmes.

Travellers to polio-endemic countries or areas who have previously received 3 doses of OPV or IPV should be offered another dose of polio vaccine as a once-only dose before departure. Nonimmunized individuals intending to travel to polio-endemic destinations should complete a primary schedule of polio vaccine, using either IPV or OPV. For people who travel frequently to polio-endemic areas but who stay only for brief periods, a one-time only additional dose of a polio vaccine after the primary series should be sufficient to prevent disease.
Before travelling abroad, persons living in a polio-endemic country should have completed a full course of vaccination against polio, preferably with OPV, to boost mucosal immunity and reduce the risk of WPV shedding. Such travellers should receive an additional dose of OPV 112 months prior to each international travel. In case of urgent travel, a minimum of 1 dose of OPV should be given, ideally 4 weeks before departure.

All children worldwide should be immunized against polio, and every country should seek to achieve and maintain high levels of coverage with polio vaccine.

Hepatitis B

Typical immunization schedule for children (see Appendix 2_19.)

WHO recommended vaccine storage conditions (Appendix 17_3).

See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

WHO recommends the following schedule for infants (Appendix 39_5).

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.
Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15oC and -25oC. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15oC to -25oC if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2oC and +8oC. All other vaccines should be stored at between +2oC and +8oC at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Immunization in practice: a practical resource guide for Health workers  2004 update Module 2: The vaccines

Wait at least four weeks between doses of OPV, DTP, Hib, and HepB vaccines.

Hib

Immunization in practice: a practical resource guide for Health workers  2004 update Module 2: The vaccines

Typical immunization schedule for children (see Appendix 2_19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO recommended vaccine storage conditions (Appendix 17_3).

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

WHO recommends the following schedule for infants (Appendix 39_5).

The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.
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The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15oC and -25oC. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15oC to -25oC if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2oC and +8oC. All other vaccines should be stored at between +2oC and +8oC at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

Wait at least four weeks between doses of OPV, DTP, Hib, and HepB vaccines.

MMR

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO recommended vaccine storage conditions (Appendix 17_3).

Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15oC and -25oC. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15oC to -25oC if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2oC and +8oC. All other vaccines should be stored at between +2oC and +8oC at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.
Ensuring the quality of vaccines at country level: Guidelines for health staff

At the higher levels of the cold chain, i.e. at the national (central) and regional or provincial levels, OPV must be kept frozen between -15C and -25C.

Freeze-dried vaccines, i.e. BCG, measles, MMR and yellow fever vaccines, may also be kept in this temperature range (-15C and -25C) if there is sufficient space in the cold chain, but this is neither essential nor recommended. At other levels of the cold chain these vaccines should be stored between +2C and +8C. All other national immunization service vaccines should be stored between +2C and +8C at all levels of the cold chain.

Measles

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

Typical immunization schedule for children (see Appendix 2_19.)

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO recommended vaccine storage conditions (Appendix 17_3).

Immunization in practice: a practical resource guide for Health workers 2004 update Module 6: Holding an immunization session

See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

WHO recommends the following schedule for infants (Appendix 39_5).
Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15oC and -25oC. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15oC to -25oC if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2oC and +8oC. All other vaccines should be stored at between +2oC and +8oC at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Ensuring the quality of vaccines at country level: Guidelines for health staff

At the higher levels of the cold chain, i.e. at the national (central) and regional or provincial levels, OPV must be kept frozen between -15C and -25C.

Freeze-dried vaccines, i.e. BCG, measles, MMR and yellow fever vaccines, may also be kept in this temperature range (-15C and -25C) if there is sufficient space in the cold chain, but this is neither essential nor recommended. At other levels of the cold chain these vaccines should be stored between +2C and +8C. All other national immunization service vaccines should be stored between +2C and +8C at all levels of the cold chain.

Meningococcal

Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15oC and -25oC. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15oC to -25oC if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2oC and +8oC. All other vaccines should be stored at between +2oC and +8oC at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.
**Mumps**

**Temperature sensitivity of vaccines**

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15°C and -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2°C and +8°C. All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

**New Vaccines**

**Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)**

Countries considering a change in policy should conduct a thorough evaluation of the epidemiological, financial and operational implications before introducing IPV. At a minimum, the potential burden of OPV-related adverse events (i.e. VAPP) should be verified. Second, there should be a sound understanding of how political leaders and the general public perceive the importance of OPV-related adverse events and its possible impact on the acceptance of other vaccines. Third, the cost-effectiveness of introducing IPV should be analysed using a range of potential vaccine prices. Fourth, there should be the capacity for sustainable financing of IPV. Finally, the operational implications of introducing IPV should be studied, taking into consideration the current antigens offered in the routine immunization schedule, the existing or planned combinations of those antigens and other immunization policy decisions that may be taken in the medium term.

**Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)**

Having reviewed the available scientific and operational data on both IPV and the global polio eradication effort, WHO recommends that IPV is not introduced alone or in a sequential schedule in any of the following circumstances: (i) in the tropical, developing country setting; (ii) in countries that were recently or are currently polio-endemic or have substantial contacts with such an area; (iii) in countries using the WHO/EPI routine vaccination schedule (i.e. doses administered at 6, 10, 14 weeks); and/or (iv) in countries where the routine vaccination coverage is <90% DTP3 coverage (3 doses of diphtheria-tetanus-pertussis vaccine.)
Open Vials

The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.

Outbreak Control

WHO recommended standards for surveillance of selected vaccine-preventable diseases

For polio:
- All outbreaks should be investigated immediately.
- All AFP cases under 15 years of age or with paralytic illness at an age where polio is suspected should be reported immediately and investigated within 48 hours, and two stool specimens should be collected 24-48 hours apart and within 14 days of the onset of paralysis.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The ACPE (Advisory Committee on Polio Eradication) recommended that the risk of importation from polio-infected areas should be reduced further by ensuring all travellers from such areas are immunized, regardless of their age or immunization status; it proposed that a standing recommendation be established to this effect under the International Health Regulations (IHR) (2005).

Pentavalent

The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.
Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15°C and -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2°C and +8°C. All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Policy

Proper handling and reconstitution of vaccines avoids programme errors

Oral polio vaccine (OPV) is the only vaccine that still needs to be kept deep-frozen at 20°C at central and at provincial store levels whenever possible. However, OPV may be stored at +2 to +8°C for up to 6 months. So, in any emergency or for polio national immunization days (NIDs), it may be possible to store OPV at this temperature relying on the vaccine vial monitors (VVMs) to warn of its condition.

Thermostability of vaccines

Oral poliomyelitis vaccine is unstable except when held at very low temperatures (frozen). When distribution is not imminent, it is advisable to store the vaccine at temperatures of -20°C or less, since this halts deterioration in vaccine potency.

Thermostability of vaccines

WHO management recommendation is that OPV should not be kept at refrigerator temperatures (0°C to 8°C) at health centres for more than one month, nor transported at these temperatures for more than one week.

Thermostability of vaccines

WHO requirements for thermostability for OPV: Each final lot of OPV must undergo the accelerated degradation test to confirm that its stability is satisfactory. Representative final containers of the vaccine have to be incubated at 37°C for 48 hours. The total virus content in both exposed and unexposed vials is determined concurrently with that of a trivalent reference preparation. The vaccine passes the test if the loss on exposure is not greater than a factor of 100.5 infectious units per human dose. The national control authorities are to specify the minimum virus titres per human dose.
**Thermostability of vaccines**

Poliomyelitis vaccines were remarkably stable within the pH range 6.5-7.2. A vaccine can be maintained in this pH range by preventing the loss of carbon dioxide from a bicarbonate-containing vaccine, keeping the air space above the vaccine to a minimum, and packing the vaccine in tightly stoppered containers.

**WHO-UNICEF policy statement on the use of vaccine vial monitors in immunization services**

VVMs have been in use with oral polio vaccine (OPV) since 1996. If adequate training is provided they are well accepted by health workers and managers. They have contributed to the success of national immunization days, particularly in areas with a weak cold-chain infrastructure, and they clearly help to reduce vaccine wastage.

**Immunization in practice: a practical resource guide for Health workers 2004 update Module 1: Target diseases**

All member states of WHO agreed in 1988 to eradicate polio, and WHO aims to certify the world as free of the disease by 2005.

There are four core strategies to stop transmission of the wild poliovirus and certify all WHO regions polio-free by the end of 2005 (page 15):
- high infant immunization coverage with four doses of oral polio vaccine in the first year of life;
- supplementary doses of oral polio vaccine to all children under five years of age during national immunization days (NIDS);
- surveillance for wild poliovirus through reporting and laboratory testing of all cases of acute flaccid paralysis (AFP) among children under fifteen years of age;
- targeted mop-up campaigns once wild poliovirus transmission is limited to a specific focal area.

**Immunization in practice: a practical resource guide for Health workers 2004 update Module 1: Target diseases**

OPV is recommended for both routine immunization and supplementary campaigns for polio eradication. IPV is also an effective vaccine. But OPV is less expensive, safe, and easy for health workers and volunteers to administer.

**Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines**

Administration summary: OPV (see Appendix 2_5)
Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

(Supplementary immunization with OPV) is usually conducted in large scale campaigns (National Immunization Days) where two doses of OPV, one month apart, are given to all children under five years of age regardless of how many doses they have received in the past. Many rounds of National immunization days maybe conducted in a country however there is no risk associated with receiving multiple doses of OPV.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

Typical immunization schedule for children (see Appendix 2_19.)

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

If a child has diarrhoea when you give OPV, administer an extra dose: that is, a fifth dose at least four weeks after he or she has received the last dose in the schedule.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO recommended vaccine storage conditions (Appendix 17_3).

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

At the higher levels of the cold chain, i.e., at primary, and regional intermediate stores oral polio vaccine (OPV) must be kept frozen between -150C and -250C.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO international shipping guidelines (WHO/V&B/01.05) do not require use of icepacks for freeze-sensitive vaccines, although current EPI policy continues to recommend that vaccines should be transported in-country with conditioned icepacks. Unfortunately, evidence from the field indicates a serious problem of compliance with the icepack conditioning recommendations. In order to overcome this problem, WHO has recently carried out tests using chilled water packs instead of icepacks for in-country vaccine transport. These tests have shown that it is quite safe to transport vaccines other than OPV in cold boxes containing chilled water packs at a temperature from +2C up to +8C. Transportation with chilled water packs can be repeated for the same vaccines up to four times, each not exceeding 48 hours of delivery time.

(I)f the decision is taken to use chilled water packs for vaccine transport, OPV should be packed separately and should continue to be transported with icepacks. (See also Monitoring vaccine wastage at country level, Annex 5 (WHO/V&B/03.18).)
Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

Vaccination against polio will need to continue (at least until poliovirus transmission has been interrupted globally) because of the threat of wild poliovirus importation. However, an increasing number of polio-free countries are determining that the risk of paralytic poliomyelitis associated with continued routine immunization using oral poliovirus vaccine (OPV) is greater than the risk of importation or laboratory handling of wild poliovirus. Some of these countries have introduced inactivated poliovirus vaccine (IPV) a safe and effective alternative for routine immunization using one of two approaches: replacement of OPV by IPV and introduction of a sequential IPV/OPV schedule (in which 13 doses of IPV would be followed by 23 doses of OPV.) Tropical developing countries pose a special challenge for policy formulation on IPV. In these countries, given the unresolved issues related to the immunogenicity of IPV when administered in the WHO/Expanded Programme on Immunization (EPI) vaccination schedule, the continued focal circulation of wild poliovirus on two continents, the relatively high cost of IPV and the operational complexities of introducing this vaccine, WHO does not as of July 2003 recommend the adoption of IPV alone or in a sequential schedule. It is expected that this position will be reviewed late 2004 and, if appropriate, revised according to the additional information that has become available on IPV effectiveness, logistic implications, and on further progress towards polio eradication. WHO is encouraging operational studies and introduction projects to evaluate these issues.

Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

In 1988 a global eradication target (was set) by the World Health Assembly (to be accomplished by 2000). The polio eradication initiative developed the following four strategies: (i) achieving and maintaining high routine infant vaccination coverage with OPV; (ii) establishing surveillance for poliomyelitis and poliovirus through acute flaccid paralysis (AFP) notifications and laboratory investigation; (iii) conducting mass OPV campaigns (i.e. national immunization days or NIDs) to eliminate widespread circulation of wild poliovirus; and (iv) carrying out house-to-house OPV mop-up campaigns to interrupt any remaining chains of transmission.
Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

Countries considering a change in policy should conduct a thorough evaluation of the epidemiological, financial and operational implications before introducing IPV. At a minimum, the potential burden of OPV-related adverse events (i.e. VAPP) should be verified. Second, there should be a sound understanding of how political leaders and the general public perceive the importance of OPV-related adverse events and its possible impact on the acceptance of other vaccines. Third, the cost-effectiveness of introducing IPV should be analysed using a range of potential vaccine prices. Fourth, there should be the capacity for sustainable financing of IPV. Finally, the operational implications of introducing IPV should be studied, taking into consideration the current antigens offered in the routine immunization schedule, the existing or planned combinations of those antigens and other immunization policy decisions that may be taken in the medium term.

Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

WHO recognizes that IPV may have an important role in the post-certification era and encourages operational studies and pilot projects to provide better understanding of the performance of this vaccine in different areas. WHO is particularly interested that opportunities for IPV introduction be fully exploited to study the effects on seroconversion and document its impact on VAPP and on the circulation of OPV-derived polioviruses.

Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

Having reviewed the available scientific and operational data on both IPV and the global polio eradication effort, WHO recommends that IPV is not introduced alone or in a sequential schedule in any of the following circumstances: (i) in the tropical, developing country setting; (ii) in countries that were recently or are currently polio-endemic or have substantial contacts with such an area; (iii) in countries using the WHO/EPI routine vaccination schedule (i.e. doses administered at 6, 10, 14 weeks); and/or (iv) in countries where the routine vaccination coverage is <90% DTP3 coverage (3 doses of diphtheria-tetanus-pertussis vaccine.)

WHO recommended standards for surveillance of selected vaccine-preventable diseases

Poliomyelitis is targeted for eradication. Highly sensitive surveillance for acute flaccid paralysis (AFP), including immediate case investigation, and specimen collection are critical for the detection of wild poliovirus circulation with the ultimate objective of polio eradication. AFP surveillance is also critical for documenting the absence of poliovirus circulation for polio-free certification.
**WHO recommended standards for surveillance of selected vaccine-preventable diseases**

Recommended types of surveillance for polio:
1) Aggregated data on AFP cases should be included in routine monthly surveillance reports.
2) Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as zero reporting).
3) All outbreaks should be investigated immediately.
4) All AFP cases under 15 years of age or with paralytic illness at an age where polio is suspected should be reported immediately and investigated within 48 hours, and two stool specimens should be collected 24-48 hours apart and within 14 days of the onset of paralysis.
5) Active surveillance: Regular weekly visits should be made to selected reporting sites that are most likely to admit acute flaccid paralysis patients (e.g. major hospitals, physiotherapy centers) to look for unreported AFP cases.

**Guidelines on the international packaging and shipping of vaccines**

For OPV, the following instruction should be stated in the AWB: Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15oC to -25oC (i.e., +5oF to -13oF).

**Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation**

WHO recommends the following schedule for infants (Appendix 39.5).

**Ensuring the quality of vaccines at country level: Guidelines for health staff**

At the higher levels of the cold chain, i.e. at the national (central) and regional or provincial levels, OPV must be kept frozen between -15C and -25C.

**The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)**

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.
Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15°C and -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2°C and +8°C. All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Temperature sensitivity of vaccines

Current recommendations (for OPV) require that, for maintenance of potency, the vaccine must be stored and shipped at low temperatures (-20°C).

Temperature sensitivity of vaccines

Each final lot of OPV must undergo the accelerated degradation test to confirm that its stability is satisfactory. Representative final containers of the vaccine have to be incubated at 37°C for 48 hours. The total virus content in both exposed and unexposed vials is determined concurrently with that of a trivalent reference preparation. The vaccine passes the test if the loss on exposure is not greater than a factor of 100.5 infectious units per human dose. The national regulatory authorities are to specify the minimum virus titers per human dose.

Ensuring the quality of vaccines at country level: Guidelines for health staff

At the higher levels of the cold chain, i.e. at the national (central) and regional or provincial levels, OPV must be kept frozen between -15°C and -25°C.

Freeze-dried vaccines, i.e. BCG, measles, MMR and yellow fever vaccines, may also be kept in this temperature range (-15°C and -25°C) if there is sufficient space in the cold chain, but this is neither essential nor recommended. At other levels of the cold chain these vaccines should be stored between +2°C and +8°C. All other national immunization service vaccines should be stored between +2°C and +8°C at all levels of the cold chain.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

Wait at least four weeks between doses of OPV, DTP, Hib, and HepB vaccines.
WHO recommended standards for surveillance of selected vaccine-preventable diseases

For polio:
_ All outbreaks should be investigated immediately.
_ All AFP cases under 15 years of age or with paralytic illness at an age where polio is suspected should be reported immediately and investigated within 48 hours, and two stool specimens should be collected 24-48 hours apart and within 14 days of the onset of paralysis.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

WHO does not, as of July 2003, recommend the adoption of IPV, either alone or in a sequential schedule, in developing countries for the following reasons: unresolved issues related to the immunogenicity of IPV when administered at birth, six, ten and 14 weeks of age in the EPI vaccination schedule, the continued focal circulation of wild poliovirus on two continents, the relatively high cost of IPV and the operational complexities of introducing a vaccine which requires syringes and needles, while OPV is given orally.

Procurement

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO international shipping guidelines (WHO/V&B/01.05) do not require use of icepacks for freeze-sensitive vaccines, although current EPI policy continues to recommend that vaccines should be transported in-country with conditioned icepacks. Unfortunately, evidence from the field indicates a serious problem of compliance with the icepack conditioning recommendations. In order to overcome this problem, WHO has recently carried out tests using chilled water packs instead of icepacks for in-country vaccine transport. These tests have shown that it is quite safe to transport vaccines other than OPV in cold boxes containing chilled water packs at a temperature from +2C up to +8C. Transportation with chilled water packs can be repeated for the same vaccines up to four times, each not exceeding 48 hours of delivery time.

(I)f the decision is taken to use chilled water packs for vaccine transport, OPV should be packed separately and should continue to be transported with icepacks (See also Monitoring vaccine wastage at country level, Annex 5 (WHO/V&B/03.18).)

Guidelines on the international packaging and shipping of vaccines

For OPV, the following instruction should be stated in the AWB: Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15oC to -25oC (i.e., +5oF to -13oF).
Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

SAGE reinforces the need to keep manufacturers, national regulatory authorities and other stakeholders fully apprised of developments in post-eradication planning through mechanisms such as the annual meeting of OPV and IPV manufacturers.

Program Management

Immunization in practice: a practical resource guide for Health workers 2004 update Module 1: Target diseases

All member states of WHO agreed in 1988 to eradicate polio, and WHO aims to certify the world as free of the disease by 2005.

There are four core strategies to stop transmission of the wild poliovirus and certify all WHO regions polio-free by the end of 2005 (page 15):
- high infant immunization coverage with four doses of oral polio vaccine in the first year of life;
- supplementary doses of oral polio vaccine to all children under five years of age during national immunization days (NIDS);
- surveillance for wild poliovirus through reporting and laboratory testing of all cases of acute flaccid paralysis (AFP) among children under fifteen years of age;
- targeted mop-up campaigns once wild poliovirus transmission is limited to a specific focal area.

Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

Vaccination against polio will need to continue (at least until poliovirus transmission has been interrupted globally) because of the threat of wild poliovirus importation. However, an increasing number of polio-free countries are determining that the risk of paralytic poliomyelitis associated with continued routine immunization using oral poliovirus vaccine (OPV) is greater than the risk of importation or laboratory handling of wild poliovirus. Some of these countries have introduced inactivated poliovirus vaccine (IPV) a safe and effective alternative for routine immunization using one of two approaches: replacement of OPV by IPV and introduction of a sequential IPV/OPV schedule (in which 13 doses of IPV would be followed by 23 doses of OPV.) Tropical developing countries pose a special challenge for policy formulation on IPV. In these countries, given the unresolved issues related to the immunogenicity of IPV when administered in the WHO/Expanded Programme on Immunization (EPI) vaccination schedule, the continued focal circulation of wild poliovirus on two continents, the relatively high cost of IPV and the operational complexities of introducing this vaccine, WHO does not as of July 2003 recommend the adoption of IPV alone or in a sequential schedule. It is expected that this position will be reviewed late 2004 and, if appropriate, revised according to the additional information that has become available on IPV effectiveness, logistic implications, and on further progress towards polio eradication. WHO is encouraging operational studies and introduction projects to evaluate these issues.
Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

In 1988 a global eradication target was set by the World Health Assembly (to be accomplished by 2000). The polio eradication initiative developed the following four strategies: (i) achieving and maintaining high routine infant vaccination coverage with OPV; (ii) establishing surveillance for poliomyelitis and poliovirus through acute flaccid paralysis (AFP) notifications and laboratory investigation; (iii) conducting mass OPV campaigns (i.e. national immunization days or NIDs) to eliminate widespread circulation of wild poliovirus; and (iv) carrying out house-to-house OPV mop-up campaigns to interrupt any remaining chains of transmission.

Global Advisory Committee on Vaccine Safety, 34 December 2003

GACVS was informed of the (poliomyelitis eradication) programmes decision to stop oral polio vaccine use after certification of eradication in light of the adverse effects associated with its long-term use. It acknowledged that there are four critical elements of work for the period following the global interruption of polio transmission: finalizing the strategy for discontinuing oral polio vaccine after certification; providing country-level guidance on decisions regarding future use of inactivated polio vaccine; ensuring the necessary laboratory capacity for continued surveillance; and mainstreaming (integrating into routine services) the highly experienced and competent polio eradication infrastructure and personnel that have been developed for the programme.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

(SAGE) noted that any switch to inactivated poliovirus vaccine brings potential new challenges with diphtheriatetanuspertussis and combination vaccines; and strongly supported immunization activities in countries currently or recently endemic for polio. These could be through high-coverage routine service, good supplementary immunization activities, or a combination of both, stressing that by whatever means all children need to be protected from polio.

Research

Introduction of inactivated poliovirus vaccine into oral poliovirus vaccine-using countries (WHO position paper)

WHO recognizes that IPV may have an important role in the post-certification era and encourages operational studies and pilot projects to provide better understanding of the performance of this vaccine in different areas. WHO is particularly interested that opportunities for IPV introduction be fully exploited to study the effects on seroconversion and document its impact on VAPP and on the circulation of OPV-derived polioviruses.
Rubella

Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81.1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15°C and -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2°C and +8°C. All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

SAGE - recommend to WHO

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The ACPE (Advisory Committee on Polio Eradication) recommended that the risk of importation from polio-infected areas should be reduced further by ensuring all travellers from such areas are immunized, regardless of their age or immunization status; it proposed that a standing recommendation be established to this effect under the International Health Regulations (IHR) (2005).

Schedule

Immunization in practice: a practical resource guide for Health workers 2004 update Module 1: Target diseases

OPV is recommended for both routine immunization and supplementary campaigns for polio eradication. IPV is also an effective vaccine. But OPV is less expensive, safe, and easy for health workers and volunteers to administer.

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines

(Supplementary immunization with OPV) is usually conducted in large scale campaigns (National Immunization Days) where two doses of OPV, one month apart, are given to all children under five years of age regardless of how many doses they have received in the past. Many rounds of National immunization days maybe conducted in a country however there is no risk associated with receiving multiple doses of OPV.
If a child has diarrhoea when you give OPV, administer an extra dose: that is, a fifth dose at least four weeks after he or she has received the last dose in the schedule.

WHO recommends the following schedule for infants (Appendix 39_5).

Wait at least four weeks between doses of OPV, DTP, Hib, and HepB vaccines.

WHO does not, as of July 2003, recommend the adoption of IPV, either alone or in a sequential schedule, in developing countries for the following reasons: unresolved issues related to the immunogenicity of IPV when administered at birth, six, ten and 14 weeks of age in the EPI vaccination schedule, the continued focal circulation of wild poliovirus on two continents, the relatively high cost of IPV and the operational complexities of introducing a vaccine which requires syringes and needles, while OPV is given orally.

The ACPE (Advisory Committee on Polio Eradication) recommended that the risk of importation from polio-infected areas should be reduced further by ensuring all travellers from such areas are immunized, regardless of their age or immunization status; it proposed that a standing recommendation be established to this effect under the International Health Regulations (IHR) (2005).
Weekly Epidemiological Record, No. 23 2010

The primary series of 3 OPV vaccinations should be administered according to the schedules of national immunization programmes, for example at 6 weeks, 10 weeks, and 14 weeks, or at 2 months, 4 months, and 6 months. In addition, a birth dose should be given as soon as possible after birth when the potential for poliovirus importation is very high or high and the transmission potential is high or moderate. The interval between doses of OPV or IPV should be 4 weeks.

Weekly Epidemiological Record, No. 23 2010

IPV is given intramuscularly (preferably) or subcutaneously, and may be offered as a component of fixed combinations of vaccines. A primary series of 3 doses should be administered beginning at 2 months of age. If the primary series begins earlier (for example, with a 6-week, 10-week and 14-week schedule) then a booster dose should be administered after an interval of 6 months (for a 4-dose schedule). Where sequential IPV/OPV is used, WHO recommends that IPV be administered at 2 months of age (e.g. an IPV-OPV-OPV schedule) or at 2 months and 3-4 months of age (e.g. an IPV-IPV-OPV-OPV schedule); in both schedules IPV should be followed by at least 2 doses of OPV.

Weekly Epidemiological Record, No. 23 2010

Each dose in the primary series, whether IPV or OPV, should be separated by 4-8 weeks, depending on the risk of exposure to polio in early childhood. Both IPV and OPV may be administered simultaneously with other vaccines in national childhood immunization programmes.

Tetanus

The use of opened multi-dose vials of vaccine in subsequent immunization sessions (WHO Policy Statement)

See "Multi-Dose Open Vial" section of the "General" chapter in this catalogue for policies relevant for DTP, DT, TT, DTP-hepB, DTP-hepB-Hib, hepatitis B, liquid formulations of Hib and OPV.
Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15oC and -25oC. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15oC to -25oC if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2oC and +8oC. All other vaccines should be stored at between +2oC and +8oC at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Travellers

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The ACPE (Advisory Committee on Polio Eradication) recommended that the risk of importation from polio-infected areas should be reduced further by ensuring all travellers from such areas are immunized, regardless of their age or immunization status; it proposed that a standing recommendation be established to this effect under the International Health Regulations (IHR) (2005).

Weekly Epidemiological Record, No. 23 2010

Travellers to polio-endemic countries or areas who have previously received 3 doses of OPV or IPV should be offered another dose of polio vaccine as a once-only dose before departure. Nonimmunized individuals intending to travel to polio-endemic destinations should complete a primary schedule of polio vaccine, using either IPV or OPV. For people who travel frequently to polio-endemic areas but who stay only for brief periods, a one-time only additional dose of a polio vaccine after the primary series should be sufficient to prevent disease.

Weekly Epidemiological Record, No. 23 2010

Before travelling abroad, persons living in a polio-endemic country should have completed a full course of vaccination against polio, preferably with OPV, to boost mucosal immunity and reduce the risk of WPV shedding. Such travellers should receive an additional dose of OPV 112 months prior to each international travel. In case of urgent travel, a minimum of 1 dose of OPV should be given, ideally 4 weeks before departure.
VPD Surveillance

WHO recommended standards for surveillance of selected vaccine-preventable diseases

Poliomyelitis is targeted for eradication. Highly sensitive surveillance for acute flaccid paralysis (AFP), including immediate case investigation, and specimen collection are critical for the detection of wild poliovirus circulation with the ultimate objective of polio eradication. AFP surveillance is also critical for documenting the absence of poliovirus circulation for polio-free certification.

Recommended types of surveillance for polio:
1) Aggregated data on AFP cases should be included in routine monthly surveillance reports.
2) Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as zero reporting).
3) All outbreaks should be investigated immediately.
4) All AFP cases under 15 years of age or with paralytic illness at an age where polio is suspected should be reported immediately and investigated within 48 hours, and two stool specimens should be collected 24-48 hours apart and within 14 days of the onset of paralysis.
5) Active surveillance: Regular weekly visits should be made to selected reporting sites that are most likely to admit acute flaccid paralysis patients (e.g. major hospitals, physiotherapy centers) to look for unreported AFP cases.

Vaccine Administration

Immunization in practice: a practical resource guide for Health workers 2004 update Module 2: The vaccines
Administration summary: OPV (see Appendix 2_5)

Immunization in practice: a practical resource guide for Health workers 2004 update Module 6: Holding an immunization session
See Appendix 6_19 for chart entitled, "Administering vaccines to infants" BCG, DTP, DTP-HepB, HepB, measles, yellow fever, OPV"
Vaccine Handling

Proper handling and reconstitution of vaccines avoids programme errors

Oral polio vaccine (OPV) is the only vaccine that still needs to be kept deep-frozen at 20°C at central and at provincial store levels whenever possible. However, OPV may be stored at +2 to +8°C for up to 6 months. So, in any emergency or for polio national immunization days (NIDs), it may be possible to store OPV at this temperature relying on the vaccine vial monitors (VVMs) to warn of its condition.

Thermostability of vaccines

Oral poliomyelitis vaccine is unstable except when held at very low temperatures (frozen). When distribution is not imminent, it is advisable to store the vaccine at temperatures of -20°C or less, since this halts deterioration in vaccine potency.

Thermostability of vaccines

WHO management recommendation is that OPV should not be kept at refrigerator temperatures (0°C to 8°C) at health centres for more than one month, nor transported at these temperatures for more than one week.

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

WHO recommended vaccine storage conditions (Appendix 17_3).

WHO-UNICEF effective vaccine store management initiative: Modules 1 - 4

At the higher levels of the cold chain, i.e., at primary, and regional intermediate stores oral polio vaccine (OPV) must be kept frozen between -15°C and -25°C.

Ensuring the quality of vaccines at country level: Guidelines for health staff

At the higher levels of the cold chain, i.e. at the national (central) and regional or provincial levels, OPV must be kept frozen between -15°C and -25°C.
Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81.1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15°C and -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2°C and +8°C. All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Temperature sensitivity of vaccines

Current recommendations (for OPV) require that, for maintenance of potency, the vaccine must be stored and shipped at low temperatures (-20°C).

Ensuring the quality of vaccines at country level: Guidelines for health staff

At the higher levels of the cold chain, i.e. at the national (central) and regional or provincial levels, OPV must be kept frozen between -15°C and -25°C.

Freeze-dried vaccines, i.e. BCG, measles, MMR and yellow fever vaccines, may also be kept in this temperature range (-15°C and -25°C) if there is sufficient space in the cold chain, but this is neither essential nor recommended. At other levels of the cold chain these vaccines should be stored between +2°C and +8°C. All other national immunization service vaccines should be stored between +2°C and +8°C at all levels of the cold chain.

Vaccine Quality

Thermostability of vaccines

WHO requirements for thermostability for OPV: Each final lot of OPV must undergo the accelerated degradation test to confirm that its stability is satisfactory. Representative final containers of the vaccine have to be incubated at 37°C for 48 hours. The total virus content in both exposed and unexposed vials is determined concurrently with that of a trivalent reference preparation. The vaccine passes the test if the loss on exposure is not greater than a factor of 100.5 infectious units per human dose. The national control authorities are to specify the minimum virus titres per human dose.
Thermostability of vaccines

Poliomyelitis vaccines were remarkably stable within the pH range 6.5-7.2. A vaccine can be maintained in this pH range by preventing the loss of carbon dioxide from a bicarbonate-containing vaccine, keeping the air space above the vaccine to a minimum, and packing the vaccine in tightly stoppered containers.

Temperature sensitivity of vaccines

Each final lot of OPV must undergo the accelerated degradation test to confirm that its stability is satisfactory. Representative final containers of the vaccine have to be incubated at 37°C for 48 hours. The total virus content in both exposed and unexposed vials is determined concurrently with that of a trivalent reference preparation. The vaccine passes the test if the loss on exposure is not greater than a factor of 100.5 infectious units per human dose. The national regulatory authorities are to specify the minimum virus titers per human dose.
Temperature sensitivity of vaccines

The recommended conditions for storing vaccines used in immunization programmes are shown in Appendix 81_1. This diagram also indicates the maximum times and temperatures in each case. At the higher levels of the cold chain, i.e., at national (primary), and regional or province level, OPV must be kept frozen between -15°C and -25°C. Freeze-dried vaccines (i.e., BCG, measles, MMR and yellow fever) may also be kept frozen at -15°C to -25°C if cold chain space permits, but this is neither essential nor recommended. At other levels of the cold chain (intermediate vaccine stores and health facilities), these vaccines should be stored between +2°C and +8°C. All other vaccines should be stored at between +2°C and +8°C at all levels of the cold chain. Liquid formulations of vaccines containing diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type b, IPV and their combinations should not be frozen.

Ensuring the quality of vaccines at country level: Guidelines for health staff

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