Polio

Program Management

(SAGE) noted that any switch to inactivated poliovirus vaccine brings potential new challenges with diphtheria–tetanus–pertussis 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.

Where feasible, integration (of measles campaigns) may be considered with other mass vaccination, such as polio vaccination, and with vitamin A supplementation. However, integration with other such interventions must not compromise the quality of measles SIAs.

Examples of public health interventions that have been integrated with measles SIAs include:

- Injectables: rubella vaccine, yellow fever vaccine, tetanus toxoid; for these, immunization safety and injection safety issues must be implemented with utmost care.
- Orally-administered medication or interventions: oral polio vaccine (OPV), vitamin A, anthelminthic treatment.
- Others: distribution of insecticide-treated nets.

Measles SIAs provide an opportunity for raising population immunity to polio via the administration of OPV to children under five years (Appendix 80_13.) Inclusion of a single dose of OPV in this manner is only for the purpose of providing booster doses, and not as an eradication strategy.
Polio

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.

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One of the most important recent developments regarding polio eradication programming is the 2003 tactical shift to increase the focus of attention and resource allocation for: supplementary immunization and enhanced surveillance in polio endemic and high-risk countries; enhanced surveillance/timely responses to importations in polio-free areas; and improvement of routine immunization in all areas.


There are two preconditions that need to be in place before one could contemplate cessation of immunization with OPV. Firstly, that there is global containment and (transmission of) wild poliovirus stops, and secondly that there are national surveillance and response strategies in place.


GACVS was informed of the (poliomyelitis eradication) programme’s 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.

Global Advisory Committee on Vaccine Safety, 3–4 December 2003

27 June 2008
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 1–3 doses of IPV would be followed by 2–3 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.

**Procurement**

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.
**Polio**

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 +2°C up to +8°C. 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).)

**Vaccine Quality**

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.
Polio

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

Cold Chain Equipment

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.

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

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.
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.

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.

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.
Polio

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

Multi-dose Open Vials

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.

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

Schedule

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

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

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.

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Polio

(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.

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.
Polio

Although IPV is deemed to be safe, its efficacy is somewhat unclear, such that WHO is not currently recommending its use for countries with recent endemics or risk of importation.

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Outbreak Control

(A)ll polio-free countries must now regard polio importations as public health emergencies, with enhanced surveillance and immunization activities to detect and respond to such events.

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.

Surveillance of Vaccine Preventable Disease

(A)ll polio-free countries must now regard polio importations as public health emergencies, with enhanced surveillance and immunization activities to detect and respond to such events.

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.
**Polio**

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.

*WHO–recommended standards for surveillance of selected vaccine-preventable diseases*

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**Research**

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)*

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Polio

Introduction of Vaccines

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.

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.)