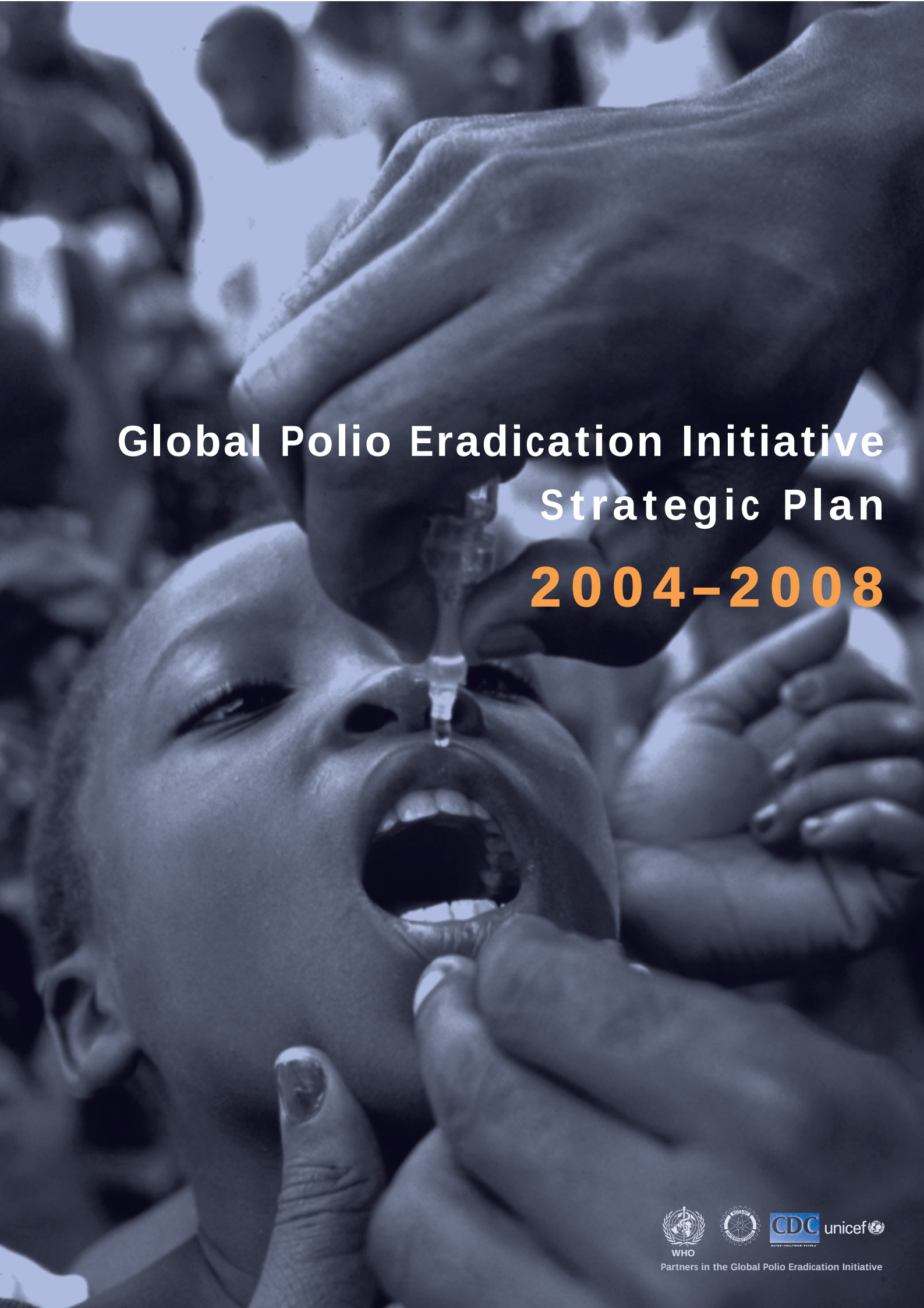

# Global Polio Eradication Initiative Strategic Plan 2004–2008

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# Global Polio Eradication Initiative
# Strategic Plan

# 2004–2008

# Contents

# Abbreviations and Acronyms

| | |
|---|---|
| **AFP** | acute flaccid paralysis |
| **AFR** | WHO African Region |
| **AMR** | WHO Region of the Americas |
| **ARVs** | anti-retroviral drugs |
| **CCM** | Country coordination mechanism |
| **CDC** | US Centers for Disease Control and Prevention (USA) |
| **CIDA** | Canadian International Development Agency |
| **cVDPV** | circulating vaccine-derived poliovirus |
| **DFID** | Department for International Development (United Kingdom) |
| **EC** | European Commission |
| **EMR** | WHO Eastern Mediterranean Region |
| **GAVI** | Global Alliance for Vaccines and Immunization |
| **GCC** | Global Commission for the Certification of the Eradication of Poliomyelitis |
| **GOARN** | Global Outbreak Alert and Reponse Network |
| **kfW** | Kreditanstalt für Wiederaufbau (Germany) |
| **ICCs** | interagency coordinating committees |
| **IDS** | integrated disease surveillance |
| **iNIDs** | intensified national immunization days |
| **IPV** | inactivated poliovirus vaccine |
| **iSNIDs** | intensified subnational immunization days |
| **ITD** | intratypic differentiation |
| **ITN** | insecticide treated net |
| **JICA** | Japan International Coorporation Agency |
| **MDGs** | millennium development goals |
| **mOPV** | monovalent oral polio vaccine |
| **NCCs** | national certification committees |
| **NGOs** | nongovernmental organizations |
| **NIDs** | national immunization days |
| **OPV** | oral polio vaccine |
| **RCCs** | regional certification commissions |
| **RED** | Reach Every District |
| **SIAs** | supplementary immunization activities (e.g. NIDs, SNIDs, mop-ups) |
| **SEAR** | WHO South-East Asia Region |
| **SNIDs** | subnational immunization days |
| **TAGs** | technical advisory groups |
| **TCG** | global Technical Consultative Group for Poliomyelitis Eradication |
| **UN** | United Nations |
| **UNF** | United Nations Foundation |
| **UNICEF** | United Nations Children's Fund |
| **USAID** | United States Agency for International Development |
| **VAPP** | vaccine-associated paralytic poliomyelitis |
| **VDPVs** | vaccine-derived polioviruses |
| **VPDs** | vaccine-preventable diseases |
| **WHA** | World Health Assembly |
| **WHO** | World Health Organization |
| **WPR** | WHO Western Pacific Region |

# 1 Executive Summary

By end-2003, poliomyelitis had been eliminated from all but 6 countries[1] in the world as a result of the Global Polio Eradication Initiative, the largest international public health effort to date. Nearly 5 million children are walking who would otherwise have been paralyzed by polio and 1.25 million childhood deaths have been averted by distributing Vitamin A during the polio immunization campaigns.

Once polio has been eradicated, the world will reap substantial financial, as well as humanitarian, dividends due to foregone polio treatment and rehabilitation costs. Depending on national decisions on the future use of polio vaccines, these savings could exceed US$ 1 billion per year.

The Global Polio Eradication Initiative Strategic Plan 2004-2008[2] outlines activities required to interrupt poliovirus transmission (2004-2005), achieve global certification and mainstream the Global Polio Eradication Initiative (2006-2008), and prepares for the Global OPV Cessation Phase (2009 & beyond). This Plan reflects the major tactical revisions that were introduced in 2003 to interrupt the final chains of polio transmission, the revised timeframe for certification of eradication, and the decision to stop immunization with oral polio vaccine (OPV) globally as soon as possible after global certification.

Of the 4 objectives outlined in the Plan, the over-riding objective is the rapid interruption of polio transmission in the 6 remaining endemic countries. Eliminating these reservoirs during 2004-2005 is now an urgent international public health issue because the cessation of mass immunization campaigns in most polio-free countries has left the world increasingly vulnerable to importations of this disease. Objective 1 of the Plan details the supplementary immunization, routine immunization, and surveillance activities needed to finish the job of eradication and protect the investment made in polio-free areas. Particular attention is given to 'intensifying' supplementary immunization activities to improve quality and reach every child. The Plan highlights the 3 countries linked to over 95% of cases in 2003: Nigeria, India and Pakistan. It recognizes, however, that with the reduction in polio transmission in India and Pakistan in late 2003, the risks to global eradication are increasingly concentrated in Nigeria. The postponement of eradication activities in key areas of that country in 2003 led to a marked increase in the number of polio-paralyzed Nigerian children and the re-infection of at least 5 neighbouring countries. The narrow window of opportunity that now exists to eradicate polio can only be exploited if the leaders of the endemic areas ensure that every child is immunized during intensified supplementary immunization activities in 2004 (SIAs).

Objectives 2 and 3 of the Plan outline activities for certifying the world polio-free and preparing for the Global OPV Cessation Phase that will follow. With the certification process and criteria having been validated in three WHO regions, Objective 2 focuses on improving surveillance quality (especially in the 19 countries yet to achieve certification-standard), reversing declines in surveillance sensitivity in the regions that have been certified, and completing Phase II of the *Global Action Plan for the Laboratory Containment of Wild Polioviruses*. Objective 3 outlines the implications of the 2003 decision to stop OPV after global certification. Although trivalent OPV will continue to be the vaccine of choice for routine immunization through 2008, the plan outlines the work required to develop the specific products needed to facilitate the safe cessation of OPV. These products include: a 3rd edition of the Global Action Plan for the Laboratory Containment of Wild Polioviruses (specifying the longterm requirements for wild poliovirus, vaccine-derived polioviruses and Sabin-strains), monovalent OPV (mOPV) stockpiles, IPV produced from Sabin strains (S-IPV), and appropriate IPV-containing combination vaccines. The plan also discusses the

[1] Countries with ongoing indigenous wild polioviruses in 2003, in order of intensity of transmission, were: Nigeria, India, Pakistan, Niger, Afghanistan and Egypt.
[2] This plan replaces and updates the Global Polio Eradication Strategic Plan 2001-2005. WHO Document No. WHO/Polio/00.05.

development of mechanisms to ensure that countries which desire or need these products have access to them by 2008.

The fourth and final objective of the plan addresses the work required to integrate and/or transition the substantial human resources, physical infrastructure and institutional arrangements that were established for polio eradication into other disease control, surveillance and response programmes. This objective also details the programme of work to 'mainstream' those polio eradication activities that must be continued indefinitely (i.e. surveillance, stockpiles, containment) into existing national, WHO and UNICEF structures and mechanisms for managing other serious pathogens which are subject to high biosafety levels.

The greatest risks to achieving the annual milestones of this plan are ongoing wild poliovirus transmission in any of the 6 remaining endemic countries and an increased frequency of polio outbreaks due to circulating vaccine-derived polioviruses (cVDPVs). Implementing the full activities outlined in the Plan requires continued technical support from a strong polio eradication partnership, financing for the shortfall of US$ 150 million to interrupt poliovirus transmission, and identification of funding for the US$ 380 million budget to achieve global certification and mainstream the Global Polio Eradication Initiative.

The Global Polio Eradication Initiative Estimated External Financial Resource Requirements 2004–2008 outlines the resources required to implement the Global Polio Eradication Initiative Strategic Plan 2004–2008[3] and the financial implications of the major risks to the annual milestones of the Plan. ❐



[3] WHO/UNICEF Global Polio Eradication Initiative Estimated External Financial Resource Requirements 2004-2008.

# 2 Background

In 1988 the World Health Assembly (WHA), the annual meeting of the ministers of health of all Member States of the World Health Organization, voted to launch a global initiative to eradicate polio. As a result of the Global Polio Eradication Initiative, the largest international public health effort to date, by late-2003 polio had been eliminated from all but 6 countries and fewer than 1000 children had been paralysed by the disease that year. More notably, nearly five million children were walking who would otherwise have been paralysed by polio and 1.25 million childhood deaths had been averted by distributing vitamin A during the polio immunization campaigns.

The international decision to pursue eradication of this devastating disease was based on sound evidence from the WHO Region of the Americas (AMR) as to the technical feasibility of such a goal, and on the political and societal support best exemplified by the commitment of the service organization Rotary International to raise financial resources and advocate for polio eradication. In the 15 years since the decision to eradicate polio, an extensive network of national governments, international agencies, private corporations, foundations, bilateral donors, humanitarian organizations, nongovernmental organizations (NGOs) and development banks have formed a "global polio partnership", spearheaded by the World Health Organization (WHO), Rotary International, the US Centers for Disease Control and Prevention (CDC) and the United Nations Children's Fund (UNICEF).

Between 1988 and the mid-1990s, there was a limited reduction in the number of endemic countries as the partnership was developed, broader political commitment secured and further evidence of the operational feasibility of the AMR strategies established, particularly in the Western Pacific Region (WPR). From the mid-1990s, it was possible to rapidly scale-up eradication

**Figure 1: Key targets to *interrupt poliovirus transmission* (2004-2005), achieve *global certification and mainstream the Global Polio Eradication Initiative* (2006-2008), and during the *Global OPV Cessation Phase* (2009 & beyond)**

activities so that by the end of the decade over 575 million children were regularly being reached with oral polio vaccine (OPV) through the efforts of an estimated 20 million volunteers in every low- and middle- income country in the world. Today, the technical feasibility of polio eradication has been demonstrated through the elimination of the disease from 210 countries, territories, areas, and large geographic areas of the six remaining endemic countries. By late 2003, the remaining chains of wild poliovirus transmission, concentrated primarily in just five states or provinces of Nigeria (1), India (2) and Pakistan (2), were the result of missing substantial numbers of children during both routine and supplementary polio immunization activities during the preceeding years.

Since the Global Polio Eradication Initiative was launched, the work of the global polio partnership, including national governments, has been guided by a series of multi-year strategic plans, the last of which was published in 2000[4]. The Global Polio Eradication Initiative Strategic Plan 2004–2008 replaces and updates the 2000 Plan. This Plan outlines the key activities required to interrupt poliovirus transmission (2004–2005), achieve global certification and mainstream the Global Polio Eradication Initiative (2006–2008) and prepares for the subsequent Global OPV Cessation Phase (2009 & beyond) (Figure 1). The plan reflects the major tactical revisions of strategy which were introduced in 2003 to interrupt wild poliovirus transmission worldwide, the revised timeframe for the certification of polio eradication globally, and the substantial increase in the knowledge base for development of policies for the period after global certification of polio eradication. This Strategic Plan serves as the basis for the annual work planning of individual partner agencies and national programmes. ❐

[4] Global Polio Eradication Strategic Plan 2001–2005 (WHO/Polio/00.05).

# 3 Goal

THE goal of the Global Polio Eradication Initiative is to ensure that poliovirus transmission is interrupted globally through coordinated national and international action, that the full humanitarian and economic benefits of eradication are realized, and that the lessons and infrastructure from its implementation are utilized in the strengthening of health systems and control of other important diseases. ❐

# 4 Objectives and Milestones

## 4.1 Objective 1: Interrupt Poliovirus Transmission

*By late 2003, wild poliovirus was endemic in only six countries. Of the three countries which accounted for 95% of cases globally, two (India and Pakistan) were at the lowest levels of wild poliovirus transmission ever, again reaffirming the biologic and technical feasibility of polio eradication. With the reduction of cases in these countries and improvement of quality of activities, the risks to global eradication are increasingly concentrated in Nigeria, where cases increased markedly in 2003, with subsequent re-infection of a number of neighbouring countries. Consequently, in 2003 the number of countries suffering polio cases due to importations was the highest ever recorded. In 2003 alone, responding to importations cost over US$ 20 million in emergency mop-up activities. Rapidly eradicating the final polio reservoirs in 2004 has now become an urgent international public health issue. With the cessation of mass campaigns in most polio-free countries, the world is increasingly vulnerable to polio and the consequences of importations are increasingly grave. The narrow window of opportunity which now exists to eradicate polio can only be exploited if the leaders of endemic areas, particularly in five key states/provinces worldwide, ensure that every child is immunized during intensified mass immunization activities in 2004.*

### Strategic Approach:

Interruption of wild poliovirus transmission has been pursued using a combination of routine and supplementary immunization activities (SIAs), guided by high quality surveillance (see also section 4.2).

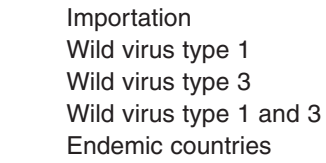
High routine coverage with at least three doses of oral poliovirus vaccine (OPV3) has been the foundation of the Global Polio Eradication Initiative. However, global OPV3 coverage was only 67% in 1988 and never reaching more than 80% in subsequent years. More importantly, even with good OPV3 coverage polio has persisted in many developing countries due to a combination of factors. For example, the level of seroconversion to OPV3 is often substantially lower in developing, tropical climates compared with temperate climates due to host (e.g. concomitant infections, malnutrition), programmatic (e.g. cold chain failures) and environmental factors, requiring substantially more doses to seroconvert an individual. Furthermore, sub-optimal sanitation, high population density and tropical climates combine to facilitate the transmission of any enterovirus in these areas, including polioviruses. In such settings, wild poliovirus can continue to circulate even in highly immunized populations, requiring synchronized campaigns with OPV to interrupt transmission.

Consequently, in endemic countries national immunization days (NIDs) during the low transmission season for polioviruses have been conducted to interrupt the major chains of transmission by rapidly increasing systemic and intestinal immunity among all children aged less than five years. All endemic countries had introduced NIDs by the end of 1999. Where epidemiologically appropriate, NIDs have been coordinated across national borders.[5] House-to-house mop-up campaigns, targeting at least one million children, were added to NIDs to interrupt the final chains of transmission. In 1999 the WHA called for the acceleration of activities, urging endemic countries to increase the number of NID rounds conducted each year, to add subnational immunization days (SNIDs) in particularly high-risk areas, and to introduce a house-to-house vaccine delivery strategy for NIDs and SNIDs.[6] In April 2003, as a result of an increasing geographic restriction of poliovirus transmission and increasingly limited resources,

[5] Examples are: Operation MECACAR, west and central Africa synchronized NID operations and synchronization of activities between China and the SAARC countries.

[6] Fifty-second World Health Assembly. *Poliomyelitis eradication*. World Health Organization, Geneva, 1999 (resolution WHA52.22).

**Figure 2: Wild poliovirus*, 1 January 2003 – 09 December 2003**




*Excludes viruses detected from environmental surveillance and vaccine derived polioviruses.
Data in WHO HQ as of 09 Dec 2003.



the global Technical Consultative Group for Poliomyelitis Eradication (TCG) advised concentrating advocacy, financing and human resources on the remaining endemic areas to increase both the number and quality of SIAs. To rapidly stop the final chains of transmission in reservoir areas, from 2004 a series of intensified mass immunization campaigns, overseen by the highest levels of government, will target the very limited number of states or provinces which now threaten the global eradication goal.

## Situation Analysis:

By late 2003, wild poliovirus transmission had been interrupted in all but six countries in the world. Three of these countries, Nigeria, India and Pakistan, accounted for 95% of cases. Within these countries, however, endemic transmission was highly restricted geographically. Of the remaining geographic areas with ongoing transmission of indigenous wild polioviruses,[7] the five states/provinces to which 75% of global cases could be linked are of particular concern: Kano in Nigeria, Uttar Pradesh and Bihar in northern India, and Sindh and North West Frontier Province in Pakistan (Figure 2). In two of the three other endemic countries, Afghanistan and Niger, epidemiologic and virologic data demonstrated highly focal endemic transmission, as well as repeated importations from the "global reservoir" with which they shared a border (i.e. Pakistan and Nigeria respectively). In Egypt endemic transmission was highly localized.

In all of the endemic areas, the continued transmission of polio is the result of vaccinators having missed large numbers of young children during NIDs and/or SNIDs which had been designed to deliver supplementary OPV doses to *all* children. In most of these areas, especially within the densely populated, major reservoir areas of Nigeria, India and Pakistan, this problem is further compounded by very low routine immunization coverage with OPV3, often less than 25%.



[7] Areas of endemic transmission of indigenous wild polioviruses at end-2003: Southern region in Afghanistan; greater Cairo and "rest of Egypt" in Egypt; Bihar, Uttar Pradesh and West Bengal in India; Niger; northeast, north-central, north-west and central zones of Nigeria; Baluchistan, Northwest Frontier Province, Punjab and Sindh in Pakistan.

Although endemic polio transmission is now geographically restricted, wild poliovirus importations have continued to paralyse children in polio-free areas. Between 1999 and mid-2003, a total of 12 such importations were detected with over 70 children paralysed in Africa, Asia, Europe, and the Western Pacific. In the first nine months of 2003 alone, virus from the northern Nigeria reservoir reinfected Burkina Faso, Chad, Ghana, Togo and part of Niger, as well as polio-free states within Nigeria such as Lagos, requiring an international immunization response. To date, all such polio outbreaks have eventually been controlled through large-scale OPV mop-up operations, though sometimes as late as six months after the index case had been detected. In addition to the risk of importations, during 2000–2002 a total of 28 polio cases in the Dominican Republic, Haiti, Madagascar and the Philippines, confirmed the real, though rare, risk of polio outbreaks due to circulating vaccine-derived polioviruses (cVDPVs). Although these cVDPV outbreaks were readily stopped with OPV mop-up operations, the capacity to detect and respond to such events must be in place until well after the use of OPV in routine immunization has stopped.

## Expected Results:

**1. Intensified mass immunization activities in endemic areas (iSNIDs or iNIDs[8]):** The highest priority for the Global Polio Eradication Initiative is the interruption of wild poliovirus transmission in the remaining endemic countries of Nigeria, India, Pakistan, Niger, Egypt and Afghanistan. Among the remaining geographic areas with endemic transmission of indigenous wild poliovirus,[9] particular attention is required in the five key reservoir states/provinces of Kano (Nigeria), Uttar Pradesh and Bihar (India) and Sindh and North West Frontier Province (Pakistan). To stop transmission in all infected areas as rapidly as possible, intensified activities are planned to repeatedly vaccinate the large cohorts of susceptible young children that rapidly accumulate in these areas due to large populations, high birth rates and very low routine immunization coverage. Reaching over 90% of

**Table 1: Baseline NIDs and SNIDs planned for polio eradication 2004–2008***
**Note: additional mop-up activities will be required**

| | | Baseline | NIDs/SNIDs | | |
|---|---|---|---|---|---|
| | Priority | Country | 2004 | 2005 | 2006 |
| A | Endemic countries | Afghanistan | 4/1 | 2/0 | |
| | | Egypt | 3/2 | 2/0 | |
| | | India | 5/1 | 2/2 | 2/0 |
| | | Niger | 4/0 | 0/2 | |
| | | Nigeria | 4/2 | 4/2 | 2/0 |
| | | Pakistan | 5/2 | 2/2 | 2/0 |
| B | Highest risk countries | Benin | 4/0 | | |
| | Countries bordering Nigeria at risk of importation: | Burkina Faso | 4/0 | | |
| | | Cameroon | 0/4 | | |
| | | Chad | 2/2 | | |
| | | Côte d'Ivoire | 2/0 | | |
| | | Ghana | 4/0 | | |
| | | Togo | 4/0 | | |
| | Recently endemic | Angola | 2/0 | 0/2 | |
| | | DR Congo | 0/2 | | |
| | | Ethiopia | 0/2 | | |
| | | Somalia | 2/2 | 0/2 | |
| | | Sudan | 0/2 | | |
| | Countries bordering India at risk of importation: | Bangladesh | 2/0 | | |
| | | Nepal | 2/0 | | |

*Assumes wild poliovirus is interrupted by end-2004. See Global Polio Eradication Initiative Estimated External Financial Resource Requirements 2004-2008 for contingency plans and their financing implications.

[8] iSNIDs: intensified subnational immunization days; iNIDs: intensified national immunization days.
[9] See footnote 7.

children during intensified polio activities will require:

- direct oversight by the highest political and health authorities in the country to ensure accountability;
- "mapping" of local political, religious, traditional and community leaders to ensure state/province, district and community level advocacy efforts generate enhanced support from influential opinion leaders;
- detailed microplanning at the local level to ensure that every household is identified, mapped and visited by an immunization team;
- full engagement of local women's groups and other influential NGOs to ensure sufficient female vaccinators with access to all homes and communities;
- enhanced communications strategies and activities, based on epidemiologic and programme data;
- sufficient financing and, where appropriate, innovative funding mechanisms, including direct financing to peripheral level government and nongovernmental institutions, to ensure timely availability of funds at the point of operations;
- additional technical assistance from polio partners to ensure sufficient national and international expertise is available for state/province and district planning and monitoring.

iSNIDs or iNIDs will be conducted one month apart in series of 3–4 rounds, in all remaining endemic states or provinces, until 12 months after the last indigenous case (Table 1). The effectiveness of these intensified activities will be highly dependent on the presence of quality acute flaccid paralysis (AFP) surveillance, including very rapid processing of diagnostic specimens and genetic characterization of isolated viruses, to guide these activities.

**2. Emergency response mop-ups to wild poliovirus importations and/or cVDPVs:** The second priority will be to ensure that all polio-free countries and areas treat the detection of an imported wild poliovirus and/or cVDPV as a public health emergency, with standard operating procedures to mount a rapid and massive mop-up response within four weeks of confirmation of such a virus from a clinical case. To enhance national capacity to initiate such a response, standard operating procedures will be developed in each country, as outlined in the requirements of the global and regional certification commissions. At the regional level, the polio partnership will target its 2004 technical assistance to the rapid preparation of these procedures in countries which form epidemiologic blocks with the remaining reservoir areas (e.g. west and central Africa). At the global level, international requirements for the reporting of circulating polioviruses will be revised to enhance timeliness of their reporting. Adequate reserves of financial and vaccine resources are planned to facilitate emergency mop-up responses. By 2007 the management of the response to such events will be fully integrated with existing WHO and UNICEF emergency response mechanisms for other important pathogens (e.g. yellow fever, meningitis).

**3. Supplementary immunization in highest-risk polio-free areas:** The third priority of the Global Polio Eradication Initiative will be to prevent the re-establishment of wild poliovirus transmission in polio-free areas, especially within the endemic countries themselves. Consequently, in addition to the iSNIDs at least two rounds of iNIDs will continue to be conducted in each of the endemic countries for two years after the last case is detected. Two rounds of NIDs or SNIDs will also be conducted in the limited number of polio-free countries which are at particularly high risk of re-establishing endemic transmission of imported wild poliovirus due to their proximity to an endemic area, large population size and/or suboptimal OPV3 coverage. As of mid-2003, the six large countries in which the re-establishment of wild poliovirus transmission would be particularly damaging were Angola, Bangladesh, the Democratic Republic of the Congo, Ethiopia, Nepal and the Sudan. As a result of the intense polio transmission in northern Nigeria in 2003, and its repeated spread into bordering countries, NIDs or SNIDs are now also required in Benin,

Burkina Faso, Cameroon, Chad, Côte d'Ivoire Ghana and Togo. The NIDs or SNIDs in these countries will continue to be planned until the last case has been detected in the relevant reservoir areas. Specific countries and areas requiring additional SIAs will be regularly reviewed and updated, depending on routine immunization coverage, surveillance sensitivity, risk of importations and other factors. Table 1 outlines the proposed schedule of SIAs for these countries.

**4. Enhanced routine immunization coverage against polio:** The fourth priority will be to support the work of WHO and UNICEF, especially within the Global Alliance for Vaccines and Immunization (GAVI), to improve routine immunization coverage. In polio-free areas enhanced routine immunization coverage will be central to limiting the spread of importations and/or the emergence of cVDPVs. In endemic areas improvements in routine OPV coverage will enhance the impact of iNIDs, iSNIDs and mop-ups. The importance of ensuring a "birth dose" of OPV will be reinforced. The Global Polio Eradication Initiative will continue to identify for GAVI those areas at highest risk of importations and/or cVDPVs for its international and national advocacy work. Polio-funded staff will continue to work on routine immunization strengthening, giving particular emphasis to transferring polio lessons and experience to the effort to "Reach Every District" (RED) in the areas at highest risk of importations. Special attention will be given to microplanning, logistics, social mobilization, and monitoring and evaluation in the areas with low OPV3 coverage (Table 2).

**5. High quality surveillance and laboratories (see also objective 2):** To interrupt endemic chains of wild poliovirus transmission, importations and/or cVDPVs, high quality SIAs must be guided by excellent surveillance globally for circulating polioviruses. The highest surveillance priority of the Global Polio

**Table 2: Priority countries for improving OPV3 coverage to GAVI target*; WHO/UNICEF estimates for 2002 (based on data available as of October 2003)**

| Coverage | Country | OPV3 % coverage |
|---|---|---|
| 60–80% | Benin | 72 |
| | Bolivia | 79 |
| | Burundi | 69 |
| | China | 79 |
| | Djibouti | 62 |
| | Dominican Republic | 73 |
| | India | 70 |
| | Indonesia | 74 |
| | Lesotho | 78 |
| | Madagascar | 61 |
| | Malawi | 79 |
| | Micronesia (Federated States of ) | 79 |
| | Myanmar | 77 |
| | Namibia | 78 |
| | Nepal | 72 |
| | Pakistan | 63 |
| | Paraguay | 78 |
| | Philippines | 70 |
| | Senegal | 60 |
| | Solomon Islands | 68 |
| | Suriname | 73 |
| | Swaziland | 76 |
| | Togo | 63 |
| | Turkey | 78 |
| | Uganda | 73 |
| | Venezuela | 77 |
| | Yemen | 69 |
| | Zambia | 79 |
| | Zimbabwe | 74 |
| 40–60% | Afghanistan | 48 |
| | Angola | 42 |
| | Burkina Faso | 42 |
| | Cambodia | 54 |
| | Cameroon | 48 |
| | Central African Republic | 40 |
| | Chad | 40 |
| | Congo | 41 |
| | Côte d'Ivoire | 54 |
| | Democratic Republic of the Congo | 45 |
| | Ethiopia | 57 |
| | Guinea | 44 |
| | Guinea-Bissau | 50 |
| | Haiti | 43 |
| | Lao People's Democratic Republic | 55 |
| | Liberia | 50 |
| | Mali | 57 |
| | Mozambique | 55 |
| | Nauru | 59 |
| | Papua New Guinea | 46 |
| | Sierra Leone | 50 |
| | Somalia | 40 |
| | Sudan | 40 |
| | Timor-Leste | 56 |
| | Vanuatu | 53 |
| <40% | Equatorial Guinea | 39 |
| | Gabon | 31 |
| | Niger | 25 |
| | Nigeria | 25 |

* GAVI target: by 2010 or sooner, all countries will have routine immunization coverage at 90% nationally with at least 80% coverage in every district.

Eradication Initiative in 2004–2005 will be to achieve certification-standard surveillance at the national level in the 19 countries which did not achieve this level in 2003 in the three endemic regions (Table 3). Substantial work will also be required to identify and close gaps in AFP performance at the subnational level in the large countries which are currently or recently endemic.

Further attention will be given to increasing the speed with which surveillance and laboratory results from "hot cases" are communicated to those responsible for decisions on the timing and extent of SIAs. The polio partnership will support national efforts to improve AFP surveillance through the specific steps outlined under objective 2.

## Objective 1: Interrupt Poliovirus Transmission

### Indicators and Milestones

| | Milestones | | | | |
|---|---|---|---|---|---|
| Indicators | 2004 | 2005 | 2006 | 2007 | 2008 |
| Number of endemic countries | 5 | 1* | 0 | 0 | 0 |
| Percentage of planned SIAs implemented in highest risk polio-free areas (Table 1) | 100% | 100% | 100% | NA | NA |
| Percentage of countries achieving GAVI targets for DTP3/OPV3** | 30% | 40% | 50% | 60% | 70% |
| Percentage of emergency mop-ups begun within four weeks of case confirmation | 80% | 90% | 100% | 100% | 100% |
| Percentage of non-certified countries with certification-standard surveillance | 85% | 90% | 100% | 100% | 100% |

* As of end-2003, one country is at particular risk of ongoing transmission into the first half of 2005.
** Based on the rate of progress which would be required to achieve the GAVI target: by 2010 or sooner, all countries will have routine immunization coverage at 90% nationally with at least 80% coverage in every district.

### Major Challenges to the Interruption of Poliovirus Transmission

This section provides further detail on the major challenges to interrupting poliovirus transmission globally; the potential financial implications of these challenges are outlined in the Global Polio Eradication Initiative Estimated External Financial Resource Requirements, 2004–2008.

**Interruption of wild poliovirus transmission by the end of 2004:**

The most important assumption underpinning this Strategic Plan is that wild poliovirus transmission will be interrupted globally by the end of 2004 or, at the latest, in the first half of 2005. As of mid-2003, there was increasing epidemiologic, programmatic and virologic evidence that transmission would be interrupted within 12 months in Egypt, Niger and Afghanistan. The latter two countries, however, would continue to be at high risk of cross-border importations until transmission stopped in the adjacent reservoir countries of Nigeria and Pakistan. Although there is a much higher risk of indigenous polio continuing beyond end-2004 in Nigeria, India and Pakistan, data from all three countries demonstrate that transmission could stop within that period if there is sufficient political will, oversight and accountability. Large areas of all three countries have been free of indigenous poliovirus transmission for over 12 months, demonstrating that the strategies can work rapidly when properly implemented in these

countries. However, successfully building on this close political oversight will require the continued development of appropriate local responses to specific challenges as they arise, such as the anti-OPV campaign in northern Nigeria in 2003, the limited access to conservative tribal groups in parts of Pakistan and the persistent polio immunity gap among underserved populations in India. In those limited endemic areas which are still affected by conflict or insecurity, strategy implementation will continue to depend on establishing, at least temporarily, a safe working environment.

In India the marked increase in the number (6) and quality of annual NID/SNID rounds following the 2002 outbreak has substantially reduced the immunity gap[10] in children from underserved communities (from 42% in 2002 to just 13% in 2003) and, in 2003, was associated with the lowest mid-year levels of transmission ever. With continued attention to reaching very young children and underserved populations in late 2003, particularly in the northern states of Bihar, Uttar Pradesh and West Bengal, transmission could be interrupted in 2004. Of particular concern is western Uttar Pradesh, the only area in India where transmission has never been interrupted and where substantial numbers of children are still missed during SIAs. Major challenges to achieving the necessary level of SIA quality include ensuring programme continuity given the ongoing changes among senior health and political authorities in the country, heightening district level accountability for the performance of immunization teams, and expanding the ongoing efforts to reach all children in underserved populations. This work in endemic areas will need to be matched by faster, larger, high-quality mop-up responses to importations into polio-free areas, such as occurred in West Bengal in 2002 and Andhra Pradesh and Karnataka in 2003.

In Pakistan, a sufficient number of NIDs/SNIDs have been planned to interrupt transmission by the end of 2004. However, ongoing gaps in SIA quality, particularly in districts of northern Sindh and the North West Frontier Province (NWFP), could leave a substantial number of children unimmunized and compromise the impact of these activities. The mid-2003 decision of the President of Pakistan to personally monitor progress should substantially improve accountability in these areas. Because of the gaps in the formal health services in these geographic areas, further improvements in SIA quality require enhanced engagement of the local political leadership to mobilize the non-health transportation, human and communications resources necessary to reach every child. Of particular importance will be fully implementing the policy of having at least one woman (e.g. the local Lady Health Worker) on every vaccination team to ensure all communities and households can be visited to search for highest risk, unimmunized, very young children during iSNIDs. The Federally Administered Tribal Areas (FATA) will require special attention to build the necessary oversight and accountability by local political and community leaders.

As of mid-2003, the greatest risk to the end-2004 global target was Nigeria, due to the intensity of transmission in the northern states and the spread to recently polio-free areas both within and outside the country. This exacerbation of transmission was caused by a combination of substantial, ongoing gaps in SIA quality and the cancellation of key immunization activities in late-2003. Of particular concern at mid-2003 were data demonstrating that the polio immunity gap among children in some northern states, particularly Kano, was still >50%. Rapidly closing this immunity gap will require: (1) enhancing the microplanning, social mobilization, logistics and vaccination team supervision during SIAs, (2) addressing ongoing community concerns as to the safety of OPV following widespread rumours and comments to that affect, and (3) ensuring state and district level authorities are fully engaged in these activities. To facilitate this work, the polio partners have enhanced their technical assistance to the key states in coordination with federal authorities and provided extensive background materials to address concerns over vaccine safety.

**Frequency of circulating vaccine-derived poliovirus (cVDPV) outbreaks:**

The second major assumption underpinning this plan is that cVDPVs will continue to be rare events requiring only intermittent OPV mop-up campaigns to stop transmission rather than

[10] Immunity gap: percentage of children (non-polio AFP cases) receiving < 4 doses of OPV.

extensive, preventive SIAs to limit their emergence. This assumption is based on the available data, primarily from the global AFP surveillance and polio laboratory network, which has detected an average of only one cVDPV outbreak each year in the period 1999–2002, with a total of 28 cases. During the period 1999 to June 2003, the laboratory network screened over 11 000 polioviruses worldwide, 7000 of which were Sabin-related, usually isolated as a coincidental finding during the investigation of AFP cases (29 were from the 3 cVDPV outbreaks, 3 were from iVDPVs and 12 were "other" VDPVs of ambiguous origin).

Although cVDPVs appear to be rare events, the 3 recent episodes in Hispaniola, Madagascar and the Philippines have occurred under circumstances which could become more prevalent in the period 2004–2008 and thus lead to additional outbreaks. For example, common to all of these episodes was the absence of indigenous wild poliovirus, low routine OPV3 coverage and the cessation of supplementary OPV immunization activities. With the revised tactical approach in 2003 to interrupt wild poliovirus transmission, an increasing number of countries with low OPV3 coverage will stop polio SIAs in 2004–2005. It is anticipated that this decline in SIAs coverage will be in part compensated by an increase in routine OPV3 as GAVI enhances its efforts to increase coverage as laid out in its Strategic Framework for that period. Further emphasis will be placed on the inclusion of the birth dose of OPV, particularly in low coverage areas. In addition, there will be a heightening of surveillance and closer scrutiny of the VDPVs which are detected through AFP and other surveillance activities, to better understand the risk factors for, and frequency of cVDPVs.

Consequently, although the incidence of cVDPV events could increase as a result of the reduction in SIAs globally, it is anticipated that they will continue to be rare. However, the global TCG will by 2005 revisit its recommendations on the need for additional SIAs to prevent the emergence of cVDPVs. ❐

## 4.2 Objective 2: Achieve Certification of Global Polio Eradication

*THE process for certification of the global eradication of poliomyelitis has been validated through the experience of the three WHO regions that had been certified polio-free by end-2003. The global certification process is threatened, however, by ongoing gaps in surveillance quality in the three remaining endemic regions, declining surveillance sensitivity within the three regions that have already been certified, and incomplete implementation of the Global Action Plan for the Laboratory Containment of Wild Polioviruses (GAP II). In addition to interruption of wild poliovirus transmission worldwide, achieving global certification by 2008 requires rapidly addressing persistent surveillance gaps in 19 countries of Africa, the Eastern Mediterranean and South-East Asia.[11] Countries in regions which have already been certified must maintain certification-standard surveillance and high immunity levels against poliovirus. All countries must have established national plans of action for rapidly responding to wild poliovirus importations and cVDPVs and have completed Phase II containment activities. Vaccine manufacturers producing inactivated poliovirus vaccine (IPV) from wild poliovirus strains must have implemented enhanced biosafety procedures.*

### Strategic Approach:

In 1997, the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC) finalized the criteria for certifying whether the goal of polio eradication is achieved. In summary, certification of the interruption of wild poliovirus transmission is conducted on a regional basis. Each of the 6 Regional Certification Commissions (RCCs) could consider certification only when all countries in that area had submitted the appropriate documentation demonstrating the absence of wild poliovirus transmission for at least three consecutive years in the presence of excellent surveillance. The GCC further stated that for endemic and recently endemic countries, the notification and investigation of AFP cases would be the accepted standard for the purposes of certification. AFP surveillance would be of "certification standard" if three performance criteria were achieved. First, the system should detect at least one case of non-polio AFP for every 100 000 population aged less than 15 years. Second, two adequate diagnostic specimens[12] should be collected from at least 80% of AFP cases. Third, all specimens should be processed at a WHO-accredited laboratory.

For certification of *global* polio eradication, the GCC established the further criteria that all facilities holding wild poliovirus infectious and potentially infectious materials must have implemented appropriate biocontainment measures. The process of laboratory containment was developed through international consultation. A draft action plan was widely distributed for comment in 1998 prior to publication as the *Global Action Plan for Laboratory Containment of Wild Polioviruses* (WHO/V&B/99.32) in 1999, with a second edition in 2003.[13] The plan outlines phased activities to minimize the risk of reintroduction of wild polioviruses from diagnostic and research laboratories to the community. Phase I requires all countries to conduct a national search for laboratories and to create an inventory of those identified as holding wild poliovirus or potentially infectious materials. RCCs have included phase I activities as a component of the regional certification requirements. Phase II requires that laboratories listed on national inventories destroy wild poliovirus materials or maintain them under appropriate biosafety conditions. For manufacturers of IPV produced from wild polioviruses, specific guidelines defining biosafety requirements following the interruption of transmission of wild polioviruses were developed and finalized in 2003 through a collaborative process with national regulatory authorities and biosafety professionals. Global certification will require the implementation of these requirements in all countries where IPV production continues.



[11] Of these 19 countries, 7 had a population of less than 1 million people and were unlikely to sustain undetected wild poliovirus transmission.
[12] Adequate diagnostic specimens: Two stool specimens collected at least 24 hours apart, within 14 days of onset of paralysis and received in good condition at the laboratory.
[13] *WHO Global Action Plan for Laboratory Containment of Wild Polioviruses. Second edition.* World Health Organization, Geneva, 2003 (WHO/V&B/03.11).

## Situation Analysis:

As required by the GCC, RCCs have been established to oversee the process of reviewing national surveillance and containment documentation in each of the six WHO regions. National certification committees (NCCs) have been established in all countries to collate and verify the necessary information.[14] As of mid-2003, three of the six WHO regions had been certified polio-free. These regions included the 46 countries of the Americas in 1994, the 34 countries of the Western Pacific in 2000 and 51 countries of Europe in 2002. Although the three remaining "endemic" regions have achieved "certification-standard" surveillance at the regional level, 19 of the 82 countries in those regions had yet to achieve this standard at the national level during 2003 (10 in Africa, 7 in the Eastern Mediterranean, 2 in South-East Asia) (Table 3). Within a number of other countries the quality of surveillance was not uniform and did not meet the certification criteria for high quality subnational data. Figure 3 summarizes the status of national AFP surveillance indicators in endemic and certified regions. Figure 4 illustrates the worldwide network of 145 virology laboratories which forms the backbone of global AFP surveillance,[15] arranged in a hierarchical structure of national (123), regional (15) and global specialized (7) facilities. High quality performance is assured through annual proficiency testing, a formal accreditation programme, and ongoing evaluation using standard indicators. In 2002, 99% of the network laboratories were accredited by WHO; 100% of specimens were tested in a WHO-accredited laboratory by referring samples from countries where facilities were not accredited.

In mid-1999, the WHA urged all Member States "to begin the process leading to the laboratory containment of wild poliovirus".[16] As of mid-2003, 148 (68%) countries and territories had begun or completed their listing of

**Table 3: Countries not achieving one or more of the AFP Performance Indicators required for certification-standard surveillance in 2003 (data available as of 4 November 2003)**

| Region | Country | AFP cases reported (2003*) | Non-polio AFP rate | AFP cases with adequate specimens (%) |
|---|---|---|---|---|
| AFR | Algeria | 28 | 0.40 | 89 |
| | Botswana | 14 | 2.70 | 71 |
| | Cameroon | 81 | 1.30 | 77 |
| | Cape Verde* | 3 | 2.00 | 67 |
| | Equatorial Guinea* | 11 | 7.30 | 73 |
| | Liberia | 10 | 0.60 | 90 |
| | Madagascar | 65 | 1.30 | 71 |
| | Mozambique | 93 | 1.60 | 71 |
| | Sao Tome and Principe* | 1 | 1.70 | 0 |
| | Sierra Leone | 28 | 1.70 | 79 |
| EMR | Bahrain* | 1 | 0.59 | 0 |
| | Cyprus* | 1 | 0.70 | 100 |
| | Djibouti* | 1 | 0.48 | 0 |
| | Kuwait | 2 | 0.43 | 100 |
| | Lebanon | 18 | 2.37 | 72 |
| | Somalia | 85 | 3.09 | 78 |
| | West Bank and Gaza | 5 | 0.47 | 60 |
| SEAR | Bhutan | 3 | 1.24 | 67 |
| | Maldives* | 1 | 0.73 | 100 |

**Comoros, Mauritius, Reunion, Saint Helena, Seychelles and Timor-Leste did not report AFP cases in 2003 due to small populations.**
**Data in HQ as of 4 November 2003.**
**Red indicates targets not achieved.**
**Green indicates targets achieved during 2002.**
***Total population <1 million, unlikely to have sustained, undetected indigenous transmission of wild polioviruses.**
**Population Data source: United Nations Population Division, Department of Economic and Social Affairs, World Population Prospects the 2002 revision.**

[14] For the very limited number of geographic areas without a recognized national health authority (e.g. Somalia), the GCC has requested that WHO and UNICEF assume responsibility for coordinating the collection, verification and submission of the documentation required for certification.

[15] The number and distribution of network laboratories are: 8 in the Americas, 16 in Africa, 12 in the Eastern Mediterranean, 48 in Europe, 17 in South-East Asia and 43 in the Western Pacific.

[16] Fifty-second World Health Assembly. *Poliomyelitis eradication*. World Health Organization, Geneva, 1999 (resolution WHA52.22).

biomedical laboratories as part of the Phase I containment activities. This number included several large industrialized countries such as Australia, Canada, Germany and the United States of America. Worldwide, over 100 000 laboratories had been identified for surveying and 80 countries (37%) had finalized an inventory of laboratories storing wild poliovirus materials. For IPV production facilities using wild poliovirus at these sites, consensus has been reached on the need for BSL-3/polio level containment in all existing facilities, with implementation and verification activities planned for completion in 2007–2008.

### Expected Results:

**1. "Certification-standard" surveillance:**
***a) Polio-endemic regions:*** The highest priority will be to achieve and sustain certification-standard surveillance at the national level in the 19 countries of the endemic regions which did not achieve this level in 2002. Substantial work will also be required to identify and close gaps in AFP performance at the subnational level in the large countries which are currently or recently endemic (Table 3). The polio partnership will support national efforts to improve AFP surveillance through targeted technical assistance at the national and subnational levels and, where necessary and appropriate, external financing of equipment and operating costs. Attention will be given to improving the speed of surveillance and virologic data analysis and feedback at the country and regional levels, especially to meet the performance indicators for emergency response mop-ups in all regions. Joint national/international AFP surveillance reviews will continue to guide improvements.

***b) Regions certified as polio-free:*** Assisted by RCCs and National Certification Committees (NCCs), countries in certified regions should sustain polio-free status by maintaining certification-quality surveillance, achieving the highest possible immunity levels against wild poliovirus, and developing plans of action for rapidly reacting to importations of wild poliovirus. Priority will be given to identifying high-risk countries or areas where AFP surveillance sensitivity has markedly declined and/or from where enhanced AFP or supplementary surveillance data may be required for the purposes of global certification. From 2005-2006, partnership resources will increasingly be targeted to address those areas. At the same time, increased attention will be given to integrating AFP reporting into appropriate national surveillance mechanisms, if this intergration has not already been done, or expanding the AFP surveillance capacity to detect and investigate other diseases of public health importance (see section 4.4).

**2. Global access to a WHO-accredited laboratory:** The priority in this area of work will be to reduce the time required for intratypic differentiation (ITD) results to be available from endemic areas; ITD capacity will be established in all countries with major poliovirus reservoirs. For all other areas the priority will be to sustain, through global certification and OPV cessation, the international capacity that now exists to process all specimens from AFP cases in WHO-accredited laboratories. Consequently, emphasis will be given to maintaining rather than expanding the existing laboratory network, with targeted support to the small number of network laboratories which have yet to achieve accreditation. Special advocacy will be required, particularly from 2006 onward, to ensure that the national public health institutions which house the global polio laboratory network, but have a much broader mandate, continue to designate sufficient human resources, facilities and equipment to polio eradication work. During this same period, it is anticipated that the work of the polio laboratory network will actually *increase*, as it accommodates demands for supplementary virologic data in advance of global certification. These data requirements (e.g. targeted environmental surveillance) will be defined with the GCC during the period 2004–2005.

**3. Containment of wild polioviruses and VDPVs:** The priority in this area will be the further dissemination and national level implementation of the activities outlined in the second edition of the *Global Action Plan for Laboratory Containment of Wild Polioviruses* (2003). Particular attention will be given to completing the laboratory survey and inventory activities in all polio-free countries and preparing for implementation of phase II laboratory containment activities prior to global certification. From the end of 2005, the date by which wild poliovirus transmission should have been interrupted for at least one year, phase II

**Figure 3:** **AFP Performance Indicators 1 January 2003 – 25 November 2003**

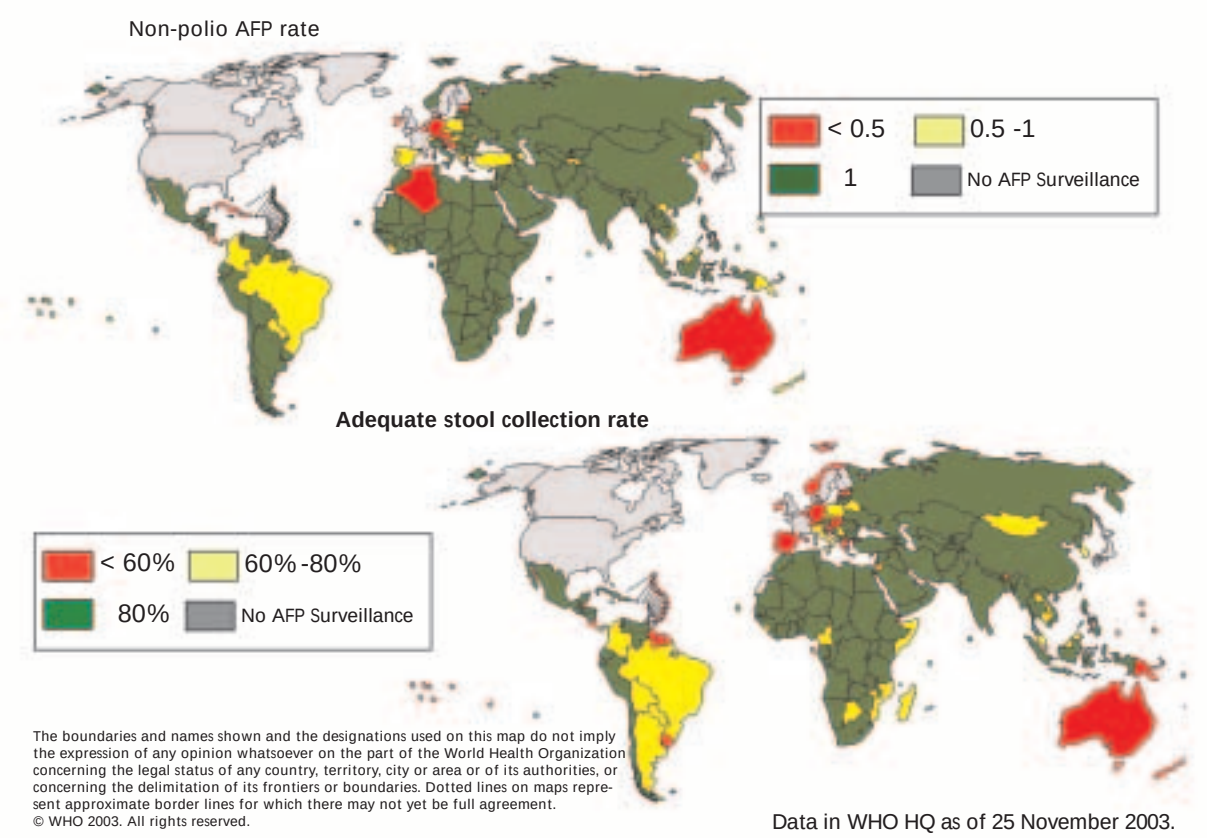
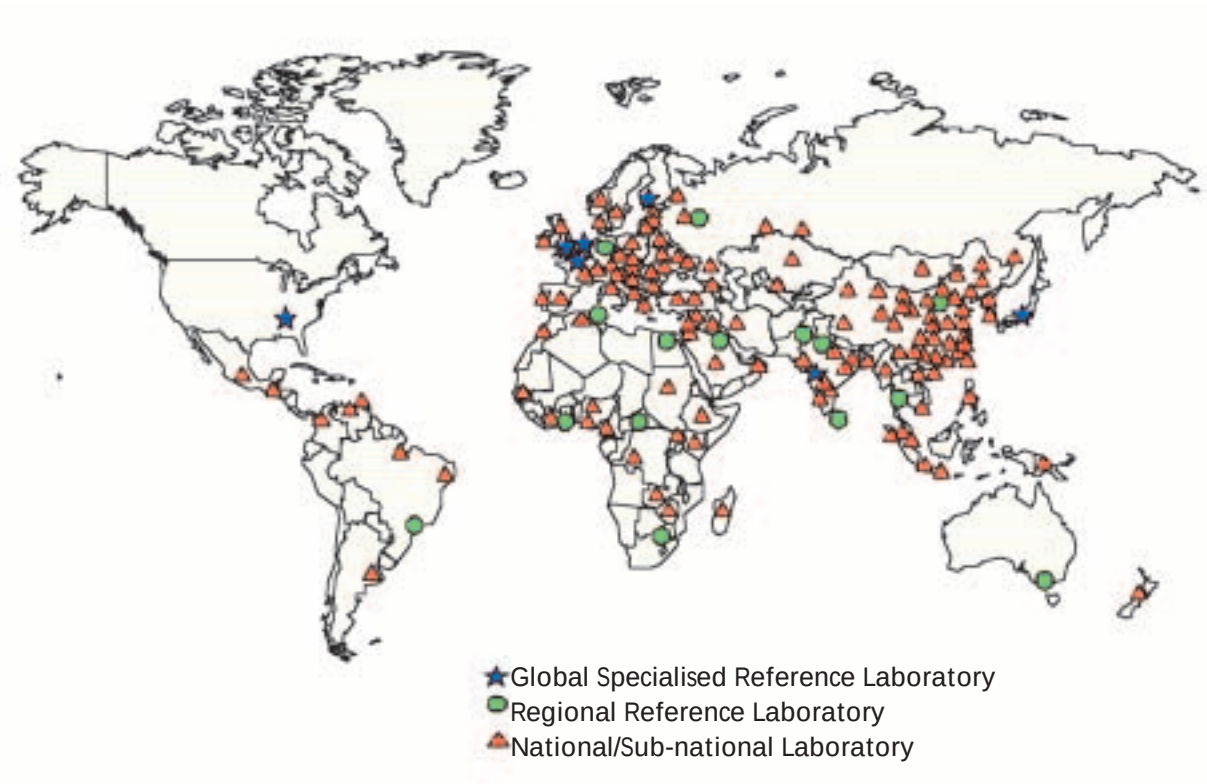



**Figure 4:** **Global laboratory network for polio eradication, 2002**



containment activities will be initiated in all countries, with particular emphasis on large industrialized countries which contain the largest stocks of wild poliovirus.

BSL-3/polio containment will be completed in facilities producing IPV from wild poliovirus, followed by the necessary validation activities and licensure by national regulatory authorities. During this period the GCC, in consultation with appropriate biosafety and other expert bodies, will establish the national, regional and global level procedures needed for reviewing and verifying the containment documentation submitted by each country as part of the certification process. Particular attention will also be given to verifying the thoroughness of national laboratory surveys to identify potentially polio-infected materials, such as specimen collections from places and periods when wild poliovirus was endemic. The process for developing long-term containment requirements for wild and attenuated poliovirus strains is outlined in section 4.3.

**4. Completion of the certification processes:** The priority in this area will be to support the work of RCCs in the three remaining endemic regions as they complete the process of training NCCs and then collect, review and decide on national documentation through an intensive series of consultations. Particular attention will be given to supporting the work of the RCC for Africa, given the large number of countries for which it is responsible. At the global level, by the end of 2005 the GCC will seek to have finalized a number of issues related to its operations, particularly (a) the additional data that will be required for global certification from the three regions which had been certified polio-free by end-2002, (b) the extent and role of environmental surveillance as a supplementary strategy prior to global certification, and (c) the mechanisms/ procedures for reviewing and verifying documentation on containment of laboratory stocks and IPV production. WHO and partners will continue to support the work of the commissions by convening or facilitating the necessary meetings, expert consultations, field visits and other activities of these bodies. ❐

## Objective 2: Achieve Certification of Global Polio Eradication

### Indicators and Milestones

| | Milestones | | | | |
|---|---|---|---|---|---|
| *Indicators* | *2004* | *2005* | *2006* | *2007* | *2008* |
| Percentage of non-certified countries with certification-standard surveillance | 85% | 90% | 100% | 100% | 100% |
| Percentage of AFP specimens processed in a WHO-accredited laboratory | 100% | 100% | 100% | 100% | 100% |
| Percentage of countries completing each laboratory biocontainment phase | 50% (phase I) | 75% (phase I) | 100% (phase I) | 100% (phase II) | 100% (phase II+) |
| Percentage of manufacturers producing wild-type IPV under BSL-3/polio | NA | NA | NA | 60% | 100% |
| Percentage of countries submitting "final" certification documentation | 60% (regional certification) | 70% (regional certification) | 85% (regional certification) | 100% (regional certification) | 100% (global certification) |

## 4.3 Objective 3: Develop Products for the Global OPV Cessation Phase

*SINCE 2000, polio outbreaks caused by vaccine-derived polioviruses (VDPVs) have conclusively demonstrated that the continued use of the OPV for routine immunization could compromise the goal of eradicating all paralytic disease due to circulating polioviruses. To minimize the long-term risks associated with OPV, the world must stop the routine use of this vaccine as soon as possible after global certification, while surveillance sensitivity and population immunity are high. Although trivalent OPV will continue to be the vaccine of choice for routine immunization for the Global Polio Eradication Initiative up to 2009, stopping OPV requires the development of a range of other products during the period 2004–2008. A third edition of the Global Action Plan for the Laboratory Containment of Wild Polioviruses will be needed by 2006, specifying the biosafety requirements for wild polioviruses, VDPVs and Sabin-strains in the Global OPV Cessation Phase of the programme (i.e. 2009 & beyond). Monovalent OPV (mOPV) will need to be licensed and stockpiled to complement or even replace the current "rolling stockpile" of trivalent OPV. The manufacture of IPV from Sabin strains (S-IPV) will be encouraged, as will the production and licensing of appropriate IPV-containing combination vaccines for those middle- or low-income countries which might choose to introduce such a vaccine. Because of the long-term risks of wild poliovirus re-introduction, the ongoing need for an OPV stockpile, and the probable future production of S-IPV, OPV production capacity will be needed indefinitely. During this period, every country must plan for the cessation of OPV use and decide whether or not to introduce IPV; countries deciding to introduce IPV must make provision for its procurement. Recognizing the challenges to developing and introducing new products, this work will be closely coordinated with GAVI.*

### Strategic Approach:

The broad policy objective for the Global OPV Cessation Phase is to minimize the risks of paralytic poliomyelitis for current and future generations at the lowest possible cost. The cessation of routine immunization against smallpox following the eradication of that pathogen in 1977 established an expectation that immunization against polio can also stop after the interruption of wild poliovirus transmission and the containment of laboratory stocks and vaccine production facilities. The smallpox experience has offered important insights into the range of issues that arise in the development of such policy. However, the issue is substantially more complex for polio due to a variety of reasons, including differences in the characteristics of the vaccines used and in the geopolitics of the era in which each eradication campaign has been conducted.

Consequently, the focus of this area of work has been to first define and quantify the risks of paralytic poliomyelitis following global certification, due to either the continued use of the OPV or the continued handling of wild polioviruses or potentially infectious materials. An agenda of research and programme work was established to inform this risk framework and to study potential strategies for their mitigation. Particular attention was given to defining the financial costs, economic implications, technical and regulatory feasibility, and operational practicality of each potential strategy. Recognizing the implications of this evolving work for polio eradication stakeholders, as well as the international health community, a consultative process was initiated to better understand these influences. A communications programme of work was established to ensure the wide dissemination of relevant scientific and programmatic data on both the risks following certification and their management as additional information became available.

In April 2003, the global TCG stated that stopping OPV would require new policies in four interrelated areas: (1) routine immunization, (2) detection and notification of circulating polioviruses as public health emergencies, (3) polio vaccine stockpiles and outbreak response mechanisms, and (4) long-term biocontainment of all poliovirus strains.

### Situation Analysis:

In 1998, a WHO-convened expert consultation on the scientific basis for stopping polio immunization concluded that given the rare but

predictable risk of vaccine-associated paralytic poliomyelitis (VAPP), the use of OPV for routine immunization should eventually stop once wild poliovirus transmission was interrupted, wild poliovirus stocks were properly contained and there was assurance that VDPV circulation would not persist. Following the confirmation in 2000 that VDPVs could indeed persist, circulate and cause polio outbreaks, subsequent consultations identified three potential options for stopping routine OPV immunization: coordinated cessation of OPV globally (possibly following immunization campaigns in low coverage areas), phased replacement of OPV with IPV for routine immunization (for at least an interim period), and the development and introduction of a new polio vaccine for routine immunization. In the same year an expert review of new vaccines for the Global OPV Cessation Phase outlined substantial manufacturing challenges and regulatory hurdles to introducing a new poliovirus vaccine. Since then the polio research agenda has focused on the feasibility and effectiveness of the first two options.

In 2001, the global TCG established an ad hoc Committee for Poliomyelitis Research to provide additional oversight of the ongoing research for post-certification policy development. By late-2002 this research had progressed to the point where the global TCG could endorse a framework of the risks of paralytic poliomyelitis after global interruption of wild poliovirus transmission. The framework classifies these risks into two categories: those due to the continued use of OPV and those due to future improper handling of wild polioviruses. The specific risks within both categories were defined, with working estimates of the frequency and potential burden of disease associated with each (Table 4). From 2001, a briefing kit on the potential risks, and post-certification policy in general, has been widely disseminated among national health authorities, polio partners, other stakeholders and interested bodies. These materials were updated in 2003 as additional information on risks following certification became available and the processes for policy development were further clarified. In 2003, WHO also published a position paper on the introduction of IPV into OPV-using countries to assist the growing number of countries, particularly in polio-free regions, which were considering or implementing a change to IPV for routine immunization, primarily due to national assessments that the risk of VAPP was increasingly unacceptable.

**Table 4: Risks of paralytic poliomyelitis following global certification***

| Risk category | Risk | Frequency | Estimated global annual burden** |
|---|---|---|---|
| Risks of polio paralysis from continued use of oral polio vaccine | VAPP (vaccine-associated paralytic polio) | 1 in 2.4 million doses of OPV administered | 250–500 cases per year |
| | cVDPV (circulating vaccine-derived polio) | One episode per year in 1999–2002 (Haiti, Madagascar, the Philippines) | Approx. 10 cases per year (total of 29 cases in three years) |
| | iVDPV (immuno-deficient excretors of vaccine-derived polio) | 19 cases since 1963 with 2 continuing to excrete; no secondary cases | <1 case per year |
| Risks of paralysis from mishandling of wild poliovirus | Inadvertent release from a laboratory | None to date | |
| | Inadvertent release from an IPV manufacturing site | One known event in early 1990s | No cases |
| | Intentional release | None to date | |

** Study and data collection is ongoing for all categories*
*** Under current polio immunization policies*

Among the key developments in the area of public consultation was a 2002 meeting at which a wide range of policy-makers from diverse backgrounds reaffirmed the international expectation, particularly among low- and middle-income countries, that routine polio immunization would eventually stop. Of equal importance was the September 2003 international consultation on vaccine-derived polioviruses which concluded that VDPVs posed a real risk to the global goal of eliminating paralytic poliomyelitis due to circulating polioviruses. That meeting further concluded that this risk would continue as long as OPV continued to be used, particularly in areas of low routine immunization coverage.

In 2003, the Global Polio Eradication Initiative was operating with a rolling stockpile of 50 million doses of trivalent OPV for responding to wild poliovirus outbreaks and cVDPVs, with a planned expansion to 75 million doses for the period 2006–2008 (as outlined below, prior to the cessation of routine OPV immunization a significantly larger stockpile of mOPV will be required). By late-2003, as a result of the above-mentioned scientific research, programme work and consultations, the Global Polio Eradication Initiative was working toward the cessation of routine immunization with OPV as soon as possible after global certification. This goal required enhancing the work to license mOPV for the vaccine stockpile, as mOPV would allow a type-specific response to cVDPVs or containment failures and thus limit the number of serotypes reintroduced to human populations. The implications of OPV cessation also led to an expanded programme of work to mainstream the

polio vaccine stockpile and response activities within WHO and UNICEF and to evaluate further the potential large-scale production of IPV from attenuated (e.g. Sabin) poliovirus strains. Finally, as WHO-coordinated research had indicated that more potent poliovirus antiviral compounds could be developed, the Global Polio Eradication Initiative continued to explore the potential role such products might have in enhancing flexibility in outbreak response scenarios.

### Expected Results:

**1. Strategy for cessation of routine immunization with OPV:** The priorities in this area of work will be to (a) refine existing estimates of the frequency and risk associated with each type of VDPV which could emerge with OPV-cessation, including the geographic areas or demographic groups at highest risk (especially for cVDPV), (b) establish standard strategies and operating procedures for responding to circulating poliovirus after OPV cessation, (c) develop local strategies to reduce specific VDPV risks (i.e. iVDPVs,[17] VDPVs in orphanages), (d) evaluate seroconversion rates, operational feasibility, costs and production capacity of IPV, alone and in combination, for low- and middle-income settings, (e) maintain the capacity to restart large-scale OPV-use if required, and (f) define the most cost-effective strategy for the coordinated cessation of OPV. Because minimizing the risk of VDPV emergence and spread at the time of OPV cessation requires high surveillance sensitivity and population immunity, these priorities must be sufficiently addressed by 2006 to allow implementation to begin.[18] Such a timeframe is needed to ensure that those countries which will want to switch to IPV on an interim or long-term basis are able to secure the necessary vaccine and financing. To facilitate decisions on post-OPV vaccination policies, from 2004 onwards, there will be extensive consultation, particularly with OPV-using countries, on the risks associated with OPV cessation. Further materials will be developed to assist countries in deciding whether or not to introduce IPV and if so how (e.g. guidelines, policy directives). Standard protocols will be implemented to study some of these experiences. Additional work will be conducted to ensure sufficient IPV capacity. Given the risks associated with IPV production using wild polioviruses, the development of IPV products based on attenuated (e.g. Sabin) strains of poliovirus will be encouraged.

**2. Detection and notification of circulating polioviruses:** With the elimination of wild poliovirus transmission globally, the detection of any circulating poliovirus must be treated as an international public health emergency to ensure it is contained with a rapid response. Consequently, routine AFP reporting and investigation will need to be supplemented by additional measures to facilitate the rapid detection and immediate notification of such events to national and international health authorities. AFP reporting will also need to be aligned with other WHO activities aimed at identifying events of international public health importance. Enhanced surveillance will be particularly important to detect potential cVDPVs, during and immediately after OPV cessation. Within one year of the last case of wild poliovirus, the reporting of any circulating poliovirus will be incorporated into existing mechanisms for dealing with events of international public health importance, such as the WHO International Health Regulations and the Global Outbreak Alert and Response Network (GOARN). The ongoing polio research agenda will continue to explore new diagnostics, tools and strategies for surveillance following global certification, including the potential role of targeted environmental sampling.

**3. Polio vaccine stockpiles and their management:** By the end of 2003 the international rolling stockpile of trivalent OPV for responding to wild poliovirus importations and/or cVDPVs consisted of 50 million doses of trivalent OPV. This stockpile will grow to 75 million doses as supplementary immunization campaigns are phased out in the period 2006–2008. Both the number of doses and range of polio vaccines in this stockpile will expand in advance of the cessation of OPV for routine immunization. The number of doses required for the stockpile over time will be calculated using a combination of national immunization policy and coverage data and modelling of the possible spread of reintroduced wild poliovirus after OPV immunization has stopped. As noted above, mOPV will be required to ensure a type-specific

[17] iVDPVs = individuals with primary immunodeficiency syndromes who are long-term excretors of vaccine-derived polioviruses (i.e. > 6–12 months).
[18] The experience from polio-free regions demonstrates that both surveillance sensitivity and polio immunization coverage begin to decline soon after certification (the latter due primarily to the cessation of supplementary OPV immunization activities).

response to cVDPVs or containment failures. IPV stocks may be required for country(ies) which have chosen to forego routine immunization against polio but are considered at risk of due to a cVDPV or containment failure in another country. OPV stocks and production capacity will need to be maintained in case routine immunization against polio must be reinstituted globally. The priorities in this area of work are the licensure of mOPV, finalization of the target number of stockpile doses for each vaccine during OPV cessation (and how these will change over time relative to population immunity), long-term containment requirements for IPV and OPV production, and the development of sustainable operating procedures to govern the maintenance and use of the stockpiles. The Global Polio Eradication Initiative will also continue its work to support the development of candidate poliovirus antivirals and public health strategies for their use which might enhance the flexibility of outbreak response options.

**4. Long-term containment of poliovirus stocks:** Following global certification, containment issues become more complex as the biosafety requirements for the handling of all poliovirus strains are increased. Wild and vaccine-derived polioviruses in particular will need to be handled similar to other serious pathogens which are under strict containment. In the period 2004–2005 a third edition of the Global Action Plan for the Laboratory Containment of Wild Polioviruses (GAP III) will be developed to deal with containment in the Global OPV Cessation Phase. The development of this plan will be used to establish international consensus on the timeframe and mechanisms for ensuring that the containment requirements for laboratory stocks of wild poliovirus and VDPVs are appropriate to the risks. The plan will also be used to define the additional requirements, in advance of OPV cessation, needed to protect against silent infection of production staff in sites which manufacture IPV. In contrast to GAP II, GAP III will also be used to establish consensus on the relevant biosafety levels for handling Sabin and Sabin-derived poliovirus strains during the Global OPV Cessation Phase. Requirements will be developed for laboratories and vaccine production sites, including those which produce IPV from well-characterized attenuated strains. During the period from 2006 onward, tools and capacity will be developed for ensuring that containment requirements are maintained in the long term in all laboratories and vaccine production facilities that hold polioviruses. The longterm monitoring of containment implementation will be aligned with the processes already in place for other pathogens which are subject to high biosafety levels. ❐

## Objective 3: Develop Products for the Global OPV Cessation Phase

### Indicators and Milestones

| | Milestones | | | | |
|---|---|---|---|---|---|
| *Indicators* | *2004* | *2005* | *2006* | *2007* | *2008* |
| Cessation of OPV for routine immunization | Guidelines and consultations on "post-OPV" options | Introduce local strategies to reduce VDPV risk | Consolidate OPV cessation strategy and national IPV decisions | Introduce protocols for cVDPV response in post-OPV era | Finalize introduction of long-term immunization policies |
| Detection and immediate notification of circulating polioviruses | Define strategies to rapidly detect circulating viruses | Assess feasibility of incorporation into IHR/GOARN* | Incorporate polio surveillance into IHR and GOARN | Begin environment sampling (if/where appropriate) | Finalize additional tools for surveillance (if applicable) |
| Polio vaccine stockpiles and emergency response ` | Align management with other stockpiles (yellow fever, meningitis, smallpox) | Define mOPV, IPV and trivalent OPV stockpile sizes for post-OPV era | Licensure of at least two mOPV suppliers | Establish contracts for mOPV stockpile | Begin assembly of mOPV stockpile |
| Long-term containment of poliovirus stocks | Research and consult on requirements for Global OPV Cessation Phase | Publication of third edition of Global Action Plan (GAP III) | Fully align with security processes for similar pathogens | Licensure of at least one IPV product from Sabin strains | Begin implementation and verification of GAP III |

* IHR = International Health Regulations; GOARN = Global Outbreak and Alert Response Network.

## 4.4 Objective 4: Mainstream the Global Polio Eradication Initiative

*THE Global Polio Eradication Initiative has supported the delivery of other health services, particularly since the mid-1990s, through such activities as vitamin A supplementation, integrated disease surveillance, refurbishment of routine immunization services, and, most recently, country-level implementation of the activities of the Global Alliance for Vaccines and Immunization (e.g. new vaccine introduction; immunization services strengthening). During the period 2004-2008, the polio partnership will accelerate the 'mainstreaming' of the Global Polio Eradication Initiative to optimize these broader benefits and to institutionalize the longterm functions of the polio programme. First, the ongoing work to transition or integrate the substantial polio-funded human resources, physical infrastructure and institutional arrangements into other disease control, surveillance and response activities will be enhanced to sustain the broader benefits of the international investment in polio eradication. This work will also minimize the risks that the conclusion of the Global Polio Eradication Initiative might pose for other programmes which rely on its infrastructure. Secondly, the longterm work of polio eradication, particularly in the areas of containment, surveillance, stockpiles and response, will be fully incorporated into existing, sustainable, national, WHO and UNICEF mechanisms and structures that have been established for other important pathogens (NOTE: the relevant milestones for mainstreaming these longterm functions are included under Objective 3).*

### Strategic Approach:

Polio eradication has relied heavily on three major activities: supplementary immunization campaigns, active surveillance with laboratory investigation of cases, and heightened partnership coordination. Throughout the course of the Global Polio Eradication Initiative, substantial effort has been made to use these activities, as well as the resources of the Global Polio Eradication Initiative, to improve the delivery of other health services, where appropriate and feasible.

In the area of SIAs (e.g. NIDs), the emphasis has been on (a) adding other interventions which were epidemiologically appropriate, operationally feasible and could be continued through routine immunization contacts, (b) improving routine immunization services by refurbishing the physical infrastructure (e.g. cold chain), updating health worker training, building data analysis capacity and reinstituting supervisory systems, and (c) increasing community demand for, and awareness of, other health services, particularly routine immunization, through massive social mobilization efforts. The range of interventions that could be added to polio campaigns, however, was often limited by the recruitment of large numbers of community helpers with minimum training in health service delivery. Consequently, the greatest attention was given to vitamin A supplements, which did not require extensive training or an injection and the delivery of which had already been linked to routine immunization contacts. In the area of surveillance, two general approaches have been taken to developing the capacity needed for polio eradication in a way which strengthened surveillance in general. In places with strong disease detection and notification, AFP reporting was integrated, if possible, into that system. In places without such capacity, AFP surveillance was established as a framework for a national integrated disease surveillance system. In the area of partnership coordination, management and support, the specific mechanisms which were developed, such as interagency coordinating committees (ICCs), technical advisory groups (TAGs) and the Advisory Group on Communication for Immunization and Polio Eradication, included in their mandates the strengthening of routine immunization.

To implement the polio eradication activities, the polio partnership invested heavily in human resources, physical infrastructure, and institutional arrangements. Mainstreaming this investment into national immunization and surveillance systems will be critical to ensuring that the experience, lessons and capacity developed through polio eradication continue to benefit these areas, especially the "United Nations General Assembly Special Session/World

Fit for Children" and GAVI goals of increasing routine immunization coverage[19] and the global measles mortality reduction targets.[20] Linkages have also been pursued to transfer the polio experience to the scaling-up of other important interventions, particularly those contributing to millennium development goals (MDGs).

As outlined under Objective 3, in the late 1990s the Global Polio Eradication Initiative began working to ensure that longterm polio-related activities could eventually be incorporated into existing mechanisms that deal with other serious pathogens. For example, since 1997-1998 the WHO Biosafety Advisory Group (BAG) that provides guidance on general international biosafety policy as well as specific expertise in areas such as smallpox, has assisted the development of the global action plans for laboratory containment of wild polioviruses. In 2002, the Global Polio Eradication Initiative began discussing the incorporation of polio into the International Health Regulations (IHR), and since 2003 the Global Outbreak Alert and Response Network (GOARN) has been formally involved in the tracking of, and response to, polio outbreaks.

The longterm maintenance of polio diagnostic laboratory capacity will be particularly important, but also challenging, due to the increasing rarity of the disease and decreasing relevance to national health priorities. Consequently, opportunities are being explored to sustain this national capacity by better intergrating its basic functions with that for either pathogens, while maintaining sufficient international specialized centers for poliovirus.

### Situation Analysis:

By mid-2003, the Global Polio Eradication Initiative had made a substantial impact on the capacity to address other health priorities in many countries. In all WHO regions, technical oversight bodies for polio eradication, known as technical consultative/advisory groups (TCGs/TAGs),[21] were being used to address the broader immunization agenda. Polio-initiated, country-level ICCs became the cornerstone of GAVI's process for providing support and are the model for the Country Coordination Mechanism (CCM) used by the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM). As early as 2001, 91% of the international polio-funded personnel and 100% of the national personnel were already spending an average of 44% and 22% of their time, respectively, on other immunization and health issues in the countries in which they worked.[22] During the five-year period 1996–2000, the polio eradication partnership invested an estimated 20% (i.e. US$ 200 million) of its budget on equipment for routine immunization and surveillance. In Africa alone, as much as 30% of the routine cold chain was replaced with polio funding.

Since 1998, the inclusion of vitamin A supplements in NIDs has averted an estimated 1.25 million childhood deaths and strengthened the links between immunization contacts and micronutrient supplementation. NIDs have also facilitated the piloting of campaign approaches for the delivery of other interventions such as insecticide treated nets (ITNs) for malaria prevention. The surveillance capacity developed for polio has been extensively used to detect and respond to diseases such as measles, neonatal tetanus, meningitis, cholera and yellow fever. In the WHO African Region (AFR), the AFP network has been used as the framework for "integrated disease surveillance" (IDS). By 1998, 86% of AFR countries had included measles and neonatal tetanus and 60% cholera and meningitis. In the Americas, surveillance for polio and measles has been closely integrated since 1994. Since 2001, WHO and UNICEF have begun systematically training polio-funded staff in key countries to assist with the implementation of the RED strategy to boost routine coverage.

Because of the increasing reliance of other international health programmes, particularly the polio-funded human resources, the Global Polio Eradication Initiative began in 1999-2000 a series of discussions on the longterm role that these resources might play in the work of GAVI and other communicable disease surveillance and control initiatives. Recognizing that the potential utility of the polio-funded human resources network went beyond immunization, in 2003 the Global Polio



[19] By 2010, routine immunization coverage of children under one year of age at 90% nationally, with at least 80% coverage in every district or equivalent unit.
[20] Reduce measles deaths by 50% by end-2005, compared to 1995 levels.
[21] TCGs/TAGs: these annual or semi-annual meetings bring together expert advisers, researchers, field staff, national programme managers and partner agencies to assist strategy development, guide policy and set operational priorities.
[22] WHO Polio Staff Survey 2001.

Eradication Initiative also started discussing the possibility of sharing activities and costs with other important health programmes such as the GOARN and the WHO and UNAIDS '3 x 5 Initiative'. From late 2003 the programme began working with the WHO Country Focus department to establish a set of pilot countries for evaluating the feasibility of expanding the work of this network in line with country-defined communicable disease priorities for WHO technical assistance, with a particular emphasis on the control of vaccine-preventable diseases.

Despite the increasing work to share costs with other programmes, by the end of 2003, many non-polio activities had become even more highly dependent on the polio eradication activities, funding and/or infrastructure. To minimize the risks inherent in this dependence, these activities, particularly those which are closely intertwined with polio campaigns (e.g. GAVI, vitamin A supplementation), must be "mainstreamed" into routine programmes within countries, WHO and UNICEF.

### Expected Results:

**1. Transition polio "campaign" elements to routine immunization programmes:** The overriding goal of this area of work will be to ensure full functional integration of the routine immunization and polio eradication infra-structures at the country level (e.g. human resources, equipment, institutional arrangements, vitamin A delivery). Such integration will help ensure that the strategic approaches and processes established for polio eradication bring district level microplanning, social mobilization and "data for decision-making" capacity for routine immunization to the levels achieved for polio campaigns. The work to develop country-specific plans for this integration will continue, with particular attention to the 15 large and/or conflict-affected countries where almost 85% of the polio human resources have been deployed. This work will be closely coordinated with the GAVI Strategic Framework 2004–2005, as the priority countries outlined in that framework closely align with those where the polio infrastructure is most extensive. As the country-specific planning advances, tools will be developed to facilitate the additional training needs for this broader programme of work. At the global level, the polio communication tools will be expanded and updated (i.e. websites, newsletters, media releases, progress reports) to promote and facilitate the active engagement of all key stakeholders in this transition to broader immunization goals.

**2. Expand or integrate AFP surveillance with other diseases of public health importance:** This work will be pursued on a country-by-country basis through two approaches. AFP surveillance will be integrated into routine disease surveillance systems in those countries with existing structures and capacity, with the first priority being countries with the strongest systems and which have been certified as polio-free. In those countries without such capacity, the AFP surveillance system will be further expanded to facilitate the detection, investigation and response to vaccine-preventable diseases (VPDs) and other diseases of public health importance (especially epidemic-prone diseases). By the end of 2004, those countries requiring substantial long-term support to maintain surveillance capacity will be identified. Planning will continue for the institutionalization of this external support into an integrated surveillance capacity that is maintained following global certification. All such countries will, by the end of 2005, have the training materials and other tools needed to expand the AFP system to include the reporting and investigation of additional diseases. Opportunities will be identified to expand the skills of polio-funded staff and facilitate their reintegration, if appropriate, into national programmes.

**3. 'Mainstream' Polio-Funded Human Resources**: Between 2004 and 2006, the target date for stopping polio SIAs in all countries, the programme will complete the ongoing process of transitioning to other funding sources those polio positions which primarily provide technical assistance for immunization activities and/or social mobilization. Particular priority will be given to working with funding streams which support routine immunization strengthening, accelerated disease control (e.g. measles mortality reduction) and/or introduction of new vaccines. Where such technical assistance is not needed, positions will be made redundant and opportunities sought with other programmes and organizations. By 2006, the programme will also have refined the human resources capacity, particularly for field

surveillance and laboratory diagnosis, that will be required through global certification and OPV cessation. In addition, from 2004 the programme will begin evaluating what proportion of the time of these polio-funded personnel at national, state and district levels could be made available for tasks related to the surveillance and control of other vaccine-preventable and communicable diseases. Where it is found feasible, the Global Polio Eradication Initiative will work with other programmes to provide additional training, establish supervisory structures and share costs. Priority for this work will be given to the 15 countries which house 85% of the polio-funded technical assistance, and begin with those which were polio-free by end-2002. The final phase of this 'mainstreaming' of the polio-funded human resources will take place from 2008 through 2010, during which all longterm polio functions will be fully incorporated into sustainable structures dealing with multiple diseases or pathogens.

**4. Mainstream the major institutional arrangements for polio eradication:** The priority in this area of work will be to ensure the continued use of polio-initiated Interagency Coordinating Committees (ICCs) and, if appropriate, TAGs, for routine immunization activities. While the functions of these groups had been expanded in virtually all countries and regions by the end of 2003, in many areas the financial and human resources required to convene and support these groups were still being provided exclusively by the Global Polio Eradication Initiative. By the end of 2006, as SIAs are concluded in almost all countries, the continuation of these institutional arrangements will require that they are also fully supported by routine immunization personnel and funding streams, potentially through GAVI itself.

**5. Support the scaling-up of other health interventions:** The focus of this work will be on identifying and supporting those areas where application of the experience and lessons from polio eradication could facilitate the MDGs, especially Target 5, the reduction of under-five mortality by two-thirds from 1990 levels by 2015. Particular attention will be given to ensuring experiences in the areas of human resources, financing and administration and management are transferred to the international efforts to sustainably reduce measles mortality and morbidity, and to expand the coverage of health interventions such as vitamin A, ITNs and anti retroviral drugs (ARVs). ❐

## Objective 4:
## Mainstream the Global Polio Eradication Initiative
### Indicators and Milestones

| Indicators | Milestones | | | | |
|---|---|---|---|---|---|
| | 2004 | 2005 | 2006 | 2007 | 2008 |
| Percentage of joint GAVI/polio priority countries implementing integrated plans | 25% | 50% | 75% | 100% | 100% |
| Percentage of countries with integrated or expanded AFP reporting, as appropriate (especially for measles and neonatal tetanus) | 50% | 75% | 100% | 100% | 100% |
| Percentage of countries with GAVI-supported ICC and, if appropriate, TAG | 25% | 50% | 75% | 100% | 100% |
| Proportion of polio-funded 'human resources' formally contributing to multi-disease programmes* | 25% | 50% | 75% | 90% | 100% |
| Percentage of countries where polio operations are fully integrated with those for measles | 50% | 75% | 100% | 100% | 100% |

*Baseline = 2003 polio-funded positions globally.

# 5 Cross-Cutting Challenges

In addition to 2 specific challenges outlined for stopping poliovirus transmission, there are 6 major challenges that cut across all of the four objectives outlined in this Strategic Plan. The following sections outline each of these challenges and the planned actions of the polio partnership to mitigate their possible detrimental effects.

## 5.1 Political Commitment and Engagement

First and foremost, continued high-level political support for, and engagement in, the global polio eradication effort is essential. In the remaining endemic countries such engagement is needed at national and subnational levels to ensure high-quality implementation of the strategies (see section 4.1). In polio-free countries endorsement is needed to improve routine immunization coverage, sustain high-quality surveillance, achieve containment of poliovirus stocks, and ensure the full documentation necessary for certification. In those countries which also provide overseas development assistance, continued support of the political leadership will be critical to ensure sufficient external financing for a disappearing disease.

To facilitate this continued political engagement, the polio partnership will continue to develop and implement country-by-country advocacy plans. Regional and global political forums will be exploited to maintain the visibility of the Global Polio Eradication Initiative in this critical period.

## 5.2 External Financing

The second major cross-cutting challenge will be to close the 2004–2005 funding gap of US$ 150 million to interrupt poliovirus transmission, and the US$ 380 million to achieve global certification and mainstream the Global Polio Eradication Initiative. The central importance of sufficient funding to the ultimate success of the Global Polio Eradication Initiative became acutely evident in early 2003 when, for the first time since 1999, it was necessary to cancel or postpone eradication activities due to a lack of financing. This financing shortfall rapidly compromised the quality of polio surveillance, especially in Africa, reduced the speed and quality of emergency outbreak responses, and hindered the implementation of activities in key reservoir areas. Continued financing gaps would substantially impact all of the major milestones outlined in this plan.

To address this funding gap, the interagency Polio Advocacy Group (PAG)[23] will continue its resource mobilization efforts. Special attention will be given to finalizing the commitment of G8 members (particularly France, Germany and Italy), to closing the funding gap for eradication activities in Africa and identifying new partners, including those interested in mainstreaming the polio infrastructure as outlined above. Attention will also be given to assisting Member States of the Organization of Islamic Conference (OIC) to operationalize their 2003 summit resolution to fund polio activities. The heightened profile of polio eradication activities within the UN agencies, and the identification of polio eradication as a global public good for health, will support efforts to expand the polio partnership and encourage other Organisation for Economic Co-operation and Development/ Development Assistance Committee (OECD/ DAC) countries to participate in this historic Initiative. The polio partnership will put a particular emphasis on securing multiyear financial commitments through 2008.



[23] PAG is an interagency group of external relations, resource mobilization and communications experts from WHO, UNICEF, UN Foundation and Rotary International that coordinates the international advocacy and resource mobilization activities across the polio eradication partnership.

## 5.3 High-Quality Polio Vaccines

A reliable supply of high-quality polio vaccines will be needed for all of the major objectives of this plan. Stopping the final chains of poliovirus transmission will require an estimated 2.5 billion doses of WHO-prequalified OPV for SIAs during the period 2004-2005. Additional OPV will be required for SIAs in high-risk countries as well as routine immunization activities; given the increasing work of the global community to improve routine immunization through efforts such as GAVI, the OPV requirements for routine immunization could increase during this period. As plans for a vaccine stockpile are developed, arrangements will need to be made to ensure continued production capacity for stockpile OPV through the Global OPV Cessation Phase as well as the continued availability of specific reagents and procedures critical for its production and quality control. In addition to OPV, it is anticipated that there will be an increasing demand for IPV, in a variety of formulations, regardless as to the long-term policy decisions for future polio immunization. The need to ensure the implementation of appropriate containment measures in large-scale IPV production facilities globally will require close collaborative efforts between manufacturers, their governmental oversight authorities, and international biosafety and biosecurity functions.

To ensure adequate supply of high-quality polio vaccines, UNICEF and WHO, in consultation with national governments, will continue to refine their long-term demand forecasting work for both OPV and IPV. WHO will develop the criteria and process for pre-qualification of IPV containing vaccines. This work will be shared regularly with OPV and IPV manufacturers through annual meetings, as well as ad hoc consultations as requested. The polio vaccine and immunization research and policy agendas will continue to inform this area of work.

## 5.4 Conflict-Affected Countries and Areas

Although the polio eradication strategies have been successfully implemented in all conflict-affected countries, these areas will continue to pose special challenges for all aspects of the eradication programme. In addition to the need to stop polio transmission in Afghanistan, substantial work is needed to improve and maintain population immunity in a much larger number of these countries. Special arrangements will be needed for some of these countries and areas to verify and submit the necessary documentation for certification. Such areas may also have particular interests which must be represented in deliberations on future polio immunization policy.

Recognizing the special needs of conflict-affected areas, the polio partnership will continue to devote a substantial proportion of its technical assistance to these areas, particularly through the deployment of long-term human resources. Ongoing work with NGO networks will be sustained and expanded. The close collaboration that has been established with the UN security apparatus in many of these areas will also continue, including the deployment of a limited number of polio-funded security officers and further investment in MOSS compliance.[24]

## 5.5 Public Information and Social Mobilization

Throughout the Global Polio Eradication Initiative, the informing and engagement of the public sector has been central to activities ranging from strategy implementation in endemic areas to resource mobilization in donor countries. In donor countries, a high profile and awareness of the Global Polio Eradication Initiative is needed to facilitate resource allocation decisions through global certification. In all countries, the development of long-term polio policies, particularly for routine immunization, will generate new demands in this area of work.



[24] MOSS compliance refers to the "minimum operating security standards" required of UN agencies working in insecure or potentially insecure areas.

Social mobilization efforts must be enhanced in the remaining endemic areas to fully engage the polio-affected populations, as well as to address rumours which may have undermined public confidence in the programme. The appropriate selection and training of vaccinators, the inclusion of women and underserved groups at all levels, the need for strong interpersonal communication skills at the service delivery level, and the development of appropriate Information, Education and Communication (IEC) messages and materials, remain key to the successful vaccination of every child.

The Global Polio Eradication Initiative will continue to place a strong emphasis on public information, social mobilization and communications during the period 2004-2008. The technical capacity which has been established in this area at the global, regional, national and subnational levels will require additional inputs and leadership to enhance support to government efforts. The inter-agency mechanisms for coordinating communications and social mobilization inputs (e.g. the Advisory Group on Communication for Immunisation and Polio Eradication, the Advisory Group on Communication for Immunisation (Africa), and National Social Mobilisation Committees) will continue. New materials will be developed and widely disseminated to support this work.

## 5.6 Biocontainment

Timely completion of the containment activities outlined in the *Global Action Plan for the Laboratory Containment of Wild Polioviruses, second edition* (GAP II), is particularly important to the 2004–2008 overall timeline for polio eradication. GAP II requires that by the end of 2004 all countries will have completed a nationwide survey of laboratories, established an inventory of all facilities holding wild polioviruses or potentially infectious materials, and implemented BSL-2/polio level safety measures. One year after the last wild poliovirus has been detected (e.g. from end-2005), all countries must begin either destroying retained materials, or increasing the level of biocontainment to BSL-3/polio. While the progress to date in implementing the GAP II demonstrates that this timeline is feasible, achieving these milestones requires accelerating containment in a number of large industrialized countries and initiating activities in many recently endemic countries. The timely introduction, validation and verification of BSL-3/polio containment measures at existing IPV production and quality control facilities using wild polioviruses, represents a particular challenge to manufacturers and national oversight authorities. The expected results for containment, outlined under objectives 2 and 3 of this Strategic Plan, highlight the activities that will be undertaken to address these challenges. ❐

# 6 Roles of Partner Agencies

## 6.1 Governments

National governments of polio-endemic, recently-endemic and polio-free countries are the owners and beneficiaries of the Global Polio Eradication Initiative, undertaking the full range of polio eradication activities outlined in this Strategic Plan. National resources contributed towards the implementation of polio eradication activities include both financial expenditures and in-kind commitments, such as the time that is contributed by volunteers, health workers and others in the implementation of NIDs. Substantial resources are also expended by governments at national, state/province, district and local community levels to pay for petrol, social mobilization, training and other costs. It has been estimated that polio endemic countries will have contributed volunteer time worth at least US$ 2.35 billion for polio eradication activities between 1988 and 2005.[25] Governments of polio-endemic and recently endemic countries also conduct advocacy with donor governments and at various multilateral forums.

## 6.2 Spearheading Partners

**World Health Organization (WHO):** Through its headquarters, regional and country offices, WHO provides the overall technical direction and strategic planning for the management and coordination of the Global Polio Eradication Initiative. WHO is responsible for ensuring that all components of the Global Polio Eradication Initiative Strategic Plan are well implemented, and has a key role in monitoring and evaluating all aspects of the Plan. WHO also coordinates operational/basic scientific research, provides operational support to ministries of health, and the training/deployment of human resources. WHO is the lead technical agency for supporting AFP surveillance systems, the global polio laboratory network, resource mobilization, donor coordination, advocacy and public information.

**Rotary International:** Through its PolioPlus program, established in 1985, Rotary International was, with the Pan American Health Organization, the first to have the vision of a polio-free world and continues to play a central role in global efforts to eradicate polio. Rotary is the world's first service organization, with a global network of 1.2 million members in more than 160 countries. More than one million Rotary members have volunteered their time and personal resources to contribute to the immunization of nearly two billion children in 122 countries. In addition, Rotary mobilizes millions of fellow volunteers to assist during NIDs. Rotary also provides urgently needed funds. To date, the organization has committed more than US$ 500 million to polio eradication. Rotary's Polio Eradication Advocacy Task Force, with the assistance of the PolioPlus National Advocacy Advisors, has played a major role in highlighting polio eradication in international forums and in influencing decisions by donor governments to contribute over US$ 1.5 billion to the global eradication effort. That amount, combined with direct funds from Rotary, has accounted for more than half the amount required for the entire global initiative. In June 2003, Rotary concluded a second membership fundraising drive, which exceeded its goal to raise an additional US$ 80 million for polio eradication.

**US Centers for Disease Control and Prevention (CDC):** The most important contribution of the Atlanta-based CDC continues to be deployment of its epidemiologists, public health experts, and scientists to WHO, UNICEF and endemic countries. In addition, a number of international and national staff in WHO and UNICEF headquarters and in the regional and country offices of both organizations are funded by CDC grants. CDC also provides funding for the procurement of OPV required for mass



[25] Global Public Goods for Health: Health economic and public health perspectives, pg.41, Smith, R., et al, eds, Oxford University Press, 2003.

immunization campaigns, and a wide range of technical expertise and laboratory support. This includes staff support for disease surveillance at global, regional and national levels and outbreak investigation, especially in areas within or bordering polio-free zones. CDC works as the "viral detective" of the four partners, using its state-of-the-art virological surveillance expertise to identify the strain of poliovirus involved and pinpoint its geographical origin. CDC also provides assistance in the development and monitoring of the 145 members of the global polio laboratory network, including funding short-term and long-term technical support in key countries. Finally, CDC conducts research which will facilitate development of long-term immunization and surveillance policies.

**United Nations Children's Fund (UNICEF):** UNICEF is the lead partner in the procurement and distribution of polio vaccines for routine and supplementary immunizations and with WHO, the strengthening of routine immunization components of the Strategic Plan. With WHO, UNICEF is the lead partner in the implementation of intensified NIDs, SNIDs and mop-up campaigns at country level. UNICEF provides technical assistance to national coordinators to develop action plans and secure logistics to access hard-to-reach places, including in countries affected by conflict. UNICEF also participates in the global process by which eradication policies and plans of action are developed; develops materials for training and public information; strengthens social mobilization efforts through its network of communications officers; and provides cold chain support. UNICEF is also an active partner in resource mobilization, advocacy and public information.

## 6.3 Donor and Technical Partners

**Agencies for international development cooperation:** These agencies play a central role in the Global Polio Eradication Initiative through the provision of multilateral and bilateral support. They also undertake high-level advocacy with endemic countries and among their peers, provide access to technical expertise within their countries, and give significant technical input through participation in global, regional and country-level ICCs and technical oversight bodies. International development agencies have contributed to the Global Polio Eradication Initiative's resource mobilization strategy and have assisted the development of long-term plans by making commitments through to global certification. Some of the long-standing partners include Canada (CIDA), Germany (kfW), Japan (JICA), the United Kingdom (DFID) and the United States of America (CDC and USAID). These donors have contributed or committed US$ 1.76 billion to the Global Polio Eradication Initiative, or 59% of all the funds received or projected, between 1985 and 2005. Partners such as Australia, Denmark, Luxembourg, the Netherlands and Norway have made significant contributions and are some of the leading supporters, especially on a per capita basis. The Global Polio Eradication Initiative is also welcoming new donor partners such as Ireland, New Zealand and the Russian Federation. In addition to focusing on development agencies in OECD countries, the Global Polio Eradication Initiative is looking to expand its relationship with key Arab and Asian nations.

**Foundations (see also 'Rotary International' under Spearheading Partners):** Foundations provide financial support, advocacy and assistance in partnership development. The United Nations Foundation (UNF) has provided substantial assistance through direct financial support, strengthening of the Global Polio Eradication Initiative's fundraising capacity, leveraging funds through matching grants and introducing other partners to the Global Polio Eradication Initiative. The UNF also works closely with the spearheading partners in global polio advocacy activities and resource mobilization efforts. After the Rotary Foundation, the Bill and Melinda Gates Foundation has been the largest donor foundation to the Global Polio Eradication Initiative having committed US$ 75 million. The Bill and Melinda Gates Foundation has also played an important advocacy and promotion role for polio eradication. The Rotary Foundation, the Bill and Melinda Gates Foundation and UNF have also supported the Global Polio Eradication Initiative by collaborating with the World Bank to implement a loan buy-down mechanism which will buy polio vaccine for Nigeria and Pakistan.

**Development Banks and Multilateral Agencies:** Institutions like the World Bank and the Inter-American Development Bank have provided access to country-level financing through the provision of "soft loans". The World Bank has also collaborated with the Bill and Melinda Gates Foundation, Rotary International and UNF to implement a funding mechanism to assist the procurement of polio vaccines for Nigeria and Pakistan. The European Commission (EC) has supported the Global Polio Eradication Initiative in countries such as India and Nigeria. Intergovernmental bodies such as the G8, the African Union and the Organization of the Islamic Conference (OIC) have strongly supported the Global Polio Eradication Initiative by providing a high profile for polio eradication in their summits and pledging both financial and political support.

**Corporations:** Corporations and members of the private sector have provided monetary and in-kind contributions to the Global Polio Eradication Initiative. Most often their contributions are for a specific area or purpose which requires targeted funding. Aventis Pasteur is the Global Polio Eradication Initiative's longest standing corporate partner having donated 120 million doses of OPV over a 10-year period. This vaccine has been earmarked for campaigns in specific African countries which are emerging from conflict. Other key corporate supporters include Wyeth, which funds the African Regional Polio Laboratory Network; the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), which coordinated a 100 million dose vaccine donation from Aventis Pasteur, GlaxoSmithKline (GSK) and Chiron; DeBeers, which provided funding for polio campaigns in Angola; and British Airways, which funded an important mop-up campaign in western Zambia. Private sector fundraising campaigns organized by Rotary International and UNF, and by the various UNICEF national committees, have also generated significant support for the Global Polio Eradication Initiative.

## 6.4 International Humanitarian Organizations and NGOs

**International humanitarian organizations:** Organizations such as the International Federation of Red Cross and Red Crescent Societies (IFRC) assist the Global Polio Eradication Initiative by conducting advocacy at international and national levels, and contributing financial, operational and technical support in selected priority countries. The Red Cross/Red Crescent societies contribute to the implementation of mass immunization and surveillance activities in the field, with emphasis on deploying networks of community-based volunteers for social mobilization. The International Committee of the Red Cross (ICRC) assists in facilitating access in areas of conflict and refugee populations.

**Nongovernmental organizations:** NGOs play a key role in the implementation of country-level activities. The NGO umbrella-organization CORE through the efforts of its many members such as ADRA, CRS, CARE, Plan International, Save the Children, and World Vision, assists the polio eradication effort by building partnerships between the government and the communities they serve, supporting supplemental immunization campaigns, assisting with AFP surveillance, and monitoring the immunization status of children. NGOs help train volunteers and health workers, transport vaccines and equipment, monitor the quality of the cold chain, and assist with communication and social mobilization activities. NGOs also play an important advocacy role, particularly at the national and subnational levels. Some NGOs, such as the Albert B. Sabin Vaccine Institute which formally joined the Global Polio Eradication Initiative in 2003, play both an international advocacy and technical advisory role. NGOs such as Médecin Sans Frontières and Save the Children have been important in reaching children in conflict-affected countries such as Angola, the Democratic Republic of the Congo and Somalia.

## 6.5 Vaccine Manufacturers

The vaccine industry plays a critical role in supporting routine and supplementary polio eradication activities by making available sufficient quantities of assured quality polio vaccine. The manufacturers make sure that sufficient quantities of vaccine are available in a timely manner by ensuring that the production and investment plans for capacity increases are initiated at the right times. To guarantee timely availability and a minimum of vaccine wastage, the vaccine industry also works in close collaboration with UNICEF and WHO which includes sharing short- and long-term demand schedules and production plans. In addition, the vaccine industry provides technical inputs and initiates research in response to product requirements after certification as suggested and defined by the new Strategic Plan. Furthermore, the industry has provided contributions in-kind on a number of occasions.

# 7 2009 & Beyond – the Global OPV Cessation Phase

The experience of the smallpox eradication initiative, combined with the risks associated with continued use of OPV, demonstrate the need to plan for a combination of longterm and time-limited polio eradication activities following certification of global polio eradication (target date 2008). The ongoing development of the products and policies needed for this phase of the Global Polio Eradication Initiative precludes a detailed assessment of the financial resources required at that time; however, it is possible to anticipate the major activities that will be required.

The longterm activities are those needed to minimize and manage the risks of re-introduction and re-establishment of wild polioviruses. For example, prior to the cessation of OPV, and indefinitely thereafter, *all* polioviruses will need to be subject to longterm containment[26]. Independent verification of appropriate storage and handling of wild and vaccine-derived poliovirus strains will be needed, particularly for manufacturing sites that amplify wild polioviruses to produce IPV. Stockpiles of monovalent OPV, and possibly other formulations, will need to be in place and maintained in the longterm. Internationally-agreed mechanisms will be required to govern the use of these stockpiles, with special attention to ensuring priority for those countries that decide to forego the use of IPV for routine immunization. Because of their longterm nature, these activities will be incorporated into existing national, WHO and UNICEF structures and mechanisms for managing the identification, response and containment of high priority pathogens.

In addition to these longterm activities, a number of time-limited actions will be needed to manage the short-term risk of circulating vaccine-derived polioviruses (cVDPVs) that will be associated with the cessation of OPV. Foremost among these activities will be the heightening and sustaining of AFP surveillance for at least two years after the cessation of OPV. Particular capacity will be needed in those areas at highest risk for the emergence of a cVPDV (i.e. those with very low routine immunization coverage) and in those countries which decide not to introduce IPV. Should the ongoing evaluation of supplementary surveillance strategies (e.g. environmental sampling) demonstrate the capacity to significantly enhance the detection of circulating polioviruses, these methods will have had to be introduced at least 1 year in advance of OPV cessation. Finally, if there is evidence that boosting population immunity substantially reduces the risk of cVDPV emergence, in some areas the cessation of OPV may need to be preceded by pulse immunization with OPV.

The use of IPV in routine immunization programmes represents a special issue. Some countries have indicated their desire to forego its use completely, some are considering a time-limited approach in which it would be used as part of a 3-5 year transition strategy during the cessation of OPV, and others have stated their intention to continue longterm IPV use for routine immunization. Although some countries may forego the use of IPV, those which do decide to use it for a time-limited period or in the longterm, will need to have introduced that vaccine by 2008 and made provision for its procurement for the necessary period. Given the inter-relatedness of decisions on IPV introduction, the use of combination vaccines and longterm national policy for other antigens (e.g. pertussis component of DTP), key stakeholders in the provision of such vaccines for routine immunization, such as GAVI, will need to be centrally involved in this process.

The resource implications of the Global OPV Cessation Phase will be developed as part of the work to establish appropriate products and policies for this period, outlined in Objective 3 of the

[26] To be developed for the 3rd Edition of the Global Action Plan for Laboratory Containment of Wild Polioviruses.

Global Polio Eradication Initiative Strategic Plan 2004-2008. The financing requirements will be driven by internationally-agreed decisions during 2005-2007 on the actual process for stopping OPV, the size and composition of vaccine stockpiles, and the future role of other polio vaccines. Given the longterm nature of many of the activities of the Global OPV Cessation Phase, the required resources will need to be raised and channelled through the sustainable structures and mechanisms into which these activities will have been incorporated. ❐

## The spearheading partners of the Global Polio Eradication Initiative are:





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