Global Polio Eradication Initiative

Strategic Plan
2004-2008

draft for consultation

WHO

CDC unicef

Partners in the Global Polio Eradication Initiative

Global Polio Eradication Initiative

Strategic Plan

2004 - 2008

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ACRONYMS

AFP	acute flaccid paralysis
AFR	WHO African Region
AMR	WHO Region of the Americas
ARVs	anti-retroviral drugs
CDC	US Centers for Disease Control and Prevention
CIDA	Canadian International Development Agency
cVDPVs	circulating vaccine-derived polioviruses
DfID	Department for International Development (United Kingdom)
GAVI	Global Alliance on Vaccines and Immunization
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
kfW	Germany
ICCs	interagency coordinating committees
IDS	integrated disease surveillance
IPV	inactivated poliovirus vaccine
iSNIDs	intensified subnational immunization days
ITD	intratypic differentiation
ITNs	insecticide treated nets
MDGs	millennium development goals
mOPV	monovalent OPV
NCCs	national certification committees
NGOs	nongovernmental organizations
NIDs	national immunization days
OPV	oral polio vaccine
RCC	regional certification commissions
RED	Reach Every District
SIAs	supplementary immunization activities
SNIDs	subnational immunization days
TAGs	technical advisory groups
TCG	Technical Consultative Group
tOPV	trivalent OPV
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

2 EXECUTIVE SUMMARY

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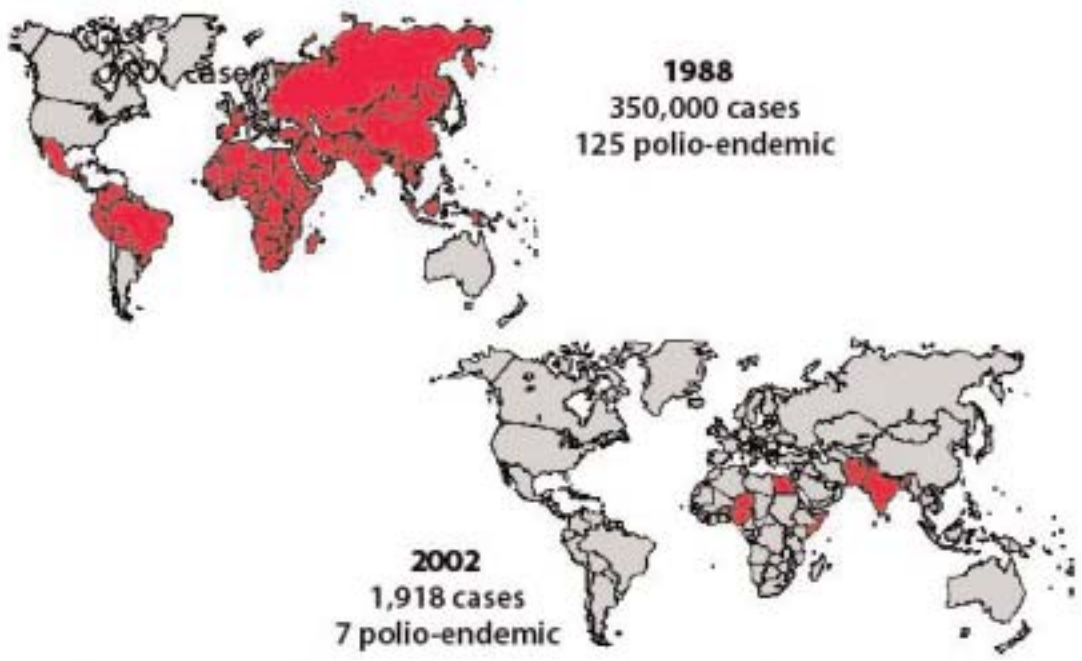
3 BACKGROUND

IN 1988 the World Health Assembly (WHA), the annual meeting of the Ministers of Health of all Member States of the World Health Organization, unanimously voted for a global effort to eradicate poliomyelitis. At the time, wild poliovirus was endemic in over 125 countries on 5 continents, and was a leading cause of permanent disability, paralysing in excess of 350 000 children every year. As a result of the Global Polio Eradication Initiative, the largest international health effort to date, by late-2003 polio had been eliminated from all but six countries and less than 1000 children had been paralysed by the disease that year.

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 on its behalf. 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, 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

Figure 1: Polio Eradication Initiative Progress 1988-2002



was possible to rapidly scale-up eradication activities so much 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 10 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 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 India (2), Nigeria (1) and Pakistan (2), were the result of missing substantial numbers of children during both routine and supplementary polio immunization activities.

Since the 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[1]. The Polio Eradication Strategic Plan 2004–2008 replaces and updates the 2000 Strategic Plan. This Plan outlines the key activities required during the *interruption of poliovirus transmission phase* (2004–2005) and *global certification phase* (2006–2008) and prepares for the subsequent *OPV cessation phase* (from 2009) (Figure 1). The plan reflects the major tactical revisions of strategy that 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 (i.e. the "post-certification" era). This Strategic Plan serves as the basis for the annual work planning of individual partner agencies and national programmes. ❐

4 GOAL

THE goal of the 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. ❐

5 OBJECTIVES AND MILESTONES

5.1 OBJECTIVE 1: INTERRUPT POLIOVIRUS TRANSMISSION

IN 2003, for the first time in history, the number of countries that suffered polio cases due to an importation was greater than the number that were actually endemic for the disease. In west Africa alone, responding to these importations cost over US$ 10 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 that now exists to eradicate polio forever can only be exploited if the leaders of endemic areas, particularly in just five key states/provinces worldwide, ensure that every child is immunized during intensified subnational immunization days (iSNIDs) in 2004.

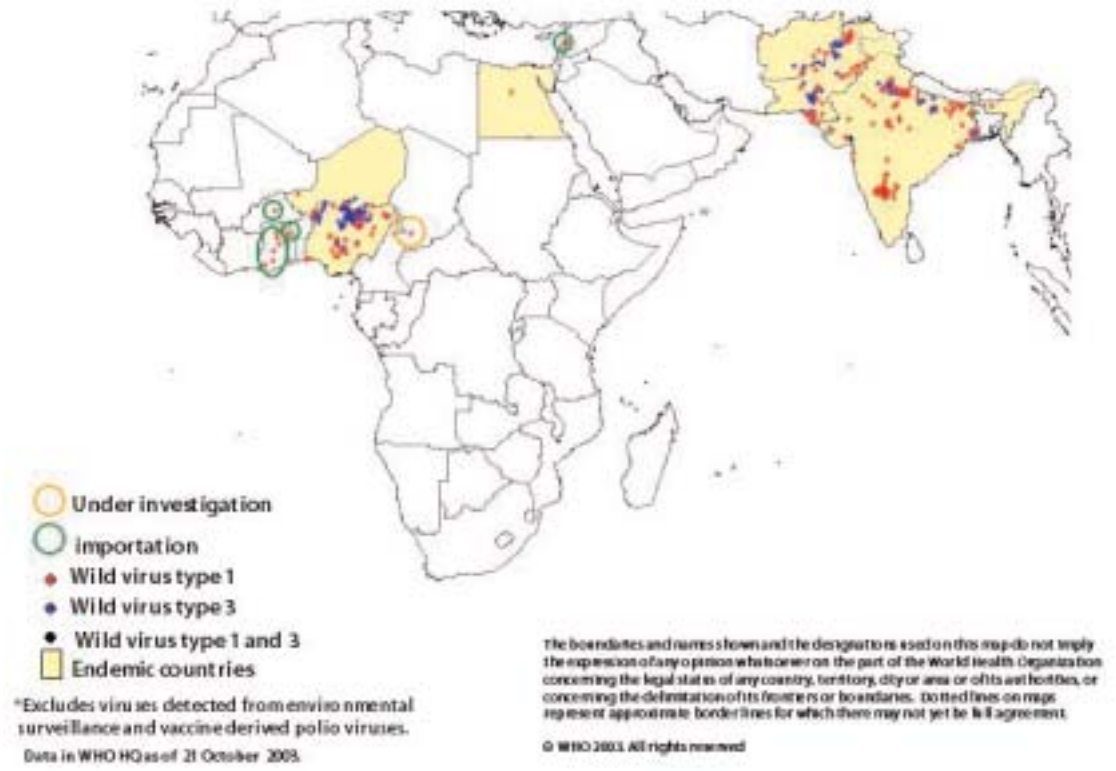
STRATEGIC APPROACH:

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

High routine coverage with at least three doses of oral poliovirus vaccine (OPV3) has been the foundation of the programme. However, global OPV3 coverage was only 67% in 1988 and it never reached 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, suboptimal sanitation, high population density and tropical climates combine to facilitate the transmission of any enteroviruses in these areas, including polioviruses. In such settings, wild poliovirus can continue to circulate even in highly immunized populations, requiring synchronized pulsing of the population to interrupt transmission.

Consequently, in endemic countries national immunization days (NIDs) during the low season for polioviruses have interrupted 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 also been coordinated across national borders.[2] House-to-house *mop-up* campaigns, targeting at least one million children, are 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

Figure 2: Wild Poliovirus*, 1 January 2003 – 23 October 2003



conducted each year, to add subnational immunization days (SNIDs) in particularly high-risk areas, and to introduce a house-to-house vaccine delivery strategy.[3] In April 2003, as a result of an increasing geographic restriction of poliovirus transmission and the limited resources available, the global Technical Consultative Group (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 iSNIDs, 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 the end of 2003, wild poliovirus transmission had been interrupted in all but six countries in the world. Three of these countries, India, Nigeria and Pakistan, accounted for 99% of cases. Within these countries, however, endemic transmission was highly restricted geographically with just five states or provinces serving as the principal virus reservoirs globally: 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 to the greater Cairo area.

In all of these 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 India, Nigeria and Pakistan, this problem is further compounded by very low routine immunization coverage with OPV3 often less than 25%.

Although endemic polio transmission is now geographically restricted, wild poliovirus importations have continued to paralyse children in polio-free areas. Between 2000, the target date for global eradication 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, Ghana, Togo and part of Niger, as well as polio-free states within Nigeria such as Lagos, resulting in an international immunization response costing over US$ 10 million. To date, all such polio outbreaks have been eventually 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 the use of OPV in routine immunization has stopped.

EXPECTED RESULTS:

1. Intensified subnational immunization days (iSNIDs) in reservoir areas: The highest priority for the eradication initiative is the interruption of wild poliovirus transmission in the remaining endemic countries of Afghanistan, Egypt, India, Niger, Nigeria and Pakistan. Particular attention is required in the five key reservoir states/provinces of Uttar Pradesh and Bihar (India), Kano (Nigeria) and Sindh and North West Frontier Province (Pakistan). To stop transmission in all infected areas as rapidly as possible, iSNIDs will repeatedly vaccinate the large cohorts of susceptible young children that rapidly accumulate in these areas due to the large populations, high birth rates and very low routine immunization coverage. Reaching over 90% of children during iSNIDs 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;
- full engagement of local women's groups to ensure sufficient female vaccinators with access to all homes and communities;
- 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 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 iSNIDs 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 in this area 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 three weeks of confirmation of a case. To enhance national capacity to initiate such a response, standard operating procedures will be developed in each country, per 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 their reporting. Adequate reserves of financial and vaccine resources will be established to facilitate mop-up responses. By 2007 the management of the response to such events will be fully integrated with existing 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 Initiative will be to prevent the re-establishment of wild poliovirus transmission in polio-free areas,

Table 1: Baseline Supplementary Immunization Activities (SIAs) required for polio eradication 2004–2008*

Baseline		NIDs/SNIDs		
Priority	Country	2004	2005	2006
A • Endemic countries	Afghanistan	4/1	2/0	
	Egypt	2/2	0/2	
	India	2/4	2/2	2/0
	Niger	2/2	2/2	
	Nigeria	2/4	2/2	2/0
	Pakistan	4/2	2/2	2/0
	Somalia	2/2	0/2	
B • Highest risk countries	Angola	2/0	0/2	
	DR Congo	0/2		
	Ethiopia	0/2		
	Sudan	0/2		
• Countries bordering Nigeria	Benin	2/0		
	Burkina Faso	2/0		
	Cameroon	0/2		
	Chad	0/2		
	Ghana	2/0		
	Togo	2/0		
• Countries bordering India	Bangladesh	2/0		
	Nepal	2/0		

**Assumes wild polio virus interrupted by end-2004. See Global Polio Eradication Initiative FRRs 2004-2008 for contingency plans and their implications.*

especially within the endemic countries themselves. Consequently, in addition to the iSNIDs at least two rounds of NIDs will continue to be conducted in each of the endemic countries for at least two years after the last case. 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 to the global eradication initiative were Angola, Bangladesh, the Democratic Republic of 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, Ghana and Togo. The NIDs or SNIDs in these countries will continue to be planned until one year after the last case has been detected in the relevant reservoir area. 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 SIA activities for these countries as of end 2003.

4. Enhanced routine immunization coverage against polio: The fourth priority in this area of

Table 2: Priority countries for improving OPV3 coverage to GAVI target of 80/80

Coverage	Country	Reporting year	OPV3 % coverage
60–80%	Bangladesh	2002	70
	Burkina Faso	2002	69
	Cameroon	2002	63
	Djibouti	2002	62
	Equatorial Guinea	2002	72
	Eritrea	2002	70
	Gabon	2002	60
	India	2002	70
	Indonesia	2002	75
	Kuwait	2000	64
	Lesotho	2002	60
	Madagascar	2002	61
	Malawi	2002	79
	Mali	2002	74
	Myanmar	2002	77
	Namibia	2002	78
	Nepal	2002	72
	Pakistan	2002	71
	Philippines	2002	70
	Senegal	2002	60
	Sudan	2002	64
	Swaziland	2002	76
	Turkey	2002	78
	Uganda	2002	73
	Yemen	2002	69
	Zimbabwe	2002	71
40–60%	Afghanistan	2002	48
	Angola	2002	42
	Cambodia	2002	54
	Chad	2002	40
	Congo	2002	41
	Côte d'Ivoire	2002	54
	Democratic Republic of the Congo	2002	45
	Ethiopia	2002	49
	Guinea	2002	58
	Guinea-Bissau	2002	50
	Haiti	2002	41
	Lao People's Democratic Republic	2002	55
	Liberia	2002	50
	Sierra Leone	2002	50
	Somalia	2002	40
	Timor-Leste	2002	56
	Togo	2002	58
<40%	Bolivia	2001	12
	Central African Republic	2002	13
	Mozambique	2002	37
	Niger	2002	25
	Nigeria	2000	22
	Papua New Guinea	2002	38

work will be to support the work of WHO and UNICEF, especially within the Global Alliance on 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 iSNIDs and mop-ups. The 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 these areas with low OPV3 coverage (Table 2).

OBJECTIVE 1: INTERRUPT POLIOVIRUS TRANSMISSION

INDICATORS AND 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	*XX*	*XX*	*XX*	*XX*	*XX*
Percentage of emergency mop-ups begun within four weeks of case confirmation	*80%*	*90%*	*100%*	*100%*	*100%*

** As of end-2003, one country is at particular risk of ongoing transmission into the first half of 2005.*

5.2 OBJECTIVE 2: ACHIEVE CERTIFICATION OF GLOBAL POLIO ERADICATION

DESPITE validation in 1994 of the process for certification of the global eradication of poliomyelitis, this goal is threatened 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). Achieving global certification by 2008 requires rapidly addressing persistent surveillance gaps in 35 countries of Africa, the Eastern Mediterranean and South-East Asia. Phase I containment activities must be completed in key countries (e.g. China, France, Japan, Switzerland and the United Kingdom) and manufacturers producing inactivated poliovirus vaccine (IPV) from wild poliovirus strains must implement 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 six 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[4] 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 *WHO global action plan for laboratory containment of wild polioviruses* (WHO/V&B/99.32) in 1999, with a second edition in 2003.[5] The plan outlines phased activities to minimize the risk of reintroduction of wild polioviruses from the laboratory 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 laboratories listed on national inventories to destroy wild poliovirus materials or to maintain them under appropriate biosafety conditions. Manufacturers of IPV from wild polioviruses must fulfil specific biosafety requirements per guidelines developed and finalized in 2003 through a collaborative process with

national regulatory authorities, biosafety professionals, and vaccine manufacturers. Global certification will require the fulfilment of these requirements by IPV manufacturers, and documented completion of phase I and II containment activities by all countries.

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.[6] As of mid-2003, three of the six WHO regions had been certified polio-free. The 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 had achieved "certification-standard" surveillance at the regional level (Table 3), 35 of the 82 countries in those Regions had yet to achieve this at the national level during 2002 (25 in the Africa Region, 7 in the Eastern Mediterranean, 3 in South-East Asia). Furthermore, within a number of countries the quality of surveillance was not uniform. Figure 3 summarizes the status of national AFP surveillance indicators in both endemic and certified regions. Figure 4 illustrates the worldwide network of 145 virology laboratories that forms the backbone of global AFP surveillance,[7] arranged in a hierarchical structure

Table 3: Countries not achieving one or more of the AFP Performance Indicators required for certification-standard surveillance in 2003

Region	Country	AFP cases reported (2003*)	Non-polio AFP rate	AFP cases with adequate specimens (%)
AFRO	Algeria	28	0.4	89
	Botswana	14	3	71
	Cape Verde	3	2.3	67
	Liberia	10	0.7	90
	Madagascar	65	1.5	71
	Malawi	42	1.2	69
	Mauritania	22	2.8	77
	Mozambique	82	1.6	70
	Namibia	4	0.8	75
	Sao Tome and Principe	1	1.9	0
EMRO	Bahrain	1	0.66	0
	Cyprus	1	0.77	100
	Djibouti	1	0.53	0
	Kuwait	2	0.46	100
	Lebanon	16	2.31	75
	Somalia	77	3.09	79
	West Bank and Gaza	5	0.52	60
SEARO	Bhutan	3	0	67
	Democratic People's Republic of Korea	58	0.95	95
	Maldives	1	0	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 9 October*

Red indicates targets not achieved.

Figure 3: AFP Performance Indicators July 2002 – June 2003

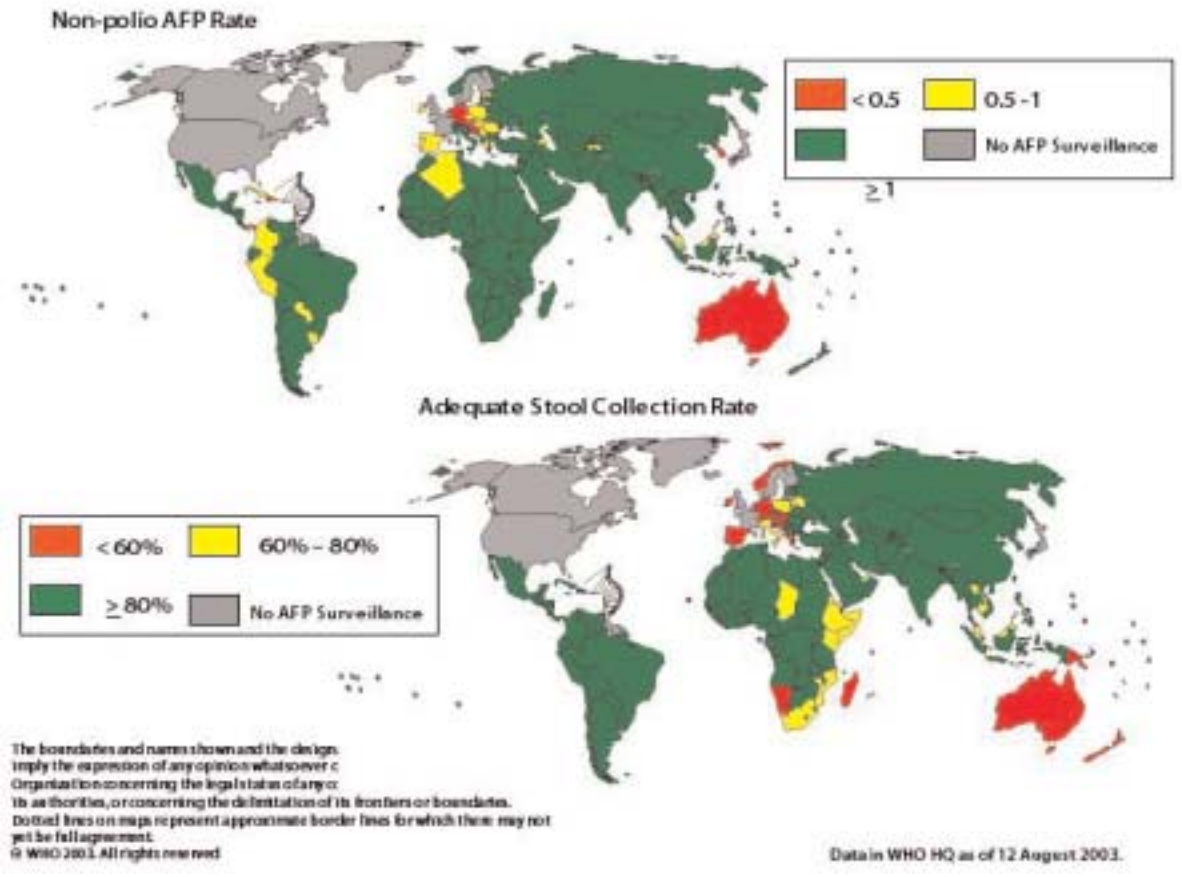
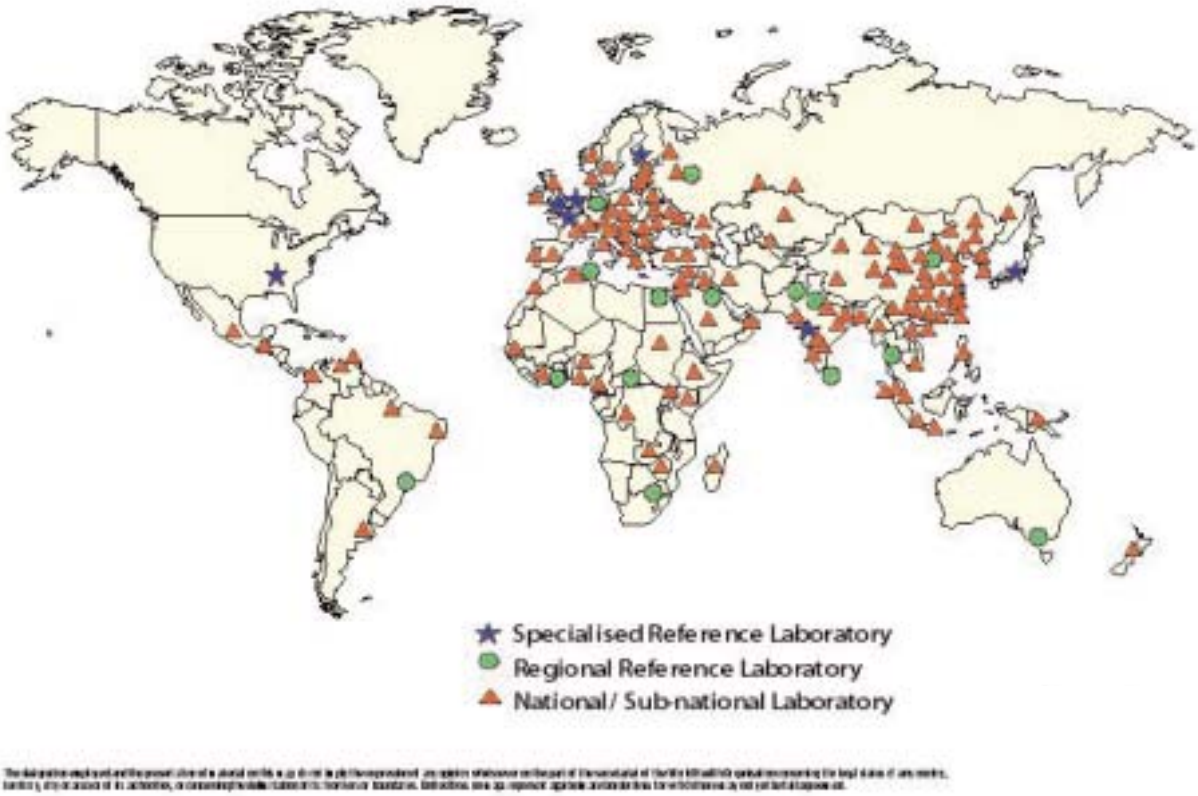


Figure 4: Global laboratory network for polio eradication, 2002



of national (123), regional (15) and global specialized (7) facilities. High quality performance is assured through annual proficiency testing, a formal accreditation programme, and on-going 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". As of mid-2003, 148 (68%) countries and territories had begun or completed their listing of biomedical laboratories. 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 by that time and 80 countries (37%) had finalized an inventory of laboratories storing wild poliovirus materials. In 2003 concurrence was established among WHO, vaccine manufacturers and regulatory agencies on the need for BSL-3 level[8] containment in all existing IPV facilities, with implementation by 2007.

EXPECTED RESULTS:

1. "Certification-standard" surveillance:

a) Polio-endemic regions: The highest priority will be to achieve certification-standard surveillance at the national level in the 35 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 sub-Saharan Africa. Joint national/international AFP surveillance reviews will continue to guide improvements.

b) Regions certified as polio-free: : Priority will first be given to identifying high-risk countries or areas where AFP surveillance sensitivity has markedly declined and/or from which enhanced AFP or supplementary surveillance data may be required for the purposes of global certification. From 2005 to 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 mechanisms, if this 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 first priority in this area will be to reduce the time required for intratypic differentiation (ITD) results to be available for 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 those 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 Global Certification Commission during the period 2004–2005.

3. Containment of wild polioviruses and vaccine-derived polioviruses (VDPVs): The first priority in this area will be the further dissemination and national level implementation of the activities outlined in the second edition of the *WHO 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 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 containment activities will be initiated in all countries, with particular emphasis on large industrialized countries which contain the largest stocks of wild poliovirus and where the current IPV producers are located. 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. The process for developing post-certification, long-term containment requirements for wild and attenuated poliovirus strains is outlined in section 4.3 below.

4. Completion of the certification processes: The first 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) what additional data will be required for global certification from the three regions which had been certified polio-free by the end of 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. The WHO Secretariat 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

Indicators	2004	2005	2006	2007	2008
Percentage non-certified countries with certification-standard surveillance	*85%*	*90%*	*100%*	*100%*	*100%*
Percentage of AFP specimens in a WHO-accredited laboratory	*100%*	*100%*	*100%*	*100%*	*100%*
Percentage of countries completing each GAP II 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)*

5.3 OBJECTIVE 3: DEVELOP POLICIES FOR THE POST-CERTIFICATION ERA

SINCE 2000, polio outbreaks caused by VDPVs have conclusively demonstrated that the continued use of 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. Consequently, within the next four years every country must decide whether or not to introduce IPV and make provision for its procurement; all wild polioviruses stocks must be under an appropriate level of biocontainment; and the current "rolling stockpile" of trivalent OPV must be complemented with monovalent OPV (mOPV), and possibly IPV.

STRATEGIC APPROACH:

The broad policy objective for the post-certification era 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. 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 in the post-certification era, due to either the continued use of 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 mitigating the post-certification risks. Particular emphasis was given to 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 post-certification risks 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) detection and notification of circulating polioviruses as public health emergencies, (2) long-term biocontainment of all poliovirus strains, (3) polio vaccine stockpiles and outbreak response mechanisms, and (4) routine immunization.

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, subsequent consultations identified three potential options for stopping routine OPV immunization: coordinated cessation of OPV globally (possibly following pulse immunization 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 post-certification era 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 to 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

Table 4: Risks of paralytic poliomyelitis in the post-certification era*

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*

materials were updated in 2003 as additional information on post-certification risks 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, that were considering or implementing a change to IPV for routine immunization, primarily due to national assessments that the risk of VAPP was increasingly unacceptable.

Among the key developments in the area of public consultation was a 2002 meeting on polio immunization policy in the post-certification era 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 immunization coverage.

In 2003, the 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. By late-2003, as a result of the above-mentioned scientific research, programme work and consultations, the 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 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.

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 on the frequency and risk associated with each type of VDPV that 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 a circulating poliovirus after OPV cessation, (c) develop local strategies to reduce specific VDPV risks (i.e. iVDPVs,[9] VDPVs in orphanages), (d) evaluate the efficacy, operational feasibility, costs and production capacity of IPV, alone and in combinations, when and where needed in 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.[10] 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. From 2004 onwards, there will be extensive consultation with OPV-using countries on the risks associated with OPV cessation to facilitate decisions on post-OPV vaccination policies. 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 large-scale 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, as

well as wild poliovirus reintroduction, 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 in the post-certification era, including the potential role of targeted environmental sampling.

3. Polio vaccine stockpile management and evolution: By the end of 2003 the international rolling stockpile of vaccine for responding to wild poliovirus importations and/or cVDPVs consisted of 50 million doses of trivalent OPV (tOPV). This stockpile will grow to 75 million doses as supplementary immunization campaigns are phased out in the period 2006–08. Both the number of doses and range of polio vaccines in this stockpile will expand in the post-certification era and in advance of the cessation of tOPV for routine immunization. As noted above, mOPV will be required to ensure a type-specific response to cVDPVs or containment failures. IPV stocks will be required for country(ies) which have chosen to forego routine immunization against polio but are considered at risk of an imported cVDPV or containment failure in another country. tOPV 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), containment requirements for polio vaccine production and the development of sustainable operating procedures to govern the maintenance and use of the stockpiles.

4. Long-term containment of poliovirus stocks: In the post-certification era, containment issues become more complex as the biosafety requirements for the handling of all poliovirus strains is increased. Wild and vaccine-derived polioviruses in particular will need to be handled similar to other serious pathogens that are under strict containment. In the period 2004–2005 a third edition of the global action plan for the containment of polioviruses will be developed to deal with containment in the post-certification and OPV cessation eras. 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 be used to define the additional requirements, in advance of OPV cessation, for protecting production staff in sites which manufacture IPV from wild poliovirus strains. 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 post-certification and OPV cessation phases. 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 long-term 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 POLICIES FOR THE POST-CERTIFICATION ERA
INDICATORS AND MILESTONES

Indicators	2004	2005	2006	2007	2008
Cessation of routine OPV	*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*	*Begin transition of final countries introducing IPV*
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)*	*Additional tools for surveillance finalized (if applicable)*
Polio vaccine stockpiles and emergency response	*Align management with other stockpiles (yellow fever, meningitis, smallpox)*	*Define mOPV, IPV and tOPV stockpile sizes for post-OPV era*	*Licensure of at least two mOPV suppliers*	*Establish contracts for mOPV stockpile*	*Begin assembly of mOPV stockpile (and possibly IPV)*
Long-term containment of poliovirus stocks	*Consultation on post-certification containment requirements*	*Publication of global action plan, third edition*	*Fully align with security processes for similar pathogens*	*Licensure of at least one IPV product from Sabin strains*	*Begin implement and verification of GAP III*

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

5.4 OBJECTIVE 4: MAINSTREAM THE POLIO ERADICATION INFRASTRUCTURE

SINCE the mid-1990s, the polio eradication infrastructure has increasingly supported a number of other health services, particularly vitamin A supplementation, integrated disease surveillance, refurbishment of routine immunization services, and, most recently, the country-level implementation of GAVI (e.g. new vaccine introduction; immunization services strengthening). As the substantial human resources, physical infrastructure and institutional arrangements established for polio eradication continue to be mainstreamed, transition or integration plans for these other activities must also be enhanced and implemented to minimize the risks to these programmes.

STRATEGIC APPROACH:

Polio eradication has relied heavily on three major approaches: supplementary immunization campaigns, active surveillance with laboratory investigation of cases, and heightened partnership coordination. Throughout the course of the eradication initiative, substantial effort has also been made to use the strategies and resources of the polio 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 and (b) improving routine immunization services by refurbishing the physical infrastructure (e.g. cold chain), updating health worker training and enhancing population awareness. The range of interventions that could be added to polio campaigns was often limited by the use of a largely volunteer workforce with minimum training. 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 being 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 to strengthen 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. In the area of partnership coordination, management and support, the specific mechanisms that were developed, such as interagency coordinating committees (ICCs) and technical advisory groups (TAGs), included in their mandates the strengthening of routine immunization.

To implement these strategic approaches, the polio partnership has 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 "UNGASS/World Fit for Children" and GAVI goals of increasing routine immunization coverage[11] and the global measles mortality and morbidity reduction targets.[12] 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).

SITUATION ANALYSIS:

By mid-2003 the 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),[13] 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, 100% of the international polio-funded personnel and 88% 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.[14] 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.

By the end of 2003, many non-polio activities had become 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 infrastructures 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 80% 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.

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 in standard AFP training activities. Opportunities will be identified to expand the skills of polio-funded staff and facilitate their reintegration, if appropriate, into national programmes.

3. 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 ICCs and, if appropriate, TAGs, for routine immunization activities. While the functions of these groups had been mainstreamed 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 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.

4. 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 between 1990 and 2015. Particular attention will be given to ensuring experiences in the areas of human resources, financing, administration and management are transferred to the international efforts to 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 POLIO ERADICATION INFRASTRUCTURE

INDICATORS AND MILESTONES

Indicators	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%
Percentage of countries where polio operations are fully integrated with those for measles	50%	75%	100%	100%	100%

6 MAJOR ASSUMPTIONS FOR THE 2004–2008 TIMELINE

A number of assumptions have been made in developing the timelines and milestones outlined in section 4 of this Strategic Plan. Of particular importance are those assumptions that affect the timelines of all objectives and which could delay the 2008 target date for global certification, and have substantial financial implications. The major assumptions that have been made relate to the target date for interruption of wild poliovirus transmission globally, and to the frequency of circulating vaccine-derived poliovirus outbreaks. The following sections provide further detail on the these major assumptions; the potential financial implications are outlined in section X.X of the "Global Polio Eradication Initiative Estimated External Financial Resource Requirements, 2004–2008".

6.1 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 Afghanistan, Egypt, Niger and Somalia. However, Afghanistan and Niger 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 India, Nigeria 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.

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[15] in children from minority 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 minority populations in late 2003, particularly in the northern states of Bihar, Uttar Pradesh and West Bengal, transmission could be interrupted in 2004. 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.

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 key 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 on every vaccination team to ensure all communities and households can be visited to search for highest risk, unimmunized and very young children during iSNIDs.

As of mid-2003, the greatest risk to the end of 2004 global target was Nigeria, due to the intensity of transmission in the northern states and the substantial, ongoing gaps in SIA quality. Of particular concern at mid-2003 were data demonstrating that the polio immunity gap among children in key 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.

6.2 FREQUENCY OF CIRCULATING VACCINE-DERIVED POLIOVIRUS (CVDPV) OUTBREAKS

The second major assumption underpinning this plan is that circulating vaccine-derived polioviruses will continue to be rare events requiring only intermittent OPV mop-up campaigns to stop transmission rather than 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 per year in the period 1999–2002, with a total of 28 cases. During the period 1999 to June 2003, the laboratory network has screened over 11 000 Sabin-related polioviruses worldwide, usually isolated as a coincidental finding during the investigation of AFP cases.

Although cVDPVs appear to be rare events, the three 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 were the absence of indigenous wild poliovirus, low routine OPV3 coverage and the cessation of supplementary OPV immunization activities. With the revised tactical approach of 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 coverage as GAVI enhances its efforts as laid out in its Strategic Framework for that period. In addition, there will

be a further heightening of surveillance and closer scrutiny of the VDPVs that are detected through AFP and other surveillance activities, to better understand the risk factors for, and frequency of, cVDPVs. On the basis of this information, the global TCG will by 2005 revisit its recommendations on the need for additional SIAs to prevent the emergence of cVDPVs.

6.3 TIMELY IMPLEMENTATION OF BIOCONTAINMENT ACTIVITIES

The other major assumption that could impact the timeline for global certification, is that containment activities will be fully implemented per the timelines outlined in the *WHO global action plan for the containment of wild polioviruses (second edition, GAP II)*. This plan requires that by the end of 2004 all countries have completed a nationwide survey of laboratories, established an inventory of all facilities holding wild polioviruses or potentially infectious materials, and have implemented BSL-2/polio level safety measures. One year after the last wild poliovirus has been detected (e.g. 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 global action plan demonstrates that this timeline is feasible, achieving these milestones requires accelerating containment in a limited number of large industrialized countries, initiating activities in many recently endemic countries and, as importantly, working with manufacturers to ensure IPV production is appropriately contained. ❐

7 CROSS-CUTTING CHALLENGES

THERE are five 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 possible detrimental effects.

7.1 POLITICAL COMMITMENT AND ENGAGEMENT IN ENDEMIC AND POLIO-FREE COUNTRIES

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 both 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 AFP surveillance, achieve containment of wild 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 in the face of 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 Initiative in this critical period.

7.2 EXTERNAL FINANCING

The second major cross-cutting challenge will be to close the funding gap of US$ XXX million for 2004–05 to interrupt wild poliovirus transmission globally, and the US$ 375 million for activities needed to achieve containment, global certification and the mainstreaming of the polio-funded infrastructure during the period 2006–08. This mainstreaming of the polio infrastructure is essential to ensure that the investment made in eradication continues to strengthen health systems, particularly global immunization, surveillance and response activities. The central importance of this issue to the ultimate success of the 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 interruption in financing 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)[16] will continue its ongoing resource mobilization efforts. Special attention will be given to finalizing the commitment of G8 members, particularly France, Germany and Italy, to close the funding gap for eradication activities in Africa and to identifying new partners, particularly those interested in mainstreaming the polio infrastructure as outlined above. 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 OECD/DAC countries to participate in this historic initiative. The polio partnership will put a particular emphasis on seeking multiyear financial commitments through global certification.

7.3 SUPPLY OF 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 polio transmission will require an estimated X.X 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 post-certification era. In addition to OPV, it is anticipated that there will be an increasing demand for IPV, in a variety of formulations, regardless of the long-term policy decisions for future polio immunization.

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

7.4 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. Finally, such areas may have particular interests that 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.[17]

7.5 PUBLIC INFORMATION, MOBILIZATION AND COMMUNICATION

Throughout the Polio Eradication Initiative, the information and engagement of the public sector has been central to activities ranging from strategy implementation in endemic areas to resource mobilization in donor countries. Most urgently, social mobilization efforts must be enhanced in the remaining endemic areas to fully engage the affected, often minority, populations, as well as to address rumours which have undermined public confidence in the Initiative. In donor countries, the high profile and awareness of the Initiative must be maintained to facilitate resource allocation decisions through global certification. In all countries, the development of post-certification policy, particularly for future routine polio immunization policy, will generate new demands in this area of work.

The polio eradication partnership will continue to place a strong emphasis on public information, mobilization and communications during the period 2004–08. The technical capacity that has been established in this area at the global, regional, national and subnational levels will be continued and where necessary expanded to support government efforts. The cross-agency mechanisms for coordinating communications and social mobilization inputs will continue. New materials will be developed and widely disseminated to support this work. ❐

8 ROLES OF PARTNER AGENCIES

8.1 GOVERNMENTS

National governments of polio-endemic, recently-endemic and polio-free countries are the owners and beneficiaries of the 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 at least US$ 2.35 billion in volunteer time alone for polio eradication activities between 1988 and 2005.[18] Governments of polio-endemic and recently-endemic countries also conduct advocacy with donor governments and at various multilateral

8.2 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 all components of the Global Polio Eradication Strategic Plan are well implemented, and has a key role in monitoring and evaluating all aspects of the Plan. WHO also coordinates operational/basic science 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.

United States 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 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 that will facilitate development of post-certification 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 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 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.

8.3 DONOR AND TECHNICAL PARTNERS

Agencies for international development cooperation: These agencies play a central role in the 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 provide significant technical input through participation in global, regional and country-level ICCs and technical oversight bodies. International development agencies have contributed to the 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, the United Kingdom (DfID), and the United States of America (USAID). These donors have contributed or committed US$ 1.76 billion to the programme, or 59% of all the funds received or projected, between 1985 and 2005. Partners like

Australia, Denmark, the Netherlands and Norway have made significant contributions and are some of the leading supporters, especially on a per capita basis. The 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 Initiative is looking to expand its relationship with key Arab and Asian nations.

Foundations: 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 Initiative's fundraising capacity, leveraging funds through matching grants and introducing other partners to the Initiative. 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 Eradication Initiative having committed US$ 75 million. The 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 Initiative by collaborating with the World Bank to implement a loan buy-down mechanism that will buy polio vaccine for countries such as 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 large endemic countries such as Pakistan and Nigeria. The European Commission (EC) and the EC Directorate-General Development have worked with the spearheading partners to financially support the Initiative in the key countries such as India and Nigeria. Intergovernmental bodies like the G8 and the African Union have strongly supported the 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 Initiative. Most often their contributions are for a specific area or purpose that requires targeted funding. Aventis Pasteur is the Initiative's longest standing corporate partner having donated 110 million doses of OPV over a 10-year period. This vaccine has been earmarked for campaigns in specific African countries that are emerging from conflict. Other key corporate supporters include Wyeth Pharmaceuticals, which funds the African Regional Polio Laboratory Network; the International Pharmaceuticals Manufacturers’ Association (IFPMA), which coordinated a 100 million dose vaccine donation from Pasteur-Merieux, 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 Initiative.

8.4 INTERNATIONAL HUMANITARIAN ORGANIZATIONS AND NGOS

International humanitarian organizations: Organizations such as the International Red Cross and Red Crescent societies assist the Initiative by assisting with the implementation of mass immunization and surveillance activities at the country level. The Red Cross/Red Crescent societies also conduct advocacy at the international and national levels and contribute financial, operational and technical support in the field. This organization also participates in technical meetings, providing guidance to the overall strategy with a particular emphasis on difficult to access areas.

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. ❐

END NOTES

1 Global Polio Eradication Strategic Plan 2001–2005 (WHO/Polio/00.05).

2 Operation MECACAR, West Africa Synchro, SAARC + China Initiative, etc.

3 WHA resolution on poliomyelitis eradication, 1999.

4 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.

5 *WHO global action plan for laboratory containment of wild polioviruses. Second edition.* Geneva, 2003 (WHO/V&B/03.??).

6 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.

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

8 BSL levels.

9 iVDPVs = individuals with primary immunodeficiency syndromes who are long-term excretors of vaccine-derived polioviruses (i.e. > 6–12 months).

10 The experience from polio-free regions demonstrates that both surveillance sensitivity and polio immunization coverage begin to decline soon after certification (the latter due to the cessation of supplementary OPV immunization activities).

11 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.

12 Define measles MR goals.

13 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.

14 Reference WHO polio-funded staff survey and UNICEF data.

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

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

17 MOSS compliance refers to the 'minimum operating security standards' required of UN agencies working in insecure or potentially insecure areas.

18 Reference: Polio Eradication, in eds. Beaglehole and Smith. Global Public Goods for Health.