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Vaccines and Biologicals

Report of the seventh meeting of the Technical Consultative Group (TCG) on the Global Eradication of Poliomyelitis

Geneva, 9–11 April 2002

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World Health Organization
Department of Vaccines and Biologicals
CH-1211 Geneva 27, Switzerland
• *Fax:* + 41 22 791 4227 • *Email:* vaccines@who.int •

Contents

Abbreviations

AFP	acute flaccid paralysis
AFR	African Region
AMR	Region of the Americas
cVDPV	circulating vaccine-derived poliovirus
DR Congo	Democratic Republic of the Congo
EAG	expert advisory group
EMR	Eastern Mediterranean Region
EPI	Expanded Programme on Immunization
EUR	European Region
GAVI	Global Alliance for Vaccines and Immunization
ICC	Interagency Coordinating Committee
IPV	inactivated polio vaccine
NID	national immunization day
OPV	oral polio vaccine
SAGE	Scientific Advisory Group of Experts
SEAR	South-East Asia Region
SIA	supplementary immunization activity
SNID	subnational immunization day
TAG	Technical Advisory Group
TCG	Technical Consultative Group
TFI	Task Force for Immunization
VDPV	vaccine-derived poliovirus
WPR	Western Pacific Region

Executive summary

The seventh meeting of the Global Technical Consultative Group for Poliomyelitis Eradication (TCG) in April 2002 noted that progress towards the eradication goal has been considerable. All of the major 2001 programme milestones had been achieved either in full or in part (see table 1). Most importantly, reported polio cases had fallen from 2971 to 480 between 2000 and 2001, with only 10 countries remaining polio-endemic at the start of 2002 (figure 1).

The TCG recognized, however, that substantial risks to achieving the eradication target remain. Of these, the funding gap of US$ 275 million constitutes the greatest threat (figure 2), especially as it could increase by US$ 150 million, should polio transmission continue into 2003. Closing the funding gap should be the highest priority of the partnership.

Among the 10 endemic countries that now constitute three "high transmission" zones (north India, Pakistan/Afghanistan, Nigeria/Niger) and three "low transmission" zones (Horn of Africa, Angola, Egypt (figure 3)) the TCG was particularly concerned with India, which reported 56 per cent of global cases in 2001, and Egypt, where the extent of transmission has been severely underestimated. The TCG was also alarmed that an inappropriate response to wild poliovirus, such as happened in Mauritania in 2001, could still occur at this late stage. Priorities were defined for each endemic country, with the establishment of a national technical oversight body (Technical Advisory Group – TAG) recommended for each.

In reviewing the priorities for non-endemic countries, the TCG questioned the adequacy of acute flaccid paralysis (AFP) surveillance in some areas due to weak AFP quality indicators and/or the high number of polio-compatible cases, especially in Africa (figure 7). Southern Africa, the Horn of Africa and Indonesia were identified as priorities for improving surveillance. Although impressed with the progress in containing wild poliovirus laboratory stocks (figure 8), the TCG emphasized the need for national coordinators and action plans in all polio-free countries by end-2002. Based on an analysis of population immunity in polio-free areas (figure 9), the TCG decided that all polio-free countries bordering a polio-endemic area should conduct national immunization days (NIDs) or subnational immunization days (SNIDs) annually; all other countries which lack 90% routine infant immunization should continue NIDs at least every three years.

The TCG evaluated the work on development of post-certification immunization policy, and identified key data gaps in several areas: the transmissibility of vaccine-derived polioviruses (VDPVs), prevalence of long-term excretors (i.e. in middle-income countries), quality of laboratory containment, vaccine

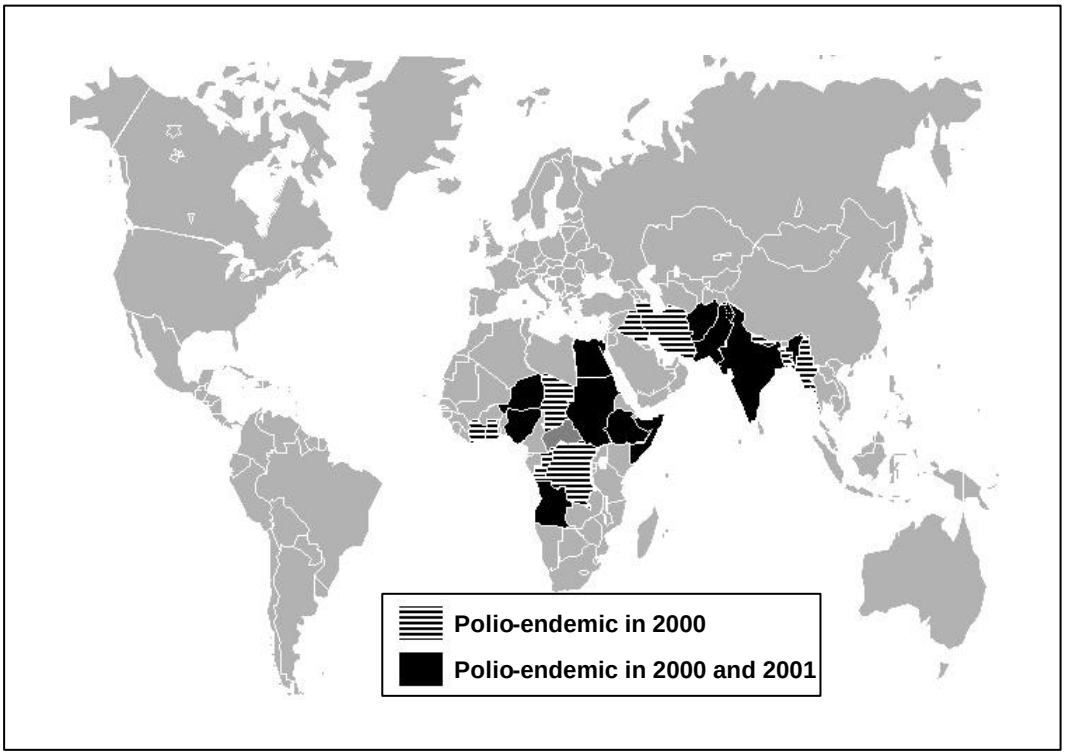
stockpiles, inactived polio vaccine (IPV) efficacy in developing countries and oral polio vaccine (OPV) production in the post-immunization era. Policy decision models, reflecting how the range of possible research outcomes could affect post-certification policy, would also need to be developed and tested through 2003.

Having deliberated on all of the major polio eradication issues, the TCG reviewed and updated the 2002-2003 milestones for each of the objectives detailed in the Global Polio Eradication Strategic Plan 2001-2005 (table 1).

1. Summary of conclusions and recommendations

Rapid progress continues towards the global interruption of wild poliovirus transmission. Between 2000 and 2001 the number of countries considered endemic for polio has decreased from 20 to 10 (figure 1). High-quality surveillance data is increasingly guiding the implementation of national programmes. The number of reported polio cases has declined from 2971 in 2000 to 480 in 2001 (as of April 2002, figure 3). Within the remaining endemic zones, progress is indicated by decreasing geographic extent of virus transmission and a reduced number of circulating virus lineages. Wild poliovirus type 2 has not been isolated since October 1999.

Figure 1: Polio-endemic countries, 2000–2001



The considerable progress towards global polio eradication was only possible through intense efforts in endemic countries and because of continued generous support from the international polio eradication partnership. During the past year, an additional US$ 425 million was raised to cover polio eradication activities through 2005. Nevertheless, a funding gap of US$ 275 million remains (figure 2), which must be urgently closed.

Global polio eradication efforts have brought considerable benefits. Since 1988, polio eradication has prevented an estimated four million children from being crippled for life, and averted at least one million childhood deaths, both through polio vaccination and the provision of vitamin A during NIDs. Further improvements in targeted social mobilization and information efforts have been an important element of success. Countries increasingly utilize polio eradication activities to further improve routine immunization services and disease surveillance.

However, the TCG is very concerned that only eight months remain to reach the goal of interrupting virus transmission globally by end-2002. Intense, greatly accelerated efforts during the remainder of 2002 and continued strong political support will be needed both to improve surveillance everywhere to reliably find and characterize all remaining foci of transmission, and to intensify supplementary immunization activities (SIAs), especially in high-risk areas, to reach all remaining unimmunized children.

Despite the considerable progress made, the TCG considers that the three zones of high-intensity transmission represent the major risks to the global eradication goal: northern India, Pakistan/Afghanistan and Nigeria/Niger (figure 3). Of particular concern is northern India, which accounted for approximately half of all virus-confirmed polio cases reported globally in 2001, and from where wild virus was imported into polio-free areas elsewhere in India and into other countries (Bulgaria and Georgia). In addition to these high transmission areas, low intensity transmission continues in the Horn of Africa (Ethiopia, Somalia, Sudan), Angola and Egypt. The TCG is concerned that the extent of virus transmission in Egypt had been severely underestimated until recently (figure 4), requiring urgent improvements in the quality of surveillance and supplementary immunization.

The recent isolation of wild poliovirus in West Africa, genetically related to a virus found in Mauritania in 2001, probably indicates a continuing focus of transmission in West Africa that had not been previously detected due to suboptimal surveillance. Response activities targeted at this focus to date have not been adequate.

Continuing transmission of wild poliovirus is the result of suboptimal implementation of polio eradication strategies in the remaining endemic countries. High-quality AFP surveillance is essential to identify problems and high-risk areas, and to guide supplementary immunization efforts (figures 5 and 6). The TCG is impressed with the overall improvements in surveillance, especially in Africa. However, serious technical and programmatic concerns about surveillance quality remain. Failure to collect sufficient clinical information and adequate stool specimens, lack of 60-day follow-up examination, and absence of expert review has resulted in the classification of large numbers of AFP cases as polio-compatible (table 1), particularly in African countries. This raises the possibility of missing ongoing virus transmission. The infrastructure of surveillance systems in many African countries remains fragile, requiring considerable continuing technical and administrative support and timely provision of adequate resources.

The TCG notes that, in addition to the rapid progress made toward stopping wild poliovirus transmission, there has also been considerable progress in the programme of work on the post-certification phase of polio eradication. The objectives of this programme of work are to address (1) the risks of re-introduction of virus into the population from laboratory stocks or long-term carriers, (2) the risks of emergence of VDPVs, and (3) the management of response activities, should these be needed in the post-eradication era. Considerable work remains to be done, particularly in establishing consensus on post-certification immunization policy.

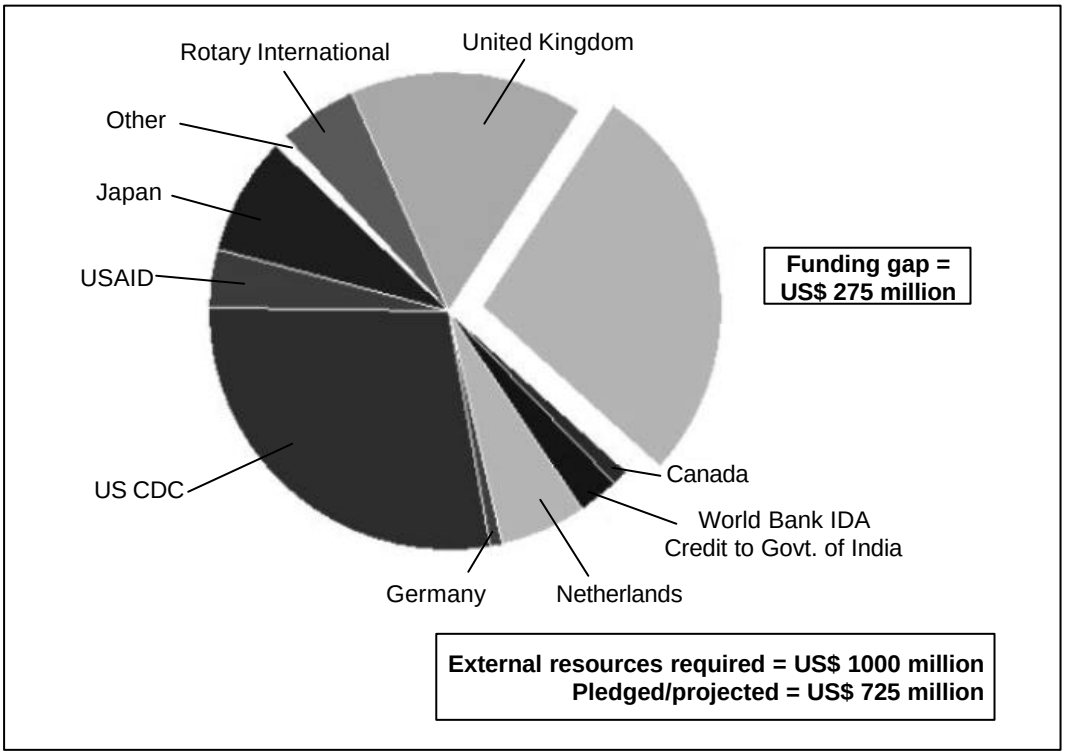
The TCG had noted during its sixth meeting (May 2001) that substantial efforts and resources will be required through 2010 and beyond, to sustain high-quality AFP surveillance, to maintain high population immunity until consensus on post-certification immunization policy is reached, and to manage the risks of re-introduction of poliovirus post-certification. The programme has begun to prepare estimates of resource requirements for the post-certification era; however, further work will be needed in this area.

2. Stopping wild poliovirus transmission

2.1 Resource requirements and resource mobilization

At its 2001 meeting, the TCG regarded the funding gap as the major risk to the initiative. While substantial progress has been made, there remains a serious gap of US$ 275 million for the period 2002-2005 (figure 2, the gap for 2002 is $80m). If virus transmission is not interrupted globally by end-2002, the funding gap will be even larger, over US$ 150 million above current projections for 2003-2005 in a worst-case scenario (i.e. if all endemic areas were to fail to stop poliovirus transmission in 2002).

Figure 2. Required and pledged/projected financial resources as well as funding gap for polio eradication, 2002–2005



Conclusion

The availability of sufficient financial resources remains critical to the success of the global polio eradication initiative. The TCG urged all partners to maintain the highest possible levels of support through certification.

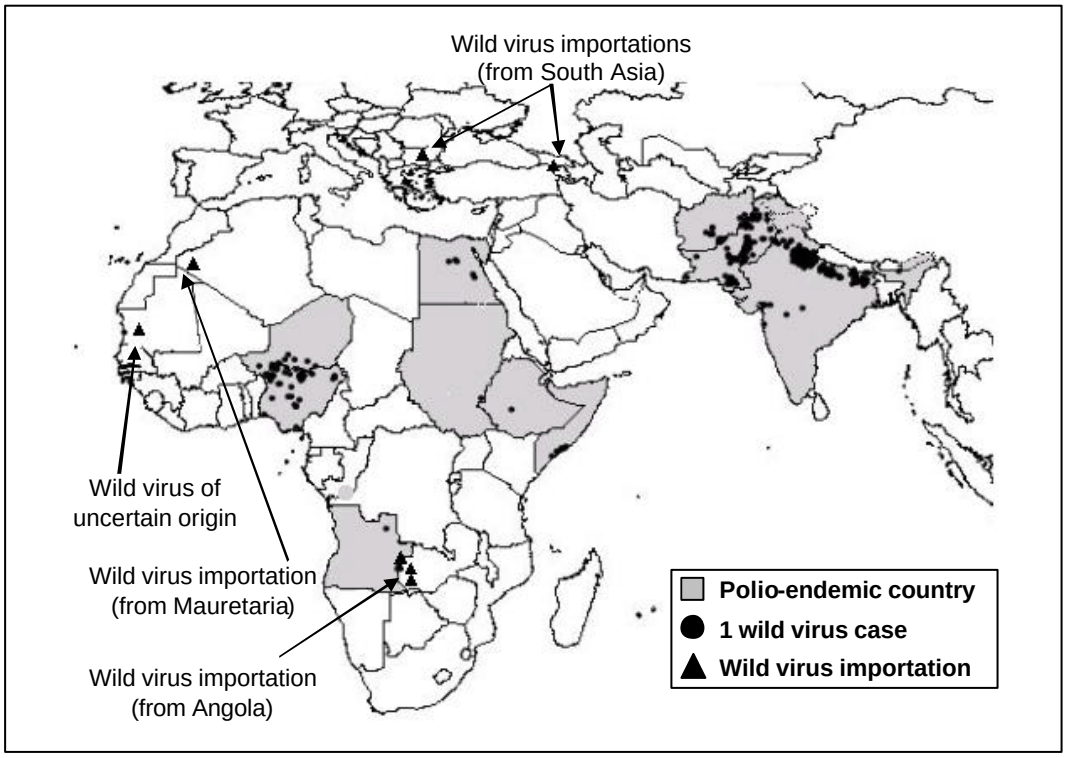
Recommendations:

- WHO and UNICEF should publish, by September 2002, revised estimates of the financial resource requirements for polio activities for the period 2003-2005. In addition to detailing the external financial resources required, this document should reflect, as much as possible, the contributions of the endemic countries themselves, as well as the financial implications of continued wild poliovirus transmission into 2003.
- The estimates of requirements for the post-certification period do not yet provide adequate information to the partnership. Based on various post-eradication scenarios outlined during the seventh TCG meeting, the estimates should be further refined by September 2003.

2.2 Endemic countries and strategic priorities for 2002

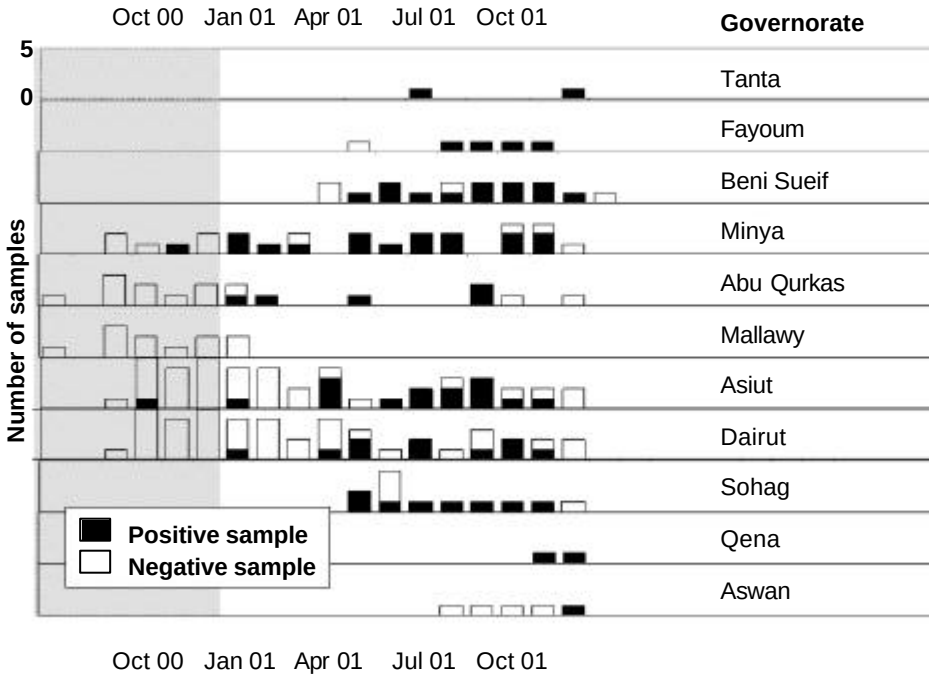
The TCG reviewed the current epidemiology in "high transmission" areas, noting the geographic and/or molecular evidence of ongoing progress in each of these areas. In summary, there has been a 50% reduction in the number of endemic districts in India, a 50% reduction in virus-confirmed cases in Pakistan/Afghanistan and recent localization of transmission in Nigeria to the north/north-west of the country (figure 3). In all "high transmission" countries, detailed programme guidance and strategic priorities for 2002-2003 have been defined by joint national-international technical advisory bodies (i.e. the Polio Expert Advisory Group in India and the Technical Advisory Group on Polio Eradication for Pakistan and Afghanistan) or an expert review (i.e. February 2002 National and International Review of Polio Eradication in Nigeria).

Figure 3: Polio-endemic countries and wild poliovirus, 2001



Of the five "low transmission" countries, only Somalia, Angola and Egypt have had wild poliovirus confirmed polio cases since 1 May 2001. However, surveillance is suboptimal in Ethiopia, and surveillance gaps remain in Angola and the Sudan. Of note, the recent wild poliovirus importation into western Zambia confirmed ongoing virus transmission in eastern Angola. In Egypt, environmental sampling confirmed that circulation of multiple lineages of wild poliovirus type 1 is widespread in Upper (possibly also in Lower) Egypt, indicating that problems in implementing AFP surveillance limit its sensitivity (figure 4). Joint national-international technical advisory groups (TAGs) have now been established for Egypt, the Sudan and Somalia.

Figure 4: Environmental surveillance for wild poliovirus, Egypt, 2000–2001



Despite clear progress in African countries west of Nigeria, a further focus of ongoing wild poliovirus transmission may exist in West Africa. Following the isolation of wild poliovirus type 1 during the first half of 2001 in Mauritania (of uncertain origin, possibly imported), wild poliovirus was recently found again in an area north of Mauritania. Comprehensive investigation, as well as complete surveillance and immunization response, are urgent.

Conclusions

Continued progress towards interruption of wild poliovirus transmission reaffirms that polio eradication is technically and operationally feasible. Insufficient financial resources continue to pose the greatest threat to the eradication initiative. At the country level, heightened attention needs to be paid to the high transmission areas, particularly India. Additionally, special attention is needed for Egypt, and Mauritania and its neighbouring countries.

Following a review of the recommendations made recently by country-level TAGs, the TCG endorsed the surveillance and immunization strategies outlined for each of the remaining endemic countries during this critical year for the global initiative. The TCG notes the significant efforts to improve social mobilization and information activities in most endemic countries. These efforts will have a positive impact on SIA quality and should be continued and further expanded.

The TCG agreed with the following proposal of the global polio eradication partnership as the priority order for resource allocation for country level activities:

a) sustaining the surveillance infrastructure worldwide;

b) ensuring sufficient supplies of oral polio vaccine;

c) ensuring high quality SIAs in endemic countries; and

d) promoting the quality of SIAs in recently endemic countries.

Given the progress in eradication in 2001 in the remaining endemic countries, areas affected by conflict are of increasing importance to global eradication. While governments and polio partner agencies have made further progress to access children in conflict-affected areas, additional well-organized efforts to identify and access critical areas will be needed in 2002.

Because of the rapidly evolving nature of poliovirus transmission worldwide, it would be premature to revise the target date for the cessation of transmission. The Global TCG does recognize, however, that the intensity of virus transmission in the "high transmission" areas, the security concerns in other endemic areas, and the necessary infrastructure work in Egypt, will make it necessary for the initiative to plan for a full programme of work through 2003.

Recommendations:

- The programme should continue to review and update specific contingency plans on a six-monthly basis to deal with potential resource gaps.
- Highest priority should be given to intensify and improve the quality of SIAs in known endemic areas, guided by reliable surveillance data. Results of systematic efforts to monitor and evaluate SIA quality should be used for immediate action to correct problems, and should be documented and provided to the respective country-level TAGs.
- Country-level TAGs or expert advisory groups (i.e. EAG in India) are performing an essential function in endemic countries. All countries endemic for polio in 2001 that do not have an advisory group should establish and convene such a group by September 2002. The terms of reference of country-level TAGs/EAGs should include:
  - critical review of the evolving epidemiology of polio in the country;
  - identification of the risks to achieving eradication, with respect to plans, strategies, and implementation of surveillance and supplementary immunization activities;
  - recommendations as to the appropriate strategies and activities to achieve eradication targets, particularly in the areas of supplementary immunization and surveillance.

- Country-level TAGs/EAGs should be convened by and report to the Minister of Health and meet at least annually. Meetings may need to be convened every six months in rapidly evolving programmes. Whenever possible, TAGs/EAGs should be joint national-international bodies with an appropriate mix of expertise in disease control and eradication. To facilitate collaboration with the Global TCG, country-level TAGs/EAGs should include a representative of the Global TCG, wherever possible. The outcome of country-level TAG/EAG meetings should be documented in brief reports, which should include a summary of key data upon which the strategic recommendations are based.
- During the course of the meetings of country-level TAGs or EAGs, or immediately thereafter, country programmes (i.e. the Ministry of Health (MOH), WHO, UNICEF and other relevant implementing agencies) should translate the recommendations into an operational programme of work. These work plans should define roles, responsibilities and timelines to guide the work of the partnership for the subsequent 6-12 months.
- Social mobilization activities have only recently been accelerated in many countries. All major endemic countries should have completed an evaluation of progress in addressing social mobilization needs by September 2002.
- Polio teams in endemic countries with conflict-affected areas should provide a detailed analysis by end-July 2002 to identify those areas where serious access problems persist and to indicate which potential mechanisms may exist to obtain access for immunization and surveillance activities.
- The TCG should convene again in late 2002 to review all available data, and to further comment on the probable timeline towards stopping wild poliovirus transmission in each of the remaining endemic countries. The partnership will be made aware of TCGs conclusions.

Country specific recommendations:

- **India**: SNIDs should be brought forward to the earliest possible time in the period recommended by the recent EAG (e.g. July and August 2002). Maximum use must be made of both surveillance and SIA quality data to assure the highest possible coverage of very young children, especially in minority groups. It is urgent to systematically evaluate the impact of efforts to improve SIA quality over the last six months and to utilize this valuable information to optimize coverage during the upcoming SIAs.
- **Mauritania/West Africa**: the possibility of a focus of previously undetected transmission in western Africa is of great concern. The WHO Secretariat should urgently clarify the situation by end-May 2002, so that all affected countries can plan and implement response activities as soon as possible.
- **Egypt**: the TCG is impressed by the frank assessment by the Egypt TAG of problems affecting the national polio eradication programme (see figure 4). The TCG urges the MOH Egypt to review the oversight of the programme at national level and requests partner agencies to provide the appropriate technical and financial support.

- **Angola**: an unprecedented opportunity currently exists to access children in all parts of Angola. All partners, especially the government of Angola, are urged to move quickly to achieve safe and effective access to all Angolan children during the planned mid-year NIDs.
- **Pakistan**: the TCG concurs with the strategy of targeting high-risk areas within the country, in addition to focusing on joint virus reservoir areas shared with Afghanistan.
- **Afghanistan**: the re-establishment of an effective programme in Afghanistan should be a global priority. All partners, including the Special Representative of the UN Secretary-General to Afghanistan, all UN agencies, and the provisional Government, are urged to give polio eradication efforts high priority and visibility, in order not to delay the interruption of transmission in Afghanistan, and not to threaten regional and global progress
- **Nigeria**: at this critical juncture of the programme, efforts to improve the quality of SIAs must be intensified, and results reported back to the regional Task Force for Immunization (TFI) and the global TCG. Specific efforts are needed to coordinate activities with Niger. Plans for the formation of an EAG for Nigeria should be carried through and the first meeting held no later than July 2002.
- **Niger**: coordination of surveillance and supplementary immunization efforts with Nigeria should be a priority until both countries are polio-free.
- **DR Congo**: continued efforts should be made to reduce the number of polio-compatible cases through timely and accurate case classification. A progress report on this work should be made to the next meeting of the regional TFI and global TCG.
- **Horn of Africa**: countries in the Horn of Africa (Ethiopia, Somalia, Sudan, and surrounding countries) should ensure appropriate coordination of surveillance and immunization activities, to ensure that no high-risk groups are missed.
- **Ethiopia**: improving the quality of surveillance should remain the focus of efforts over the next 12 months. An expert advisory group for Ethiopia should be formed by September 2002. Particular attention should be given to coordination of surveillance and supplementary immunization efforts between the Ethiopian region V and Somalia.
- **Somalia**: access to the remaining area of transmission in Mogadishu and Lower Shabelle is critical if polio is to be eradicated; all partners, especially UN agencies, are urged to advocate for access and to provide support in accessing these areas for polio eradication work.
- **Sudan**: continued attention should be paid to the quality of the national laboratory, with double-testing of specimens until quality indicators improve. All partners are urged to maintain the coordination between programmes covering northern and southern Sudan and to assure that access to all children is sustained.

3. Priorities in the pre-certification era

3.1 Certification-standard surveillance

The sensitivity of surveillance for wild poliovirus was evaluated by the TCG, beginning with a review of the key indicators (non-polio AFP rates, adequate specimen collection rates, laboratory accreditation) focusing on the Eastern Mediterranean Region (EMR), South-East Asia Region (SEAR) and African Region (AFR) (figures 5 and 6). There has been improvement in AFP surveillance in the priority countries of Nigeria, Angola and DR Congo. Considerable gaps remain however, particularly in Indonesia, southern Africa and the Horn of Africa.

Figure 5: Non-polio acute flaccid paralysis (AFP) rate, WHO African Region, Eastern Mediterranean Region and South-East Asia Region, 2001

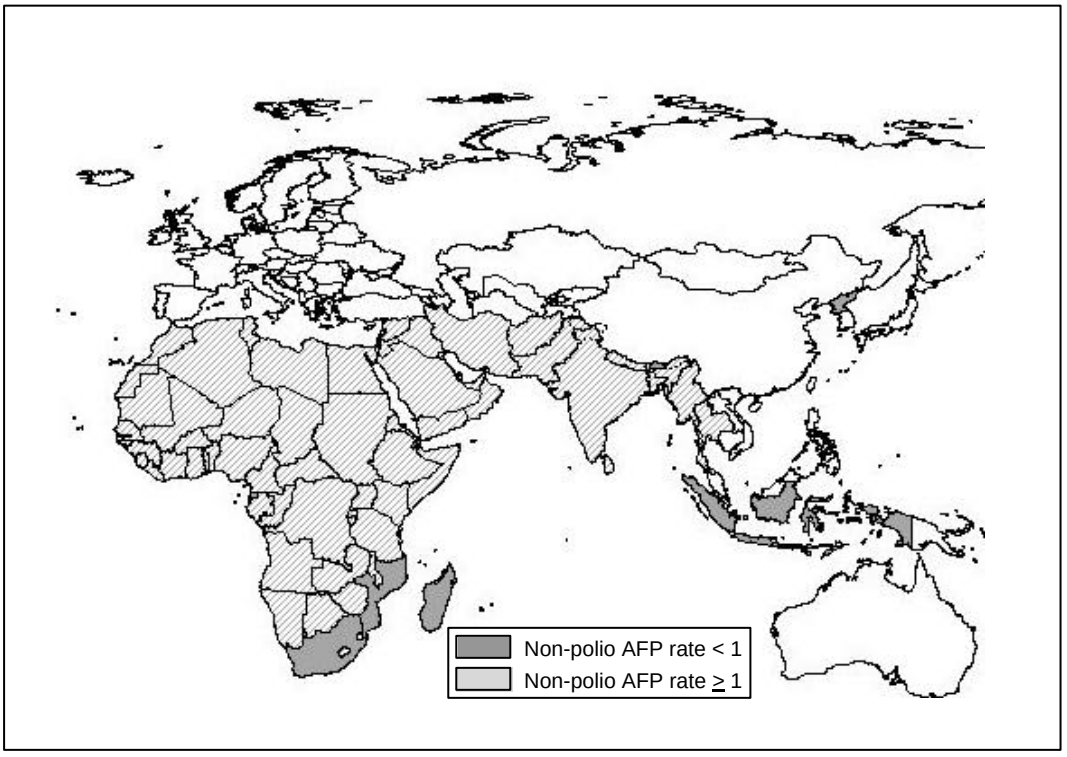
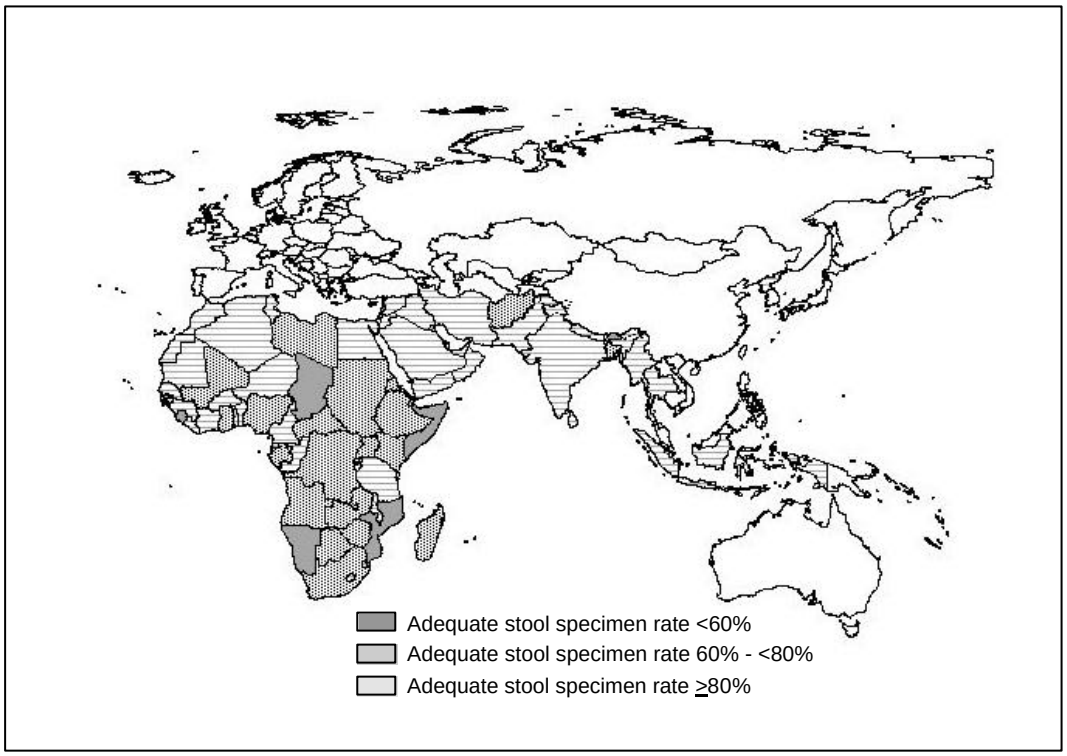


Figure 6: Percent of AFP cases with adequate stool specimens, WHO African, Eastern Mediterranean and South-East Asia regions, 2001



At its last meeting, the TCG made extensive recommendations on the use of AFP cases classified as "polio-compatible" to identify surveillance gaps and areas of potential risk of wild virus circulation. Supplementary information on surveillance sensitivity is now available from genetic sequencing data, environmental sampling and surveillance reviews.

Conclusions

While there have been recent improvements in the timeliness and accuracy of AFP case classification, there remain a large number of polio-compatible cases in many countries following adoption of the virological classification scheme during 2001, particularly in the African Region (table 1). This clearly indicates that the mechanisms for reviewing potential polio-compatible cases are not yet well enough developed. Large numbers of polio-compatible cases represent a failure of the surveillance system.

Table 1: Acute flaccid paralysis, stool specimen collection, confirmed-polio cases and polio-compatible cases, by WHO region, 2001

Region	AFP	Adequate Stool specimens	Confirmed polio	Compatibles (% of total AFP)
AFR	8 541	72%	68	946 (11.1%)
AMR	2 189	90%	10	9 (0.4%)
EMR	3 858	83%	140	77 (2.0%)
EUR	1 752	81%	3	5 (0.3%)
SEAR	10 646	83%	268	221 (2.1%)
WPR	6 527	88%	3	12 (0.2%)
Global	**33 513**	**81%**	**492***	**1 270 (3.8%)**

* Global total includes all wild-virus confirmed cases and 12 cases associated with vaccine-derived poliovirus, data as of 8 April 2002

The sequencing data presented to the TCG demonstrate high AFP surveillance sensitivity in India and Pakistan but reaffirm concerns as to the sensitivity in Egypt. Sequencing data on viruses detected in 2001 also confirms the need to further enhance sensitivity in Somalia, West Africa, the Sudan and Angola.

The TCG notes that AFP surveillance can be developed to certification-standard levels in countries affected by conflict. Despite concerns as to AFP sensitivity in conflict-affected areas, performance indicators and international surveillance reviews (e.g. DR Congo) demonstrate that AFP surveillance quality in these areas, supported where necessary by special surveillance activities such as "active search", can reliably identify wild poliovirus transmission.

The TCG recognizes the increased difficulty of international transport of laboratory reagents, supplies and samples in the period following 11 September 2001, and the increased demands that this is making on the laboratory network. Wherever possible, specific constraints to rapid transport should be identified so that they can be appropriately addressed.

Recommendations:

- The TCG notes the value of AFP surveillance reviews and recommends that:
  - all endemic countries that have not conducted a surveillance review within the last 12 months, or a review of polio activities that incorporated surveillance, should complete such a review by end-2002;
  - any polio-free country that has been unable to achieve or maintain certification-standard AFP surveillance and has not conducted a surveillance review within the last 12 months should complete such a review by end-2002, with particular priority given to the relevant countries of southern and eastern Africa;
  - the methodology of surveillance reviews should be comparable across countries. Standard tools should be developed drawing on the experience of previous reviews.
- Given the inter-regional nature of some geographic blocks (e.g. the Horn of Africa) WHO HQ should be coordinating the mapping of key surveillance indicators across regional boundaries, with the distribution of these maps and appropriate surveillance data to the concerned teams on a quarterly basis.
- Recognizing the high number of polio-compatible cases, the TCG reaffirms the importance of recommendations of previous meetings stating that all countries should:
  - maximize efforts to obtain two adequate specimens from every AFP case;
  - prioritize investigation and follow-up of cases with inadequate specimens;
  - ensure all potentially compatible cases are referred to an appropriately trained expert group for classification within 90 days of onset;
  - monitor and map polio-compatible cases at least monthly, and conduct field investigations of all compatible cases, including active case search, with particular attention to clusters of cases;
  - use data on polio-compatible cases to identify areas for improving surveillance quality and areas at risk of wild poliovirus circulation.
- At this stage of the Global Eradication Initiative, the careful analysis of data on polio- compatible cases is critical. The use of data on polio-compatible cases to identify surveillance gaps and high-risk areas should be strengthened by:
  - the augmentation, by June 2002, of guidelines for expert groups to include a standard format for the analysis of potential compatible cases;
  - re-briefing of expert groups in all countries with high proportions of polio-compatible cases;
  - close scrutiny of the classification and use of compatible cases during surveillance reviews, including the reasons for classification as polio-compatible.
- An interim report on surveillance quality in the African Region should be presented to the next meeting of the Regional TFI. The report should emphasize the mechanism for the assessment of potential polio-compatible cases, and contain an analysis of cases classified as polio compatible, and of the proportion of cases with inadequate specimens that have 60-day follow-up.

- Data on polio-compatible cases, and the trends in classification of these cases, is lacking at global level. The TCG requests a summary report to be included at the next TCG meeting, providing data on the trends in compatible cases over time, comparison of characteristics of polio-compatible cases with other non-polio AFP cases and polio-confirmed cases (e.g. age, vaccination status), and outcomes of the investigation of clusters of compatible cases.
- The TCG notes and supports the mechanism proposed by the Global Laboratory Network meeting (March 2002) for the distribution and updating of genetic sequencing data on polioviruses. The system should be brought into operation as soon as possible. The TCG should receive an update on the status of the system by end-2002 with full details by mid-2003.
- The TCG notes and supports the proposal of the Global Laboratory Network meeting (March 2002) to develop global guidelines for environmental surveillance by July 2002. These guidelines should incorporate previous WHO guidelines on the programme response (both immunization and surveillance) to wild poliovirus isolations from the environment.
- The TCG noted with concern the low percentage of stool specimens arriving at the laboratory within three days of collection, in almost all regions. Priority should be given to improving this indicator in all regions, with a report to the TCG in 2003 on the status of the indicator, the constraints to achieving it, and the potential implications, if any, for wild poliovirus isolation.

3.2 Containment of laboratory stocks of wild poliovirus

An overview of the progress with global laboratory containment was presented, and the TCG noted the progress in all WHO regions, especially in the European Region (EUR) Member States (table 2). The TCG was also updated on the major revisions to the global action plan for laboratory containment, resulting from WHO consultations in October 2001 and March 2002.

Table 2: Progress with global laboratory containment, status March 2002

	WHO region	Coordinator	Plan	Lab list	Survey	Inventory
Non- endemic	AMRO (48)	2	2	1	1	0
	EURO (51)	48	27	28	22	0
	WPRO (36)	36	36	36	36	9
Endemic	EMRO (23)	17	17	1	1	1
	SEARO (10)	3	3	0	0	0
	AFRO (48)	0	0	0	0	0
	Global (216)	106 (49%)	85 (40%)	66 (31%)	60 (28%)	10 (5%)

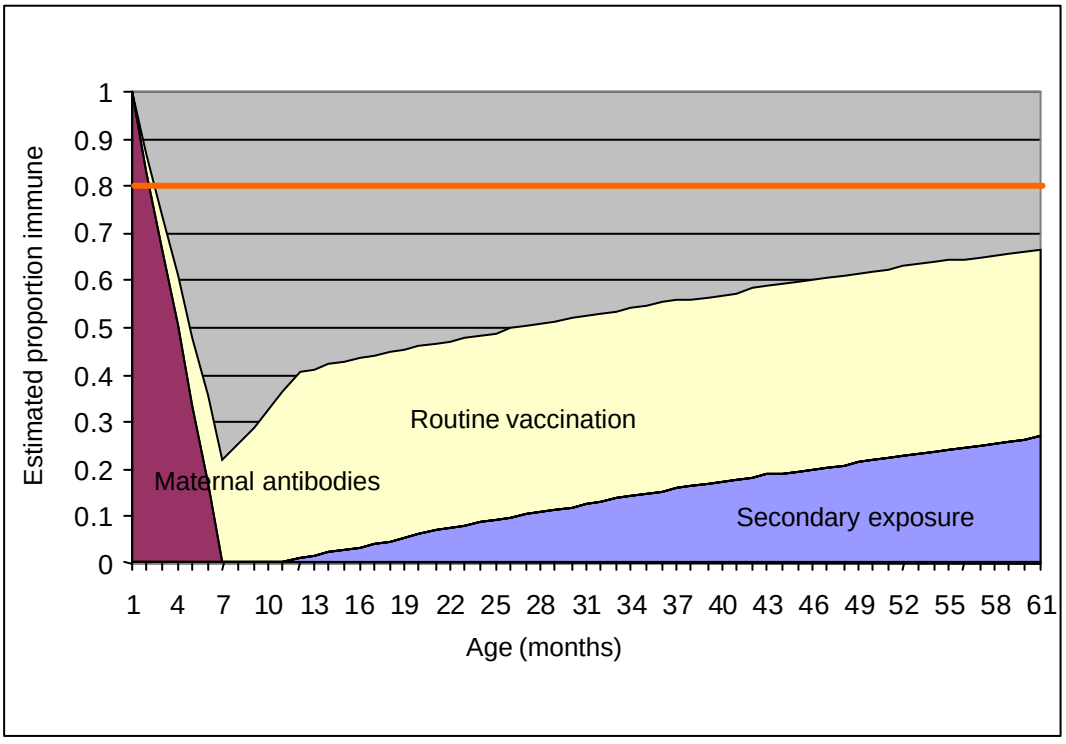
Recommendations:

- The second edition of the global action plan for laboratory containment should be completed by end-July 2002, and widely circulated.
- WHO should urge all non-endemic countries to appoint a national containment coordinator or task force and establish a national plan of action by end-2002, with particular emphasis on countries of the Americas, as well as appropriate polio-free countries of SEAR and EMR.
- Potential tools for the validation of the containment process at the national level should be developed, pilot tested and reported to the TCG by mid-2003.
- Further studies should be conducted, in at least two additional countries, to assess the risk of wild poliovirus in those materials identified as "potentially infectious" in the course of establishing national inventories in large industrialized countries. This experience should be reported to the TCG by mid-2003.

3.3 Supplementary immunization in polio-free areas

Given the risk of spread of imported wild polioviruses (Bulgaria, Georgia, Zambia) WHO has re-evaluated the role of supplementary immunization in polio-free areas. The analysis presented to the TCG (figure 7) demonstrates the importance of polio-free areas continuing to use periodic NIDs or extensive SNIDs to maintain population immunity. The occurrence of the recent vaccine-derived poliovirus outbreaks (Hispaniola, Philippines) in the presence of low population immunity provides further argument for achieving and sustaining high immunization coverage, ideally through routine immunization services.

Figure 7: Population immunity by age, assuming 50% OPV3 immunization coverage and 15% secondary exposure



Recommendations:

- In all countries, plans for SIAs should be integrated with broader multi-year national immunization plans, including those developed in conjunction with proposals for Global Alliance for Vaccines and Immunization (GAVI) support, where applicable.
- Polio-free countries that border endemic areas, or have very low immunization coverage, should continue to conduct national or subnational immunization days, as appropriate, on an annual basis.
- Countries that have been polio-free for at least three years, but have not achieved or maintained a level of 90% routine immunization of infants with three doses of OPV (OPV3 coverage), should continue to conduct NIDs at least every three years, to prevent the accumulation of susceptibles and protect against the importation of wild polioviruses. In larger countries, where appropriate, SNIDs should be conducted to cover those states or provinces with lower than 90% coverage.
- Where provision of resources for SIAs in polio-free countries is an issue, priority should be given to countries in high-risk situations and with the lowest routine coverage.
- The ongoing research on the frequency and risk factors for circulating vaccine-derived polioviruses (cVDPVs) should be used to evaluate the potential role of supplementary immunization activities following regional certification.

3.4 Post-certification immunization policy development

The TCG reviewed progress with the two-part agenda to enable an evidence-based decision on the most appropriate immunization option(s) in the post-certification era.

The first area of work, the research agenda, is proceeding well. Despite screening over 2100 Sabin-like isolates, no new episodes of cVDPV have been identified. Follow-up of the 12 long-term excretors identified during 40 years of OPV use has found that only two are known to continue to excrete, while data from the UK and USA suggest that persistent excretion occurs in at most 0.01-1% of persons with severe immunoglobulin-deficiency diseases. In the area of "new" vaccines, a review of the regulatory issues for monovalent OPV will be available by mid-2002 as well as initial estimates on the size of the stockpile required. The field component of the IPV study in Cuba to address immunogenicity and mucosal immunity in such settings has been completed. A study of the circulation of OPV-derived viruses before, during and after a switch to IPV in New Zealand has been designed to measure the effect of IPV on VDPV circulation.

Draft scenarios for IPV demand were discussed with manufacturers in March 2002, and UNICEF is preparing an exploratory request for proposals to determine the potential supply and public sector price. A proposal to prepare a clinical trial lot of Sabin-IPV is under consideration such that clinical trials could be implemented in 2003 with immunogenicity data available by 2004. To better understand the potential impact of OPV campaigns on the dynamics of VDPVs, systematic analyses of data on Sabin-like isolates after supplementary immunization activities will be completed by mid-2002.

The second area of work involves international consensus-building on policy for the post-eradication era, including evaluation of the economic, political, operational and financial implications of each option. Through advice from policy-makers, primarily from developing countries, the April 2002 meeting of the Global Health Forum on post-certification immunization policy development held in Annecy, France, just before the TCG, has generated critical information required to develop national policy for the post-certification era. This forum has also led to suggestions on appropriate mechanisms for discussing and generating policy consensus.

The TCG was presented with a detailed communications and public information plan to keep countries and interested parties abreast of the issues, and to work towards consensus on important issues related to post-certification immunization policy. The TCG also was briefed on the potential role of the International Health Regulations in the post-eradication era.

Conclusions

While acknowledging progress in implementing the programme of work related to the development of post-certification policy development, the TCG notes the following remaining gaps: (1) type of vaccines, size and operating procedures necessary for managing the vaccine stockpile needed for the post-immunization era; (2) the incidence and relevance of chronic excretion of polio vaccine virus; (3) the determinants of increased transmissibility of circulating vaccine-derived polioviruses; (4) operational and epidemiological issues surrounding the routine use of IPV; (5) assembling information in ways (i.e. decision models) that make it easier to arrive at actual policy decisions; and (6) the working relationship between the programme and vaccine manufacturers is not yet as close as is desirable.

Recommendations:

- The TCG makes the following recommendations to address the remaining major gaps in research and programmatic information needed for the development of post-certification immunization policy:
  - *Vaccine stockpile for the post-immunization era*: preliminary information on the potential size, type of vaccines and operating procedures for this stockpile should be available in 2003. The size of this stockpile should be guided by an understanding of how population susceptibility could evolve after immunization stops, the potential spread of poliovirus in various populations, and various sensitivities of surveillance to detect virus. A working group should be formed to accelerate work in this area.
  - *Long-term excretors of polio vaccine virus:* the work to evaluate the incidence and potential risk posed by severe immunodeficiency syndromes should be expanded in middle-income countries. Further work should be done to evaluate the potential transmissibility of viruses from such patients and the potential role of antiviral therapies in clearing the excretion.
  - *OPV production in the post-immunization era:* the programmatic work should be expanded to include an evaluation of the time, costs and other factors involved in restarting OPV production after immunization with OPV has been discontinued.

  - *Transmissibility of VDPVs:* further work should be done to understand the markers of transmissibility of VDPVs, particularly the utility of recombination with non-polio enteroviruses as an indicator of the risk of VDPV circulation.
  - *IPV in developing countries:* given the complexities (and uncertainties) with routine IPV use in developing countries, a multi-year pilot/ demonstration project of IPV routine use (combined with related operational research) should be explored in a tropical island setting.
- Recognizing the progress in the programmatic and scientific research agenda for development of post-certification immunization policy for polio, WHO should develop policy decision models over the next 12 months that reflect how the range of possible research outcomes would affect post-certification policy development. To better understand how differing risk perceptions might influence national or regional policy development, these decision models should be tested with a range of experts familiar with policy development in representative geopolitical areas. The outcomes of this work and its implications should be presented to the TCG in 2003.
- Experience gained from implementation of the communications plan should be used to review and revise that plan by June 2003. This should include further delineation of the goals, objectives and target audiences, the provision of communication tools for national programmes and how the communication plan will be evaluated. The results of this review should be presented to the TCG in 2003.
- The work being undertaken by different institutions, on the economic and financial implications of the possible post-certification immunization scenarios, should be consolidated by mid-2003 to provide a comprehensive view of the potential resource requirements.
- Recognizing the value of the March 2002 meeting with manufacturers on polio vaccine demand post-2005, WHO and UNICEF should plan regular meetings (at least annually, but more frequently if requested by manufacturers) to exchange information and provide a forum for discussion of the vaccine supply implications of policy options.
- WHO should, by September 2002, refine and make widely available the framework it is using for assessing and managing the risk of polio re-introduction or re-emergence once immunization against polio has been stopped.
- WHO should present to the TCG in 2003 an outline of the cross-cluster programme of work for the post-certification era, including biosafety, surveillance and response, and health systems strengthening.

3.5 Programme oversight, administration and human resources

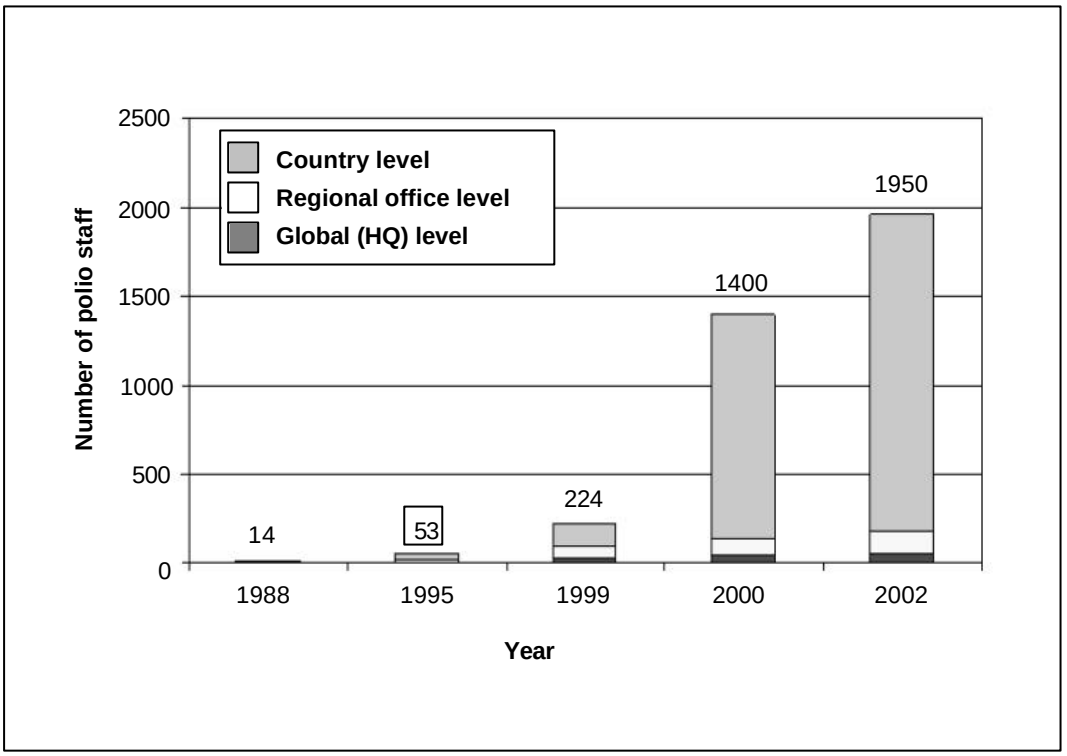
The TCG reviewed the findings of the two major evaluations of the polio initiative that had been conducted in 2001, with particular attention to the thematic evaluation commissioned by the WHO Director-General. The TCG examined the recommendations that the composition and operations of the global oversight body be revised to ensure it can fully and efficiently address all post-certification issues. In considering the optimum expertise and mechanisms for its future work, the TCG noted that its role had been changing with the advent of country-level oversight groups and the increasing attention already being given to laboratory containment and post-certification policy. The TCG also recognized that there are an increasing number of international and national fora for partners to review progress and stay abreast of evolving issues and challenges (e.g. Scientific Advisory Group of Experts (SAGE), regional TCGs and the TFI).

Since 1999 the TCG has commented on the need to enhance the WHO administrative support to polio eradication activities. The administrative challenges posed by the rapid increases in human and financial resources (see figure 8) have been compounded by the fact that most of this growth has been in countries with the weakest banking and security infrastructures. The TCG was impressed with how responsive WHO administration at all levels had been to prior TCG recommendations.

The administrative mechanisms developed to support polio eradication at global, regional and country level have enhanced the capacity of the programme to deal with rapidly evolving situations. The TCG is concerned, however, that this level of support must be maintained and where possible expanded in the period leading up to certification, particularly in the endemic regions and countries. In this critical stage it is vital to maintain the mechanisms developed to improve the speed and efficiency of administrative support. The TCG endorsed the plans to better monitor the performance of this support.

Further to the 2001 TCG recommendation to document the impact of the polio infrastructure on other health services, the results of an extensive survey on the work of WHO polio-funded personnel was presented. Initial analyses found that 91% of polio-funded personnel are regularly engaged in routine immunization activities, 65% had participated in measles or tetanus campaigns in 2001 and 68% conducted surveillance for other diseases. The TCG was impressed by the information documenting that polio eradication teams, consisting of well-trained cadres of motivated professionals, have played a major role in supporting broader immunization programmes and overall health systems. Polio eradication teams represent a very valuable national resource, which countries should plan to continue to take advantage of, even beyond certification of polio eradication.

Figure 8: Increase in the number of polio-funded staff working at global, regional and country level from 1988 to 2002



Recommendations:

- As future meetings of the Global TCG will increasingly focus on specific technical or policy issues for the post-certification era, WHO should ensure that the size of these meetings promotes and facilitates appropriate scientific presentation and discussion of the issues.
- Given the need to limit the size of future Global TCG meetings, WHO and the polio partnership should consider convening occasional public meetings, with invitation to all interested parties, to share information on the status of global polio eradication.
- Given the evolving role of the Global TCG, WHO should identify additional TCG members to strengthen expertise in the areas of international policy development, virology and biosafety. In expanding the TCG, efforts should be made to achieve a better gender balance.
- Recognizing that the move of the African Regional Office to Brazzaville will result in a transition period for support services, the TCG would like to be kept informed about progress in maintaining a high level of administrative support for poliomyelitis eradication activities in the Region.
- The analysis of the survey of WHO polio-funded personnel on their work in other immunization and surveillance activities should be completed and disseminated widely to all partners.
- The TCG reaffirms the need for human resources planning to ensure that all vital functions for achieving and maintaining polio-free status through global certification and beyond are maintained. This plan should be submitted to the next meeting of the TCG.

3.6 Milestones for the Global Polio Eradication Initiative 2002–2003

The TCG reviewed progress against the milestones outlined in each of the five major areas of the Global Polio Eradication Strategic Plan 2001-2005 (table 3). While the five major areas of work outlined in the Plan continue to be appropriate for the polio eradication partnership, however, on the basis of experience gained over the past 24 months there is a need to review and revise the scope of three of the areas (i.e. supplementary immunization, post-certification immunization policy, and impact of polio eradication on health systems), as well as the milestones for 2002-2003.

Recommendation:

- The TCG concurs with the revised scope of work and milestones of the Global Polio Eradication Initiative Strategic Plan 2001–2005, as detailed in table 1 below.

Table 3: Objectives and milestones for the Global Polio Eradication Initiative, 2002 and 2003

Objective	Milestones 2002	Milestones 2003
Interruption of poliovirus transmission	• Transmission of wild poliovirus will be stopped in all countries. • EUR will be certified polio-free.	• Maintenance of global polio-free status.
Supplementary immunization activities (SIAs)	**Endemic countries** • 3-4 NIDs/year and mop-up campaigns will continue in all countries that were endemic in 2000-2001, using a house-to-house strategy. **Polio-free countries** • Continued annual SIAs in all high-risk polio-free countries and long-term SIA plans established for all countries with OPV3 <90%.	**Endemic countries** • 3-4 NIDs/year and mop-up campaigns will continue in all countries that were endemic in 2001-2002, using a house-to-house strategy. **Polio-free countries** • Continued annual SIAs in all high-risk countries, and other polio-free countries with <90% OPV3 conducting SIAs at least every 3 years.
Certification-standard surveillance	**AFP surveillance** • Certification-standard surveillance will be achieved and maintained in all regions and in >90% of countries. **Certification** • National Certification Committees will be established in all countries including all endemic and recently endemic areas.	**AFP surveillance** • Certification-standard surveillance will be achieved in all countries of AFR, EMR and SEAR. **Certification** • Regional Certification Committees receive preliminary reports from National Certification Committees of all countries which have been polio-free for greater than 3 years.
Containment of wild poliovirus stocks	**Process** • National Task Force / Coordinator and National Plans of Action for laboratory containment are established in all non-endemic countries. **Outcomes** • National laboratory surveys are initiated in all non-endemic countries of AMR, EMR, EUR, SEAR with complete inventories in WPR.	**Process** • Regional plans of action are established for the "post wild poliovirus interruption" phase in AMR, EUR and WPR. **Outcomes** • National laboratory survey initiated in all countries with inventories complete in AMR, EUR and the non-endemic countries of EMR and SEAR.
Development of post-certification immunization policy	**Data generation** • All programmatic data required for policy development has been identified or collected. **Policy development** • A framework is developed for assessing and managing post-certification risks of polio re-introduction or re-emergence.	**Data generation** • All scientific research data required for policy development is being collected. **Policy development** • At least one forum is held with key policy-makers in each geopolitical block to receive comments on the risk framework and post-certification immunization policy options.
Strengthening health systems through routine immunization and surveillance	**Routine immunization** • Five of the countries with a large polio infrastructure will have explicit phased plans linking that infrastructure with the routine EPI goals. **Surveillance** • All countries using AFP surveillance will have established a timeframe for expansion to include the notification of at least tetanus and measles cases with laboratory capacity to diagnose measles. **Partnership** • Lessons learned from the Interagency Coordinating Committees (ICCs) are documented, with best practices defined.	**Routine immunization** • Ten countries with a large polio infrastructure will have explicit phased plans for linking that infrastructure with the routine EPI goals. **Surveillance** • All countries using AFP surveillance will have included at least tetanus and measles in the system and established laboratory capacity to diagnose measles. **Partnership** • ICC best practices are disseminated and introduced, at least in the 74 countries receiving GAVI assistance.

Annex 1: Agenda

Tuesday, 9 April 2002

08:00–08:30	Registration
08:30–08:50	Opening statements
08:50–09:00	Introductions, election of officers and adoption of agenda
Day 1:	**Stopping polio transmission**
Session 1:	**Programme objectives and overview**
09:00–10:00	2001 eradication activities, milestones and TCG recommendations Special report: resource mobilization activities and outcomes
	Discussion
Session 2:	**Endemic countries – status, risks and priorities**
10:00–10:30	High intensity transmission areas – Northern India
10:30–11:00	*Coffee break*
11:00–13:00	– Pakistan and Afghanistan – Nigeria and Niger Low intensity transmission areas – Horn of Africa: Ethiopia/Somalia/Sudan – Egypt
13:00–14:00	*Lunch*
14:00 – 15:00	– Central Africa: Angola/Democratic Republic of the Congo
15:00–15:30	Stopping polio transmission: summary of 2002-2003 supplementary immunization activities and OPV supply
15:30–16:00	*Coffee break*
16:00–18:00	Closed session of the Global TCG: recommendations on sessions 1 and 2

Wednesday, 10 April 2002

Day 2:	**The polio endgame**
Session 3:	**Priorities in the pre-certification era**
09:00–12:30	Gaps in global AFP surveillance: – AFP performance indicators including compatible cases – Global Laboratory Network performance and sequencing data – Environmental sampling data – Conflict-affected countries and areas Laboratory containment: progress and proposed revisions to the global plan of action
10:30–11:00	*Coffee break*
	Role of supplementary immunization after interrupting polio transmission
12:30–14:00	*Lunch*
Session 4:	**Development of post-eradication polio immunization policy**
14:00–15:30	Status of programmatic and scientific research: – Frequency of VDPV circulation and chronic excretors – Monovalent OPV and Sabin-IPV – IPV efficacy in the developing country setting – Impact of pulse OPV on VDPV circulation Potential vaccine requirements for the post-eradication policy options
15:30–16:00	*Coffee break*
16:00–18:00	Closed session of the Global TCG: recommendations on session 3 and 4

Thursday, 11 April 2002

Day 3:	**The polio endgame (continued)**
Session 4:	**Development of post-eradication polio immunization policy (cont.)**
09:00–10:30	Factors influencing post-eradication policy – Report of the IGH Forum International Health Regulations and the post-eradication era Programme of work in endgame communications
10:30–11:00	*Coffee break*
Session 5:	**Programme administration and milestones**
11:00–12:30	Administration: management and capacity for the polio eradication initiative Human resources – current status, activities and future plans Polio eradication initiative milestones for 2002-2003
12:30–14:00	*Lunch*
Session 6:	**Closing**
14:00–15:30	TCG conclusions and recommendations
15:30–16:00	*Coffee*
Session 7:	**Closed session of the Global TCG**
16:00–17:00	Report finalization and other business

Annex 2: List of participants

Technical Consultative Group

[*] Dr I. Arita, Agency for Cooperation in International Health, 4-11-1 Higashi-machi, Kumamoto City 862, Japan

Dr R.N. Basu, A73 Yojna-Vihar, New Delhi 110092, India

Dr P. Figueroa, Department of Epidemiology, Ministry of Health, Kingston, Jamaica (Rapporteur)

Dr Mohammed Suleiman Ali Jaffer, Ministry of Health, PO Box 393, Muscat, Sultanate of Oman
(also serves as member of the Global Certification Commission (GCC) and Chair, Steering Committee on Research for the Development of Post Eradication Immunization Policy)

Professor F.K. Nkrumah, Noguchi Memorial Institute for Medical Research (NMIMR), University of Ghana, PO Box LG 581, Legon, Ghana
(a*lso serves as member of the Global Certification Commission (GCC))*

Dr W Orenstein, Centers for Disease Control and Prevention, National Immunization Program, 1600 Clifton Road, Atlanta, GA 30333, USA
(Chair)

Global Commission for the Certification of the Eradication of Poliomyelitis

Professor A. Adams, National Centre for Epidemiology and Population Health, Australian National University, Canberra ACT 0200, Australia

Dr A. Deria, 28 Claudia Place, Augustus Road, GB-London SW19 6ES, United Kingdom

Professor S.G. Drozdov, Institute of Poliomyelitis and Viral Encephalitis of the Academy of Medical Science of the Russian Federation, Moscow 142782, Russian Federation

[*]Professor Jan Kostrzewski, Department of Epidemiology, National Institute of Hygiene, 24 Chocimska Street, PL-00-791 Warsaw, Poland

Dr R. Leke, Department of Immunology and Microbiology, Faculty of Medicine, University of Yaoundé, Yaoundé, Cameroon

Dr C. de Macedo, SMDB Conjunto 01 Casa 05, Lago Sul, Brasilia, DF 71680-010, Brazil

[*] Unable to attend.

Professor Nath Bhamarapravati, Center for Vaccine Development, Institute of Sciences and Technology for Development, Mahidol University at Salaya, Nakhonchaisri, Nakhonpathom 73170, Thailand

[*] Dr F.C. Robbins, Department of Epidemiology and Biostatistics, School of Medicine, Case Western University, 10900 Euclid Avenue, Cleveland, OH 44106-4945, USA

Sir J. Smith, 95 Lofting Road, Islington, GB-London, N1 1JF, United Kingdom

Dr Wang Ke-An, Chinese Academy of Preventive Medicine (CAPM), 27 Nanwei Road, Beijing 100050, People's Republic of China

Technical advisers

Dr J.K. Andrus, Institute for Global Health, University of California, 74 New Montgomery Street, Suite 508, San Francisco, CA, USA

Dr E. Feinglass, Institute for Global Health, University of California, 74 New Montgomery Street, Suite 508, San Francisco, CA, USA

[*]Mrs Maureen Best, Office of Laboratory Security, Health Canada, HPB Building #7, Post Locator 0700A1, Tunney's Pasture, Ottawa, ON K1A OL2, Canada

[*]Dr N.K. Blackburn, National Institute for Virology, Private Bag X4, Sandringham 2132, Johannesburg, South Africa

Dr S. Cochi, Centers for Disease Control and Prevention, National Immunization Program, 1600 Clifton Road, Atlanta, Georgia 30333, USA

[*]Dr J. Deshpande, The Enterovirus Research Centre, Indian Council of Medical Research (ICMR), Haffkine Institute Compound, Acharya Donde Marg, Parel, Mumbai 400 012, India

Dr W. Dowdle, The Task Force for Child Survival and Development, 750 Commerce Drive, Suite 400, Decatur, Georgia GA 30030, USA

Dr T. Hovi, Head, Department of Microbiology, National Public Health Institute (KTL), Mannerheimintie 166, FIN-Helsinki 00300, Finland

Dr O. Kew, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333, USA

Dr D. Salisbury, Department of Health, Room 607A, The Communicable Disease and Immunisation Team, Skipton House, 80 London Road, GB-London SE1 6LH, United Kingdom

Dr H. van der Avoort, Laboratory of Virology, RIVM, Antionie Van Leewenhoeklaan 9, Box 1, NL-3720 Bilthoven, The Netherlands

Dr W. Lim, Head Virus Unit, 9/F Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon, Hong Kong, People's Republic of China

[*] Unable to attend.

Steering Committee on Research for the Development of Post Eradication Immunization Policy

Dr J. Clemens, International Vaccine Institute, Kwanak PO Box 14, Kwanak-Ku, Seoul 151-600, Republic of Korea

Dr P. Fine, London School of Hygiene and Tropical Medicine, Keppel Street, GB-London, WC1E 7HT, United Kingdom

Professor Y. Ghendon, Frunzenskaya nab. 36, Flat 26, Moscow, 119146, Russian Federation

Dr P. Minor, Division of Virology, National Institute for Biological Standards and Control (NIBSC), Blanche Lane, South Mimms, GB-Potters Bar, EN6 3QG, United Kingdom

Dr N. Takeda, National Institute of Health (NIH), 4-7-1 Gakuen, Musashimurayama, Tokyo 208, Japan

Dr P. Wright, Department of Pediatrics, Division of Infectious Disease, Vanderbilt University Medical Center, 1161 21st Avenue South, Nashville, TN 37232 2581, USA

Country representatives

Dr A. Akhgar, Director of Primary Health Care, Afghanistan

Dr W.P. Kandolo, EPI Programme Manager, Democratic Republic of the Congo

Dr Tesfanesh Belay, Head of Family Health and Dr Yigzaw Asnakew, EPI Programme Manager, Ethiopia

Mr J.P. Sharma, Secretary of Family Welfare, Uttar Pradesh, India

Mr A. Amanullah, Secretary of Family Welfare, Bihar, India

Dr S. Sarkar, Assistant Commissioner Secretary of Family Welfare, New Delhi, India

Dr A. Barkire, EPI Programme Manager, Niger

Dr A. Awosika, Coordinator, National Programme on Immunization, Nigeria

Dr R. Hafiz, National EPI Manager, Pakistan

Dr A. El Sayed, EPI Director, Sudan

Polio Eradication Core Partner Organizations

Rotary International

Mr W. Sergeant
Mr P. Carpenter
Dr R. Scott

United Nations Children's Fund (UNICEF)

Mr C. Tinstman
Dr J.M. Okwo-Bele
Dr S. Mahendra
Dr A. Golaz
Dr V. Lara
Mr B. Isselnou
Dr K. Vanormelingen
Dr P. Salama
Dr M. Costales
Mr T. Sorensen
Dr R. Davis
Dr M. Babille
Dr R. Aziz
Dr Q. Al-Nahi
Mr M. Pecho
Ms T. De Bodt
Dr T.O. Kyaw-Myint
Ms J. Bailey
Ms S. Hall
Dr C. Dricot d'Ans
Ms L. Desomer
Dr M. Sheth

Centers for Disease Control and Prevention (CDC)

Dr R. Keegan (*Unable to attend*)
Ms D. Johnson
Dr V. Caceres
Dr M. Pallansch
Mr P. Zuber

Implementing Partners

Francois Bompart, Aventis Pasteur Limited, Connaught Laboratories Ltd, 1755 Steeles Avenue West, Toronto, Ontario M2R 3T4, Canada

Global Alliance for Vaccines and Immunization (GAVI)

Dr V. Pellegrini, International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

[*]Developing Countries and Vaccine Manufacturers Network (DCVNM)

Dr B. Morinière, International Federation of Red Cross and Red Crescent Societies (IFRC), 17 Chemin des Crêts, 1211 Geneva 19, Switzerland

[*]International Committee of the Red Cross, Geneva, Switzerland

[*] Unable to attend.

Donors' and Partners' governments

Ms S. Barrow, Canadian International Development Association (CIDA)

*Gates Foundation

*Ireland

Dr Y. Chiba, Department of International Cooperation, National Medical Centre, Japan

Ms M. Middelhoff, Permanent Mission of the Kingdom of the Netherlands to the United Nations Office and International Organizations at Geneva, the Netherlands

Dr I. Orstavik, National Institute of Public Health, Norway

*Rockefeller Foundation

United Kingdom of Great Britain and Northern Ireland

Ms Andrea Gay, United Nations Foundation, 1301 Connecticut Avenue, NW, Suite 700, Washington, DC 20036, USA

Ms Ellyn Ogden, United States Agency for International Development (USAID)

*Wellcome Trust

World Bank, 1818 H Street, MSN 3-301, Washington, DC 20433, USA

WHO Secretariat - regional and country offices

Regional Office for Africa (AFRO), Harare, Zimbabwe

Dr O. Babaniyi
Ms Y. Kerr
Dr S. Okiror
Dr M. Otten
Dr O. Tomori
Dr K. Kapitaine
Dr A. Gasasira

EPI subregional offices, African Region

Dr R. Eggers, ICP Eastern Block, Kenya
Dr D. Nshimirimana, ICP Western Block, Côte d'Ivoire
Dr J. Rasoarimalala, ICP Central Block, Cameroon

AFRO country offices

Dr R. Gama-Vaz, Angola
Dr M. Kamwa, Democratic Republic of the Congo
Dr A.B. Gaye, Democratic Republic of the Congo
Dr F. Oyewole, Ethiopia
Dr A. Jack, Nigeria

* Unable to attend.

Regional Office for the Americas (AMRO), Washington, DC, USA

Mr P. Carrasco
Dr M. Landaverde

Regional Office for the Eastern Mediterranean (EMRO), Cairo, Egypt

Dr H. Wahdan
Dr T. Gaafar
Dr F. Kamel
Dr H. Ashgar, Laboratory Coordinator

EMRO country offices

Dr A. Mounts, Pakistan
Dr N. Sadozai, Afghanistan
Dr S. Haithami, Sudan

EPI subregional offices (EMRO)

Dr H. Jafari, PAK/AFG/IRN
Dr E. Durry, SOM/SUD

Regional Office for Europe (EURO), Copenhagen, Denmark

Dr S. Wassilak
Dr G. Oblapenko
Dr G. Lipskaya
Dr N. Emiroglu

Regional Office for South-East Asia (SEARO), New Delhi, India

Dr B. Burkholder
Mr J.-G. Tezier
Dr A. Thapa

SEARO country offices

Dr G Hlady, India

Regional Office for the Western Pacific (WPRO), Manila, Philippines

Dr Y. Baoping
Dr S. Roesel
Dr W. Antowiak

WHO headquarters, Geneva, Switzerland

Other clusters

Dr D. Nabarro, Executive Director, DGO
Dr A. Asamoa-Baah, EXD/EGB
Mr Maryan Baquerot, EXD/GMG
Dr D. Heymann, EXD/CDS
Dr Johanna Larusdottir, Director EHA
Ms H. Wild, Director, FNS

HTP cluster

Dr Y. Suzuki, EXD/HTP
Dr D. Tarantola, Director, V&B
Dr B. Aylward, V&B/Polio
Dr J. Bilous, Coordinator, EPI
Dr M. Birmingham, Coordinator, VAM
Mr F. Caillette
Dr E. de Gourville, VAM
Mr H. Everts, EPI
Dr D. Featherstone, VAM
Dr J. Fournier, ATT
Dr S. Lambert, QSB
Mr C. Maher, V&B/Polio
Ms M. Mailhot
Dr J. Milstien, Coordinator, ATT
Ms L. Muller, V&B/Polio
Dr B. Nkowane, EPI
Dr J.-M. Olivé, EPI
Dr R. Sutter, VAM
Dr R. Tangermann, EPI
Mr C. Wolff, VAM
Dr D. Wood, QSB

The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The *Quality Assurance and Safety of Biologicals team* team ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The *Vaccine Assessment and Monitoring team* assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The *Access to Technologies team* endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The *Expanded Programme on Immunization* develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

Department of Vaccines and Biologicals
Health Technology and Pharmaceuticals
World Health Organization
CH-1211 Geneva 27
Switzerland
Fax: +41 22 791 4227
Email: vaccines@who.int
or visit our web site at: http://www.who.int/vaccines-documents

WHO