

WHO/V&B/03.13
ORIGINAL: ENGLISH

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

Geneva, 24–25 April 2003



Vaccines and Biologicals

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**The Department of Vaccines and Biologicals
thanks the donors whose unspecified financial support
has made the production of this publication possible.**

This publication was produced by the
Expanded Programme on Immunization
of the Department of Vaccines and Biologicals

*Ordering code: WHO/V&B/03.13
Printed: August 2003*

This publication is available on the Internet at:

www.who.int/vaccines-documents/

Copies may be requested from:

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List of abbreviations

AFP	acute flaccid paralysis
AFR	African Region
AMR	Region of the Americas
EMR	Eastern Mediterranean Region
ERC	Expert Review Committee
EUR	European Region
cVDPV	circulating vaccine-derived poliovirus
GAVI	Global Alliance for Vaccines and Immunization
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
ICC	Inter-agency Coordinating Committee
IEAG	International Expert Advisory Group
IPV	inactivated polio vaccine
iVDPV	vaccine-derived poliovirus excreted by immune-deficient individuals
NCC	National Certification Commission
NID	national immunization day
OPV	oral polio vaccine
RCC	Regional Certification Commission
SNID	subnational immunization day
SAGE	Strategic Advisory Group of Experts
SEAR	South-East Asia Region
SIAs	supplementary immunization activities
TAG	Technical Advisory Group
TCG	Technical Consultative Group
UNICEF	United Nations Children's Fund
VAPP	vaccine-associated paralytic poliomyelitis
VDPV	vaccine-derived poliovirus
WHO	World Health Organization
WHA	World Health Assembly
WPR	Western Pacific Region

1. Eradication activities and global status of polio transmission

The eighth meeting of the global Technical Consultative Group for Poliomyelitis Eradication (TCG) was held from 24 to 25 April 2003 in Geneva, Switzerland, to evaluate the current status of eradication activities, to identify remaining constraints and propose potential solutions, and to review progress in addressing information needs for policy development for the post-certification era. The TCG had most recently met in November 2002.

From the launch of the global Polio Eradication Initiative in 1988 to 2005, an estimated five million children, who would otherwise have been paralysed, will be walking because of the Initiative. In 2002 alone, the investments in human and financial resources have prevented approximately 350 000 children from being paralysed, including 35 000 children who would have died. Two hundred and nine countries, territories and areas are now polio-free, and 134 of these have been certified polio-free by independent commissions.

A truly functional global surveillance and laboratory network has been established to the benefit of every country. Hundreds of thousands of health workers have been trained or retrained in the implementation of immunization and disease surveillance activities. Millions of volunteers have been mobilized for health. This initiative has now established the groundwork to help tackle many other health issues.

Only seven countries globally could be considered as endemic for poliomyelitis as of the end of 2002. Within those seven countries, transmission in 2002 was limited to relatively small geographical areas (Fig. 1). Six states within three countries were responsible for over 75% of cases reported in 2002. However, as noted in the November 2002 interim meeting of the TCG, considerable transmission is still occurring in the three global reservoir countries (India, Nigeria, and Pakistan) (Fig. 2), and multiple chains of transmission were detected in Egypt throughout 2002. In India, several states that had been polio-free saw the re-establishment of transmission following importation of wild poliovirus from endemic northern states.

As of the date of the eighth TCG meeting, cases have been reported from all three remaining global reservoir countries in 2003. The importation of wild poliovirus from northern India into Lebanon, and from Nigeria into Ghana, in the first quarter of 2003 has provided an additional reminder of the risks to all polio-free areas of continuing transmission in reservoir countries.

Figure 1: Polio-endemic countries and reported wild-virus confirmed polio cases, 2002

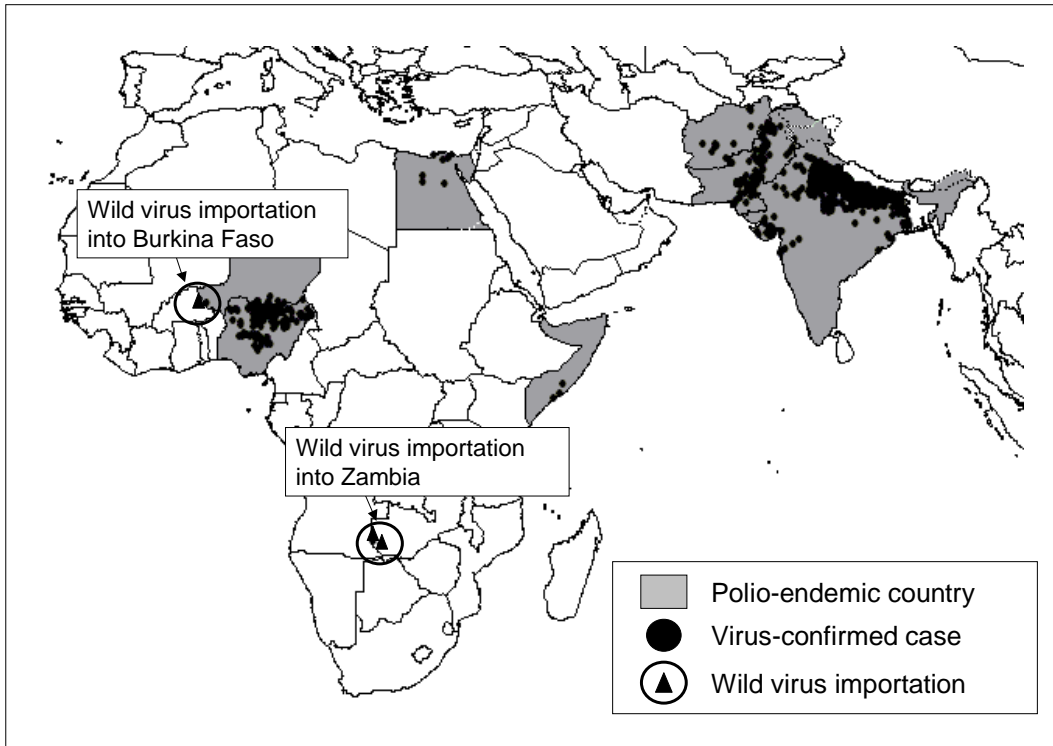
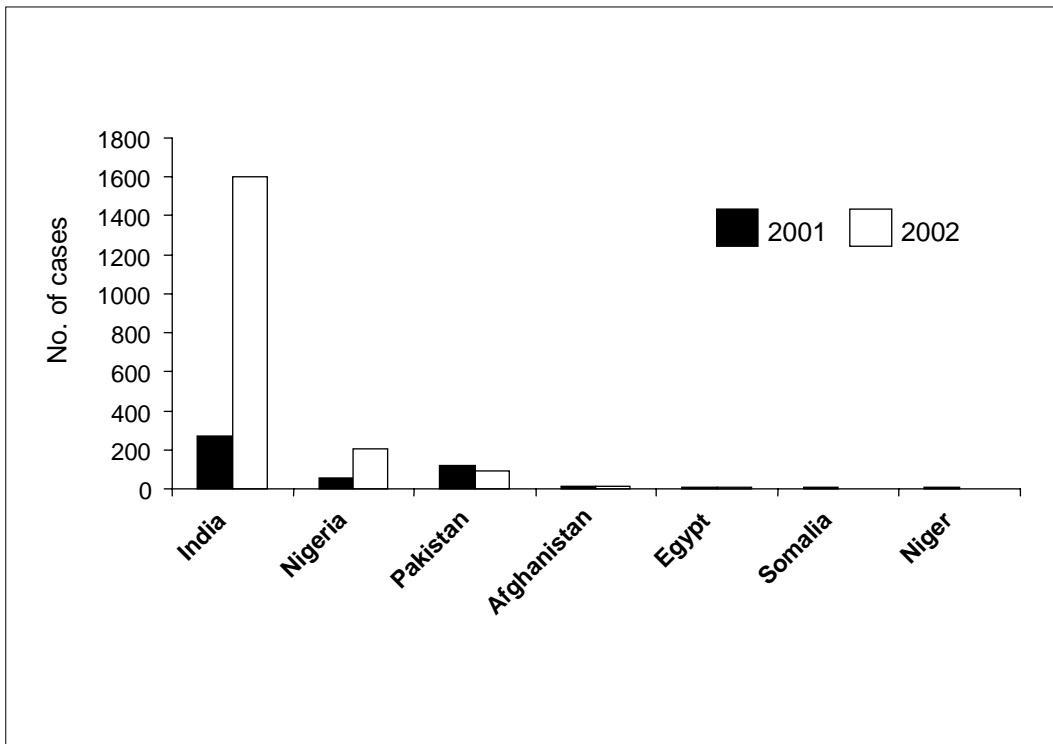


Figure 2: Confirmed polio cases 2001 and 2002 in seven countries endemic in 2002



At the November 2002 interim meeting, the TCG expressed grave concerns about achieving eradication within the next six to twelve months, particularly in Egypt, India and Nigeria. Progress has been reported to the TCG regarding the commitment to polio eradication of governments in endemic countries, particularly Egypt and India. This is an extremely welcome development. However, the major political, managerial, and operational barriers to achieving global eradication referred to in the previous meeting of the TCG are only partially overcome. Further intensive efforts by the national and state/provincial governments of the affected countries, WHO, UNICEF, and other polio eradication partners, must be made and maintained throughout 2003 and 2004 to achieve eradication. With this in mind, the TCG strongly endorses the redefining of strategic priorities by the partnership to further focus on the number one priority of interrupting transmission in the remaining endemic countries as rapidly as possible.

In conjunction with the strategic need to focus efforts, the TCG notes that while there have been considerable new financial contributions in 2003, very substantial needs still exist which must be addressed if critical activities are to be carried out. In 2003 resource availability has limited large-scale supplementary immunization activities (SIAs) to all but the highest priority countries and areas. Unless resource needs are adequately addressed, the global programme may be unable to ensure eradication in the near future, or to maintain the intensive surveillance necessary for certification. Indeed, there is the possibility of the erosion of the gains made to date if wild poliovirus spreads out from the remaining endemic areas. The TCG considers the funding gap as the single greatest impediment to achieving global polio eradication.

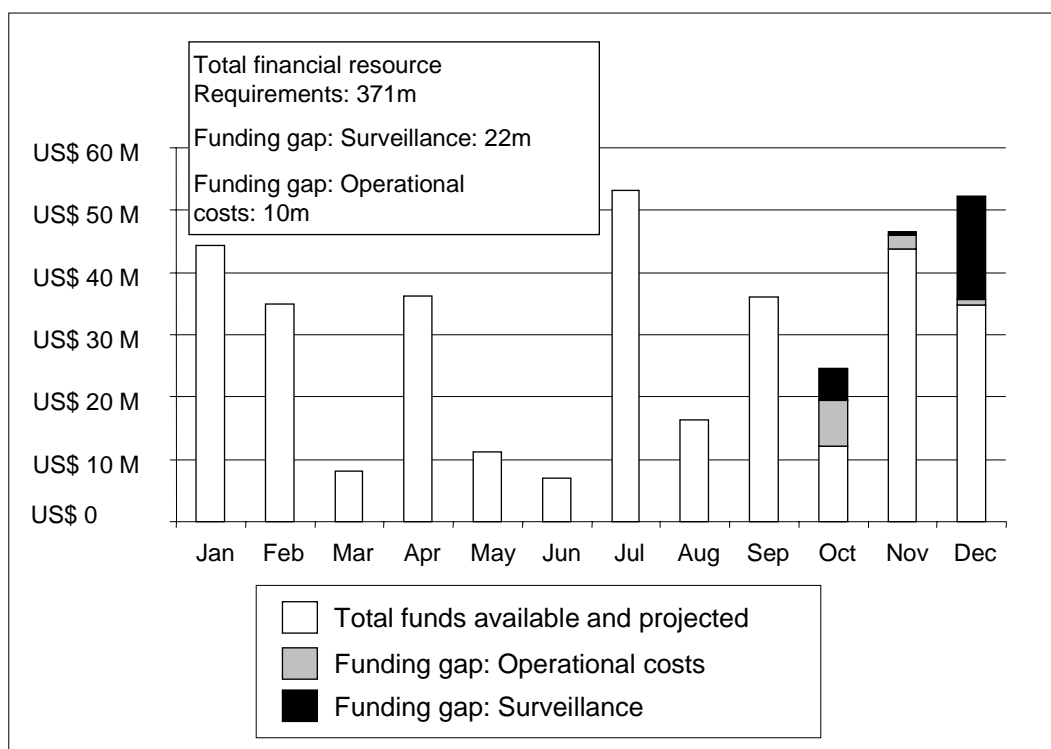
The resource needs were highlighted at a meeting of partners held in conjunction with the TCG (see report on page 28). In order to protect the global investment that has already been made in polio eradication since 1988 – approximately US\$ 2.5 billion – there is a short term critical funding gap for 2003 of US\$ 33 million (Fig. 3), and a longer term need for sustainable, predictable funding to 2008.

At this critical juncture in the global Polio Eradication Initiative, the TCG notes that high-level political attention and oversight is absolutely essential, particularly in the endemic and in donor countries. The TCG further notes the importance of ensuring that this attention not only continues, but is augmented during the transition period between the current and incoming Director-Generals of WHO.

Recommendations

- The secretariat, along with partner groups, should intensify their efforts to close the 2003 funding gap as quickly as possible, and by October 2003 generate revised budget and financing gap estimates for the period 2004–2008.
- In the context of limited resources, the TCG endorses the revised strategic approach for polio eradication activities, which will concentrate resources on the remaining endemic countries and the highest risk areas/countries where importation could re-establish transmission.
- Given the revised strategic priorities and the current global situation, the TCG recommends that the polio partners develop a new Strategic Plan for the period 2004–2008, by October 2003, as per the draft structure proposed. The plan should reflect technical, financial, and communication strategies.
- The TCG recommends that the incoming Director-General of WHO should give consideration to communicating with key endemic countries and the donor community very early in his term, to reinforce the institutional priority WHO affords to polio eradication, and to help mobilize the resources required in the second half of 2003.

Figure 3: Global polio eradication financial resource requirements, funds available/projected, and funding gap, by month, 2003



2. Stopping polio transmission

2.1 General epidemiological situation and programme progress

The TCG reviewed epidemiological and virological data available to the global programme as of 24 April 2003. In 2002 three countries, India, Nigeria, and Pakistan, demonstrated high intensity of transmission and were responsible for over 98% of cases reported globally (Fig 2). In 2003 to date four countries have reported endemic wild poliovirus: India, Niger, Nigeria and Pakistan. In addition, two countries, Ghana and Lebanon, have had importations of wild poliovirus from Nigeria and India respectively. Egypt has reported one positive environmental sample (taken in January) out of 52 tested, a reduction since 2002.

The TCG is convinced that continued transmission in the remaining endemic countries is the result of suboptimal implementation of polio eradication strategies. The major reason for continuing polio transmission in these countries is the existence of large numbers of susceptible children, particularly very young children, as a result of inadequate immunization (both insufficient quantity and/or quality of supplementary immunization, and of routine immunization). The major countries that remain endemic have very large annual birth cohorts and the number of susceptible children needed for continued transmission accumulates quickly. While vaccine quality at the point of use is regularly raised as an issue, the measures being undertaken by WHO, UNICEF, and national governments to ensure that only vaccines from pre-qualified manufacturers are used in polio eradication activities in endemic countries should address any concerns about the initial quality of vaccines.

Recommendations:

- The TCG reaffirms the critical importance of political commitment to polio eradication at all levels in the remaining endemic countries. It is essential that countries live up to the spirit of the World Health Assembly (WHA) resolutions on polio eradication, to which all have been a party, and ensure political oversight and accountability of government staff and structures for polio eradication activities. The TCG reaffirms the importance of the discussion on this topic at the WHA in May 2003, and requests that it be directly addressed in comments from the representatives of the endemic countries.
- Because of the large number of births occurring in the global polio reservoir areas in the intervals between SIA rounds, a birth dose of oral polio vaccine (OPV) should be given in endemic countries.

2.2 High intensity transmission countries/areas

2.2.1 India

In 2002 India accounted for more than 80% of all cases reported globally, primarily because of the large epidemic due to type 1 poliovirus. This epidemic spread from Uttar Pradesh to several other states, most of which had been largely polio-free in 2001. In addition to over 100 cases in Bihar, considerable numbers of cases were reported from West Bengal, Rajasthan, Haryana, Madhya Pradesh, and Gujarat (Fig. 4). Type 3 poliovirus transmission was limited and was largely restricted to Uttar Pradesh. In 2003 to date transmission of both type 1 and type 3 continues in Uttar Pradesh, with extensive type 1 transmission also in Bihar and West Bengal. Together these states account for 70% of reported cases nationally. The TCG is particularly concerned about the situation in West Bengal, which is currently reporting more cases than any other state in India. A high proportion of cases reported are from minority communities.

Following the meetings of the TCG in November 2002 and the India Expert Advisory Group in February 2003, the Government of India has planned for six large-scale SIA rounds in 2003 (two NID rounds and four SNID rounds covering 60% of the national population). The Government of Uttar Pradesh has identified staff to take responsibility for polio eradication at sub-state level, has shown increased engagement in the management of polio eradication activities, and has made efforts to improve the effectiveness of immunization teams (e.g. increasing the proportion of female vaccinators and local community members). Monitoring data from the NID rounds in January and February 2003 indicates improved quality in the highest risk areas in Uttar Pradesh, although quality in several districts has not yet reached the level necessary to stop transmission (Fig 5). In other states where transmission was re-established in 2002, NID quality was not uniform. West Bengal is of particular concern as NID quality was not adequate to stop transmission.

The TCG strongly endorses the conclusion of the International Expert Advisory Group (IEAG) that government ownership of polio eradication efforts at national level and state level in Uttar Pradesh and all other infected states remains essential to ensure that difficult strategic and operational decisions can be taken, to drive improvements in quality and to mobilize the necessary human and material resources. The TCG continues to consider that India, and the state of Uttar Pradesh in particular, constitutes the greatest challenge to the achievement of global polio eradication. While the intensified efforts of the national and Uttar Pradesh governments are very encouraging, these efforts will need to be sustained and expanded throughout 2003 and 2004 to ensure that eradication can be achieved. It remains vital to reach and engage minority populations in Uttar Pradesh and other states.

The IEAG, and the SEARO TCG, which meet in June 2003, should re-evaluate the situation in India based on the latest epidemiological information, and make recommendations on the extent of the autumn SNIDs.

**Figure 4: Wild-virus confirmed polio cases, 2001 to 2002
India, by state**

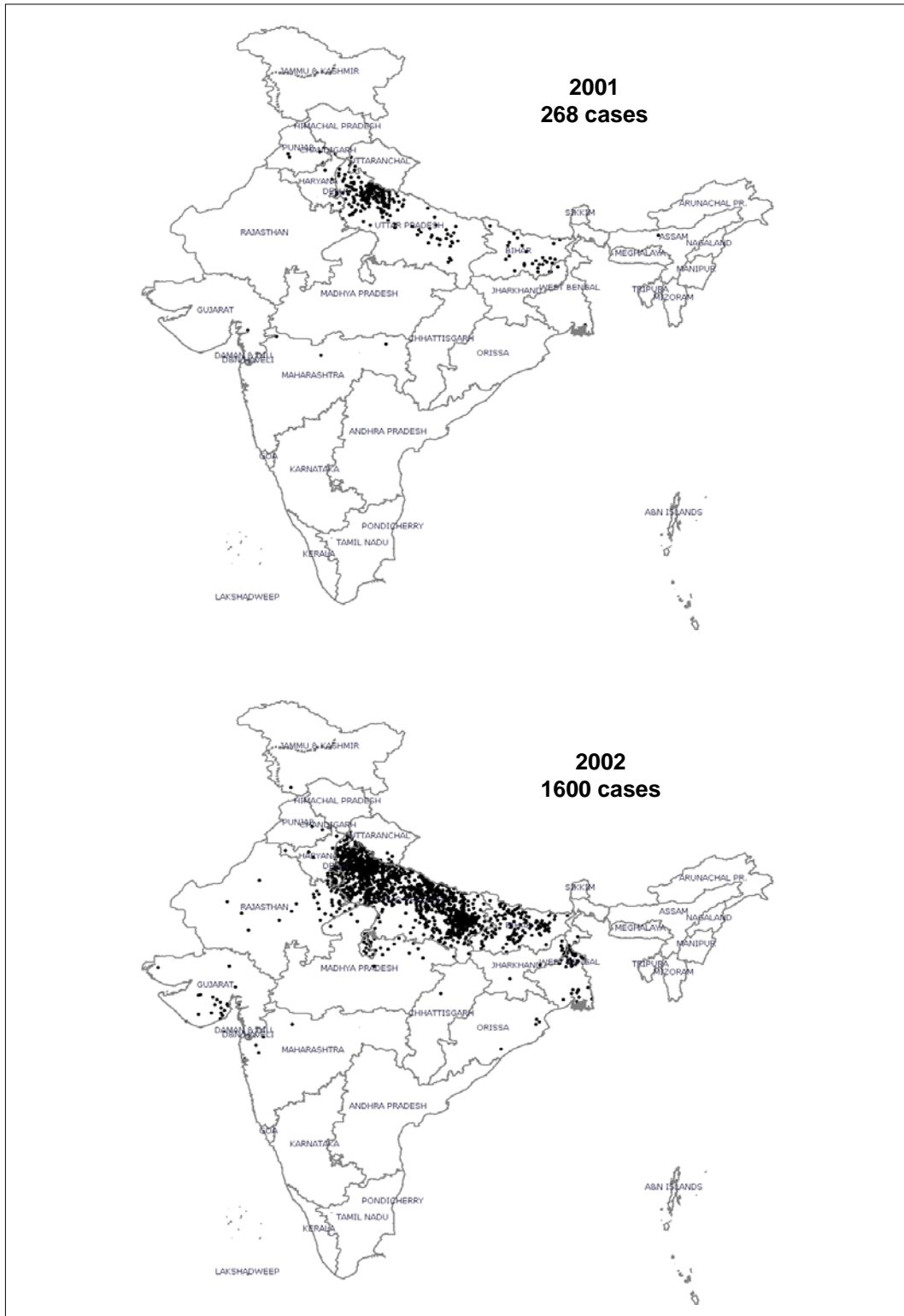
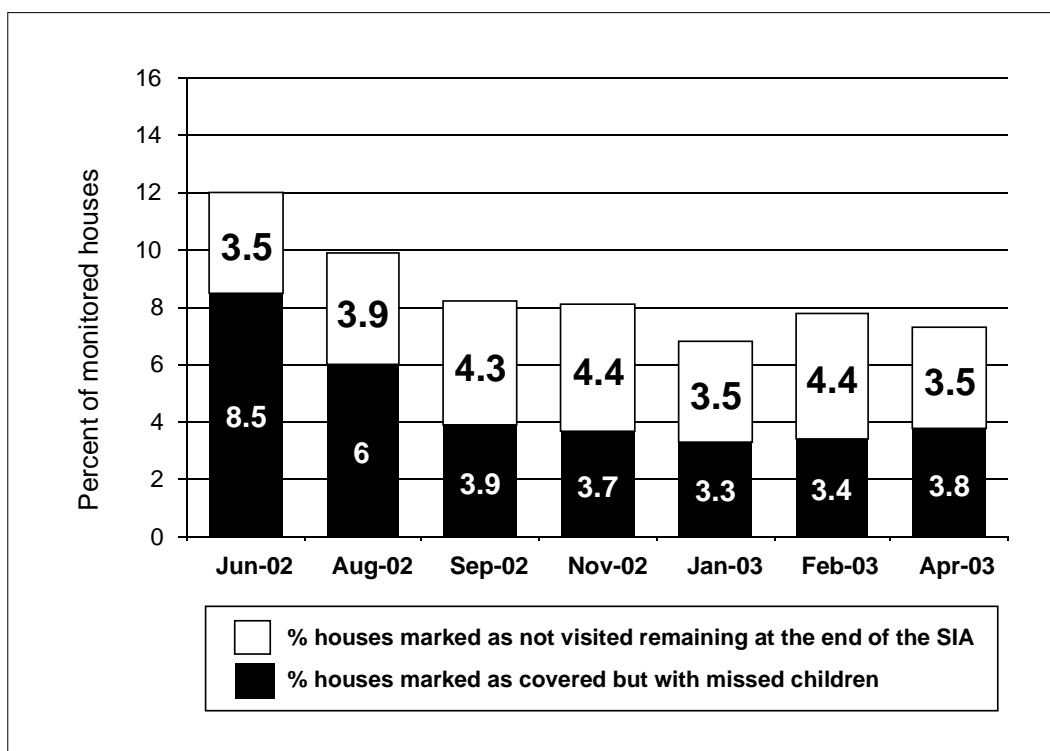


Figure 5: Percent of 'missed houses' detected through post-SIA monitoring, Uttar Pradesh state, supplementary immunization activities from June 2002 to April 2003



Recommendations:

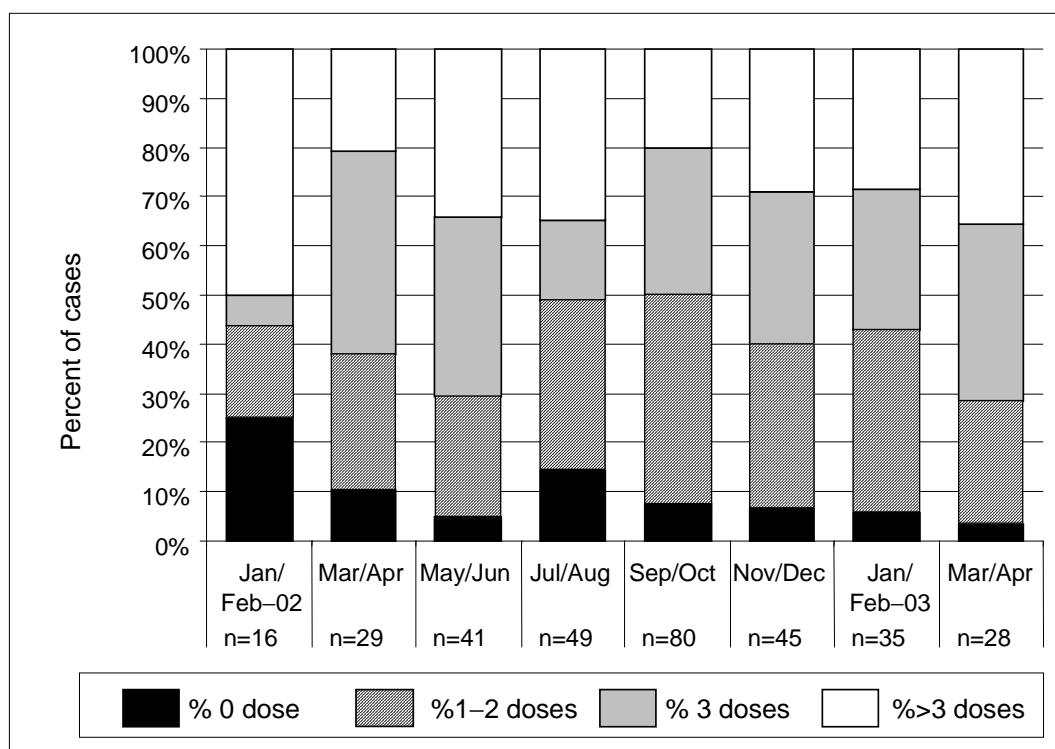
- The TCG notes and strongly endorses the IEAG recommendation for six rounds of large scale SIAs (2 NIDs and 4 SNIDs) for 2004.
- As noted by the IEAG, in 2003 mop-ups following detection of wild poliovirus should be restricted to those areas not covered by SNIDs. Mop-up strategy should be reviewed by the IEAG early in 2004 in the light of the epidemiological situation at that time.
- Extensive efforts must continue to be made to improve the quality of SIAs in all states, including monitoring, supervision, microplanning, and information/education/communication and social mobilization, to engage communities in polio eradication, especially minority communities that are currently under-immunized.
- The governments of all infected states, especially West Bengal, must adopt the intensive efforts now being undertaken in Uttar Pradesh and Bihar to improve the quality of polio eradication activities, including oversight by chief ministers and chief secretaries, and the formation of district task forces chaired by district magistrates.
- Surveillance activities must be intensified in border areas of Bangladesh, India and Nepal to rapidly identify any situation of risk of importation of wild poliovirus into polio-free areas, and to respond appropriately.

2.2.2 Nigeria

The 201 polio cases reported in Nigeria in 2002 demonstrate intense transmission in the northern states. Data from the acute flaccid paralysis (AFP) surveillance system shows that in some northern states the efforts to improve quality of SIAs has had some effect in 2002, with an improvement in the immunization status of AFP cases (Fig 6). However, in a number of states, most particularly in the north-east, most children under five years have less than three doses of OPV. If the situation in these states is not rapidly addressed, it will compromise the progress made throughout West Africa and the whole continent, as evidenced by the ongoing importations of wild poliovirus into polio-free areas.

At the November 2002 meeting the TCG stated that it is still technically feasible to interrupt transmission of wild poliovirus in Nigeria in 2003, but that major operational issues must be overcome and ownership of the programme must be greatly increased at state government level and below. Government commitment at national level in Nigeria is strong but much higher engagement is necessary at state government level in high risk states. This is particularly urgent given the suboptimal quality of recent SIAs in several states. The TCG reaffirms that if improvements in the qualities of SIAs are not sustained and expanded in 2003, especially in the highest burden states, transmission will continue into 2004.

Figure 6: OPV status of non-polio AFP cases <60 months of age in four north-west Nigerian states (Zamfara, Sokoto, Kebbi, Niger) by 20-month interval, 2002 to April 2003



Recommendations:

- Government ownership of polio eradication efforts at state level in high burden states is essential to improving and sustaining quality. Following on from previous efforts, and the changes due to the recent elections, a further consultation with governors and traditional leaders should be held in mid-year to ensure that responsibility for polio eradication is clearly taken at state level.
- The next meeting of the Nigeria Expert Review Committee (ERC) should be convened no later than July 2003.
- Recognizing that the suboptimal quality of SIAs in some states remains a major issue in 2003, the TCG urges the ERC:
 - to expand the September SNID to include all high-risk northern states to supplement planned NIDs in the fourth quarter;
 - to consider different approaches to achieving quality monitoring and implementation of SIAs in late 2003, including decentralization of aspects of planning and management to state and local government area level, improvements in supervision, and staged or rolling activities in high risk states in order to concentrate attention on a few states at a time.
- Timely disbursement of funds from international to national level, and from national to implementation level, must be assured in all future SIAs. This should be monitored by the Inter-agency Coordinating Committee (ICC) in Nigeria.

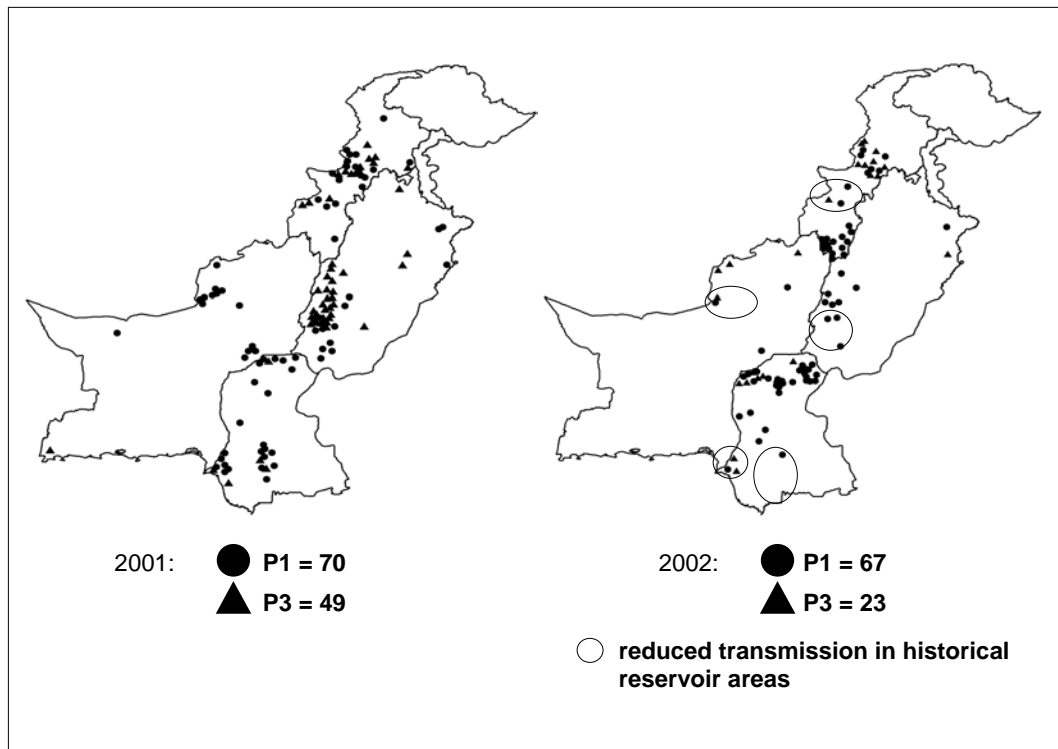
2.2.3 Pakistan

In 2002 Pakistan was the only global reservoir country to report a reduction in case numbers, approximately 25% less cases compared to 2001. Transmission was most significantly reduced in the traditional reservoir areas (Fig. 7). However, transmission has continued relatively intensively in the first quarter of 2003, particularly in northern Sindh province. Despite the generally good quality of surveillance, genetic data shows that some viruses detected in 2003 represent transmission chains that have been undetected for a year or more. Extensive monitoring of the quality of SIAs may not be adequately detecting areas of concern in all provinces.

Nonetheless, analysis of surveillance data is thorough and is used to guide programme decisions. Data from the AFP surveillance system indicates that the immunization status of children has been steadily improving since 2001 (although areas of concern remain, including Baluchistan, where the data indicates lower immunization status than in other provinces). Government commitment has previously been high at national and provincial levels, but the TCG is concerned that following the recent elections further intensive advocacy is needed to fully engage the new government at national and provincial level, as well as in the remaining infected districts.

The TCG still believes that if there is continuing progress in improving the quality of SIAs in Pakistan, transmission of wild poliovirus can be interrupted in 2003. However, this will require intensified government involvement at all levels, particularly in advocacy, and monitoring quality in reservoir areas of each province.

Figure 7: Reduced transmission in historical wild poliovirus reservoir areas, Pakistan, 2001 to 2002



Recommendations:

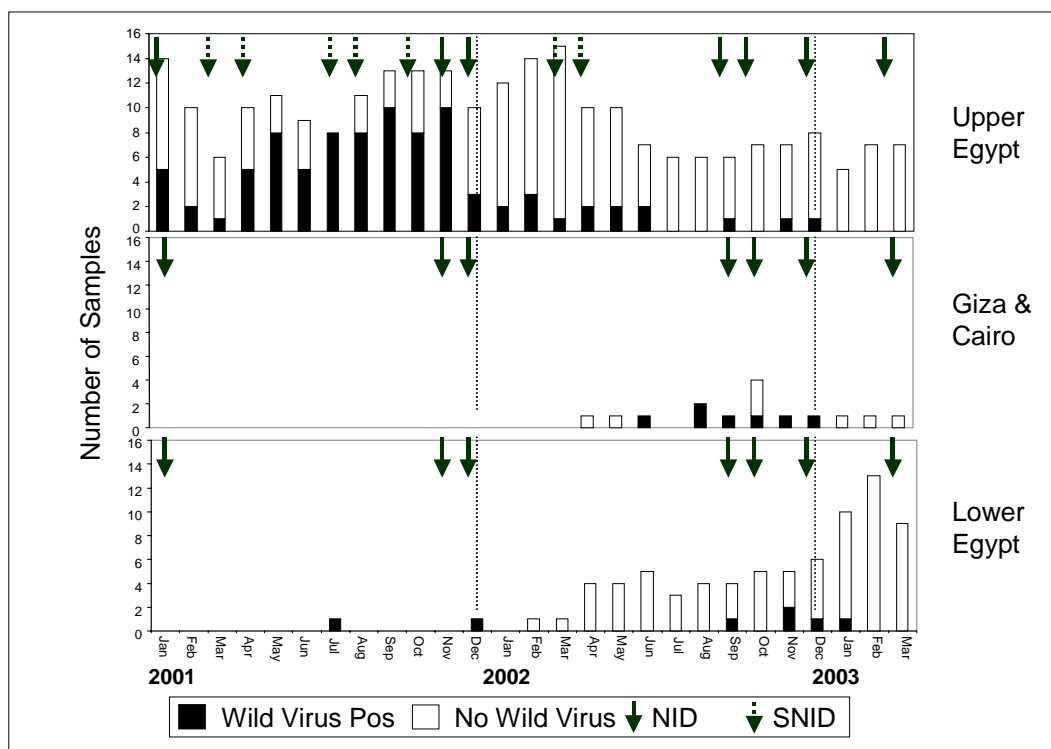
- Given the unprecedented opportunity that now exists to rapidly interrupt transmission in Pakistan, immediate steps should be taken by the partners to engage the new national and provincial government at the highest levels to make the achievement of polio eradication one of their highest priorities and to translate political commitment into action at the implementation level.
- Quality of SIAs remains the major issue; further gains in quality will require a marked increase in high level oversight to ensure accountability at district level and below, especially in known areas of transmission such as northern Sindh, Baluchistan, southern Punjab, and parts of the North West Frontier Province.
- The TCG endorses the proposed SIA plan of four rounds of NIDs and four rounds of SNIDs in 2003. The TCG also endorses the strategy of concentrating on identified reservoir and high-risk areas with the aim of stopping transmission in 2003.
- With ongoing transmission in areas already targeted as high-risk in 2002, the monitoring strategy for SIAs should be reviewed and, if necessary, revised; in particular, extensive use of national and international independent monitors in coming rounds in areas of ongoing transmission.

2.2.4 Egypt

At the November 2002 meeting, the TCG considered that Egypt represented one of the greatest concerns among remaining countries with wild poliovirus transmission. In 2002 environmental sampling provided evidence of widespread transmission, persistent presence of multiple lineages, and failure to identify cases of polio despite improving surveillance indicators.

The TCG was impressed by the recent substantial and encouraging developments in Egypt. Detection of positive samples from the environment appears to have decreased, in 2003 with only one positive sample detected out of 52 tested (Fig. 8). However, this represents the situation in the low season, and the distribution of sampling sites in lower Egypt may not yet be extensive enough to provide reliable information. The AFP surveillance system is detecting more cases and as yet no polio cases due to wild poliovirus have been detected in 2003. A reward system for reporting of AFP cases has been successfully implemented. Data on the SIA rounds in late 2002 and early 2003 indicate improved quality (over 1 million more children reached compared with previous years). However, these improvements are recent and the TCG emphasizes that unless improvements are sustained, particularly with respect to transparency of reporting, transmission may persist. The Government should be encouraged to maintain its initiatives to ensure programme transparency.

Figure 8: Environmental surveillance by region, Egypt, 2001 to March 2003



Recommendations

- Environmental sampling in Lower Egypt should be strengthened by the addition of further appropriate sites in the Giza-Cairo area by the end of May 2003, taking into account the need to assure high-quality laboratory processing of samples.
- Depending on developments over the first half of 2003, the government should reconvene the Technical Advisory Group (TAG) in mid-year to determine if it is necessary to add a third NID or large-scale SNID round in the autumn.
- For improvements in SIA quality to be sustained, extensive pre-planning of each round should be instituted in every governorate, concentrating on the development of clear and achievable microplans; the planning process should begin at least two months in advance of the planned rounds.

2.3 Low intensity transmission countries

Afghanistan and Somalia have maintained strong programmes despite major challenges, including insecurity, conflict, and large scale population movements. In 2002, indigenous transmission in each country was highly focused, type 3 in Mogadishu and surrounding areas in Somalia, and type 1 primarily in the southern region of Afghanistan. Neither country has detected a case to date in 2003. In both countries, the national TAGs are active in identifying constraints to programme implementation and proposing solutions.

Niger demonstrated continued low-grade transmission in 2002, and the detection of ongoing type 3 transmission in 2003 demonstrates that the quality of SIAs has been inadequate. Genetic evidence demonstrates that the cases in 2002 and 2003 are the result of ongoing transmission in Niger, rather than solely importation of wild poliovirus from Nigeria.

Recommendations:

- In countries with low grade wild poliovirus transmission, monitoring of surveillance and SIAs should be concentrated on the remaining areas of known/suspected transmission, e.g. Kandahar area in Afghanistan, Mogadishu and surrounds in Somalia.
- In Niger, efforts should be concentrated on the May and June SNID rounds to ensure the highest possible quality in known areas of virus circulation.

2.4 Importations and their implications

The TCG noted during the interim meeting in November that the isolation of a wild poliovirus in Burkina Faso in 2002, close to the border with Niger, demonstrated the risk of transmission spreading across several West African countries from the reservoir in Nigeria, and this risk has been unfortunately confirmed by the detection of type 1 poliovirus in Ghana in February 2003. Genetic evidence demonstrates that the virus found in Ghana is related both to the Burkina Faso and Niger type 1 viruses detected in 2002, and to northern Nigerian viruses of the same lineage. Viruses originating in Nigeria will continue to threaten all of West Africa until polio transmission in that country is interrupted.

A further importation in 2003 has occurred in Lebanon, where a virus of very recent northern India origin was detected from an AFP case with onset in January. The TCG has previously noted that India is the greatest risk to global polio eradication; India also is the greatest threat to the polio-free status of other countries, having in recent years exported wild poliovirus to Bulgaria, China, Georgia, Syria, and now Lebanon (Fig. 9).

Figure 9: Wild virus importations into polio-free areas, 1999 to 2003



Recommendations:

- Full investigation of the Ghana and Lebanon importations should be completed as rapidly as possible and a decision made as to the extent of the immunization response. Response activities in both countries should be completed at the latest by the end of June 2003.
- Following full investigation of the Ghana importation and the immediate response, and the collection of additional surveillance data from Ghana and neighbouring countries, a decision should be made by August 2003 on whether the response should be extended to include full autumn NID rounds for Benin, Burkina Faso, Ghana and Togo and possibly SNIDs in bordering areas of Cameroon and Chad, in addition to Niger and Nigeria in West Africa.
- The TCG reaffirms that any detection of wild poliovirus in a polio-free area should be considered a public health emergency and a response mounted immediately as per the existing outbreak response guidelines. This is particularly important from 2003 onwards, given the scaling back of preventive SIAs in most countries.

3. Use of data in the Polio Eradication Initiative

Every case of polio should be regarded as a programme failure and the reasons for the occurrence should be determined. This includes evaluating the immunization status of the case and determining for those who are inadequately vaccinated, the reasons. The TCG is concerned that data is still not being fully analysed and understood by those responsible for national programme decisions. To encourage better use of data, the TCG is making the following recommendations.

Recommendations:

- Prior to every TCG meeting, summary case data should be made available to the TCG, including details of immunization status, age, sex, and any other available pertinent details. Where cases are inadequately immunized, the reasons for failure to immunize should be specified as far as possible.
- SIA monitoring data on the reasons for failure to immunize missed children should be summarized for presentation to the TCG.
- Simple, standard analyses of field vaccine efficacy (adjusted for age) should be done in all endemic countries prior to the next TCG.
- Printed or electronic versions of slide presentations should be made available to the TCG one week in advance of the next meeting date. A standard format for presentation should be developed by the secretariat on behalf of the TCG and disseminated to the presenters.

4. Social mobilization and communications

The TCG notes the review of social mobilization and communication activities being conducted in global reservoir countries in response to previous TCG recommendations, and commends the partners for their cooperation in the conduct of the review. Many lessons have been learned in communications and social mobilization over the past few years, particularly in mass information/education/communication and in the development of networks for social mobilization. However, there remain issues in social mobilization and communication that must still be addressed.

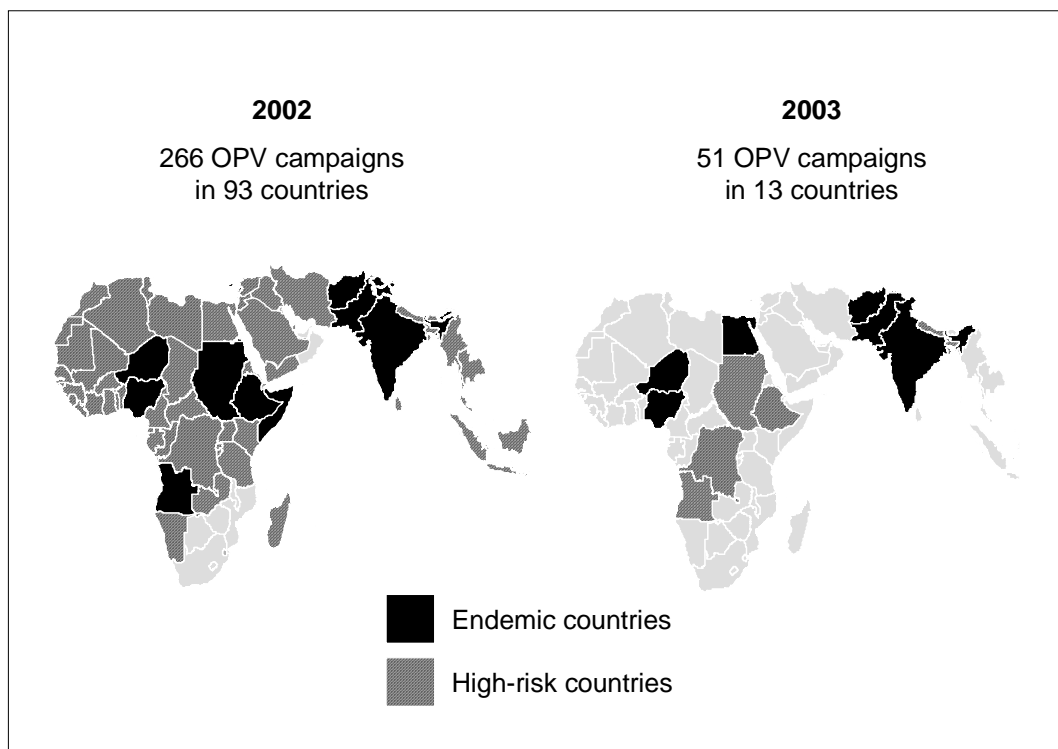
Recommendations:

- The TCG urges the partners to finalize the social mobilization and communication review by the end of May 2003, incorporating feedback from countries, and to then address the issues raised by the review and report on progress at future meetings of the TCG.
- Social mobilization and communication should be fully integrated with the technical direction of programmes at national and subnational level in India, Nigeria, and Pakistan. Particular attention should be given to the use of epidemiological data, especially data on polio cases and on children missed during immunization activities, for planning social mobilization and communication strategies, as well as social data to develop particular approaches.
- Social mobilization and communication should be targeted to those communities that are under-immunized and at highest risk of transmission in all endemic countries, particularly India, Nigeria, and Pakistan, to help ensure that the last remaining vulnerable groups are reached.

5. Supplementary immunization strategy 2003

As noted, the TCG is in agreement with the strategic priorities for 2003 outlined by the global programme. The priorities rest on four essential measures: first, the achievement of excellent quality and adequate number of large scale SIAs in all remaining endemic countries; second, the achievement and maintenance of excellent surveillance in all polio-free countries to ensure rapid detection of potential wild virus importations or circulating vaccine-derived polioviruses (cVDPVs); third, the development of a capacity to respond to emergencies as and when they occur and fourth, the continuation of limited SIAs in countries with large populations and low routine coverage where the risk of re-establishing transmission is particularly high.

Figure 10: Supplementary OPV immunization campaigns in polio-endemic and “high-risk” countries, 2002 and 2003



The TCG sees three priorities for SIA activities in 2003 (Fig. 10), in the following order:

1. polio-endemic countries (India, Nigeria, Pakistan, Egypt, Afghanistan, Niger and Somalia);*
2. countries where wild poliovirus importations occur (currently Ghana and Lebanon);**
3. recently endemic countries at high risk of re-establishment of transmission, should poliovirus be imported (Angola, Bangladesh, the Democratic Republic of the Congo, Ethiopia, Nepal and Sudan).

Recommendations:

- The TCG endorses the SIA plan for 2003 presented for the endemic and highest risk countries, but requests country TAGs to monitor the situation and recommend modifications to these plans if necessary. All other countries must maintain excellent surveillance and improve routine immunization coverage to reduce the risk of importations and subsequent outbreaks.
- In line with the revised strategic approach, WHO & UNICEF must establish an emergency response capacity (i.e. resources allocated for operations and vaccine) to deal with any importations or other situations of great risk, and complement the overall strategy of concentrating on endemic and highest risk areas. A revolving reserve fund of approximately US\$ 10 million should be held for vaccine and operational cost needs.
- From a technical standpoint, continuing NIDs should not be seen as a substitute for the development of strong surveillance and routine immunization. Polio-free countries with less than 85% routine coverage should concentrate on improving routine services. Routine OPV coverage should be monitored every six months to assure that appropriate coverage levels are being achieved.
- Decisions on future SIA policy in polio-free countries will be made by the end of 2005 pending further information on the risks of importations and of cVDPV.

* Listed from highest to lowest burden of disease

**2003 data as of 20 May 2003

6. AFP surveillance and certification progress and priorities

The TCG reviewed data on global AFP surveillance. General progress continues to be made in improving surveillance systems in countries in all endemic regions (Table 1). In particular, the continued strong performance of the global laboratory network has greatly improved the capacity of AFP surveillance to identify areas of risk. The TCG notes the successful completion of surveillance reviews (Fig. 11) in most endemic and high-risk countries, and the identification of specific areas/countries of concern for follow-up.

Table 1: Performance indicators for AFP surveillance, World Health Organization regions, 2002 and 2003*

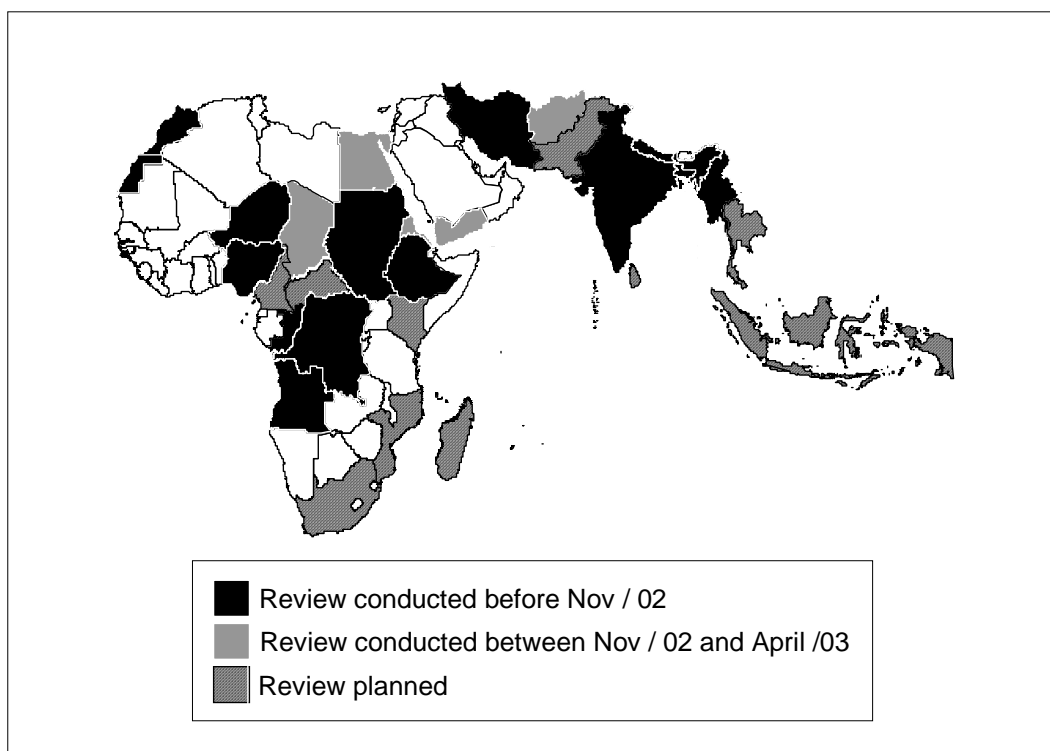
	No. reported AFP cases		Annualized non-polio AFP rate**		% AFP with adequate specimens		Virus-confirmed cases	
	2002	2003	2002	2003	2002	2003	2002	2003
African	8 540	1 729	3.10	2.20	81%	90%	207	34
Eastern Mediterranean	4 596	1 630	2.26	2.11	88%	90%	114	24
South-East Asia	12 914	3 274	1.95	1.09	83%	85%	1 599	77
American	2 119	496	1.27	0.88	91%	81%	0	0
European	1 775	520	1.18	1.08	83%	84%	0	0
Western Pacific	6 231	1 250	1.34	0.69	88%	89%	0	0
Global	36 175	8 899	1.90	1.28	87%	87%	1,920	135

However, the TCG noted with concern that surveillance quality in some polio-free countries, including some recently free countries, had deteriorated. Africa in particular is a major cause of concern. Many countries in the Western and Central African block have suboptimal AFP surveillance in the first part of 2003. Most worrying, Angola has had a notable deterioration of surveillance indicators in 2003. The risks of poor surveillance have been amply demonstrated in the African Region in recent years due to numerous importations of wild poliovirus from endemic into polio-free countries, and also by the recent cVDPV outbreak in Madagascar.

* 2003 data as of 20 May 2003

**Per 100 000 children aged <15 years

Figure 11: International reviews of AFP surveillance conducted and planned (April 2001 to 2004)



Although the global laboratory network is in general functioning to a very high standard, the TCG has concerns over some laboratories, including reference laboratories serving endemic countries such as the regional reference laboratories in Cote d'Ivoire and Ghana. At this stage of the Initiative, the programme cannot afford to lose faith in the reliability of laboratory results in endemic countries.

Three WHO regions – the Americas (1994), Western Pacific (2000) and European Region (July 2002) – are now certified as free of indigenous wild poliovirus. These regions encompass 134 countries and reporting entities, with a total population of more than three billion people. Activities towards certification of the eradication of indigenous wild poliovirus continue in all endemic regions. All countries of the African, South-East Asian and Eastern Mediterranean Regions (with the only exception of Somalia) have now established national certification committees (NCCs). Following a priority schedule that reflects their polio-endemic status, all NCCs have begun to report and submit documentation to the respective Regional Certification Commission (RCC). There is increasingly close coordination of certification and laboratory containment activities at the national and regional level.

The TCG notes the continued progress with implementation of phase I of laboratory containment in both the general laboratory community and inactivated poliovirus vaccine (IPV) production facilities and congratulates all countries that have completed phase activities and submitted a national laboratory inventory. The recent isolation of wild poliovirus type 2 reference strains (MEF-1) from seven AFP cases in India further emphasizes how crucial it will be for all countries to fully implement laboratory containment requirements before global certification. The TCG also notes the progress made towards developing mechanisms for the validation of containment, as well as the better definition of the roles and responsibilities of various groups for validating containment achievements.

Recommendations:

- The TCG endorses the current schedule of surveillance reviews for the second half of 2003 but requests the secretariat to consider repeating reviews in areas where significant problems have been identified, or where health systems are particularly weak, and to submit a revised schedule to the TCG at its next meeting.
- A report on surveillance in Africa should be submitted to the TCG at the next meeting, detailing the surveillance situation, the status of indicators by country and high-risk area, and measures being undertaken to improve surveillance.
- The TCG defers to the Global Certification Commission (GCC) a decision on adoption of the proposal defining roles and responsibilities for documenting and validating laboratory containment measures, and on piloting it in a polio-free region.
- The TCG encourages all countries without ongoing polio transmission, particularly in regions already certified as polio-free, to complete phase I of laboratory containment by the end of 2003.
- The TCG requests that an update on the proposed methodology for validation of laboratory containment achievements be presented at a subsequent TCG meeting.
- The TCG would like to see further data on the risks posed by potentially infectious materials (e.g. specimens collected from polio-endemic areas for other purposes) held in laboratories, at a subsequent meeting.

7. Post-certification policy development

To date, the major focus of the post-certification policy development work has been on defining the risks of polio in the post-certification era, and the potential strategies for managing those risks. These risks have now been defined as those due to either vaccine-derived polioviruses (vaccine-associated paralytic poliomyelitis (VAPP), circulating vaccine-derived poliovirus (cVDPV) or immunodeficient excretors of vaccine-derived poliovirus (iVDPV)) or wild polioviruses (inadvertent release from a break in containment or intentional release). The framework summarizes current knowledge on the magnitude of these risks, suggests how these risks are expected to evolve over time, and outlines the expected impact of the risk-management strategies (Table 2). This framework will be of particular utility in discussions with OPV-using countries.

Table 2: Risks of polio paralysis 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	2–4 cases per million birth cohort	250–500 cases per year
	cVDPV	One episode per year in 1999–2002 (Haiti, Madagascar, the Philippines)	Approximately 10 cases per year (total of 29 cases in three years)
	iVDPV	19 cases since 1963 with 2 continuing to excrete; no secondary cases	<1 case per year
Risk 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.

This meeting of the TCG focused on three specific elements of post-certification policy development: (a) the ongoing work to define the magnitude of the risks due to continued OPV use, (b) long-term IPV supply and interim IPV policy guidelines for OPV-using countries, and (c) the development of vaccine stockpiles for the post-certification era.

Table 3: Results of laboratory screening for vaccine-derived polioviruses, (VDPV) 1999-2001 and 2002, by WHO region

WHO region	Vaccine strains tested with 2 ITD methods								Strains with >1% sequence difference from Sabin strains									Isolates
									cVDPV*			iVDPV*			VDPV* pending			
	P1	P2	P3	All	P1	P2	P3	All	P1	P2	P3	P1	P2	P3	P1	P2	P3	
2002																		
AFR	281	266	403	950	280	261	403	944	0	4	0	0	0	0	0	1	0	0
AMR	16	14	20	50	16	14	20	50	0	0	0	0	0	0	0	0	0	0
EMR	35	25	8	68	33	25	8	66	0	0	0	0	0	0	0	0	0	2
EUR				806				797	0	0	0	1	0	0	8	0	1	0
SEAR	274	243	351	868	274	243	351	868	0	0	0	0	0	0	0	0	0	0
WPR	86	181	116	383	86	181	116	383	0	0	0	0	0	0	0	0	0	0
Total	692	729	898	3125	689	724	898	3108	0	4	0	1	0	0	8	1	1	2
1999-2001																		
AFR				197				187	0	0	0	0	0	0	0	1	0	10
AMR				256				224	31	0	0	1	0	0	0	0	0	0
EMR				478				398	0	0	0	0	0	0	0	3	0	76
EUR				853				824	0	0	0	1	1	0	2	0	2	26
SEAR				1561				1561	0	0	0	0	0	0	0	0	0	0
WPR				78				63	3	0	0	0	0	0	0	0	0	12
Total				3423				3257	34	0	0	2	1	0	2	4	2	124

* See explanatory text on page 22.

7.1 Vaccine-derived polioviruses (VDPVs)

The WHO poliovirus laboratory network screens vaccine isolates with both an antigenic and a genetic method of intratypic differentiation. Over 6500 vaccine strains have now been screened in this way (Table 3). One new cVDPV episode was identified in 2002, in Madagascar, making a total of four episodes in all. Analyses of these episodes suggests that risk factors for emergence of cVDPV are suboptimal OPV coverage creating a population immunity gap in a wild poliovirus-free area.

With respect to iVDPVs, one new long-term excretor was identified in 2002 giving a total of 19 known iVDPVs since the introduction of OPV. Of these 19, two continued to excrete in 2002. Long-term excretion may occur after inadvertent OPV administration in congenital antibody deficiency. Many countries in which such patients survive longest have switched to IPV, so numbers of new long-term excretors are expected to be small.

A small number of isolates are also being identified with the virological properties of a VDPV (>1% genetic drift in the VP1 part of the poliovirus genome) but cannot be classified as either cVDPV or iVDPV. The finding of a VDPV in an under-immunized Roma population in Romania in 2002 prompted an immunization response to close a population immunity gap in this community that historically has been susceptible to poliovirus outbreaks. Programmatic and scientific research will continue to evaluate how cVDPV, iVDPV and VDPV risks evolve.

7.2 IPV policy and supply

The TCG was presented with interim WHO policy guidelines for countries in polio-free areas that currently use OPV and are considering the introduction of IPV into routine immunization schedules. The draft guidelines advise that countries considering a change in polio immunization policy should first conduct a thorough evaluation of the epidemiological, financial, operational and policy implications. Currently, WHO does not recommend the adoption of IPV alone or in a sequential schedule in tropical developing countries for the following reasons: a) the unresolved issues related to the immunogenicity of IPV in this setting; b) the continued focal circulation of wild poliovirus on two continents; c) the relatively high cost of IPV; and d) the operational complexities of introducing this vaccine. This position will be regularly reviewed and, if appropriate, revised.

UNICEF presented an overview of research conducted on long-term IPV supply. The data and the analysis revealed that multinational manufacturers had investment programmes to increase their IPV capacity to an extent where all potential demand scenarios (excluding countries that may be expected to be self-producing) could be met. After 2005, sufficient IPV for most low income and lower-middle income countries could be made available with a 12 to 18 months lead time. The potential availability does not entirely meet the demand scenarios for the low income countries that currently produce or fill OPV for domestic consumption (China, India and Indonesia). However, two out of three manufacturers from these countries indicated that a WHO recommendation for IPV would incline local producers in these countries to develop IPV production capacity. The data for all market segments revealed much variation on what other antigens were being considered for incorporation with IPV. The research also indicated that prices around US\$ 1 per dose for

monovalent IPV are being anticipated by the manufacturers. Importantly, one of the economic analyses presented estimated that the break-even price for replacing OPV in routine immunization programmes (in the post-certification era) with IPV would be US\$ 0.30 per dose.

7.3 Vaccine stockpiles for the post-certification era

Whatever post-certification immunization policy is adopted, a global stockpile of OPV is considered essential. The development of a comprehensive stockpile plan is underway. Based on the immunization responses to cVDPV episodes to date, initial estimates of the size of the stockpile have been made (Table 4). These assume that three rounds of vaccination with OPV would be needed, with an average of seven million doses per round. The model also assumes that it would be prudent to plan for up to six episodes of cVDPV per year and that three of these could occur simultaneously. Based on these assumptions the stockpile size would need to be of the order of 842 million doses. These initial estimates will be further refined. It is planned to commission research on the optimal outbreak response for the post-certification era, and also on the logistics of a WHO-maintained stockpile. A consultation is planned on stockpile issues in 2004.

Table 4: Initial estimates of OPV vaccine stockpile based on cVDPV outbreak responses

	From now till OPV cessation	Cessation +5 years	Cessation +10 years
Filling of existing bulk (months)	3		
Production of new bulk (months)	18		
Delay between detection and SIA (months)	2		
Average doses per round for <5 (millions of doses)	7	9	12
Number of rounds	3	3	3
Number of concurrent VDPV episodes	3	3	2
Number of episodes per year	6	6	3
Target population as multiple of <5	1	2	3
Required min. stock as filled product (nr of rounds)	2	2	2
Required minimum stock in bulk (years)	2	2	2
Margin (%)	0.3	0.3	0.3
mOPV stock (millions of doses)	Filled		
	Bulk		
	Total	328	842
		842	842

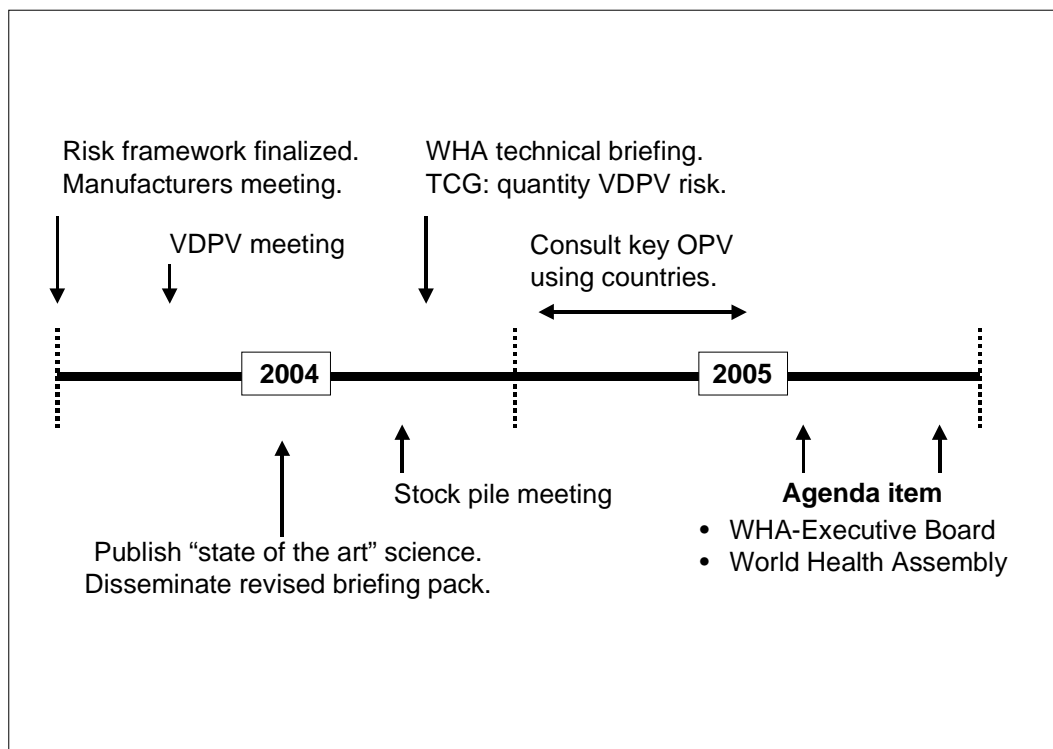
7.4 Post-certification policy development

With the consolidation in 2002 of the framework for assessing and managing the risks of paralytic polio in the post-certification era it is now appropriate to expand the policy development work. The global TCG recognizes and concurs that post-certification policies on polio will be needed in four major areas:

- Surveillance and notification of polio in the post-certification era.
- Long-term containment of all polioviruses.
- Vaccine stockpiles and mechanisms for their use.
- Routine childhood immunization.

Recognizing that the WHA will be a critical forum for negotiating longterm policy in these areas, WHO is planning a technical briefing of Assembly delegates in May 2004, followed, if appropriate, by a full agenda item for the Assembly in 2005. The period 2003 through mid-2004 will see the further consolidation of programmatic and research data in preparation for these discussions, including specific consultations on VDPVs and vaccine stockpiles (Fig. 12). Notably, the January 2004 issue of the Bulletin of the World Health Organization will be dedicated to summarizing the “state of the art” scientific data on the risks of polio in the post-certification era. In conjunction with the development of this theme issue, the post-certification briefing pack will be completely revised and updated for dissemination to all WHO Member States, polio eradication stakeholders and other interested parties in the first quarter of 2004.

Figure 12: Timeline for development of post-certification immunization policy



Recommendations

- The TCG endorses the current programme and timeline for post-certification policy development work, and emphasizes the importance of a technical briefing, on the risk framework and policy options, to WHO Member States at the WHA in 2004.
- The TCG endorses the basic thrust of the proposed WHO policy paper on “IPV introduction into OPV-using countries”. Following appropriate modification, WHO should take this proposed policy paper through the internal WHO process and formally release it by the third quarter of 2003.
- The preliminary work on a vaccine stockpile should now be taken further. A detailed proposal on the form it would take should be presented as a central part of post-certification policy discussions at the TCG meeting in early 2004.
- The TCG endorses the strategy for revising the briefing package on post certification policy development; the package should be available for widespread dissemination in the first quarter of 2004.

Global Polio Partners' meeting

Summary and conclusions

On 24 April 2003, on the occasion of the eighth meeting of the Technical Consultative Group on the Global Eradication of Poliomyelitis (TCG), WHO and UNICEF co-hosted a Global Polio Partners' Meeting. The objectives of the meeting were twofold. First, to inform partners how the Initiative is managing the acute funding crisis of 2003, and secondly to brief them and seek their input on the development of the strategic plan and budget for 2004–2008. The meeting was co-chaired by Dr Anarfi Asamoah-Baah, Executive Director, Health Technology and Pharmaceuticals, WHO and Mr Omar Abdi, Deputy Director, Program Division, UNICEF.

The meeting included representatives from each of the spearheading partners of the global Polio Eradication Initiative – WHO, Rotary International, the U.S. Centers for Disease Control and Prevention, and UNICEF – and more than 50 other participants from polio-endemic countries, donor governments, foundations and corporations.

Presentations were made on the restructuring of strategic approach for polio eradication, and on the strategic plan and budget framework: 2004–2008. Dr Carole Presern from the Permanent Mission of the United Kingdom to the United Nations Office at Geneva moderated the discussions following the presentations. On 25 April, Dr Presern presented the outcome of the meeting to the TCG on the Global Eradication of Poliomyelitis.

Managing the acute funding crisis of 2003: restructuring of the strategic approach for polio eradication

Dr Bruce Aylward, Coordinator, Polio Eradication Initiative, WHO, made a presentation on the restructuring of the strategic approach for polio eradication in 2003. The increasingly focal transmission of polio in 2002, wherein 99% of the cases were reported from India, Nigeria and Pakistan, coupled with an acute funding shortfall in early 2003, prompted a revision of the strategic approach for polio eradication, to focus SIAs on only 13 countries.

The funding shortfall for 2003 developed when, in late 2002, key partners indicated that it would not be possible to provide expected year-end resources, and others indicated that they would have to postpone or reschedule their polio eradication grants. The Initiative managed this funding crisis by instigating various measures to cut costs and optimize cash flow, revising the strategic approach, and renewing efforts

to identify new financing or re-schedule existing funds. These efforts will enable the Initiative to maintain a positive cash flow until September 2003. However, even if all of the existing pledges for 2003 are realized, there will remain a funding gap of US\$ 33 million for activities in late 2003 and the first quarter of 2004.

In the discussions following the presentation, partners recognized that the short-term funding gap for 2003 has the potential to undermine the eradication effort and the realization of this global public good for health. While concurring with the TCG's recommendation that resources be focused on the remaining endemic countries, and countries facing the highest risk of importation, concern was expressed about the risks posed by the scaling back of the scope of SIAs, especially in the Democratic Republic of the Congo and Ethiopia. Partners also highlighted the importance of the revised strategy being communicated quickly to countries and the ICCs.

Participants supported the need for mobilizing additional resources, and called on the Initiative to also ensure that the existing resources are used efficiently and creatively. They stressed the need for the Initiative to broaden its financial resource base by reaching out to NGOs, non-G8 countries, foundations and the private sector for funding. Participants suggested that alternative funding sources such as humanitarian funding, debt relief and sector-wide approaches (SWAs) be explored. It was also proposed that coordinated activities between the Polio Eradication Initiative and other programmes such as GAVI, vitamin A and measles mortality reduction be highlighted so as to facilitate access to new funding sources.

Participants welcomed the commitment by the Governments of India and Nigeria to fully exploit the bilateral funding opportunities provided by the European Commission and the World Bank/Bill and Melinda Gates Foundation/Rotary International-UN Foundation *Investment Partnership for Polio*. They also offered their support to local in-country fundraising efforts and underscored the importance of reflecting the contributions made by the endemic countries themselves to the Initiative.

Conclusions

- Partners emphasized the need to expand the partnership base and highlighted the importance of using existing multilateral fora such as the G8, the African Union, the World Health Assembly, and the OECD/DAC to mobilize resources for polio eradication.
- While endorsing the need to expand the financial resource base, partners called on the Initiative to recognize by June 2003 recent contributions made to fill the 2003–2005 funding gap, especially from the G8. This would demonstrate accountability to donors for pledges made, while taking into account possible increases in the overall budget.

Strategic plan and budget framework: 2004–2008

Dr. Jean-Marie Okwo Bele, Chief, Immunization Activities, Program Health Section, UNICEF made a presentation on the strategic plan and budget framework: 2004–2008. The restructuring of the strategic approach for polio eradication in light of the evolving epidemiology of the poliovirus and the acute funding shortfall for 2003, have rendered the existing *Global Polio Eradication Strategic Plan 2001–2005* obsolete. In addition, key stakeholders have requested that the Initiative provide a longer time horizon for polio eradication activities to facilitate efforts to provide multi-year support. Consequently a new Global Polio Eradication Strategic Plan 2004–2008 is being developed. An outline of the plan and the proposed timeframe and process for its development was shared with partners for review and feedback.

Partners endorsed the development of a 2004–2008 Strategic Plan. They called on the Initiative to ensure the new plan reflects input from countries and includes specific milestones, as per the existing plan. The need to ensure sufficient provisions in the plan for addressing emergency outbreaks in high-risk areas was highlighted. They also emphasized the importance of the development of a fundraising strategy and a communication strategy to accompany the new plan.

Partners stressed the importance of “objective four” of the strategic plan outline: that provided a framework to realize the full benefits from polio eradication. They supported the expansion of the use of the polio infrastructure to other health initiatives and remarked that the development of the new plan provides an opportunity to incorporate the lessons learned from polio eradication in other areas such as immunization, surveillance and partnership management. By working to realize the full benefits of polio eradication, partners suggested that the Initiative could identify and exploit additional funding opportunities.

Conclusions

- Partners endorsed the development of a new Strategic Plan for 2004–2008 along the proposed structure with four main objectives.
- Partners suggested that the new plan place polio eradication within the broader context of the millennium development goals for health, such as reducing under five years of age mortality rates.
- Partners agreed that the development of a comprehensive budget to accompany the plan, including the financial impact of different risk scenarios, would be helpful in securing funding through to global certification.

Annex 1: Agenda

Thursday, 24 April 2003

08:30 – 09:00	Registration	
09:00 – 10:30	Opening statements Introductions and review of agenda	
Session 1	Programme objectives and overview	
	Eradication activities and outcomes in 2002–2003 to date	WHO/HQ
	Framework for the Strategic Plan 2004–2008	
Session 2	Strategic Plan objective 1: Stopping polio transmission	
	Pakistan	EPI/Pakistan
10:30 – 11:00	<i>Coffee break</i>	
	Nigeria	NPI/Nigeria
	Egypt	EPI/Egypt
	India	EPI/India
	Evaluation of social mobilization in priority countries	C. S. Taylor, UNICEF/WHO
13:00 – 14:00	<i>Lunch break</i>	
14:00 – 15:30	Summary of priorities: other endemic areas	
	• EMR: Afghanistan, Somalia	EMRO
	• AFR: Niger	AFRO
	Supplementary immunization strategy and OPV supply for endemic and non-endemic areas.	WHO/UNICEF
15:30 – 16:00	<i>Coffee break</i>	
16:00 – 18:00	Closed Session of the global TCG Global Polio Partners' meeting (concurrent)	

Friday, 25 April 2003

09:00 – 09:30	Report from the Global Polio Partners' meeting	Meeting Chair
Session 3	Strategic Plan objective 2: Achieving global certification	
09:30 – 10:30	Poliovirus surveillance <ul style="list-style-type: none">• AFP and Labnet performance and priorities Containment of polioviruses <ul style="list-style-type: none">• Proposed implementation structure	WHO/HQ WHO and task force
10:30 – 11:00	<i>Coffee break</i>	
	Certification of polio eradication <ul style="list-style-type: none">• Regional status and major issues	Global Commission
Session 4	Strategic Plan objective 3: Developing polio immunization policy for the post-certification era	
	Introduction and overview Programmatic and scientific research <ul style="list-style-type: none">• Surveillance for VPDVs (AFP and environmental)• Frequency and burden of cVDPVs and iVDPVs	D. Wood/WHO
12:30 – 14:00	<i>Lunch break</i>	
	Policy development and communications <ul style="list-style-type: none">• WHO IPV position paper• IPV supply• Plan of action: vaccine stockpile development• Economics of post-certification policies Summary of timeline and major milestones	T. Cherian/WHO S. Hall/UNICEF V. Carceres/CDC N. Sangrujee/CDC D. Wood/WHO
15:30 – 16:00	<i>Coffee break</i>	
16:00 – 18:00	Closed session of the global TCG Global Polio Partners' meeting (concurrent)	

Annex 2:

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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* 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.

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