

PD-ABU-071

**PARTICIPATION
AT THE SCIENTIFIC ADVISORY GROUP
OF EXPERTS (SAGE) MEETING, WHO/HQ
JUNE 9-11, 1998**

Geneva, Switzerland

Robert Steinglass

BASICS Technical Directive: 000-HT-51-023
USAID Contract Number: HRN-C-00-93-00031-00

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SUMMARY

The writer participated at the meeting of the Scientific Advisory Group of Experts (SAGE) at WHO in Geneva from 9-11 June 1998.

Technical issues relevant to both the Global Program on Vaccines and the Children's Vaccine Initiative were discussed at this meeting. The annotated agenda of the meeting appears in Appendix A; the list of participants is in Appendix B. The list of documents and documents relevant to the agenda items appear, respectively, in Appendixes C and D.

Recommendations from the meeting appear in Appendix E. Some recommendations of particular interest to BASICS related to—

- the impact of health reforms on national immunization programs
- integration of vitamin A into immunization programs
- polio eradication
- measles control
- control of neonatal tetanus
- improving the quality of immunization data
- injection safety
- vaccine procurement
- financing for existing and new vaccines
- demand forecasting

As BASICS has contributed at global and country levels in the above subjects, the writer was able to participate actively in the meeting. The materials generated at the meeting have been distributed by the writer to relevant BASICS staff and consultants.

APPENDIXES

APPENDIX A
Annotated Agenda

Annotated Agenda

Scientific Advisory Group of Experts (SAGE)
Geneva, 9-11 June 1998

GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION



World Health Organization
Geneva

CHILDREN'S VACCINE INITIATIVE





**Meeting of the GPV and CVI Scientific Advisory Group of Experts (SAGE)
Salle A, WHO/HQ Geneva, Tuesday to Thursday, 9 - 11 June 1998**

ANNOTATED AGENDA

Tuesday, 9 June 09:00 - 17:45

- 09.00-09.30 Opening of the meeting
Introduction of the Chair and the Members
Overview by Dr J.W. Lee, Director, GPV
- 09.30-10.15 Reports on progress in implementing 1997 SAGE recommendations (45')
presentations from EPI, VRD, VSQ
- 10.15-10.30 Discussion on foregoing reports (15' + 30' after the coffee break)

10.30-11.00 *coffee break*

- 11.00-11.30 Discussion on foregoing reports (30')
- 11.30-11.45 Immunization and health systems: Which way forward for EPI?
Dr B. Melgaard (15')
- 11.45-12.20 Discussion and recommendations (35')
- 12.20-12.30 What is the quality of EPI data? Mr Anthony Burton (10')

12.30-14.00 *LUNCH*

- 14.00-14.15 What are the critical issues for achieving the polio eradication goal for the year
2000? Dr H. Hull (15')
- 14.15-14.30 Current WHO studies in the development of new methods for quality control
of oral poliomyelitis vaccine and polio diagnosis. Dr Peter Wright (15')
- 14.30-14.45 What research is needed for polio eradication and the post-eradication
strategies. Dr Stephen Cochi (15')
- 14.45-15.15 Discussion and recommendations (30')

15.15-15.30 Phasing measles control and eliminating activities in the context of the polio eradication initiative. Dr J.-M. Olivé (15')

15.30-16.00 Coffee break

16.00-16.15 Can modelling of measles epidemiology help to define optimal immunization strategies? Dr Nigel Gay (15')

16.15-16.45 Discussion and recommendations (30')

16.45-17.00 Can Td replace TT globally? Dr F. Gasse (15')

17.00-17.15 Increasing incidence of Pertussis in adults as a result of the limited duration of vaccine-induced immunity: what can we do about? Dr Marc LaForce (15')

17.15-17.45 Discussion and recommendations (30')

18.00 RECEPTION ON THE TERRACE OF THE WHO CAFETERIA

Wednesday, 10 June

09:00 - 16:30

09.00-10.00 Review and adoption of previous day's recommendations

10.00-10.15 When should we use typhoid vaccines?
Drs B. Ivanoff and D. Heymann (15')

10.15-10.30 Pre-filled monodose injection devices: a safety standard for new vaccines?
Drs J. Lloyd and T. Aguado (15')

10.30-11.00 Coffee break

11.00-11.30 Discussion and recommendations (30')

11.30-11.45 A broad strategy for the safety of all injections
Mr M. Zaffran (15')

11.45-12.00 To what extent are vaccine adverse events a deterrent to immunization?
Dr C.J. Clements (15')

12.00-12.15 How can GPV assess the scientific basis for alleged adverse effects of vaccination? Dr P.-H. Lambert (15')

12.15 -12.45 Discussion and recommendations (30')

12.45-14.00 LUNCH

14.00-14.15 Procurement: How can we strengthen and implement a changed role for WHO in vaccine procurement? Mr P. Evans (15')

14.15-14.30 Financing: What are our options? Dr H. J. Choi (15')

- 14.30-15.00 Discussion and recommendations (30')
- 15.00-15.15 Demand forecasting: What are the models we can use to forecast aggregate demand for vaccine manufacturing? Dr M. Kawano (15')
- 15.15-15.30 New vaccines: With the increase of developing country research groups and manufacturers, how can we be sure that WHO quality standards are reached? Dr J. Milstien (15')

15.30-16.00 Coffee break

- 16.00-16.30 Discussion and recommendations (30')

Thursday, 11 June

09:00 - 17:00

What actions will accelerate the introduction of new vaccines

- 09.00-09.20 Accelerating the introduction of new vaccines. Brief presentations on:
- Lessons learned from HB, Hib, yellow fever and other 'new' vaccines, including combinations.
 - Models for considering new vaccine introduction
 - How can quantitative assessments help policy choices?
 - In what countries should we consider 'new' vaccine introduction?
- (20')
- 09.20-10.30 Discussion: What actions will accelerate 'new' vaccine introduction most effectively? (70')

10.30-10.50 Coffee break

- 10.50-11.45 Continuation of above discussion (55')
- 11.45-12.45 What actions are most needed to implement the CVI Strategic Plan? (60')

12.45-14.00 LUNCH

Public-Private sector collaboration

- 14.00-15.00 In what areas is public-private sector collaboration most needed from the public sector perspective - research, orphan vaccines, industrial development, licensing, policy formulation, marketing, tendering, pricing or advocacy? (60')

15.00-15.20 Coffee break

- 15.20-16.20 Review and adoption of previous day's recommendations (60')
- 16.20-17.00 Review of today's recommendations, and final summing up (40')
- 17.00 Close of the meeting

APPENDIX B
List of Participants

List of Participants

Scientific Advisory Group of Experts (SAGE)
Geneva, 9-11 June 1998

GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION



World Health Organization
Geneva

CHILDREN'S VACCINE INITIATIVE





World Health Organization
**Global Programme for
Vaccines and
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**Meeting of the GPV and CVI Scientific Advisory Group of Experts (SAGE)
Conference Room A, WHO Headquarters, Geneva
9 - 11 June 1998**

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APPENDIX C
List of Documents

List of documents

Scientific Advisory Group of Experts (SAGE)
Geneva, 9-11 June 1998



GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION



World Health Organization
Geneva

CHILDREN'S VACCINE INITIATIVE



LIST OF DOCUMENTS

GPV-CVI/SAGE.98/01	Annotated Agenda	✓
GPV-CVI/SAGE.98/02	List of Participants	✓
GPV-CVI/SAGE.98/03	List of Documents	✓
GPV-CVI/SAGE.98/04	Documents relevant to agenda items	✓

WORKING PAPERS

GPV-CVI/SAGE.98	Reports on progress in implementing the 1997 SAGE recommendations: EPI, VRD, VSQ	✓
GPV-CVI/SAGE.98/WP.01	A retrospective analysis of national immunization coverage estimates reports to WHO, 1991-1996	✓
GPV-CVI/SAGE.98/WP.02	Current WHO studies in the development of new methods for quality control of oral poliomyelitis vaccine and polio diagnosis	✓
GPV-CVI/SAGE.98/WP.03	Phasing measles control and eliminating activ etc. (New title to come)	✓
GPV-CVI/SAGE.98/WP.04	Replacing tetanus toxoid (TT) and diphtheria-tetanus toxoid (DT) with tetanus-diphtheria toxoid (Td) - DRAFT	
GPV-CVI/SAGE.98/WP.05	When should we use typhoid fever vaccines?	✓
GPV-CVI/SAGE.98/WP.06	Pre-filled monodose injection devices: A safety standard for new vaccines, or a revolution in the delivery of immunization?	✓
GPV-CVI/SAGE.98/WP.07	A broad strategy to promote the safety of all injections	✓
GPV-CVI/SAGE.98/WP.08	To what extent are vaccine adverse events a deterrent to immunization?	✓
GPV-CVI/SAGE.98/WP.09	Procurement of vaccines: roles and responsibility	✓
GPV-CVI/SAGE.98/WP.10	Financing of new vaccines: what are our options?	✓
GPV-CVI/SAGE.98/WP.11	Demand forecasting: what are the models we can use to forecast aggregate demand for vaccine manufacturing?	✓
GPV-CVI/SAGE.98/WP.12	New vaccines: with the increase of developing country research groups and manufacturers, how can we be sure that WHO quality standards are reached?	✓
GPV-CVI/SAGE.98/WP.13	Immunization and health reform: the implications of decentralisation.	✓
GPV-CVI/SAGE.98/WP.14	What actions will accelerate the introduction of new vaccines?	

BACKGROUND DOCUMENTS FOR PRESENTATIONS

- | | | |
|---|---|---|
| Presentation by Dr Harry Hull | Polio Eradication - Status Report 1998 and critical issues for achieving the Year 2000 target | ✓ |
| Presentation by Dr Stephen L. Cochi | Draft conclusions of the working group of the meeting on the scientific basis for stopping immunization against poliomyelitis | ✓ |
| Presentation by Professor F. Marc LaForce | Increasing incidence of pertussis in adults: what are the issues and what could be done about it? | ✓ |
| Presentation by Dr Nigel Gay | (something may be available at the meeting) | |

REPORTS AND PROGRAMME DOCUMENTS

- | | | |
|---------------|---|---|
| WHO/GPV/97.05 | Report of the meeting of the Scientific Advisory Group of Experts (SAGE) 11-13 June 1997 | ✓ |
| CVI/GEN/97.04 | The CVI Strategic Plan "Managing Opportunity and Change: A Vision of Vaccination for the 21 st Century" | ✓ |
| CVI/GEN/98.01 | Children's Vaccine Initiative/Rockefeller Foundation Conference on the Global Supply of New Vaccines, Bellagio, February 1997 | ✓ |
| CVI/GEN/98.06 | Progress Report of the CVI Secretariat | ✓ |
| CVI/GEN/98.07 | Proposed CVI Secretariat Plan of Activities and Budget for 1998 | ✓ |
| WHO/GPV/98.01 | Programme Report 1997 | ✓ |
| WHO/GPV/98.03 | Brochure for the Global Programme for Vaccines and Immunization, 1998 | ✓ |

APPENDIX D

Documents Relevant to Agenda Items

Documents relevant to agenda items

Scientific Advisory Group of Experts (SAGE)
Geneva, 9-11 June 1998

GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION



World Health Organization
Geneva

CHILDREN'S VACCINE INITIATIVE



DOCUMENTS RELEVANT TO AGENDA ITEMS

Tuesday, 9 June	09:00 - 17:45	Documents
09.00-09.30 Opening of the meeting Introduction of the Chair and the Members Overview by Dr J.W. Lee, Director, GPV		Annotated Agenda List of Participants List of Documents Documents relevant to Agenda Items
09.30-10.15 Reports on progress in implementing 1997 SAGE recommendations - presentations from EPI, VRD, VSQ		Reports from EPI, VRD, VSQ
11.30-11.45 Immunization and health systems: Which way forward for EPI? Dr B. Melgaard		GPV-CVI/SAGE.98/WP.13
12.20-12.30 What is the quality of EPI data? Mr Anthony Burton		GPV-CVI/SAGE.98/WP.01
14.00-14.15 What are the critical issues for achieving the polio eradication goal for the year 2000? Dr H. Hull		Background document Polio Eradication - Status Report 1998 and critical issues for achieving the Year 2000 target
14.15-14.30 Current WHO studies in the development of new methods for quality control of oral poliomyelitis vaccine and polio diagnosis. Dr Peter Wright		GPV-CVI/SAGE.98/WP.02
14.30-14.45 What research is needed for polio eradication and the post-eradication strategies. Dr Stephen Cochi		Background document Draft conclusions of the working group of the meeting on the scientific basis for stopping immunization against poliomyelitis
15.15-15.30 Phasing measles control and eliminating activities in the context of the polio eradication initiative. Dr J.-M. Olivé		GPV-CVI/SAGE.98/WP.03
16.00-16.15 Can modelling of measles epidemiology help to define optimal immunization strategies? Dr Nigel Gay		(paper may be available at meeting)

16.45-17.00 Can Td replace TT globally? Dr F. Gasse	GPV-CVI/SAGE.98/WP.04
17.00-17.15 Increasing incidence of Pertussis in adults as a result of the limited duration of vaccine-induced immunity: what can we do about? Dr Marc LaForce	Background document Increasing incidence of pertussis in adults: what are the issues and what could be done about it?
Wednesday, 10 June 09:00 - 16:30	
09.00-10.00 Review and adoption of previous day's recommendations	Recommendations from Tuesday 9 June
10.00-10.15 When should we use typhoid vaccines? Drs B. Ivanoff and D. Heymann	GPV-CVI/SAGE.98/WP.05
10.15-10.30 Pre-filled monodose injection devices: a safety standard for new vaccines? Drs J. Lloyd and T. Aguado	GPV-CVI/SAGE.98/WP.06
11.30-11.45 A broad strategy for the safety of all injections Mr M. Zaffran	GPV-CVI/SAGE.98/WP.07
11.45-12.00 To what extent are vaccine adverse events a deterrent to immunization? Dr C.J. Clements	GPV-CVI/SAGE.98/WP.08
12.00-12.15 How can GPV assess the scientific basis for alleged adverse effects of vaccination? Dr P.-H. Lambert	
14.00-14.15 Procurement: How can we strengthen and implement a changed role for WHO in vaccine procurement? Mr P. Evans	GPV-CVI/SAGE.98/WP.09
14.15-14.30 Financing: What are our options? Dr H. J. Choi	GPV-CVI/SAGE.98/WP.10
15.00-15.15 Demand forecasting: What are the models we can use to forecast aggregate demand for vaccine manufacturing? Dr M. Kawano	GPV-CVI/SAGE.98/WP.11

15.15-15.30 New vaccines: With the increase of developing country research groups and manufacturers, how can we be sure that WHO quality standards are reached? Dr J. Milstien	GPV-CVI/SAGE.98/WP.12
Thursday, 11 June 09:00 - 17:00	
09.00-09.20 What actions will accelerate the introduction of new vaccines	GPV-CVI/SAGE.98/WP.14
11.45-12.45 What actions are most needed to implement the CVI Strategic Plan?	CVI/GEN/97.04 The CVI Strategic Plan "Managing Opportunity and Change: A Vision of Vaccination for the 21 st Century"
14.00-15.00 Public-Private sector collaboration	CVI/GEN/98.01 Bellagio Report
15.20-16.20 Review and adoption of previous day's recommendations	Recommendations from Wednesday 10 June
16.20-17.00 Review of today's recommendations, and final summing up	

APPENDIX E

Recommendations from the SAGE Meeting

SAGE RECOMMENDATIONS 1998

In order of agenda item presentations

Monday, 9 June

Health reform

Health reform has implications for immunization programmes in many countries. SAGE discussed the need to ensure that key essential functions of immunization systems be maintained at the central level: Functions such as policy setting, programme management procurement of vaccine and equipment, quality control and international coordination were clearly identified. In addition, surveillance needs close coordination between the central and peripheral levels. It was also pointed out that immunization coverage and surveillance indicators provide valuable core health sector indicators throughout the HSR process. GPV should closely work with agencies and governments implementing such reforms to ensure that these indicators are considered.

Participants pointed to a number of concerns whereby provision of immunization could be jeopardized by the HSR process. PAHO experience with HSR has shown that decentralization lead to a deterioration of the quality of polio surveillance indicators. Hence, when services are decentralized, attention should be paid to the preservation of immunization data that could be lost in the integration of information systems.

The need to identify new health/immunization financing mechanisms was pointed out as one of the main areas to be addressed since it is often intrinsically related to the drive for health sector reforms in devolving finances to peripheral levels where they become vulnerable to competing demands.

- SAGE recognizes the importance to immunization programmes of the current move towards health reform in many countries. As countries undertake such reforms, the risk from decentralization of immunization services take on a special importance.
- SAGE strongly recommends that certain elements of immunization programmes especially policy making, programme management, quality control, regulatory activities, surveillance and national monitoring should remain under central level authorities.
- SAGE notes with concern that immunization services may not receive adequate funding by local authorities when there are competing demands for the same resources. SAGE urges countries to consider carefully aspects of immunization programmes that can be decentralized and will strengthen local services, as well as those elements that should be retained at central level.

- SAGE recommends that coverage and surveillance indicators are used to monitor the impact of decentralization and health reform on delivery of immunization services.

Vitamin A

SAGE strongly supports the initiative to administer vitamin A with immunizations delivered after 6 months of age in areas where vitamin A deficiency is a significant public health problem. This is recognized as a major opportunity for improving child survival. The vitamin A supplements should be given either to the mother at any immunization contacts up to 6 weeks post-partum or to the child from 9 months onward at measles vaccine contact and at any special campaigns. SAGE recommends:

- the development of a joint GPV/NUT plan to evaluate the impact of this strategy on health status.
- research on efficacy and safety of this strategy using other EPI antigens, at ages younger than the scope of the current WHO guidelines, and, as appropriate, at other doses of vitamin A.

Influenza in Hong Kong

SAGE recognized the importance of the cases and deaths occurring between May and December 1997 in Hong Kong from influenza (H5N1), a strain previously only found in birds. SAGE recommends to WHO:

- Increased surveillance for avian forms of influenza virus.
- GPV/EMC should provide a briefing paper of the world status of the virus and the potential for vaccine production at the next SAGE meeting.
- International collaboration to develop a vaccine against this strain.

Yellow fever

SAGE notes with concern the continued high number of outbreaks due to yellow fever that remains a disease with high mortality for which there is no specific treatment. The vaccine is safe, highly effective, provides long-lasting protection after a single dose, and is available to developing countries for only US\$ 0.17 per dose. The vaccine has been recommended by WHO for inclusion in national immunization programmes of at risk countries since 1991. SAGE is pleased to note that, faced with the spread of *Aedes aegypti* mosquito vector in the Americas, all at risk countries in the Americas added yellow fever vaccine to their EPI during the past year. SAGE notes with concern that in Africa, progress has been very slow in introducing yellow fever vaccine. SAGE strongly recommends:

- For those countries at risk of yellow fever in Africa, accelerated efforts are required to include the vaccine in national programmes, to improve disease surveillance, and to provide a rapid response to outbreaks.

Improving the quality of immunization data

There is a need to improve the quality of reported immunization data, since it is being used increasingly for major decision-making, including national and international decision-making. SAGE also discussed the increasing importance of monitoring reliable immunization data at the district level in countries undergoing health reform

SAGE recommends that:

- GPV increases efforts and resources into improving the quality of national immunization data (and validating these data) in the context of strengthening the national health information systems.

Polio

POLIO ERADICATION - CONCLUSION

The SAGE notes the dramatic progress towards global polio eradication by the year 2000, recognizing that in the decade since the initiative was launched there has been a 90% decline in reported cases worldwide, with the virus now being restricted to sub-Saharan Africa and south Asia. This achievement is especially remarkable given that there has been a chronic shortfall in the human and financial resources needed for this task.

Because of the extraordinary benefits that the successful conclusion of this eradication initiative holds for the global community the SAGE strongly urges that WHO markedly accelerate polio eradication activities to meet the year 2000 goal. A failure of this eradication initiative, due solely to insufficient leadership or resources, would have profound implications for other disease control initiatives and public health programmes in general.

POLIO ERADICATION - RECOMMENDATIONS

1. The SAGE recommends that as a matter of urgency, the Director-General of WHO call upon the appropriate international leadership to define specific mechanisms for ensuring that the commitment which has already been declared for the goal of polio eradication by the year 2000 is translated into reality. As this goal is only feasible if the necessary funding is rapidly secured, the Director-General should ensure that the immediate and long-term resources are identified by late 1998 and that those funds are made available to the programme in a timely manner.

2. While continuing NIDs in all endemic countries, GPV should rapidly expand the intensity of eradication activities in the global priority areas. Particular

emphasis should be given to implementing extra NID rounds and widespread mopping-up in the global reservoirs, posting additional country level staff to accelerate AFP surveillance, and fully implementing the strategies in areas affected by conflict.

3. Because of the need for open discussion of the successes and constraints facing the initiative in its final stages, the SAGE recommends that an annual report on progress towards global polio eradication be made to the World Health.

Measles

- Considering the high burden of measles disease still observed in some countries and recognising that high routine coverage among infants continues to be one of the cornerstones of any measles control programme; the SAGE encourages all countries in the measles control phase to evaluate the reasons for low coverage and, to identify effective actions to improve measles routine immunization coverage. In polio endemic countries or countries with focal poliovirus transmission, acceleration of measles control aiming at measles mortality reduction should be the priority rather than setting a national measles elimination goal. Campaigns should be implemented to reach all children aged 9 months to 3-5 years in urban and peri-urban areas and other high-risk areas. In addition, these countries should provide Vitamin A during any supplemental vaccination activity and ensure adequate case management, as effective ways to obtain further reduction in mortality. *Provisions to ensure injection safety should be part of the planning process as per UNICEF/WHO recommendations.*
- A well-defined surveillance component with identification of the required resources for at least 2 years and indicators for impact evaluation should be part of any proposal to conduct supplemental measles immunization activities aiming at measles control/elimination.
- Continued measles transmission in some industrialised countries have call the attention of the SAGE on the need to encourage Japan and countries in Europe to accelerate efforts to interrupt measles virus transmission. A measles elimination plan for the European Region has been prepared and it is important that high level political support is obtained from the Regional Office and all member countries to ensure it's proper implementation.
- There is a need to continue to develop simpler, more accessible methods for estimating measles susceptibility profile to assist countries in identifying the appropriate target age groups and the required frequency of the supplemental immunization activities aiming at measles elimination. WHO/GPV should co-ordinate research studies to evaluate the potential role in measles transmission of an increasing proportion of susceptible adults. This is in light of the current measles elimination goals set in some regions and the fact that in recent measles epidemics nearly half of the

cases reported occurred among young adults. Similarly, WHO/GPV should co-ordinate the evaluation of recently developed test for measles diagnosis and establish their potential for introduction in the field as an additional tool to monitor susceptibility and measles virus transmission.

Td

Elimination of neonatal tetanus remains a priority for GPV. During recent outbreaks of diphtheria in the former USSR and in some developing countries, cases have been documented in older ages. This reflects a change in the epidemiology of diphtheria, partly due to high coverage with DTP. The reduced immunity in adults needs new strategies to counter this trend. School-based programmes for administering booster doses of tetanus toxoid are required to cover the gaps in immunity against tetanus created by the respective strategies of primary immunization with three doses of DTP during infancy and TT to women of child-bearing age. Replacing TT by Td for both these strategies provides a programmatic answer to both problems, especially in light of documented high school attendance in key countries. Additional programmatic advantages include the safety of Td in all age groups including pregnant women. SAGE therefore recommends:

- TT should be replaced by Td in a phased manner. As first priority, TT should be replaced in all countries that have DTP-3 coverage of 70% or more for at least 5 years. Where school-based boosters are given, evaluation of the use of Td to replace the initial boosters of DT should be considered.
- WHO should provide assistance, as needed, to countries as they switch production to, or increase production of Td.
- The need for two DTP boosters should be reviewed in light of the proposed school-based Td strategy and the local epidemiology of pertussis. There should be consultation with industry and regulatory bodies before final recommendations are made.
- As with all changes in immunization strategy, there should be consultation with vaccine manufacturers and regulatory bodies to ensure supply capacity and vaccine efficacy using the revised strategy.

Pertussis

- ^{incidence} Further prospective population-based studies are needed to measure the ~~prevalence~~ and clinical characteristics of pertussis in adolescents and adults, so that the disease burden in this age group can be defined.
- A diagnostic test that can serve as an unambiguous serologic marker of recent infection with *B. pertussis* is needed.
- Further studies are needed to examine to duration of protection after immunization with acellular pertussis vaccine.
- Although a WHO pertussis case definition is available for or research studies, there is need for WHO to develop and promote a standard pertussis case definition for routine surveillance.

Wednesday, 10 June 1998

Vaccination against typhoid fever

In view of the high disease burden attributed to *Salmonella typhi* (around 600 000 deaths/year), the growing problem posed by multi-drug antibiotic resistance and the availability of two effective vaccines (injectable Vi and oral Ty21a), the SAGE strongly recommends that vaccination against typhoid fever is encouraged in school-age children, using currently existing vaccines, in countries where this disease constitutes an important health problem. Opportunities should be sought to give this vaccine at the time of Td boosting in this age group.

Injection safety and vaccine delivery

1. SAGE notes with great concern that the reuse of standard disposable syringes and needles, a practice reported and documented in all regions of the world, puts recipients of all types of injections at risk of infection by bloodborne pathogens.
 - ◆ As a first step, SAGE recommends that GPV continues to review and analyse existing data on unsafe injection practices and solicits broad scientific review.
1. SAGE commends the initiatives of the EPI towards safer injections. In particular, it notes with great satisfaction the collaboration that has taken place among WHO divisions (GPV, DAP, EMC and HRB) to draft a strategy for the safety of all injections.
 - ◆ Sage strongly recommends that further efforts be made to finalise this plan and gather broad support from all partners including industry.
1. While commending the successful implementation of the WHO/UNICEF "bundling strategy" in which auto-destruct syringes, safety boxes and good quality vaccines are procured together in the context of mass immunization campaigns, SAGE urges that further efforts are required to move towards the safer administration of vaccines.
 - ◆ As a first immediate step, SAGE recommends that all donors supporting immunization programmes discontinue the purchase of standard disposable syringes/needles that are not autodestruct and ensure that the funds they provide to support immunization programmes are not used by countries for the purchase of standard disposables
 - ◆ SAGE also recommends that GPV and its partners collaborate to facilitate technology transfer for the local production of AD syringes
1. SAGE endorses the long-term strategy to plan and promote development, in close collaboration with industry, (a) a safer, simpler delivery system for new vaccines based on mono-dose, pre-filled injection devices and (b)

formulations with increased thermo-stability and their corresponding delivery systems.

- ◆ As a first step, SAGE recommends that the costs of the proposed delivery system and the benefits on safety, quality and performance of immunization services be elaborated and presented to the next SAGE meeting.
- ◆ In parallel, efforts to obtain proof of principle data on methodology to stabilize vaccine and its administration should be expedited.

Adverse events and effects of vaccination

In view of the increasing allegations of adverse events following immunization (AEFIs) which are disrupting coverage and undermining confidence in vaccines and services, the SAGE strongly recommends GPV/CVI to undertake the following:

- Advocate an appropriate worth to vaccines.
- Continue training for health care staff so that AEFIs can be minimized and responded to appropriately.
- Establish a surveillance system capable of monitoring and providing up to date information in all countries.
- When feasible, identify and assess potential risks of delayed immunological or oncogenic effects at pre-clinical stages, monitor late side effects during clinical trials and establish rigorous post-licensure (phase 4 trials) surveillance.
- Develop international consensus of relative risks involving all the major players under WHO leadership.
- Establish a GPV network of collaborating scientists and laboratories able to provide appropriate and rapid scientific responses.
- Use social science investigation to provide understanding of behavior and triggers for action by parents seeking immunization.

Vaccine procurement

Encouraged that many countries are becoming self-sufficient in vaccine supply through procurement, SAGE commended the work being done in helping countries purchase vaccines. However it was acknowledged that there are risks to national programmes if countries purchase vaccines without due regard to their special nature, without the full involvement of the EPI to define programme needs or without the involvement of an NCA with vaccine regulatory skills to approve national acceptability. There is a need to increase the availability of procurement training and procurement assistance for countries and agents purchasing vaccines directly.

In addition to offering extra technical support to countries and agents purchasing vaccines, it was recognised that there are areas in which WHO could provide increased support. Changes should be made within WHO in order to improve services offered to UNICEF, other agencies and countries. Of particular concern was the ability of VSQ to be able to make assessment of new companies and new vaccines in preparation for the expanding use of additional vaccines.

It was observed that the separation of BLG and the Expert Committee from the operational aspects of assessments by VSQ was appropriate. Ways to make the process of assessment by closer co-operation with competent NCA's should be continually sought.

SAGE noted with satisfaction the strong re-commitment from UNICEF to purchase and introduce new vaccines.

Recommendations

1. The NCA and EPI shall in all cases be involved in the standard setting in the procurement of vaccines. Countries not yet having an NCA should be encouraged to seek assistance from WHO/UNICEF. WHO/UNICEF will offer to support all developing countries in accordance with their needs.
2. The WHO procurement system should improve its existing services. The quality assurance assessment system needs to follow one standard and be expanded to include the assessment of traditional vaccines, which are only now being introduced into the routine immunization programmes, e.g. M.M.R.; as well as the assessment of new vaccines and combinations and to make these services more available to agents and countries. For this purpose extra funding is required. The additional funding required should be obtained from WHO regular budget and from all the purchasing agencies that make use of the system.
3. The procedure in place at WHO for evaluation of newly licensed vaccines for purchase by UN agencies should be reviewed. SAGE recommends that GPV convene a working group for this purpose.

Financing for existing and new vaccines

Financing for new vaccines and the sustainability of financing for existing vaccines are among the most critical issues facing immunization programmes. Despite the fact that immunization is the most cost-effective health intervention available today, the SAGE notes substantial weaknesses in the global infrastructure to finance both the supply of existing vaccines and the introduction of new vaccines, particularly in low income countries. These shortcomings represent a threat to further progress towards bringing the benefits

of vaccines to the world's children. Therefore the SAGE strongly recommends that:

- Country-specific approaches be developed. This includes:
 - The elaboration of national vaccine supply plans. WHO should give support to these by collecting, analyzing, disseminating information and proposing financing options and guidelines.
 - A focus of resources to the countries of greatest need (Bands A and B).
- WHO examine and address the financing needs of the present and the future through collaborative efforts with UNICEF and all involved partners including the private sector.
- Development banks become more committed to and involved in the development of sustainable financing for vaccines. WHO is urged to engage these organizations and to provide them, other partners, and countries with the necessary technical assistance and global coordination to ensure the effective elaboration and implementation of vaccine financing mechanisms at the country level.
- Other mechanisms, such as trust funds, be considered as well. One approach which may be facilitated by health care reform is diverting curative care financing for preventive approaches such as vaccines.

Demand forecasting

Demand forecasting for vaccines is needed in four situations: for routine use, for outbreak response immunization, for accelerated immunization activities, and for new vaccine introduction. National capacity to plan for vaccine supply is especially important. The development of methods to respond to the needs of countries experiencing economic crises should also be considered. For the latter three situations, global coordination of demand with manufacturing capacity is critical. The SAGE notes the activities of GPV to strengthen demand forecasting capacity in countries, and the models proposed to develop estimates of demand. The following recommendations are proposed:

- GPV should strengthen the function of coordinating global demand with global production capacity for accelerated immunization activities, outbreak response, and the introduction of new vaccines.
- Given the importance of including a time dimension in demand forecasting for the introduction of new vaccines, the SAGE recommends the continuation of efforts in collaboration with partners to address this through the development of explicit modeling techniques and the verification of such models against actual data.

Quality for vaccine development

The SAGE notes the need for an intensification of WHO activities in relation to the quality control, standardization, and clinical evaluation of new vaccines, particularly in relation to countries lacking regulatory expertise. However, the SAGE feels that accreditation of national regulatory authorities is a subject of such importance that it merits more internal discussions within WHO which may lead to a decision to bring it before the World Health Assembly. Furthermore, the SAGE is aware that the work of GPV on improvement of vaccine quality could not continue without close collaboration with the Biologicals Unit and the Expert Committee on Biological Standardization, which develops guidelines and advice for National Control Authorities, and of the need for these guidelines to reflect current scientific advances.

The SAGE makes the following recommendations:

- To provide guidance to investigators, manufacturers and international agencies in the development of products for WHO-sponsored clinical trials, the SAGE recommends elaboration of guidelines on criteria for manufacture, quality control, and standardization of novel vaccines appropriate to their enrollment for clinical evaluation to supplement already existing guidelines covering other aspects of the vaccine development process. This activity should proceed with input from all appropriate groups within WHO, including VSQ and the Biologicals Unit, using a consultative process which seeks input from knowledgeable experts. The guidelines, which should be advisory rather than restrictive, should then be submitted to the Expert Committee on Biological Standardization for review.
- The SAGE recognizes the need for an approach to identify those countries whose national regulatory authorities have the capacity to oversee the vaccine development process, and recommends that GPV consider steps to implement such an activity.
- Because the current situation with the production of brain-derived vaccines, especially rabies vaccine, in many countries highlights some of the problems of vaccine development, the SAGE recommends that GPV, in collaboration with appropriate units within WHO, prepare for the next meeting a briefing paper on the global situation with respect to rabies vaccines.

Financing existing and new vaccines

Dr Stephen Cochi

Despite the fact that immunization is the most cost-effective health intervention available today, the SAGE notes substantial weaknesses in the global infrastructure to finance both the supply of existing vaccines and the introduction of new vaccines, particularly in low income countries. These shortcomings represent a threat to further progress toward bringing the benefits

of vaccines to the world's children. Therefore, the SAGE strongly urges the following actions:

1. A clear statement from the SAGE to the World Bank and regional development banks that the global immunization community requires that these development organizations take a more active leadership role in financing the establishment of sustainable national vaccine funding schemes for countries in need.
2. That WHO (and UNICEF) provide the necessary technical assistance and global coordination to both the development banks and the host countries to ensure effective implementation of vaccine financing mechanisms at the country level.

Thursday, 11 June

CVI recommendations

DRAFT 2: RECOMMENDATIONS FROM THURSDAY MORNING, 11 JUNE 1998

1. It was agreed that the time lag between the development of a new vaccine and its introduction and widespread use should be progressively reduced. In addition, the disparity in the timing of introduction of new vaccines in relation to both the developed and developing world, and the private and public sectors, is unacceptable. The message of SAGE must be clear but simple: the poorest countries must have the same access to the same traditional and new vaccines as the richest, and that there should be a single quality standard for vaccines across the world. There is a good medical case for this, a good economic case, and a case for "the force of reason, not the reason of force".

WHO/GPV and CVI should use their best endeavours to reduce this delay. Further, in planning the scale of production of new vaccines, it is important that more precise information is available concerning demand, particularly requirements in developing countries. The processes of vaccine production and the development of clear data on needs must therefore run in parallel to speed up production.

2. Combined vaccines are likely in the future to have a much wider role in immunization, and decisions and strategies to extend vaccine use need to reflect this. In considerations of procurement and supply, options for resourcing vaccines can be constrained by the desirability of purchasing appropriate combinations. This must be taken into account when looking at vaccine supply strategies and advocacy efforts.
3. SAGE members were unanimous in their views on the urgency of additional resources to complete the eradication of polio and for the introduction of new vaccines. However, it was emphasized that progress towards extending vaccination in developing countries, as well as introducing "new" vaccines, would also depend on the *reallocation* of resources in the face of evolving priorities. The cost-effectiveness and health economics benefits of vaccination must be strongly advocated when making a case for resources.

4. In order to avoid duplication of effort and to help secure satisfactory outcomes, WHO and CVI should use their unique roles to assist in the dialogue between vaccine manufacturers and developing country customers to ensure that potential sources of supply and more optimally linked to needs and issues of affordability. Joint ventures and partnerships between the manufacturing industry, international organizations and national immunization programmes could also address important issues such as quality control and the transfer of technology.
5. SAGE members noted that the words "policy" and "politics" need to be differentiated. Further, although it was important to bring politicians on board in the decision-making process for modelling the introduction of new vaccines, their role should not overlap with that of public health or immunization programme experts.] ?
6. SAGE members considered that we have been too modest in discussion on the true value of vaccines. There was therefore a call for a more proactive, detailed and realistic assessment of future financial requirements if opportunities for expanded use of existing vaccines and the introduction of new vaccines are to be successfully exploited. The enormous progress made to date should be recognized and promoted in more dynamic advocacy efforts for resource mobilization; moreover, the cost-effectiveness of vaccines is undeniable, and perhaps the most successful health intervention available. "The dimension of resources available should match the vision; the vision should not be reduced to match the resources."
7. It was noted that in some poorer countries, governments were increasing their contribution to the production of their vaccination programmes and that this was a significant motivating factor. However, the impact of the additional costs associated with the introduction of new vaccines would reduce the perceived contribution of governments, thereby reducing their motivation. Special attention must be given to this critical aspect in the Vaccine Independence Initiative in the introduction of new vaccines. Specifically, measures must be taken so that governments are rewarded,

rather than penalised, for achieving good immunization coverage levels, when looking at the allocation of resources. However, it was important to bear in mind the need for a complete, unfragmented vaccine infrastructure in a country, from both the procurement, delivery and financing perspectives, when looking at a country's self-sufficiency targets. In this respect, a renewed approach may be needed to avoid countries, and particularly the poorest nations, paying 90% of their vaccines in delivery costs.

8. Many members cautioned that the "unfinished agenda" must not be neglected in the analysis of the introduction of new vaccines, and particular attention was paid to neonatal tetanus, where simple cost-effective measures were available.
9. SAGE noted with satisfaction the excellent progress being made in the establishment and scientific activities of the International Vaccine Initiative in Korea. It welcomed the collaboration proposed, endorsed the Research Plan developed by its Board, and hoped to be kept closely informed of the progress in this important Initiative.
10. SAGE members reiterated on numerous occasions the need for increased advocacy efforts to achieve the above recommendations, and congratulated the CVI Secretariat on the prominence of this aspect in its 1998 Strategic Plan.
11. It was recommended that a detailed options appraisal should be undertaken in relation to the role of CVI and the provision of advocacy for vaccination and for its funding. In this, consultation with industry would be of crucial importance. SAGE recognized the key role of CVI to date and the success of its activities in bringing global vaccination to its present level. Members of SAGE expressed the wish to continue its advisory role, for CVI as well as for GPV.