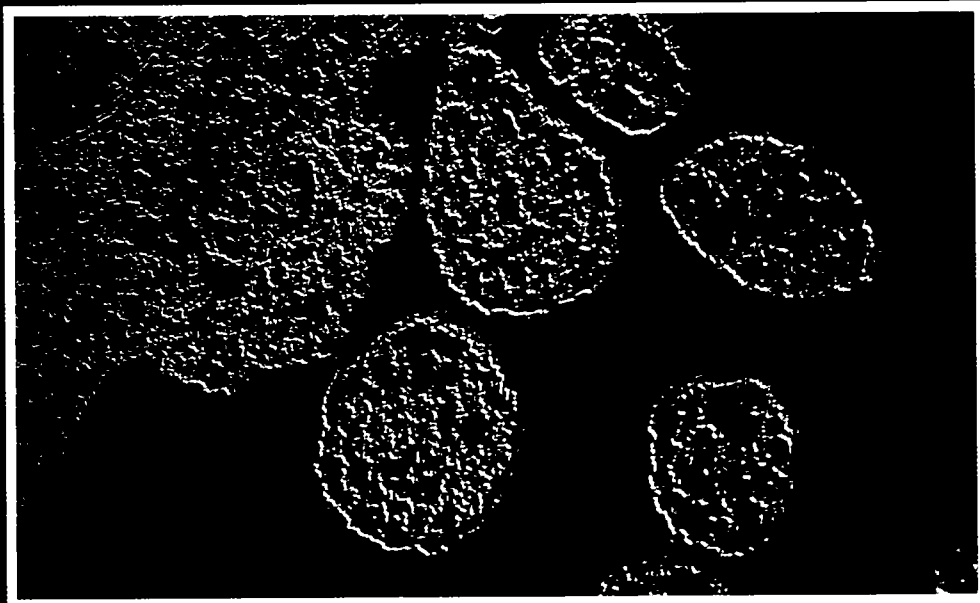


Managing Opportunity
and Change:
A Vision of Vaccination
for the 21st Century



The CVI Strategic Plan

Managing

Opportunity

and Change:

A Vision of

Vaccination for

the 21st Century



Because the existing vaccine is underused, the measles virus (*front cover*) still kills over a million children each year. A vaccine against diarrhoea caused by rotavirus (*back cover*) is a high priority to reduce the 400 000-800 000 deaths that this pathogen causes each year.

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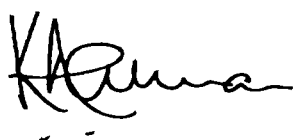
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Secretary General's Message to the Participants in the Children's Vaccine Initiative

Protection from infectious diseases is one of the greatest benefits that any government can ensure for each generation. Vaccination plays a major part in providing that protection, ensuring child health and fostering human development.

I applaud the efforts that collaborators in the Children's Vaccine Initiative, in both public and private sectors, are making to extend the control of infectious diseases through vaccine research, development, production, quality assurance, supply, utilization and monitoring of impact. As a strong believer in prevention, I encourage you to greater collective efforts to control the remaining scourges as soon as possible, and to prepare for new threats which will undoubtedly emerge.

Future generations will be in your debt.



KOFI A. ANNAN
Secretary-General
United Nations



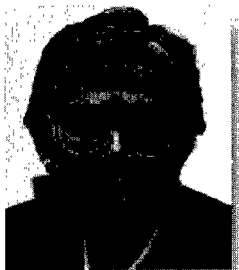
Foreword

This revised *Strategic Plan* sets out the priorities for working together to protect the world's children from infectious diseases. It is published jointly by the co-sponsoring agencies of the Children's Vaccine Initiative - the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank, the World Health Organization (WHO) and the Rockefeller Foundation.

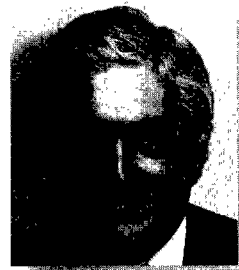
Since the founding of the initiative in 1990, following the World Summit for Children, much progress has been made in vaccine development and immunization. Most notably, the global eradication of poliomyelitis is now within immediate reach – an opportunity that must not be lost. Progress may also be measured by the range of new vaccines and vaccination approaches now available for preventing infectious diseases. Global health needs have changed over the last few years, and so have the organizations which serve them. One thing, however, remains unshaken – our shared belief that vaccination represents an exceptionally effective intervention to protect the health of children and, through them, to foster sustainable human development.

The prospects for expanding the protection against infectious diseases provided by vaccines have never been greater. The Children's Vaccine Initiative provides an objective, open and impartial forum for exchanging information and viewpoints, coordinating activities, and catalysing worldwide efforts in vaccine development and immunization.

As we enter a new century and a new era in vaccination, we commit ourselves anew to working together to achieve the vision of the CVI. Through this effort, we can protect millions more children each year from suffering, disability and death. □



CAROL BELLAMY
Executive Director
United Nations Children's Fund
(UNICEF)



JAMES WOLFENSOHN
President
World Bank



JAMES GUSTAVE SPETH
Administrator
United Nations Development
Programme (UNDP)



GORDON CONWAY
President
Rockefeller Foundation



GRO HARLEM BRUNDTLAND
Director-General
World Health Organization (WHO)

The heads of the World Health Organization and the Rockefeller Foundation when the CVI Strategic Plan was first printed were Hiroshi Nakajima and Peter Goldmark respectively.

Preface

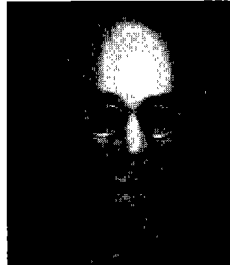
The Children's Vaccine Initiative (CVI) was founded following the 1990 New York World Summit for Children. At that time, close to 80% of the world's children were being routinely immunized against six diseases early in life - polio, diphtheria, tetanus, pertussis, measles and tuberculosis. While current immunization efforts against these diseases save two to three million lives each year, millions more still die from these diseases and others for which vaccines are needed.

In 1990, need, opportunity and optimism were galvanized into action to create the CVI. This is a collective, international effort designed to harness new scientific developments to increase protection from infectious diseases, and to simplify vaccine delivery to benefit all the world's children.

The first *CVI Strategic Plan*, prepared in 1992-1993, outlined medium and long-term actions needed to bring these goals to reality. This revised *Strategic Plan* reflects five years of experience in working together to better protect children from infectious diseases through the development and application of safe, effective, easy to deliver and widely available vaccines.

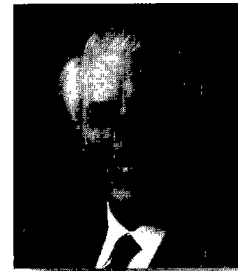
This *Plan* fundamentally affirms the directions of the previous version, while adding to it new directions that will increase the ultimate effectiveness of our collective efforts. Increased attention is devoted to furthering societal commitment to vaccines, to accelerating the introduction of new vaccines and vaccination technologies, and to fostering public-private sector collaboration to achieve these shared goals as rapidly as possible.

Implementation of this *Plan* requires vigorous, concerted action by all members of the CVI coalition. We must not forsake tomorrow's children by failing to act today. □



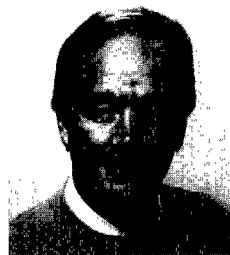
A handwritten signature of John La Montagne in dark ink.

JOHN LA MONTAGNE
Chair
CVI Task Force on Strategic Planning



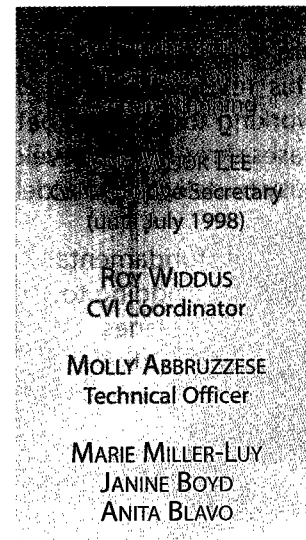
A handwritten signature of Sir Gustav Nossal in dark ink.

SIR GUSTAV NOSSAL
Chair
CVI Scientific Advisory
Group of Experts (SAGE)



A handwritten signature of Bjørn Melgaard in dark ink.

BJØRN MELGAARD
Executive Secretary
Children's Vaccine Initiative



VICTOR LEE
Executive Secretary
(until July 1998)

ROY WIDDUS
CVI Coordinator

MOLLY ABBRUZZESE
Technical Officer

MARIE MILLER-LUY
JANINE BOYD
ANITA BLAVO

The Children's Vaccine Initiative:

**“Working together
to protect children from
infectious diseases”**

Mission Statement

Working together
to protect
children from
infectious
diseases.

The Children's Vaccine Initiative (CVI) is a global coalition of organizations from the public, non-governmental and private sectors, including the vaccine industry, working together to maximize protection against infectious diseases through the development and utilization of safe, effective, easy-to-deliver and widely available vaccines.

To accomplish this, the CVI Secretariat creates forums and promotes activities designed to:

- Enhance communication and consensus among contributors to the vaccine development and application continuum, in particular between the public and private sectors;
- Define needs, priorities and strategies of action;
- Promote coordination;
- Communicate the health and economic value of vaccines; and
- Mobilize additional resources for critical activities.

Launched at the World Summit for Children in 1990, the CVI is co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Health Organization, the World Bank and the Rockefeller Foundation.



Photo UNICEF/Ellen Iomlie

Summary

The 20th century has been witness to a transformation in the control of infectious diseases that affect children. Smallpox has been eradicated from the globe, transmission of poliomyelitis has been interrupted in many parts of the world and the disease may soon be eradicated, and measles rates have been drastically reduced in some regions. These accomplishments, which save approximately seven to eight million lives every year, were made possible by the discovery and use of effective vaccines. We can now build on these gains in public health through the utilization of many other vaccines that are currently available but in limited use. These highly cost-effective vaccines can save the lives of millions more children. It is estimated that the wider use of the currently available vaccines to prevent *Haemophilus influenzae* type b (Hib), hepatitis B, measles and rubella could prevent up to three million deaths and enormous suffering in children and adults each year. Vaccines and technologies under development also offer great potential if widely applied.

The challenge for the 21st century is to make sure that the enormous impact of vaccines on the health and well-being of the population is maintained and expanded, so that all of the world's children benefit from existing vaccines, and new vaccines are incorporated into use as rapidly and efficiently as possible. Vaccines that effectively prevent rotavirus diarrhea, pneumococcal pneumonia, meningococcal meningitis in infants and cholera in older children and adults are near initial introduction and, if made widely available, could prevent up to two million deaths due to these diseases each year. Research efforts currently under way to develop new vaccines effective for the prevention of malaria, tuberculosis, *shigella* dysentery, *E.coli* diarrhea, respiratory syncytial virus (RSV), HIV and other infections which are presently

The challenge for the 21st century is to make sure that the enormous impact of vaccines on the health and well-being of the population is maintained **and** expanded.

not preventable through vaccination, are likely to yield products or viable candidates in the next ten years, saving the lives of many more millions of children and adults (Annex 1).

The aim of the Children's Vaccine Initiative (CVI) is to better protect children from infectious diseases through vaccination. The purpose of this *Strategic Plan* is to outline a series of concerted actions that must be taken to ensure that the public health goals possible through vaccination are attained and that success is sustained. These actions require the active engagement and involvement of partners from all elements of the vaccine 'continuum' – research; development; production, regulation and quality assurance; supply; introduction and use in the community; and assessment of impact (Annex 2)¹. This infrastructure is now facing a range of opportunities and challenges as a result of a series of changes that have occurred in the world of vaccines. The most important of these changes is that the global investment in basic research, begun about 50 years ago, is now paying rich dividends in the availability of new vaccines. The pace of this innovation is expected to increase well into the next century and beyond. Also, vaccination programmes have been shown to be extremely effective. The global efforts of national governments, supported by WHO, UNICEF and many other groups, have dramatically altered historic disease patterns and markedly reduced death rates from many common infections of childhood. At the same time, widespread use of antibiotics to treat infectious diseases is resulting in the emergence of antibiotic resistance, a danger that could be avoided by effective vaccines. Public expectations that vaccines can and do reduce the rates of disease have been vividly reinforced. Increasingly sophisticated production technology and higher development costs will mean that future vaccines will cost more. Finally, the vaccine industry continues to undergo important changes, including significant consolidation, as it adjusts to the new dynamics of a global marketplace for its products.

We must take the advances to date and apply them to a series of specific goals in the prevention of infectious diseases which can best be achieved through the concerted, coordinated efforts of the many segments of the vaccine development and delivery 'infrastructure'. Specifically, the following disease control goals are recommended by this *Strategic Plan*:

¹ Promising vaccine candidates should progress through this idealized 'continuum' into routine use smoothly and without delays. However, the 'continuum' presently has a significant number of shortcomings. It often lacks cohesion and experiences delays because it is composed of many autonomous components that are largely unorchestrated and uncoordinated (Annex 2).

- **effective global control of measles, HBV, Hib and rubella** (most, if not all, potentially eradicable), through broader implementation in all regions, by no later than 2005 (see Annex 1);
- **accelerated development and introduction of priority new and improved vaccines²** that will reduce deaths due to infectious diseases and increase the number of diseases preventable through immunization (see Annex 1); and
- **development of vaccines and vaccination technologies that simplify immunization programmes** through such means as oral or other mucosal delivery, or reducing the number of injections.

The concerted actions needed to accomplish the vision of the Children's Vaccine Initiative (CVI), as well as the disease control goals outlined above, are both realistic and attainable. These will require mobilization and collaboration to engage and strengthen efforts of contributors in all stages of the vaccine continuum, in and between both the public and private sectors. It is critical that the CVI collectively pursue key strategic objectives in the following areas:

Development

- fostering the development of new and improved vaccines (especially vaccines which will simplify immunization);
- promoting respect for and protection of intellectual property;
- assisting in the development of vaccines which have limited apparent commercial prospects, yet great public health potential;

Supply

- promoting consistent high quality in all vaccines;
- encouraging governments towards self-reliance, adequate financing of immunization programmes and the targeting of external assistance at the most needy countries;

² Rotavirus, pneumococcal, RSV, improved influenza, improved TB, HIV and STD vaccines for global use, and malaria, meningococcal, Dengue, JEV and selected diarrhoeal vaccines for mostly regional use. See Annex 1 for the possible time frame for these vaccines

- creating and expanding demand for vaccines;
- planning to provide for vaccine supply in emergencies;

Utilization

- promoting the selection and introduction of priority new vaccines into immunization programmes;
- promoting the safety of injection practices;
- encouraging the collection of national information on which to base estimates of the burden and costs of infectious diseases (for decision-making on vaccine introduction);
- supporting social and behavioral research designed to achieve a better understanding of factors leading to increased societal acceptance and use of vaccines;
- promoting access to national delivery systems and vaccines;
- encouraging the creation of mechanisms for the delivery of vaccines to target groups beyond infants and women of childbearing age;

Advocacy

- increasing the awareness of the value of vaccination to society and to national decision-makers, thus increasing the demand for vaccines in all countries; and
- mobilizing the resources needed to support all of these efforts.

The Declaration of New York, which launched the CVI at the World Summit for Children in 1990, set visionary goals for vaccines and vaccination programmes (Annex 3). It foresaw a world in which all children would be protected from the ravages of infectious diseases through the use of simpler, preferably oral or other mucosal vaccines that would be administered early in life. Significant progress has been made along the path towards that dream. In the short span of seven years, the CVI has been singularly effective in advancing this agenda through a variety of interconnected efforts and activities. The original

CVI Strategic Plan, drafted in 1992-1993, presented a number of options for advancing the goals, and much has been learned as a result. CVI task forces, such as the Task Force on Situation Analysis, revealed the economic dimensions and dynamics of the vaccine industry and identified new strategies for collaboration. Partnerships with other interested parties allowed CVI to focus attention on the research needed to develop combination vaccines. Through collaboration among its many partner organizations, CVI has effectively promoted improved vaccine production and quality throughout the world. All of these accomplishments were made possible due to the unique role that CVI has as an organization that facilitates interaction and communication, especially between the private and public sectors of the vaccine continuum (Annex 4).

The vision of CVI cannot be achieved without greater awareness among the general public and policy makers, or without better information on the burden of diseases. The vision will only be achieved in a timely manner if greater collective efforts are made to accelerate priorities. Thus among the activities in this report, five stand out as particularly needing additional resources: assessing disease burden, advocacy, completing development and introduction of globally important vaccines, enhancing collaboration and mobilizing additional resources.

The CVI, as a global coalition, is ideally positioned to facilitate rapid progress towards, and widespread implementation of, needed vaccines. The vision of CVI can become a reality if CVI continues successfully to recruit and engage partners along the whole vaccine continuum. New and expanded efforts will need to be incorporated into the activities of CVI collaborators (Annex 5) and will require substantial new resources beyond present expenditures on global vaccination (Annex 6). The CVI Secretariat must help to enhance communication among all parties by providing forums for discussion and by continuing to identify needs, priorities and strategies that advance the shared vision. The CVI can effectively serve the critical need for advocacy, coordination and mobilization of needed resources that this *Plan* defines. The path ahead is clear albeit difficult. The concerted efforts of all partners of the vaccine continuum must be engaged if the common goal of improving the lives of children throughout the world through the development and optimal use of safe, effective vaccines is to be achieved. □



Photo: UNICEF/Sean Sprague

Introduction

The Task Force on Strategic Planning developed this *Strategic Plan* for the Children's Vaccine Initiative in a series of meetings and discussions between May 1996 and May 1997 (Annex 7). This *Plan* builds on the momentum established by the original 1993 *CVI Strategic Plan*, which defined four medium-term objectives, summarized as follows:

- To improve vaccine availability by promoting mechanisms that ensure a sustained supply of affordable, quality vaccines for childhood immunization programmes.
- To develop improved and new vaccines, including a focus on the development of combination vaccines based on diphtheria-tetanus-pertussis (DTP) vaccines.
- To focus efforts on capacity building, especially in the areas of vaccine production, quality control, research and development.
- To provide forums for discussions of these issues and for resource mobilization.

Significant progress has been, and is continuing to be made in addressing these four objectives. These medium-term objectives require the continuous engagement and participation of all members of the vaccine continuum in order to provide effective control of infectious diseases by immunization.

A number of efforts since the creation of the CVI illustrate increasing commitment to vaccine development and delivery. The United States Congress, for example, has targeted additional resources to the National Institutes of Health, specifically to CVI goals. The European

While the distant future is uncertain, we must act now.

Commission is well aware of the importance of vaccines and immunization, and is therefore providing an important support to research and development efforts in the field of vaccines targeted by this report. The possibility of complementarity and new momentum provided by this Strategic Plan to ongoing and future European Union research activities is most welcome. Rotary International has mobilized financial and human resources to support global polio eradication, and the UNDP fostered the concept of an International Vaccine Institute, launched in October 1997 with substantial support from the Government of Korea.

The Task Force on Strategic Planning elected to develop the new *Strategic Plan* to build on the significant accomplishments already achieved, and to respond more effectively to emerging transitions both in the vaccine world and in the global economy (Annex 8). Such transitions include the growing wish of a number of developing countries to make decisions about introducing new vaccines, and the increasing ability of certain developing countries to become self-sufficient in running and financing their own immunization programmes. In another important area of change, it is clear that new vaccines of global appeal will generally not be inexpensive products when initially introduced. The new *Strategic Plan* reflects the need to respond to such changes by exploring options that will facilitate maximum choice, while ensuring that the poorest countries continue to be supplied with quality vaccines at affordable prices.

To develop this *Plan*, the Task Force pursued two approaches concurrently. First, progress against the first *Plan* was reviewed and the problems associated with reaching the original objectives were identified (Annex 9). Second, the Task Force sought to identify significant recent developments – such as new technologies or approaches to immunization programmes – that were relevant and needed to be incorporated into the new *Strategic Plan*. In addition, the Task Force developed a statement to communicate succinctly and directly the mission of the CVI – essentially to bring order to a disjointed system.

In the development of the new *Strategic Plan*, Task Force members outlined which elements in the vaccine continuum were most critical to achieve success, considered the obstacles that must be overcome for the *Plan* to be successful, and outlined general approaches to the achieve-

ment of objectives. Finally, the Task Force identified a series of milestones by which to measure progress. It is important to note that the new *CVI Strategic Plan* is not intended to serve as a detailed activities plan for all CVI collaborators, but rather as a broad framework within which individuals and organizations may contribute different activities based on their comparative advantages and interests (Annex 10).

As a 'framework', this *Plan* identifies actions needed over the next few years to bring to reality desirable outcomes that may take 10 to 15 years to come to fruition. Without concerted action, the likelihood that these outcomes will be achieved is much less, possibly even non-existent. Given that new, potentially unpredictable developments will occur in the vaccine world, the *CVI Strategic Plan* needs to be seen as a general guide requiring periodic revisions every three to five years. Such updating will confirm the validity of the *Plan* and/or allow for refinement in its areas of emphasis. While the distant future is uncertain, we must act now. □



Photo WHO/Japan

Key elements of the *Strategic Plan*

The four main elements of the new *CVI Strategic Plan* are outlined below, each accompanied by its principal objectives.

1. Facilitating development of new and improved vaccines

Expansion of disease control efforts through existing vaccines, as well as new and improved vaccines, requires a long-term commitment to supporting global capacities for research and development. This includes not only the support for institutions engaged in this activity, but also for the informal networks that emerge to address each vaccine as it moves through the vaccine continuum. This is especially critical for those vaccines which, for the moment, are perceived to have little commercial appeal, yet great public health potential, such as vaccines to prevent tuberculosis or malaria.

Today, the development of vaccines relies heavily on the strategic use of intellectual property rights (IPRs) that provide assurance to investors that a vaccine candidate will be able to find markets that provide a fair return on invested funds. Without a good system to protect and respect IPRs, it is unlikely that new vaccines will become available.

1.1 To foster the development of new and improved vaccines (especially vaccines which will simplify immunization):

- develop consensus on priority new vaccines and the improvement of existing vaccines;
- acquire epidemiologic and economic data on infectious diseases to guide decision-making;

- promote research and development efforts on new vaccines, vaccines using combination methodologies, and/or vaccines based on new technologies;
- promote research and development efforts for oral and other mucosally delivered vaccines which are easy to deliver, and can give better protection than injectable vaccines against pathogens entering the body via mucosal surfaces;
- promote the development of vaccines which are freer from adverse reactions;
- promote the development and use of more thermostable vaccines;
- strengthen local and regional institutions devoted to epidemiology, vaccine research, clinical trials, development, quality control, regulation and quality assurance;
- harmonize technical requirements for vaccine licensing and production, based upon a scientific consensus; and
- harmonize vaccine delivery schedules.

1.2 To promote respect for and protection of intellectual property:

- promote and support protection of intellectual property, in line with the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property (such protection, in turn, serves to provide stimulus for innovation); and
- develop mechanisms that assist in the transaction and negotiation of intellectual property rights that lead to the wide introduction, or improvement, of priority vaccines.

1.3 To assist in the development of vaccines which have limited apparent commercial prospects, yet great public health potential:

- provide information on the impact of so-called 'orphan' diseases in endemic areas to help guide decision-making on research and development priorities; and

- facilitate the evaluation and production of vaccines of limited commercial interests.

2. Promoting the wide availability of quality vaccines

The potential impact of vaccines can only be realized if the vaccines are available and used in national immunization programmes. Adequate quantities of quality vaccines must be accessible to all countries. The vaccine financing infrastructure must be expanded and strengthened to support the introduction of new vaccines. Governments must take increasing responsibility for financing their national vaccine needs as well as their immunization programmes in general. This is required both to ensure sustainability and to allow external support to be more targeted at the neediest countries. It is also important to balance the objective of supplying affordable vaccines to the neediest countries with the need for adequate revenue to stimulate and sustain new vaccine research and development. A central strategy to achieving both of these ends is price-tiering – a strategy by which different markets are offered different, but appropriate and affordable prices (see Annex 11).

2.1 To promote consistent high quality in all vaccines:

- encourage the establishment of National Control Authorities (NCAs) with the appropriate control functions in every country;
- enhance and rationalize local and regional efforts to improve vaccine quality;
- encourage adequate support for research related to the assurance of vaccine quality;
- ensure the availability of reference materials necessary to assure vaccine quality; and
- foster communication among National Control Authorities, regional regulatory bodies, WHO, and other organizations interested in vaccine quality.

2.2 To encourage governments towards self-reliance, adequate financing of immunization programmes and the targeting of external assistance at the most needy countries

- develop and promote tools and financing mechanisms, such as revolving funds like the UNICEF Vaccine Independence Initiative (VII) and the PAHO Revolving Fund;
- strengthen selected 'local' or regional vaccine producers – those determined to be economically and technically viable – to ensure reliable production of quality vaccines;
- improve prospects for self-reliance by improving efficiency and avoiding vaccine overstocking and wastage;
- strengthen national procurement systems to enable governments to undertake direct procurement of quality, affordable vaccines effectively;
- coordinate the donor community to encourage national governments to take greater financial responsibility for their vaccine supplies and immunization activities, as well as to target donor financial support at those countries in greatest need (defined as countries in the UNICEF/WHO bands A&B, see Annex 11); and
- support National Control Authorities adequately, so that they can perform the functions necessary to ensure the quality of all vaccines whether imported or produced locally.

2.3 To create and expand demand for vaccines:

- inform the public and decision makers on the value of disease prevention and the role of vaccination as a cost-effective health intervention;
- improve the credibility of national and global demand forecasts by strengthening the link between need and actual financing and use of priority vaccines;

- facilitate the supply of vaccines at reasonable market terms by mobilizing additional resources for their purchase;
- make needed vaccines available to all countries by employing procurement systems or innovative financing mechanisms that include specific attention to the needs of the poorest countries for new vaccines (see Annex 11);
- promote the understanding of “affordability” and how its definition varies with perceived value as well as available resources; and
- identify strategies and share data with public and private manufacturers which will improve the supply of existing and future vaccines.

2.4 To plan to provide for vaccine supply in emergencies (such as outbreaks or disruptions of production):

- identify currently available vaccines that may be needed in quantities exceeding routine supply capacity because of potential outbreaks;
- identify diseases for which routine vaccine delivery is most at risk from disruptions in production and distribution; and
- formulate and implement strategies for meeting unexpected demands or disruption in routine supply (such as financing strategies and creation of stockpiles managed to ensure the availability of potent vaccines).

3. Promoting the introduction and use of needed vaccines

One of the major challenges to the vaccine continuum is to manage and facilitate the process of introducing a new or improved vaccine into an immunization programme. The technical dimensions of this problem may not be as difficult as the logistic and financial problems that need to be solved. One of the major challenges to the successful introduction of a vaccine is the mobilization and coordination of inter-

national, national, community and individual efforts in support of the introduction of a new or improved vaccine, especially to prevent an infectious disease when the impact of that disease is not fully appreciated in the community. Data collection is important for establishing disease burden; it should also be used to monitor progress and refine programmes, *inter alia* to eliminate inequalities in access.

3.1 To promote selection and introduction of priority new vaccines into immunization programmes:

- develop guidelines to encourage selection and introduction of new vaccines by national immunization programmes;
- supply technical support (epidemiologic, biotechnological and economic) for the design and implementation of new immunization programmes;
- incorporate regional needs in selection of vaccines for national immunization programmes when epidemiologic circumstances warrant their inclusion (such as for yellow fever, hepatitis B, Hib, typhoid and cholera);
- develop relevant morbidity and mortality data; and
- monitor and disseminate lessons learned from countries adopting new vaccines early.

3.2 To promote the safety of injection practices:

- promote education and training of health personnel on injection safety;
- promote strategies for improving injection safety, such as the supply of auto-destruct syringes; and
- promote research and development of technologies that improve injection safety (improved jet injections and needle-free injection technologies).

3.3 To encourage the collection of reliable information on which to base estimates of the burden and costs of infectious diseases (for national decision-making on vaccine introduction):

- strengthen national infectious disease surveillance for existing and emerging infectious diseases;
- encourage the collection of data from additional sources of epidemiologic information (such as serologic studies and antenatal screening);
- strengthen efforts to assess both the economic and social costs of infectious diseases including links between these and poverty; and
- link epidemiologic data to priority-setting for vaccine research, development and introduction at national, regional and global levels.

3.4 To support social and behavioural research designed to foster a better understanding of factors leading to increased societal acceptance and use of vaccines:

- promote investigation of public and policy-maker knowledge of, and attitudes towards infectious diseases;
- promote investigation of public and policy-maker knowledge of, and attitudes towards vaccination, including adverse events and injection safety; and
- promote investigation of public and policy-maker attitudes towards prevention of disease and willingness to pay for protection.

3.5 To promote access to national delivery systems and vaccines:

- identify groups with low immunization rates and target them for innovative and intensified efforts to increase access;
- encourage innovative approaches for improving distribution and delivery of vaccines;

- foster methods to encourage participation of the community (especially mothers) and to ensure gender equality;
- coordinate and mobilize donors, where needed, for critical elements of infrastructure such as the cold chain;
- decentralize authority and accountability for immunization service delivery while assuring policy formulation and monitoring capacity at national levels; and
- maintain a balanced use of resources in countries by promoting regional or global initiatives only when absolutely essential, and after full consultation with countries in greatest need of routine programme strengthening.

3.6 To encourage creation of mechanisms for delivery of vaccines to target groups beyond infants and women of childbearing age:

- strengthen policies and programme implementation regarding booster doses for basic paediatric vaccines;
- identify and create appropriate opportunities (such as school entry or pre-adolescence) for reaching unimmunized individuals, or for delivery of vaccines expected to be available in the near future against sexually transmitted diseases (STDs), including HIV/AIDS;
- promote the concept of vaccination as a preventive measure relevant to all stages of life – infancy, childhood, adolescence, adulthood and maturity.

4. Fostering a culture of prevention through advocacy for vaccines

The real magnitude of infectious diseases is not always recognized. One of the great paradoxes of public health is that as control over an infectious disease is established by the effective use of vaccines, the community's perception of the risk of that infection diminishes. This diminished appreciation for the risks of disease and the benefits of

immunization requires our immediate attention since experience has shown that as vaccination rates drop, infectious diseases re-emerge and epidemics can ensue. Effective control of a disease may easily falter, leading to its re-emergence. This circumstance compels continued attention to immunization programmes and action to maintain local and political commitment to them. This can be done only through active efforts which inform the public of the benefits and risks of vaccination, the real risks of infectious diseases in their community, and the impact of these problems on society as well as the individual. Similar efforts must also be directed at opinion leaders and those who provide resources so that support to immunization efforts can be dramatically expanded to provide better protection.

4.1 To increase awareness of the value of vaccination to society and to national decision-makers, thus increasing the demand for vaccines in all countries:

- actively engage all partners in the vaccine continuum to provide information to their constituencies on the value of immunization programmes and vaccines;
- promote the use of mass media sources, such as the internet, to address the value of immunization and vaccines;
- identify community leaders to act as advocates for immunization programmes and vaccines; and
- inform decision-makers on the benefits of immunization and vaccines to their communities.

4.2 To mobilize the resources needed to support all of these efforts:

- develop accurate estimates of the morbidity and mortality attributed to infectious diseases in the community through the use of epidemiologic, economic and scientific resources in the vaccine continuum;
- develop accurate estimates of the economic impact of infectious diseases and the benefits to be derived by immunization;

- establish a clear agenda of action for decision-makers including ascertaining that vaccine supplies, immunization infrastructure, financing and support systems (such as training; education and communication materials; and monitoring systems) are adequate to meet the present and future public health needs either locally, nationally or globally;
- ensure participation of the community (especially of mothers) in the planning and promotion of immunization programmes, and
- develop active information campaigns for the public on immunization programmes, vaccines and the risks of infectious diseases. □

Implementing the *CVI Strategic Plan*

The task of implementing the *CVI Strategic Plan* rests collectively with the collaborators in the Initiative aided by the CVI Secretariat, since the CVI is not itself an ‘operational’ entity. The key elements and strategic objectives outlined above need to be further reviewed by collaborators in the CVI coalition and translated into new or strengthened activities – and goals – for their organizations, taking into account their respective mandates or missions, and current efforts. Annex 10 can serve as a planning and monitoring guide for collaborating agencies and the CVI Secretariat. The CVI Secretariat itself will undertake for the Initiative as a whole the various functions described in the mission statement to facilitate the coordinated implementation of the *Plan* and achievement of its objectives (Annex 12). Most, if not all of the activities outlined above will need enhanced collaboration and cooperation between the public and private sectors, a primary focus of the CVI Secretariat.

To foster further commitment to the goals outlined in this *Plan*, the Task Force on Strategic Planning recommends that the CVI convene a World Summit for Children’s Vaccination (Annex 13). □

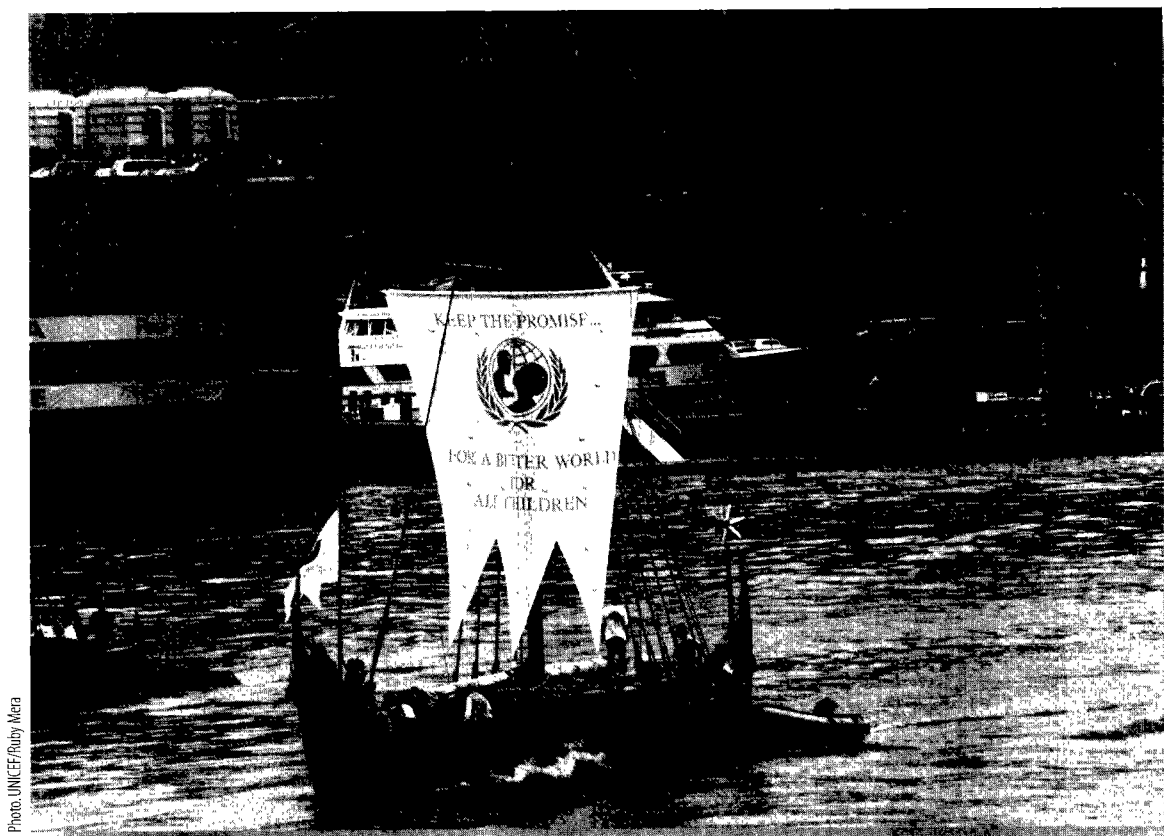


Photo: UNICEF/Ruby Mara

"Keep The Promise... For a Better World for all Children"

Annex 1

Major vaccination targets: burden of disease, medical costs and estimated cost of prevention

The priorities in the following table were selected by the Task Force on Strategic Planning, taking into account and balancing the following factors:

- the burden and perceptions of the target disease;
- appropriateness of vaccination as a preventive measure;
- the availability of other practical means to prevent or treat a disease;
- the suitability of the vaccine for wide utilization;
- likely efficacy, particularly in infants, of a given vaccine;
- ease of addition to current immunization schedules;
- availability in a combination product;
- cost and supply capacity; and
- other potential benefits of the product.

Evaluating vaccination options

Building the present infrastructure for disease control through vaccination was undertaken largely on the basis of humanitarian arguments for averting disease. *Post facto* calculations of lives saved and costs showed vaccination to be among the most cost-effective health interventions (World Bank, 1993 *Investing in Health*).

As health intervention options have proliferated, the need to assess the relative merits of different courses of action has increased. Attempts to quantify health benefits and costs of vaccination options can help in choosing among options, and in justifying the investments needed to pursue the most favorable ones. Such quantitative analyses help

inform, but do not replace, policy making, which must also incorporate subjective judgments.

In an effort to provide support to those making policy decisions, the CVI Secretariat staff has developed a 'framework', with broad guidance from epidemiologists, economists, vaccinologists and national immunization programme managers, to support evaluation of vaccination policy options. Rigorous application of such methods requires considerable data collection and assumptions where information may not be precisely known (for example, where disease burden data or treatment costs are uncertain, or where the price of a new vaccine, for different markets is not known). Because of these uncertainties, results are usually presented as a range of plausible values. Nonetheless, their relative magnitude can be informative.

These methods can be applied at local, national, regional and global levels. For each country they incorporate, based on its development and epidemiology, data or estimates of infection/disease incidence, treatment costs and vaccination programme costs. Global estimates are compiled by aggregating country level calculations. A systematic assessment of many of the options listed in the following table has been initiated by the CVI Secretariat. A number of assessments have been completed to date which are indicated by a footnote in the following table, together with estimates made by other groups of costs or benefits. Other assessments are in progress or planned, and further results will be made available through periodic CVI publications to be announced in the *CVI Forum*. □

Annex 1 Major vaccination targets: burden of disease, medical costs and estimated costs of prevention

Goal	Burden of Target Disease ¹	Direct Medical Cost of Disease ² (US\$)	Resources Needed (US\$) (annual except where otherwise noted)	Comments
A. Application of existing tools – broader implementation, new strategies or wider introduction (to 80% or above wherever needed) By 2005				
Polio Eradication	40 - 50 000 new cases of severe disability per year		\$2.7 billion total for years remaining to completion of eradication (of which \$800 million – \$1.0 billion is needed from external sources for endemic countries)	\$1.5 billion annual savings, following cessation of vaccination
Measles control improved world wide (as a prerequisite for eradication after 2010)	700 000 - 1 500 000 child deaths	> \$900 million ³ (> 66% in high income countries)	\$250 million to achieve 90% coverage with 2 doses; estimated \$4.5 billion required for all years to eradication ³	Eventual savings after cessation of vaccination to be calculated
HB vaccine (wider use)	800 000 deaths among adults, mostly from infections in early childhood	> \$1 billion	Estimated \$65 million annually to support low income countries; \$256 million for global use	Cost of prevention dependent on vaccine cost and number of doses
Hib vaccine (wider use)	400 000 - 700 000 child deaths	> \$750 million (80% in high middle- and high- income countries ³)	\$1 billion worldwide from all sources ³	Disease burden estimates need to be improved
Rubella vaccine (wider use)	Approximately 300 000 severe congenital malformations in newborns	Calculation planned	Calculation planned	

¹ Estimated annual disease burden in late 1990s of which some significant fraction could be averted.

² Estimated annual medical costs.

³ Estimates by CVI Secretariat methods; other estimates are from various other sources.

Annex 1 Major vaccination targets: burden of disease, medical costs and estimated costs of prevention

Goal	Burden of Target Disease ¹	Direct Medical Cost of Disease ² (US\$)	Resources Needed (US\$) (annual outlay where otherwise noted)	Comments
Selected regional or endemic disease vaccines				
<i>Yellow fever vaccine use in high risk countries</i>	Up to 30 000 deaths, all ages	Unknown	\$4.6 million for routine programme in high risk countries. Estimated \$17 million to provide catch up immunization on a one time basis	Outbreak control costly: precise disease burden difficult to calculate
<i>Japanese Encephalitis Virus (JEV) vaccine</i>	10 000 to 12 000 deaths, all ages, one third of cases with neurological sequelae	Calculation planned		Utility of existing and new vaccines for wider use needs to be assessed
<i>Meningococcal Meningitis (polysaccharide vaccine)</i>	20 000 to 30 000 deaths average, higher in epidemics	Calculation in progress	Variable	Utility of existing vaccines for wider use needs to be assessed; epidemic control costly
<i>Use, in selected countries, of other new and combination vaccines including typhoid, HA, fHP-HB, DTap, varicella and vaccines against tick borne encephalitis and Lyme disease</i>	Dependent on target population	Dependent on target population	Dependent on target population	Wider public or private sector use of existing vaccines in high risk countries to be further considered
B.1 Completing development, licensing and introduction of imminent vaccines By 2000-2002 effectiveness trials in developing countries completed, by 2005-2007 introduction occurring widely if successful				
<i>Rotavirus vaccine</i> (licensed for use in the USA on 31 August 1998)	400 000 - 600 000 child deaths	> \$1.8 billion	\$900 million for developing countries, assuming tiered pricing at \$0.50-\$2.00/dose	Current vaccine has unknown efficacy in countries where most deaths occur
<i>Pneumococcal conjugate vaccine</i> (License application anticipated late 1998)	Approx 1 000 000 child deaths	Calculation in progress	\$1.6 billion for developing countries, assuming tiered pricing at \$3-10/dose	Epidemic control costly
<i>Meningococcal conjugate vaccine</i>	20 000 to 30 000 deaths average, higher in epidemics	Calculation in progress	Calculation in progress	For older children and adults
<i>Shigella vaccine, improved</i>	Approx 120 000 deaths, all ages	Calculation planned	Calculation planned	Global burden of disease needs further study
<i>Lyme disease vaccine</i>	Global estimate not available	Calculation planned	Calculation planned	

¹ Estimated annual disease burden in late 1990s of which some significant fraction could be averted.

² Estimated annual medical costs.

³ Estimates by CVI Secretariat methods; other estimates are from various other sources.

Annex 1 Major vaccination targets: burden of disease, medical costs and estimated costs of prevention

Goal	Burden of Target Disease ¹	Direct Medical Cost of Disease ² (US\$)	Resources Needed (US\$) (annual except where otherwise noted)	Comments
B.2 Medium-term development needs				
Between 2000 and 2005 efficacy and effectiveness trials anticipated, by 2010 introduction occurring wherever needed if successful				
RSV vaccine	400 000 – 500 000 child deaths	Calculation planned	Calculation planned	Disease burden estimates uncertain, need to be improved
Dengue and JEV (improved) vaccines for high risk countries	Dengue, up to 30 000 deaths; JEV, 10 000 to 12 000 deaths; all ages	Calculation planned	Calculation planned	
Bacterial diarrhoeas and typhoid (improved), for high risk countries	Total of approximately 2.0 million deaths (mostly children)	Calculation planned	Calculation planned	Shigella and E. coli vaccines are main diarrheal vaccine candidates
Malaria vaccine	Approximately 2.1 million deaths including 1.2 million children, mainly in Africa	Calculation planned	Calculation planned	
Influenzae vaccine improved	Periodic pandemics; disease burden uncertain	Calculation planned	Calculation planned	No vaccine delivery system in most of world for adults
HIV/AIDS vaccine	Presently approximately 3.0 million new infections annually, mostly in young adults, likely to result in premature death	Calculation planned	Calculation planned	Future annual new infections and deaths difficult to estimate

¹ Estimated annual disease burden in late 1990s of which some significant fraction could be averted.

² Estimated annual medical costs.

³ Estimates by CVI Secretariat methods; other estimates are from various other sources.

Annex 1 Major vaccination targets: burden of disease, medical costs and estimated costs of prevention

Goal	Burden of Target Disease ¹	Direct Medical Cost of Disease ² (US\$)	Resources Needed (US\$) (annual except where otherwise noted)	Comments
B.3 Priority targets for longer term research and development Promising candidates in efficacy and/or effectiveness trials in developing countries by 2005-2010				
<i>Influenza vaccine improved</i>	Periodic pandemics; disease burden uncertain	Calculation planned	Calculation planned	No vaccine delivery system in most of world for adults
<i>TB improved vaccine</i>	3.0 million deaths all ages	Calculation planned	Calculation planned	
<i>Other sexually transmitted disease vaccines (Chlamydia, Neisseria gonorrhea)</i>	200,000 deaths (congenital Syphilis) and millions of cases of infertility	Calculation planned	Calculation planned	
<i>Vaccines against other parasitic diseases, including Leishmaniasis and Schistosomiasis</i>	Total of approximately 1 million deaths; high prevalence chronic morbidity	Calculation planned	Calculation planned	Numerous causes; suitability of vaccine prevention versus other options needs consideration

¹ Estimated annual disease burden in late 1990s of which some significant fraction could be averted.

² Estimated annual medical costs.

³ Estimates by CVI Secretariat methods; other estimates are from various other sources.

Annex 2

The vaccine development and utilization continuum

Figure 1 Players and Factors in the Continuum

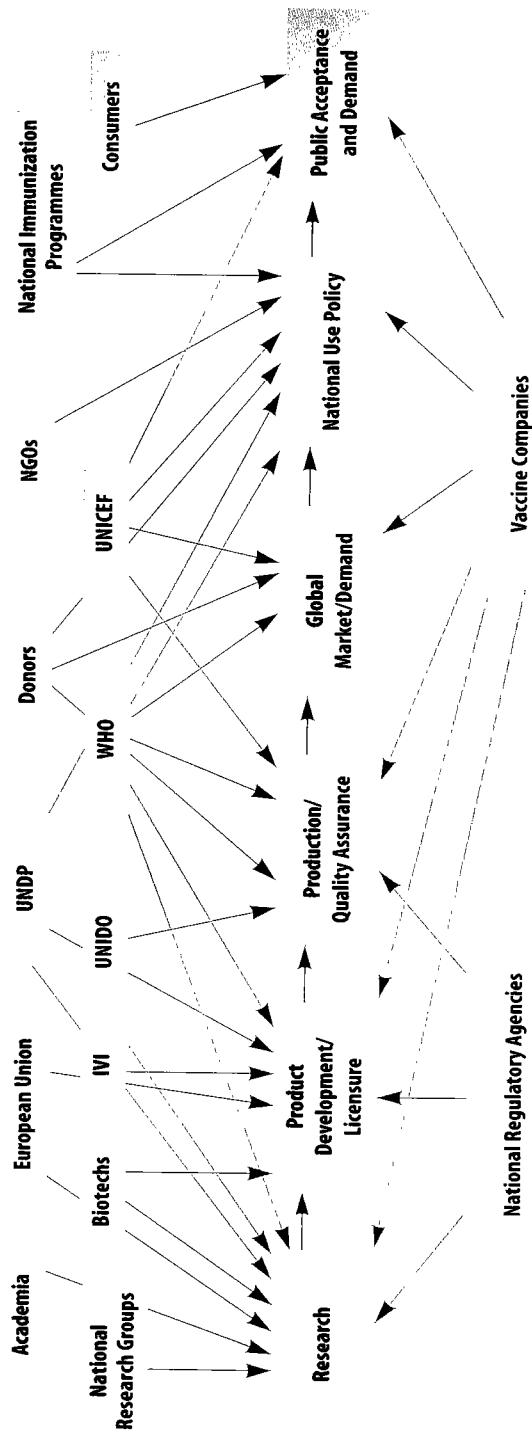
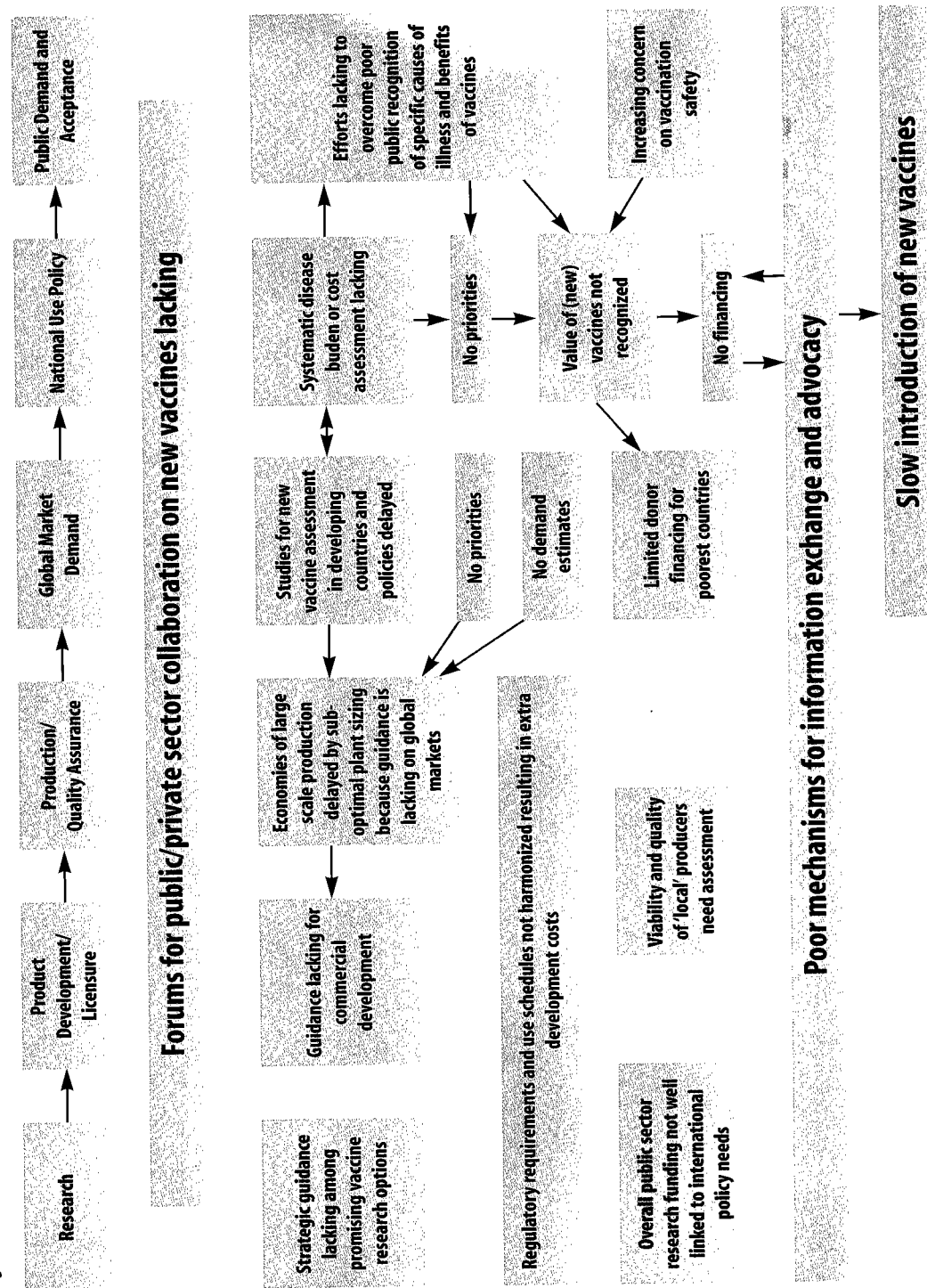


Figure 2 Present Shortcomings within the Continuum



Annex 3

The Children's Vaccine Initiative: 10 September 1990

Children represent the most vulnerable segment of every society - and they are our present and the future. Good health, especially of children, promotes personal and national development. Scientific progress, matched with improved capacities of all countries to immunize their children, provides an unparalleled opportunity to save additional lives and prevent additional millions of disabilities annually through a global "Children's Vaccine Initiative".

Working together, national and international agencies, service organizations and private voluntary agencies around the world have demonstrated the feasibility of providing immunization to over 70% of children in the developing world, saving approximately two to three million children per year from those preventable diseases. Furthermore, countries around the world have demonstrated public interest in mobilizing to protect their children. With universal immunization using the current vaccines, two to three million more deaths could be prevented annually. Development of new vaccines against diseases could save another five to six million lives annually during this decade.

Universal immunization will be facilitated by accelerating the application of current science to make new and better vaccines, benefiting children in **all** countries. These include vaccines which:

- require one or two rather than multiple doses;
- can be given earlier in life;
- can be combined in novel ways, reducing the number of injections or visits required;
- are more heat stable, retaining potency during transport and storage, particularly at tropical temperatures;
- are effective against a wide variety of diseases not currently targeted by immunization but which take a heavy toll of needless deaths,

including AIDS, acute respiratory infections, diarrhoeas, and important parasites; and

- are affordable.

Work on vaccines themselves must be accompanied by investments which bring them rapidly into large scale and inexpensive production and effective use. Such investments are needed to simplify production and quality control methods; to support field trials; to speed licensing; to develop approaches – including production in developing countries – which assure that vaccines are available for all, to simplify the logistics of storing, transporting and administering vaccines and to strengthen national epidemiological and applied research capacities, especially in developing countries, so that each vaccine is used to best advantage.

We, an international group of experts in the field of research and application of vaccines, acting in our individual capacities to review the great contribution which new and improved vaccine can make during the current decade to the health of all the world's children:

Urge national leaders, the heads of national and international agencies concerned with vaccine development and use, commercial enterprises, and private and voluntary groups - harnessing the scientific and technical capacity of the world, North and South - to commit themselves to a **Children's Vaccine Initiative** which aims to produce and deliver "ideal children's vaccines", which: provide lasting protection against a wide range of diseases, need fewer contacts, have more heat stability, are simpler to administer and are affordable.

And,

Request the World Health Organization, in fulfillment of its constitutional mandate as the directing and coordinating authority on international health work, to catalyze global efforts towards these ends by taking the lead in establishing an International Task Force for Vaccine Development with UNDP, UNICEF, The World Bank, and other interested international, national, public and private organizations to coordinate their efforts through exchanging infor-

mation, agreeing upon priorities, monitoring and evaluating research results, helping organize and coordinate clinical trials of vaccines, promoting the development, production and incorporation of improved and new vaccines into national immunization programmes, and facilitating resource mobilization. □

Photo. WHO/Ministry of Health, Mexico



Annex 4

Progress towards CVI goals: achievements of collaborators in the CVI

The Declaration of New York identified a range of goals and collective action for vaccine development and vaccine delivery. The Declaration led to new thinking, new activities, and increasing collaboration which resulted in progress towards CVI goals. In some cases the projects which led to these advances may have been in place prior to 1990, but it is possible the Declaration of New York and the creation of CVI strengthened commitment to the projects. Advances include not only products and their application, but also new strategies and mechanisms through which further progress will be achieved. Major accomplishments since 1990 are highlighted below:

Integration of the vaccine development and utilization continuum

- Widening recognition of the necessity to integrate components of the vaccine continuum in order to accelerate and maximize the benefits of vaccines (for example, the creation by WHO of the Global Programme for Vaccines and Immunization).
- New efforts to achieve consensus on priorities between all major players in the vaccine continuum, including industry (such as broad collaboration on the revised *CVI Strategic Plan*).
- Increasing effort to use resources in the most efficient manner, through priority setting and rational allocation strategies.
- Establishment of new mechanisms for increasing communication and coordination among contributors to vaccine development and application, namely the CVI Consultative Group, the Task Force on Strategic Planning, Product Development Groups, and Working Groups on Vaccine Demand, Supply and Financing, and on Advocacy and Information Exchange.
- Increased dialogue between the vaccine industry and public sector agencies through CVI sponsored activities such as the 1997

Bellagio Conference, and other mechanisms including the WHO/GPV/VRD Steering Committees.

- Improved understanding by the public sector of vaccine industry economics through commissioned external analyses.
- Widening recognition that adequate revenues and appropriate pricing according to different markets are inextricably linked to industry's development of new vaccines; and the incorporation of this concept into new strategies to ensure early, wide access to future vaccines of global importance.

Development of new and improved vaccines

- Newly licensed vaccines: improved cholera (2), improved typhoid, improved (acellular) pertussis, hepatitis A and varicella.
- Newly licensed combinations: DTP-Hib, DTP-HB, DTP-Hib-Hb, DTaP, DTaP-IPV, DTaP-Hib, HA-HB and Hib-HB.
- An increase in vaccine candidates in development to the highest number ever (Jordan Report, NIAID, 1997).
- A strong, demonstrated interest by industry in the development of combination vaccines (CVI Forum, #11).
- An increase in the range of new technologies under investigation by major and new vaccine developers. These technologies should simplify vaccine delivery.
- The demonstration of Hib vaccine effectiveness in Chile and the Gambia.
- Development, testing and licensing of rotavirus vaccine and completion of pneumococcal vaccine Phase III efficacy trials in the USA.
- Development of vaccines of regional importance such as meningococcal conjugate and Dengue vaccines.

Assuring the wide availability of vaccines

- Increased attention to assuring the supply and quality of vaccines, arising from the activities of the CVI Task Force on Situation Analysis for Global Vaccine Supply (TFSA), and the CVI Task Force on Quality Control, including the creation by WHO of a Vaccine Supply and Quality (VSQ) Unit in GPV.
- The first comprehensive global assessments of global vaccine supply by the TFSA.
- Identification and assessment of 14 priority countries undertaking 'local' vaccine production, covering 75% of the world's children.
- In-depth evaluation of three local producers (Egypt, Indonesia, South Africa) to assess long-term viability and role in the supply of future vaccines.
- Identification of key factors for guiding decisions on rational, viable local production: production scale; capacity for Good Manufacturing Practices (GMP) and production consistency; capacity to take on new technologies; performance meeting demand and scale-up; credibility of quality and existence of a National Control Authority; management structure and legal status, including adequate autonomy. These criteria now form the basis of detailed studies of particular manufacturers.
- New strategies for UNICEF vaccine procurement to enhance access to future vaccines, initiated in 1995.
- Strengthening National Control Authorities.
- Improvement in the proportion of DTP vaccine used in national immunization programmes that is of known good quality from 54% in 1993 to 73% in 1997.

Vaccine application and disease control

- Substantial progress towards global polio eradication, including polio elimination in the Americas since 1991.

- Progress in measles control, especially in the Americas, through the adoption of new periodic mass campaigns.
- Hepatitis B vaccine adoption since 1990 in many high-risk and richer countries, now preventing 400 000 infections annually, approximately 30% of infant and childhood infections that would otherwise result in adult deaths from cirrhosis and liver cancer.
- Use of rubella vaccine in over 70 countries, decreasing the incidence of congenital abnormalities in infants born to mothers infected in pregnancy.
- Adoption of Hib vaccine by 24 countries, mostly since 1990, including use in Chile, Uruguay, Qatar and the Gambia.
- New strategies emerging for targeting assistance to the neediest countries.

Capacity building

- Increased awareness of the need for new resources for surveillance around the world, in part resulting from recognition of the threat of emerging, or re-emerging infectious diseases.
- Establishment in 1995 of the first international institution devoted to research and capacity building related to vaccines – the new International Vaccine Institute, Seoul, Korea, developed through a UNDP initiative and supported by the Government of Korea.

Recognition of the value of vaccines and the mobilization of resources

- Increasing investment by developing countries in their immunization programmes. Between 1990 and 1997, the proportion of the poorest, smallest countries (UNICEF/WHO Band A countries) paying some portion of their vaccine needs rose from 2% to 25%. For UNICEF/WHO Bands B and C, the proportion rose from 40% to 70%, and from 80% to 90%, respectively.
- Increasing investment by the public sector in vaccine development,

to an estimated US\$400 million annually in 1997. Increases in vaccine expenditures by the United States and European Commission are particularly noteworthy. Some new funds have been provided for agencies with activities specifically related to the CVI goals of simplifying vaccine delivery, such as the US National Institutes of Health (NIH). A significant portion of recent increases is due to additional funds for HIV/AIDS vaccine development.

- Increased funding of new product development by private sources, major companies and venture capital which is at an all time high, approximately US\$500 million.
- Creation by the UNDP, with significant financial support from the Government of Korea, of the new International Vaccine Institute (IVI), located in Seoul, Korea, with partner institutions in a number of other Asian countries.
- Clarification of the need for expanded and specific activities in advocacy for vaccines and resource mobilization, as a prerequisite for further progress towards appropriate, full application of new tools emerging from the vaccine development 'pipeline'.

Simplifying and improving vaccines and vaccine delivery

- Development by vaccine companies and licensing of a wide range of new combination vaccines (see above and CVI Forum #11) which permit immunization with fewer contacts or injections.
- Development and licensing of acellular pertussis vaccines which have fewer adverse reactions and should lead to improved public acceptance of immunization.
- Development of approaches for single-dose tetanus vaccines to the Phase I clinical trials stage, through a CVI-WHO/GPV Product Development Group (PDG).
- Development of approaches to the Phase III clinical testing stage for a more thermostable oral polio vaccine, through a CVI Product Development Group which included representatives of the vaccine manufacturing industry.

- Development of vaccine vial monitors (VVMs) through collaboration with WHO/VSQ, the Program for Appropriate Technology in Health (PATH) and USAID. VVMs are designed to reduce vaccine wastage and extend the use of vaccines to difficult to reach places 'beyond the cold chain'.
- Discovery of the immunizing potential of 'naked' DNA and its early clinical evaluation for a number of diseases including malaria, influenza and HIV/AIDS. The DNA vaccine approach, if successful, could lead to a new approach to multi-antigen, fewer dose vaccines.
- Exploration of a range of vaccine 'vector' approaches such as vaccinia, canary pox and BCG. Some of these appear to have promise in limited applications and merit further research.
- Preclinical and early clinical testing of a wide range of new potent adjuvants that may facilitate reduction in the number of vaccine doses required for full immunization.

Conclusion

Since the CVI was launched, there have been significant new developments at the early stages of the vaccine continuum. Much of this has, however, only been applied in industrialized countries, and even there incompletely. The pace of innovation is increasing. This highlights the need for concerted action so that the potential for public health benefits in all areas of the world is accelerated and maximized. □

Annex 5

Actions to be taken for successful implementation of the *CVI Strategic Plan*

The development and maintenance of political will at the highest level was essential to the success of Universal Childhood Immunization (UCI) by 1990. In 1994, a Steering Committee for Lessons Learned on Sustainability of Child Immunization, in its study commissioned by UNICEF, identified several factors critical to sustainability and further development of child immunization services. Although no single factor guarantees sustainability, political commitment was identified as continuing to be of critical importance. Mobilization of politicians and, by extension, government workers and social leaders helps to provide credibility and resources for immunization. Efforts to advocate at the highest political level for essential health services for children such as immunization must be maintained. The leaders must continually be informed of the important role of the traditional and new vaccines in improving child health in each country setting.

The world is also experiencing a wave of decentralization efforts. This is affecting the way local priorities are set and the way health services are financed and provided. It is, therefore, vital that advocacy for immunization be increasingly targeted to local decision-makers as well. Local health authorities will have to be empowered to take on a stronger advocacy role. This will require, among other things, support to the development of such skills.

Commitment of civic society and demand for the services by families is also a critical factor in keeping immunization a priority. The concept and practice of immunization needs to be integrated into the "health consciousness" of people and thus, to their daily lives. Media, local leaders and other partners need to be used to reach this objective. The political commitment of donors and international organizations will be critical to the sustainability and further development of immunization programmes. There is a concern that the tremendous potential of new vaccines to improve the welfare of children in the poorest countries will not be realized for lack of start-up funds. Advocacy to obtain international political commitment is critical to reap the full benefits of past and ongoing investment in immunization services for children.

To make the benefits of expanding vaccination a reality, all the different individuals and organizations, from both the public and private sectors, must collaborate by pursuing different actions based on their comparative advantage and capabilities. More specifically:

National governments should:

- create a budget line for national vaccination efforts;
- meet UNICEF self-sufficiency targets;
- design 5-year national plans for immunization;
- ensure that national immunization programmes use vaccines of known good quality only;
- create, or strengthen, National Control Authorities responsible for vaccines;
- assess the rationale for any local, government-supported vaccine production and assure viability of supply for existing and new vaccine needs; and
- recognize the value of disease prevention through vaccination and increase, accordingly, investment in both basic research and infectious disease surveillance.

International organizations should:

- develop recommendations that encourage all countries to implement the widest practical range of vaccination activities to protect children against infectious diseases;
- reaffirm and implement the strategies articulated for targeting support at the neediest countries, such as the UNICEF procurement strategy for new vaccines;
- develop and implement new strategies for the targeting of financial support for vaccination activities at the neediest countries;

- offer technical assistance based on the organization's comparative strengths (such as UNIDO offering its assistance to selected local vaccine producers to help ensure the reliable manufacture of high quality vaccines);
- propose incentive policies such as World Bank low-interest rate lending to countries based on their vaccine purchases; and
- develop pro-active methods, in collaboration with industry, to guide the introduction of priority new vaccines into use in developing countries.

The donor assistance community should:

- provide support within the context of national plans and in accordance with strategic global recommendations on specific issues, such as self-sufficiency targets and assessment of viability of local production, and
- teach selected countries how to procure quality vaccines at competitive prices on the international market.

The commercial vaccine industry should:

- establish a 'partnership' with the public sector in the interest of children's health. (This envisaged 'partnership' entails the public sector emphasizing financial and procurement support to the neediest countries);
- review conclusions from public-private meetings, such as the Bellagio Conference of 3-7 February 1997, and implement suggestions therein;
- consider licensing intellectual property in a way that provides for the production of new vaccines for all markets;
- consider tiered prices and tiered royalties to reduce the price of vaccines to the poorest countries; and
- continue actively to invest in vaccine research and development.

Academia and research institutions should:

- review and implement relevant suggestions from public-private sector coordination and collaboration meetings (such as the Bellagio Conference). □

Annex 6

Estimated global expenditures in vaccine development and immunization

A comprehensive estimate of expenditures on vaccine development and immunization would include funds allocated to support the following activities:

- research;
- clinical trials;
- vaccine development, including manufacturing processes;
- applications for marketing 'license' to regulatory agencies;
- regulatory sciences and quality assurance;
- production and quality control costs;
- supply and marketing;
- use, 'in the field', including distribution; and
- surveillance.

Expenditures towards these activities are made by a wide variety of funding sources:

- research funding agencies, including national agencies and foundations;
- major vaccine companies, emerging global producers, 'local' producers and research oriented 'biotech' vaccine developers;
- national control agencies;
- national, regional and local disease control agencies;
- health insurers;

- nongovernmental organizations;
- international health agencies;
- national development assistance agencies; and
- individuals.

No comprehensive global assessment of such expenditures has ever been conducted as far as could be determined by the Task Force on Strategic Planning. Some prior studies e.g. on the cost of immunizing children in developing countries (approximately US \$1.5 billion) were limited in scope and are now somewhat out of date. However, they provide useful information on the possible magnitude of some components in the overall picture. Estimates of the global vaccine market, at around US \$3 to \$3.2 billion in 1994 also provide useful, but incomplete information.

Although an assessment of current expenditures is identified by the Task Force as an important basis for estimating the magnitude of new resources needed to achieve its goals, the time and resources needed to make such an estimate were beyond those available to the Task Force members.

Extrapolation from the limited partial information available suggests that global vaccine development and immunization expenditures may be around \$10 billion annually. A better estimate will be developed for future revisions of the *Strategic Plan*. The crude estimate of \$10 billion gives an order of magnitude to compare against other expenditures, some of which are listed below.

Global expenditures

Total health expenditures 1992
US \$1,581 billion

Vaccine/immunization spending 1994
US \$10 billion (crude estimate)

Health R&D expenditures 1992
US \$55.8 billion

Vaccine R&D
less than US \$1 billion

Sources: *Investing in Health Research and Development*, World Health Organization, 1996; and estimates by the CVI Secretariat

Annex 7

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Managing opportunity and change: emerging transitions in vaccination

The first phase of global vaccination efforts is coming to a close. Based on the example set by smallpox eradication – that global disease control and, in some cases, eradication, through immunization is achievable – a number of collaborators around the world launched, during the first phase of global vaccination, an effort to control certain widespread paediatric diseases. Although national immunization programmes launched this effort ‘locally’, the overall effort was centrally led by the WHO Expanded Programme on Immunization (EPI) and UNICEF. The bulk of the financial support came from the donor assistance community. The foundation of early immunization programmes was based on vaccines that had been available for many years – usually over 20 or 30 – such as BCG, OPV, DTP and measles. By the time these vaccines were incorporated into national programmes, they were readily produced and could be made available inexpensively by major manufacturers. No sophisticated cost-effectiveness analyses were required to justify their inclusion in a proposed national or global ‘package’.

The availability of the six, traditional vaccines helped establish immunization services as the vehicle for comprehensive child health care delivery programmes. Under the banner of the Expanded Programme on Immunization (EPI) and the push for Universal Childhood Immunization (UCI), this approach resulted in greater than 80% worldwide immunization coverage by 1990. This outstanding success has been called the greatest public health achievement ever. Without central advocacy and a clear focus, the current delivery system which reaches 80% of the world’s children would not have been built. The success achieved thus far has, in fact, changed the disease prevention environment and created a new starting point for considering the future.

By 1990, in the aftermath of the push for Universal Childhood Immunization, a number of emerging trends had become apparent:

- A number of developing countries are making rapid economic progress and have reached a stage at which they are taking increas-

ing responsibility for their own immunization programmes. Since donors and international agencies cannot sustain the burden of paying for immunization programmes in all developing countries, particularly when some are in less need than others, the current UNICEF/WHO strategy has been developed to target support to the neediest countries while encouraging self-sufficiency among others.

- An increasing number of developing countries have progressed to the point of having programmes strong enough to take on more than the minimum basic recommended vaccines.
- Countries increasingly wish to make their own decisions about introducing new vaccines, rather than follow a global 'recipe'.
- New vaccines, which may have global appeal, will generally not be inexpensive 'commodity' products because they are at an earlier stage in their product life-cycle. The production technologies and requirements for assuring safety, efficacy and consistency of quality of these new vaccines mean that they are typically more expensive to produce, and are consequently priced higher, even when offered to UNICEF at the marginal cost of production.
- Other new vaccines, which may be specific to developing countries, may be difficult to get produced if their costs are high while their markets hold little promise of return profits to manufacturers. New mechanisms must be developed to encourage the development and manufacture of such 'orphan vaccines'. The setting of priorities for encouraging the development of commercially unattractive vaccines becomes of paramount importance because resources are finite.
- There is the recognition of the need to use increasing quantities of existing vaccines for more effective disease control (through supplementary strategies, routine boosters, etc.).
- The existence of efficient delivery systems in many developing countries is creating an impetus for shorter delays between vaccine licensing, which usually takes place in the industrialized world, and use in developing country programmes.

- Supply sources for future vaccines will be much more restricted in number than those of traditional vaccines. This is both because the new vaccines, or products, may be proprietary (covered by intellectual property protections of various sorts), and because their production technologies are inherently more difficult, thus making 'local' production less likely.
- In parallel to the above, an increasing emphasis is being placed on quality by national immunization programmes who demand good vaccines, and by the public who become less willing to tolerate adverse reactions as the perceived risk of a disease diminishes. The emphasis on quality and actions by national control authorities (NCAs), means that the role played by 'local' producers in developing countries will be less significant in the global supply of new vaccines. Some may, however, continue to play a role through joint ventures with major vaccine companies.
- The high costs of new product development, the desire to access new products and maintain a full product range, and the need to access profitable markets, has fueled a trend towards mergers and acquisitions in the vaccine industry. Whereas a dozen years ago there were many major producers, there are now only five or six companies that have major international business.
- The growth of biotechnology is also changing the face of the vaccine industry. Biotechnology is rapidly multiplying the number of possible approaches which can be explored to make a particular vaccine. The number of small companies investigating candidate vaccines, particularly in North America, adds a new dimension to the array of candidates in the early stages of the vaccine pipeline. However, the vast majority of these companies do not have product development capabilities or experience and will need to link up with companies that do.
- Finally, in most countries it is slowly being recognized that community acceptance of immunization efforts is a critical ingredient for success. Social and behavioural research on attitudes and access to immunization, therefore, needs to be conducted to guide the process of expanding protection.

Since the ultimate result of all these emerging transitions is not necessarily predictable, it is probably most accurate to say that vaccination and vaccine development are in a state of rapid change. The changes are bringing a plethora of new choices for protecting children from infectious diseases. If they are not utilized in a timely manner, millions of children will have died because of lack of foresight and commitment. It is certain that only proper anticipation and on-going orchestration of these changes will result in the fruits of the science being properly applied to the benefit of children everywhere.

The criteria for making decisions at each point in the process – from a promising research lead to the selection of the next vaccine to add to the schedule – will need to be clear and well articulated. Yet decisions to move forward at each step also represent the opportunity costs of the roads not traveled. As the time lines are long, it must also be recognized that the opportunity costs may be substantial. The complexity and the potential for chaos due to incompatible decisions, wrong decisions, or no decisions at all, at different points in the continuum is already greatly increasing. Efficiency will be greatly facilitated by regular communication between all organizations in the continuum, and by achieving some consensus on the priorities which could provide a framework for the operation of individual organizations. Thus the strategic planning process must encompass the “end to end” mission of the CVI – the whole of the vaccine continuum from research through utilization – by taking a hard look at each of the decision points, revisiting them on a regular basis, and assisting in the management of the changes that are already with us. □

Annex 9

A "report card" on the 1992-1993 CVI Strategic Plan

Objective	Achievements	Lessons learned	Future actions
<p>The medium-term objectives specified in the 1992-1993 CVI Strategic Plan were:</p> <p>1. <i>To promote mechanisms to ensure a sustained supply of affordable, quality vaccines for childhood immunization programmes by:</i></p> <p>a) <i>Improving national and international supply systems; and</i></p>	<p>➤ Established and operated the CVI Task Force on Situation Analysis for Global Vaccine Supply (TFSa), the first group to conduct a global assessment of vaccine supply.</p> <p>➤ Established a CVI Task Force on Vaccine Quality that assessed global efforts to ensure vaccine quality and produced guidelines on the establishment and functions of National Control Authorities for vaccines.</p> <p>➤ Facilitated, through collaboration with UNICEF, WHO and vaccine manufacturers, mechanisms for financing international and national vaccine supply including the Vaccine Independence Initiative, the banding strategy for targeting assistance to countries in greatest need, and the new UNICEF tender.</p> <p>➤ Convened a meeting on public-private sector collaboration on 'The Global Supply of New Vaccines' in Bellagio, Italy, February, 1997.</p>	<p>➤ The CVI has been able to have the most impact in this area, particularly through collaborative activities between CVI co-sponsors and vaccine manufacturers. While a great deal of success has been achieved in vaccine supply, financing and quality improvement, much work remains to be done and CVI will continue to work actively in this area.</p> <p>➤ Increased national funding of vaccine supply will be essential if immunization programmes are to be sustainable in the face of rising cost, cut-backs in international organizations and donor fatigue.</p> <p>➤ Increased collaboration between industry and the public sector will be essential in ensuring an adequate worldwide supply of appropriate vaccines.</p>	<p>➤ Continue the work of the TFSa through an already created multi-organizational Working Group on Vaccine Demand, Supply and Financing.</p> <p>➤ Help countries identify where to acquire vaccines; how to acquire them; how to assure their quality; and how to finance vaccines as costs rise and resources diminish.</p> <p>➤ Hold periodic high-level round-table discussions between industry and the public sector which will address global vaccine supply.</p> <p>➤ Address vaccine financing mechanisms.</p>

Objective	Achievements	Lessons learned	Future actions
<p>b) <i>Promoting local production of vaccines in accordance with a global plan.</i></p>	<ul style="list-style-type: none"> ➤ Identified and assessed 14 priority countries undertaking 'local' vaccine production, covering 75% of the world's children (Mission Reports available through the CVI Secretariat). ➤ Evaluated, in-depth, three local producers, in Egypt, Indonesia and South Africa, to assess the long-term viability and role in the supply of future vaccines. ➤ Supported, in collaboration with PAHO, the Latin American Network of Quality Control Laboratories (SIREVA). ➤ Strengthened numerous National Control Authorities. ➤ Improved the proportion of DTP vaccines used in national immunization programmes of known good quality from 54% in 1993 to 74% in 1997. 	<ul style="list-style-type: none"> ➤ The role of local production in vaccine supply needs further examination as the technologies for producing new vaccines may be more costly and more complex. 	<ul style="list-style-type: none"> ➤ Further develop and implement a new mechanism for evaluating local production.
<p>2. <i>To develop new and improved vaccines by focusing on:</i></p> <p>a) <i>Promoting the development and introduction of DTP combination vaccines including DTP-HBV; DTP-Hib; DTP-pneumococcal vaccine, and DTP-typhoid vaccine.</i></p>	<ul style="list-style-type: none"> ➤ Industry developed and licensed DTP-Hib; DTP-HB; DTP-Hib-HB; DTap-Hib; DTap-IPV; Hib-HB; and HB-HA combinations. ➤ On-going development, by industry, of many other combination vaccines including Hib-Pneumococcal; and Hib-Pneumococcal-Meningococcus. 	<ul style="list-style-type: none"> ➤ The role of the CVI Secretariat in the development of new and improved vaccines should be to convene different actors throughout the vaccine development and introduction continuum so that there is a consensus on priority vaccines to be developed. This is particularly important given long lead times and increasing costs of vaccine development. 	<ul style="list-style-type: none"> ➤ Increase public/private sector dialogue to achieve consensus and expedite vaccine development (as well as addressing aforementioned supply issues). ➤ Develop burden of disease and cost-effectiveness mechanisms which help systematically to identify priority vaccines for introduction, as well as for development. ➤ Convene workshops which teach national policy-makers how to use cost-effectiveness methods in determining resource allocation for existing and new vaccines.

Objective	Achievements	Lessons learned	Future actions
b) Promoting the development of improved childhood vaccines, including thermostable oral polio (tsOPV), single-dose tetanus toxoid, and early-administration measles;	<ul style="list-style-type: none"> ➤ Convened Product Development Groups (PDGs) for Thermostable Oral Polio Vaccine (tsOPV), single-dose tetanus toxoid and improved measles vaccines. ➤ Demonstrated the feasibility of a more thermostable OPV and supported the progression of single-dose tetanus vaccines to the stage of clinical trials. 	<ul style="list-style-type: none"> ➤ The public sector needs to rely on the private sector for its expertise in industrial vaccine development. ➤ The GPV/EPI decision not to adopt a previously requested more stable OPV illustrates the need for continuous assessment and communication on vaccine development projects, especially concerning improved products. Also, it emphasized that public acceptance of the need for the product must be assessed. ➤ Where there is no consensus on the need for an improved vaccine, such as for measles, it is not realistic to expect commercial investment as there may be no market. 	
c) Promoting the improvement and incorporation into childhood immunization programmes of other existing vaccines such as those against hepatitis B, Hib Japanese encephalitis, and typhoid; and	<ul style="list-style-type: none"> ➤ Coordinated preparation of <i>An Agenda to Expedite the Global Prevention of Haemophilus influenzae type b (Hib) Disease</i> (available through the CVI Secretariat). 	<ul style="list-style-type: none"> ➤ The introduction of vaccines entails different activities than the development of vaccines and should thus be given distinct consideration. ➤ The adoption of 'new, improved vaccines' presents greater challenges than the adoption of 'new vaccines' against diseases which were not previously vaccine preventable. 	
d) Promoting the development of new vaccines against pneumococcus, malaria, shigellosis, tuberculosis, dengue, enterotoxigenic <i>E. coli</i> , meningococcus and rotavirus.	<ul style="list-style-type: none"> ➤ Initiated preparation of other collaborative agendas, including an agenda for pneumococcal disease. ➤ Supported an agenda for rotavirus activities. 		

Objective	Achievements	Lessons learned	Future actions
<p>3. To include capacity building programmes in most of CVI operations through the transfer of skills and technology for production, research and development, evaluation and others.</p>	<ul style="list-style-type: none"> ➤ Advised in the development of the International Vaccine Institute (IVI) in Seoul, Korea — a UNDP initiated and CVI affiliated institute which emphasizes human resource and institutional development within the vaccine field. 	<ul style="list-style-type: none"> ➤ Although the CVI Task Force on Strategic Planning endorsed, at its meeting in May of 1996, the importance of capacity building activities, it felt that these activities are perhaps best incorporated by individual organizations as they implement their projects, rather than organized by an 'umbrella' organization such as CVI. 	<ul style="list-style-type: none"> ➤ Cooperate with the IVI, CVI co-sponsors, and other institutions in capacity building. ➤ Mobilize resources for capacity building.
<p>4. To provide a number of support services by which the CVI Secretariat links the different collaborators in the vaccine continuum</p>	<ul style="list-style-type: none"> ➤ Published and distributed the first CVI Strategic Plan. ➤ Organized a Task Force on Strategic Planning to review and revise the original CVI Strategic Plan. ➤ Convened six Consultative Group Meetings around the world which brought together the leading international experts in the fields of vaccine development and immunization. ➤ Arranged annual meetings of the CVI Meeting of Interested Parties (MIP) and the CVI/GPV Scientific Advisory Group of Experts (SAGE), the two advisory bodies of the CVI. ➤ Identified the importance of advocacy for vaccines and immunization. 	<ul style="list-style-type: none"> ➤ As noted throughout this document, the Task Force on Strategic Planning was able to review and revise the CVI Strategic Plan thoroughly. ➤ The 'convening' role of CVI is particularly important in that CVI is a unique body which can bring together all the different actors in the fields of vaccine development and immunization from both the public and private sectors in an open, neutral forum. ➤ The advisory bodies continue to be a valuable means for providing guidance to CVI. 	<ul style="list-style-type: none"> ➤ Hold periodic meetings with the Task Force to monitor implementation of the Strategic Plan. ➤ Convene an Interim Consultative Group meeting in 1998. ➤ Prepare for a World Summit on Vaccination for the Year 2000 ➤ Continue to hold regular meetings with CVI advisory groups. ➤ Increase advocacy for both CVI and vaccines in general (this is an important new objective outlined by the Task Force which can be noted throughout the revised Plan).

Objective	Achievements	Lessons learned	Future actions
	<ul style="list-style-type: none"> ➤ Mobilized resources for both 'core' CVI Secretariat activities, as well as activities conducted by CVI collaborators (please see Annex 12 for current CVI Secretariat activities). ➤ TFSA evolved into a multi-organizational Working Group on Vaccine Demand, Supply and Financing. ➤ Tested Product Development Groups as a mechanism for accelerating vaccine development. ➤ Tested consensus 'Agendas' to expedite vaccine introduction. 	<ul style="list-style-type: none"> ➤ Additional mechanisms are needed for allowing organizations to express a stated affiliation with CVI to increase both their sense of ownership and participation. ➤ The identity of CVI is sometimes unclear to other organizations, thus hindering their participation in the greater coalition. 	<ul style="list-style-type: none"> ➤ Create a multi-organizational Working Group on Advocacy and Information Exchange. ➤ Develop a mechanism for organizational affiliation with CVI. ➤ Develop a mission statement for CVI.



Photo: UNICEF/Sean Sprague

Annex 10

Achieving the vision: proposed strategies, activities and implementation of the *CVI Strategic Plan*

A 'working tool' for monitoring implementation of the Plan (to be used and filled in by collaborating agencies)

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
Develop new and improved vaccines 1.1 To foster the development of new and improved vaccines (especially vaccines which will simplify immunization)	1.1.1 develop consensus on priority new vaccines and the improvement of existing vaccines						
	1.1.2 acquire epidemiologic and economic data on infectious diseases to guide decision-making						
	1.1.3 promote research and development efforts on new vaccines, vaccines using combination methodologies, and/or vaccines based on new technologies						
	1.1.4 promote research and development efforts for oral and other mucosally delivered vaccines which are easy to deliver, and can give better protection than injectable vaccines against pathogens entering the body via mucosal surfaces						

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
1.2 To promote respect for, and protection of, intellectual property	1.1.5 promote the development of vaccines which are free from adverse reactions						
	1.1.6 promote the development and use of more thermostable vaccines						
	1.1.7 strengthen local and regional institutions devoted to vaccine research, development, quality control, regulation and quality assurance						
	1.1.8 harmonize technical requirements for vaccine licensing and production, based upon a scientific consensus						
	1.1.9 harmonize vaccine delivery schedules						
	1.2.1 promote and support protection of intellectual property, in line with the WTO Agreement on Trade Related Aspects of Intellectual Property						
	1.2.2 develop mechanisms that assist in the transaction and negotiation of intellectual property rights						
	1.3.1 provide information on the impact of so-called 'orphan' diseases in endemic areas to help guide corporate decision-making on research and development priorities						
	1.3.2 facilitate the evaluation and production of vaccines of limited commercial interest						
1.3 To assist in the development of vaccines with limited apparent commercial prospects							

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
Promote the wide availability of quality vaccines							
2.1 To promote consistent high quality in all vaccines	2.1.1 encourage the establishment of National Control Authorities with the appropriate functions in every country						
	2.1.2 enhance and rationalize local and regional efforts to improve quality						
	2.1.3 encourage adequate support for research related to the assurance of vaccine quality						
	2.1.4 ensure the availability of reference materials necessary to assure vaccine quality						
	2.1.5 foster communication among National Control Authorities, regional regulatory bodies, WHO, and other organizations interested in vaccine quality						
2.2 To encourage governments towards self-reliance, adequate financing of immunization programmes and the targeting of external assistance at the most needy countries	2.2.1 develop and promote tools and financing mechanisms, such as revolving funds like the UNICEF Vaccine Independence Initiative and the PAHO Revolving Fund						
	2.2.2 strengthen selected 'local' or regional vaccine producers - those determined to be economically and technically viable - to ensure reliable production of quality vaccines						

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
2.3 To create and expand demand for vaccines	2.2.3 improve prospects for self-reliance by improving efficiency and avoiding vaccine overstocking and wastage						
	2.2.4 strengthen national procurement systems to enable governments to undertake direct procurement of quality, affordable vaccines effectively						
	2.2.5 coordinate the donor community to encourage governments to take greater financial responsibility for their vaccines, as well as to target vaccine financial support at the neediest countries (defined as countries in UNICEF/WHO bands A & B)						
	2.2.6 support National Control Authorities adequately, so that they can perform the functions necessary to ensure the quality of all vaccines whether imported or produced locally						
	2.3.1 inform the public and decision makers on the value of disease prevention and the role of vaccination as a cost-effective health intervention						
	2.3.2 improve the credibility of national and global demand forecasts by strengthening the link between need and actual financing and use of priority vaccines						

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
2.4 To plan to provide for vaccine supplies in emergencies (such as outbreaks or production disruptions)	2.3.3 facilitate the supply of vaccines at reasonable market terms by mobilizing additional resources for their purchase						
	2.3.4 make needed vaccines available to all countries by employing centralized procurement systems or innovative financing mechanisms that include specific attention to the needs of the poorest countries for new vaccines						
	2.3.5 promote the understanding of "affordability" and how its definition varies on perceived value as well as available resources						
	2.3.6 identify strategies and share data with public and private manufacturers which will improve the supply of existing and future vaccines						
	2.4.1 identify currently available vaccines that may be needed in quantities exceeding routine supply capacity because of potential outbreaks						
	2.4.2 identify diseases for which routine vaccine delivery is most at risk from disruptions in production and distribution						

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
	2.4.3 formulate and implement strategies for meeting unexpected demands or disruption in routine supply, (such as financing strategies and creation of stockpiles managed to ensure the availability of potent vaccines)						
Promote the introduction and use of needed vaccines							
3.1 To promote selection and introduction of priority new vaccines into immunization programmes	3.1.1 develop guidelines to encourage selection and introduction of new vaccines by National Immunization Programmes						
	3.1.2 supply technical support (epidemiologic, biotechnological, and economic) for the design and implementation of new immunization programmes						
	3.1.3 incorporate regional needs in selection of vaccines for national immunization programmes, when epidemiologic circumstances warrant their inclusion (such as for yellow fever, hepatitis B, Hib, typhoid and cholera)						
	3.1.4 develop relevant morbidity and mortality data						
	3.1.5 monitor and disseminate lessons learned from countries adopting new vaccines early						

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
3.2 To promote the safety of injection practices	3.2.1 educate and train health care workers in the safety of injection practices						
	3.2.2 promote strategies for improving injection safety such as supply of auto-destruct syringes						
	3.2.3 promote research and development of technologies that improve injection safety, such as improved jet injectors and needle-free injection technologies						
3.3 To encourage the collection of reliable information on which to base estimates of the burden and costs of infectious diseases (for national decision-making on vaccine introduction)	3.3.1 strengthen national infectious disease surveillance for existing and emerging infectious diseases						
	3.3.2 encourage the collection of data from additional sources of epidemiologic information (such as serologic studies and antenatal screening)						
	3.3.3 strengthen efforts to assess both the economic and social costs of infectious diseases, including links between these and poverty						
	3.3.4 link epidemiologic data to priority-setting for vaccine research and development at national, regional and global levels						

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
3.4 To support social and behavioural research designed to foster a better understanding of factors leading to increased societal acceptance and use of vaccines	3.4.1 promote investigation of public and policy-maker knowledge of, and attitudes towards infectious diseases						
	3.4.2 promote investigation of public and policy-maker knowledge of, and attitudes towards vaccination, including adverse events and injection safety						
	3.4.3 promote investigation of public and policy-maker attitudes towards prevention of disease and willingness to pay for protection						
3.5 To promote access to national delivery system and vaccines	3.5.1 identify groups with low immunization rates and target them for innovative and intensified efforts to increase access						
	3.5.2 encourage innovative approaches for improving distribution and delivery of vaccines						
	3.5.3 foster methods to encourage participation of the community (especially mothers) and to ensure gender equality						
	3.5.4 coordinate and mobilize donors, where needed, for critical elements of infrastructure (e.g. cold chain)						

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
3.6 To encourage creation of mechanisms for delivery of vaccines to target groups beyond infants and women of child bearing age	3.5.5 decentralize authority and accountability for immunization service delivery while assuring policy formulation and monitoring capacity at national levels						
	3.5.6 maintain a balanced use of resources in countries by promoting regional or global initiatives only when absolutely essential						
	3.6.1 strengthen policies and programme implementation regarding booster doses for basic paediatric vaccines						
	3.6.2 identify and create appropriate opportunities (such as at school entry or pre-adolescence) for reaching unimmunized individuals, or for delivery of vaccines expected to be available in the near future against STDs, including HIV/AIDS						
	3.6.3 promote the concept of vaccination as a preventive measure relevant to all stages of life, infancy, childhood, adolescence, adulthood and maturity						

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
Foster a culture of prevention through advocacy for vaccines							
4.1 To increase awareness of the value of vaccination to society and to national decision-makers, to increase the demand for vaccines in all countries	4.1.1 actively engage all partners in the vaccine continuum to provide information to their constituencies on the value of immunization programmes and vaccines						
	4.1.2 promote the use of mass media sources, such as the internet, to address the value of immunization and vaccines						
	4.1.3 identify community leaders to act as spokesmen for immunization programmes and vaccines						
	4.1.4 inform decision makers on the benefits of immunization and vaccines to their countries						
4.2 To mobilize the resources needed to support all of these efforts	4.2.1 develop accurate estimates of the morbidity and mortality attributed to infectious diseases in the community through the use of epidemiologic, economic and scientific resources in the vaccine continuum						
	4.2.2 develop accurate estimates of the economic impact of infectious diseases and the benefits of immunization						

Objectives	Strategy	Timeframe	Progress indicators	Implementing agencies	Total approx. annual resources	CVI Secretariat role	CVI Secretariat resource needs
	4.2.3 establish a clear agenda of action for decision-makers including ascertaining that the vaccine supplies, immunization infrastructure, financing and support systems are adequate to meet the public health need either locally, nationally, or globally						
	4.2.4 ensure participation of the community (especially mothers) in the planning and promotion of immunization programmes						
	4.2.5 develop active information campaigns for the public on immunization programmes, vaccines and the risks of infectious diseases						

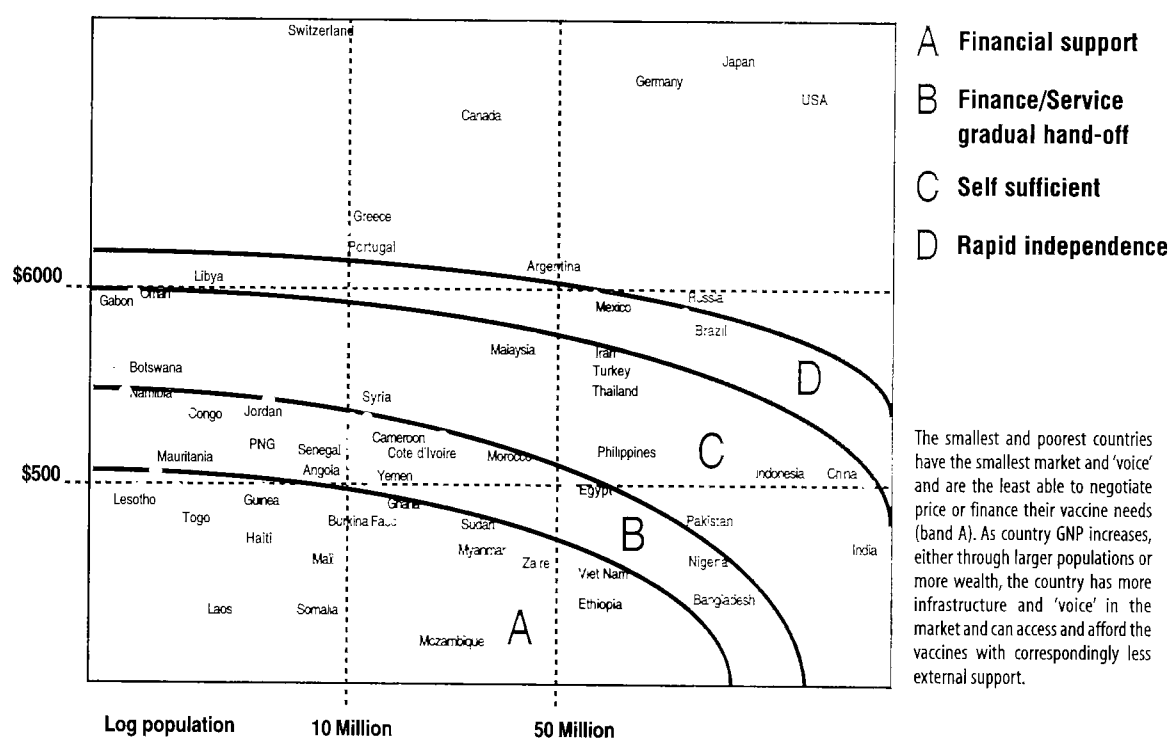


Photo: UNICEF/Claudio Edinger

Annex 11

Encouraging financial sustainability of immunization programmes and targeting assistance at those countries in greatest need

The key players in any plan to encourage financial sustainability of immunization programmes are the countries themselves, the donor assistance community, international organizations and vaccine manufacturers. The UNICEF/WHO 'banding', or 'targeting strategy', divides countries into four groups – bands A, B, C, or D – based on their projected capacity to be self-sufficient (please see figure 1 below). Three key factors influence the type of support needed for a sustainable vaccine supply in a given country; the relative GNP per capita, the total population and, most importantly, the total market size (GNP). Based on their stratification, countries are encouraged to set self-sufficiency goals by which they pay from 10% to 100% of their vaccine needs. Donors and international organizations are using the stratification for targeting assistance, and vaccine manufacturers are using the stratification for tiering vaccine prices.



Countries

Most developing countries are anxious to have total control of their own programmes and be as financially independent as possible. The targeting strategy provides the Ministry of Health with a minimum financial goal which can be used to emphasize the importance of sustainable financing during budget discussions with the Ministry of Finance. The strategy also highlights the different weaknesses which exist in countries and develops support which address these specific constraints. All countries want to be able to introduce new vaccines. However, the neediest countries simply cannot afford the new vaccines and, without help, will have to wait 15-20 years longer than their wealthier neighbours. This strategy of targeting donor assistance at those countries in greatest need helps assure poor countries which have strong programmes and high disease burden, that they will have access to priority new vaccines. It builds on the success of the immunization programme, requiring countries to take greater responsibility in the future.

Donors and International Organizations

Donors have invested heavily in immunization programmes for the last 20 years. Many donors have expressed the desire to "hand-off" the financial responsibility of immunization programmes to governments. Donors have also expressed grave concerns about the financial feasibility of introducing new vaccines. While most donors believe new vaccines are a priority, they know their organizations cannot finance the introduction of new, more expensive vaccines in all countries. The targeting strategy provides donors with a rational, systematic method to increase national independence while filling critical gaps. The strategy also clarifies and increases national responsibility, and identifies priority countries for receiving support for the introduction of new vaccines. Thus maximum impact with limited funds is assured for the introduction of new vaccines.

Manufacturers

Vaccine manufacturers rely on market forces to determine their priorities for investment in a new vaccine. The developing market has been a low priority partly because markets did not exist and because market

forces were skewed by global procurement policies developed in the 1980's. Historically, UNICEF procured vaccine on behalf of almost every developing country – roughly 85% of the world's population. This centralized procurement at a marginal price was possible for the traditional vaccines because, as they had been in the public domain for 25-60 years, there was excess production capacity, no intellectual property rights and no hope of altering the markets.

While this situation was positive in the short term and allowed developing countries to access vaccines at very inexpensive prices, it had a negative side, namely that developing country markets were viewed as not commercially attractive and therefore uninteresting. Firms gave very low priority to investment in the products or capacity to produce new vaccines needed by developing country markets. As new products were developed for industrial country markets and recommended for global use, UNICEF sought a single low price for all countries. As these new products were at an earlier stage in their life cycle, however, manufacturers were unwilling to provide a lowest tiered price which would be available for ALL countries, regardless of market potential. If a central procurement agency insisted on one price, manufacturers would almost certainly offer the going market price in the wealthier developing countries.

The UNICEF/WHO targeting strategy acknowledges the differing ability of countries to pay for vaccines. Most governments can assure access to affordably priced vaccines through normal market channels. They do not require international intervention into the markets on their behalf, though they may require support in implementing systems to assure the quality of vaccines procured directly, or in strengthening the viability of the national vaccine production in order to access new technologies. The targeting strategy entails that consolidated procurement of new vaccines at special rates by international procurement agencies, such as UNICEF, emphasize supply to the neediest countries in bands A and B. It allows other countries to procure vaccines at prevailing market rates directly or, if they so choose, via procurement agencies. Historically, manufacturers have had low interest in serving individual countries in bands A and B, and have not been able to sell products in these markets. They are, therefore, willing to provide a special marginal price for these countries to a procurement agency. Through targeting, UNICEF has moved from involvement in markets

in roughly 85% of the world to focusing, for the newest vaccines, on the neediest 25%. Manufacturers have a growing interest in serving the needs of the developing world, are beginning to compete amongst themselves for these markets and are willing to offer a non-market, lowest tiered price to the neediest. They also welcome the targeting strategy's implicit acknowledgment that the overall revenues of manufacturers influence their capacity to develop new vaccines.

Conclusion

The targeting strategy acknowledges the tremendous advances in establishing immunization programmes over the last 20 years. Most countries now have strong, nationally owned programmes. The next steps for many countries are to increase the sustainability of their programmes, take greater financial responsibility and begin the process of introducing new vaccines. The role of donors is evolving with the changing needs of countries. Financial support for traditional or new vaccines is not needed in all countries across the board but continues to be absolutely critical in a small number of neediest countries. Finally, targeting opens the vaccine supply to more sustainable, normal market forces and concentrates market interventions and distortions to a limited number of countries in which market forces do not work to address public health needs. Greater targeting in the overall global vaccine market helps increase the value of developing country markets and, therefore, the likelihood that their needs will be addressed. Targeting also reinforces the system of price-tiering, thus increasing the probability that all countries will be able to access vaccines at prices they can afford. □

Annex 12

Summary of CVI Secretariat activities and budget for 1997-1998

Highlights of the proposed CVI Secretariat activities for 1997-1998 are described below. These illustrate the role that the CVI Secretariat can play in facilitating collaboration among contributors and in advancing progress towards overall CVI goals. Background details and budget information can be found in the complete document entitled *Proposed CVI Secretariat Plan of Activities and Budget for 1997 (CVI/GEN/97.01)* and in the activity plan for 1998 to be published in early 1998.

Three themes underlie the planned activities. These are:

- accelerating the development and introduction of priority new and improved vaccines, and better vaccination methods, wherever needed;
- promoting better recognition of the value of immunization; and
- strengthening cooperation between the public and private sectors in pursuit of CVI goals.

Consensus development

Strategic planning and priority setting

- **Managing Opportunity and Change: A Vision of Vaccination for the 21st Century – *The CVI Strategic Plan*** will be completed by the CVI Task Force on Strategic Planning. The *CVI Strategic Plan* provides a broad vision of how vaccination can best protect children in the next ten to twenty years, and the actions needed to achieve this progress. The Plan will be disseminated and promoted widely in 1998.
- **Assessments of the health benefits and costs of new vaccines and other vaccination policy options** will be continued, to assist in developing policies, priority setting (among the 15 or more vaccines in late development) and to guide new vaccine introduction at country level.

- **Public-private sector collaboration on new vaccines** will be promoted, *inter alia* through a meeting with industry on global supply for priority new vaccines addressing intellectual property, and the potential roles of market segmentation, export and local production (held Bellagio, Italy, 3-7 February 1997). Follow-up meetings will be held between vaccine company CEOs and CVI Co-sponsor agency heads.
- **Financing vaccines and vaccination services in general** will be encouraged through planning and convening a conference on expanding 'Sustainable Financing for Vaccination Programmes', to bring together the whole range of relevant parties.
- **A multi-organization Working Group on Vaccine Demand, Supply and Financing** will be convened periodically to coordinate strategies and implement activities to remove critical barriers to the wider adoption of new vaccines.
- **Meetings will be organized** with emerging research and development ('biotech') vaccine developers and with emerging global suppliers to address public health needs, licensing and supply strategies.
- **Neglected 'orphan' vaccines of public health importance**, and possible scientific or policy actions to accelerate their development, will be identified through a meeting with industry.
- **A meeting on priority diagnostic needs** for effective control of infectious diseases will be convened.
- **Early public-private sector dialogue on vaccine supply needs for late-phase polio eradication and expanded measles control** will be promoted through (a) meeting(s).
- **Vaccine research and development opportunities** will be monitored, including assessment of emerging information on the contribution of pathogens to conditions not previously recognized as having a causal or precipitating infectious agent.

Creating a supportive environment for vaccine research and development

- **International harmonization of technical requirements for vaccine licensing and production** will be promoted with WHO Biologicals Unit, industry, US Food and Drug Administration, the European Commission, and other regulatory bodies, with the aim of reducing the length and costs of vaccine development, and ensuring wide vaccine availability.
- **The international standardization of schedules** for vaccine use will be promoted, thus reducing costs of vaccine trials and overall development costs (with WHO and the European Commission and/or the Council of Europe).
- **Respect for and protection of intellectual property (IPRs)** will be promoted through the dissemination of a CVI Position Paper.
- **Awareness will be raised among researchers, intellectual property holders and managers**, of the vaccine supply needs of developing countries and strategies to meet them, such as market segmentation with tiered prices and tiered royalties.
- **A position paper on vaccine supply economics** will be prepared and disseminated to support targeting of UNICEF procurement to the poorest countries.
- **Collaboration** will be encouraged with the International AIDS Vaccine Initiative (IAVI) in areas of CVI expertise, in particular the economics of vaccine supply and intellectual property issues.
- CVI, as the 'umbrella' under which the new International Vaccine Institute, Seoul, Korea, was created, will continue to support development of its programme and resources.

Strategy coordination for priority vaccines: development, introduction and quality

- **Vaccine development and introduction** will be monitored through general support for Task Force on Strategic Planning and *ad hoc* groups.

- **Selected candidates not yet designated for use in the Expanded Programme on Immunization will receive special attention** to accelerate their development, where necessary, and/or wider use; i.e. *Haemophilus influenzae* type b (Hib), rubella, improved pertussis, rotavirus, pneumococcal, Japanese Encephalitis Virus, and single-dose tetanus toxoid vaccines.
- **Combination vaccine** needs and alternative strategies for multi-antigen delivery will be assessed, or reassessed, from global, regional and epidemiologic perspectives.
- **New vaccine technologies will be strategically assessed** to accelerate their availability and application to CVI goals of simplifying and improving immunization. These include DNA vaccines, oral/mucosal vaccine delivery, and transgenic plants as vaccine sources.
- **Collaboration with the International Vaccine Institute (IVI)** will be encouraged on selected projects.
- **Financial support to implementation of activities by CVI collaborators** will include resources for the following activities:
 - Implementation of activities in the development and/or introduction of priority vaccines, in particular where the CVI Secretariat has developed or will develop with partners an agenda to expedite control of the target disease, e.g. *Haemophilus influenzae* type b (Hib), pneumococcal meningitis and respiratory disease, rotavirus diarrhoea and single-dose tetanus toxoid vaccine. Units supported will include the WHO Division of Child Health and Development (CHD), the Global Programme for Vaccines and Immunization (GPV) and the Biologicals Unit (BLG).
 - Support to regional vaccine quality assurance networks: The balance of funds previously provided to WHO/GPV/VSQ through the CVI Secretariat will be used in 1997 to complete establishment of these networks. (These resources were pledged to this purpose prior to the creation of GPV's Vaccine Supply and Quality Unit. Henceforth, resources for such field implementation will, it is hoped, be provided by GPV).

- Support for activities in assessing the viability of 'local' producers which will support the above-mentioned Working Group on Vaccine Demand, Supply and Financing.

Advocacy, information exchange and resource mobilization

A realistic strategy for expanding advocacy for vaccination – and new vaccines in particular – has been formulated in light of the resources likely to be made available to the CVI Secretariat. Its implementation will begin in 1997, subject to the availability of resources. Its main elements include targeting specific products to selected audiences of decision makers, resource providers or potential allies critical to expanding vaccination efforts. The strategy will be executed by CVI partners and the CVI Secretariat, coordinated through a new Working Group on Advocacy and Information Exchange. It entails:

- **Briefing of CVI cosponsor agency heads** annually to renew their commitment to CVI goals.
- **Active provision of information to immunization programme policy makers** to assist them in deciding to recommend new vaccination efforts. Such information may include data on vaccine availability, cost, effectiveness, and disease burden. The products through which this is done will include in-depth articles, such as those already produced on Hib, pneumococcal and rotavirus vaccines (CVI Forums N° 12, 13 and 14) or other specially-developed materials on new vaccines.
- **Active provision of information to decision makers in ministries of health and ministries of finance (and donors for the poorest countries)** regarding the social and economic benefits of new vaccination efforts and resources needed to support them. Some of this information will be developed through other activities (e.g. cost-effectiveness assessments of new vaccines), but it will need presentation in a suitable format for these audiences.
- **Provision of information to potential 'allies'** on the potential benefits of new vaccination efforts. Potential allies include: scientists; physicians, especially paediatricians; others concerned with public health; nongovernmental organizations; socially-concerned

business; and political leaders. Efforts for these audiences will be conducted primarily through improved access to information and wider *CVI Forum* distribution and, to a lesser extent, through targeted efforts as specific needs arise.

- **Defense of attacks against vaccination** that are scientifically inaccurate through the provision of support to the World Health Organization's Global Programme for Vaccines and Immunization to develop state-of-the-art position papers on known adverse reactions to vaccines and allegations about vaccines safety issues that are scientifically inaccurate or not substantiated.
- **Advocacy to international leading institutions and potential loan backers** for the establishment and capitalization, where necessary, of new funding mechanisms specifically to facilitate the introduction of new vaccines for selected countries, or for support to immunization in general.
- **Development of specific advocacy 'tools'** for use in these efforts, including brochures on new vaccines and raising new resources, videos, films and poster designs.
- **An internet site that would facilitate access to information resources** on vaccines and vaccination on the internet that are currently not indexed or otherwise linked.
- **An improved internet site for the CVI.**

Regional activities

- **Strengthening vaccine quality assurance through regional networks** will continue to be supported.
- **Advocacy for immunization in Africa** will be supported, to continue and deepen commitment to vaccination initiated at the 1996 Organization of African Unity Summit.

General

Proposed activities will need US \$5.5 to \$6.0 million each year. A contingency budget is prepared annually omitting those activities which would be dropped if funds are insufficient. Presently, there is a budgetary shortfall for 'core' CVI Secretariat activities.

All activities are conducted with the opportunity for the full involvement of industry decision-makers, particularly those who hold management level positions and are responsible for long-range strategic planning. □



Photo: UNICEF/Fran Antmann

Proposal for a World Summit for Vaccination

Background Information

A Children's Vaccine Initiative (CVI) World Summit for Vaccination early in the twenty-first century would honour the ten-year anniversary of the launching of CVI by the Declaration of New York, directly preceding the 1990 World Summit for Children. The CVI has since evolved into an umbrella organization which fosters consensus building and facilitates the coordination of activities between the different individuals and institutions, from both the public and private sectors, which work in vaccine research, development, supply, quality assurance, introduction and delivery.

Every year since its launch in 1990, the CVI has convened an open meeting of approximately 200 of the leading international experts in the fields of vaccines and immunization. Termed the 'Consultative Group', this meeting has been the one time each year when all CVI collaborators come together to meet, share information and review recent progress in vaccines and immunization. This breadth of communication among all contributors is necessary to expedite the goal of the CVI – to maximize protection against infectious diseases through the development and application of safe, effective, easy-to-deliver and widely available vaccines. Previous CVI Consultative Group Meetings have taken place in Switzerland, Japan, the Netherlands, Brazil and Senegal. Future meetings will take place every two years, with the next meeting being scheduled for 1998.

Proposal for the CVI World Summit for Vaccination

Early in the 21st century, the CVI Secretariat would like to bring its Consultative Group and government leaders together in a World Summit for Vaccination. This Summit would be a time to review in a global scientific forum the great progress achieved to date in global vaccination, to form a consensus about priorities for the 21st century, and to secure political commitment to these goals. The Summit would build on the spirit of collaboration achieved in former Consultative Group Meetings, and would review the revised CVI Strategic Plan as a reference point from which to begin deliberations. The meeting would last three to five days, with the first day being dedicated to a review of

progress achieved in the latter half of the 1900s. The next days would be structured for discussion, consensus forming, the development of action-oriented declarations and the commitment of resources in the following four main areas: 1) the development of new and improved vaccines; 2) assuring the availability of affordable, quality vaccines; 3) promoting the introduction and use of needed vaccines; and 4) fostering a culture of prevention through advocacy for vaccines.

One particularly important function of the Summit would be the recruitment of those people who are able to back scientific declarations with political commitment for action: heads of state, or other high-level government officials such as prime ministers, governors or senators; national policy-makers from both the health and finance sectors; directors of international organizations; and directors of agencies from the donor assistance community. It is envisaged that these people would participate in tandem, or sequentially with the leading international experts in the fields of vaccines and immunization who routinely participate in the CVI and lend their considerable expertise to meeting deliberations. A third group of participants in the meeting would be media representatives from as broad a spectrum as possible. It is essential that the public be informed, and continually reminded, that vaccines and immunization are one of the most cost-effective health interventions to date, and that they save the lives of millions of children every year. A fourth and final group of meeting participants would be the consumers of vaccines.

Specific objectives of the meeting

- To bring together, in a neutral forum, the following four groups of people: 1) politicians and policy-makers from around the world; 2) both public and private sector experts in the fields of vaccines and immunization; 3) communications specialists and media representatives; and 4) consumers of vaccines, including doctors and national immunization programme managers.
- To review progress made in the fields of vaccine and immunization during the latter half of the 1900s by the greater CVI coalition, as well as the CVI Secretariat.

- To develop consensus, in the form of four action-oriented declarations, on goals to be achieved in the areas of: 1) the development of new and improved vaccines; 2) assuring the availability of affordable, quality vaccines; 3) promoting the introduction and use of needed vaccines; and 4) fostering a culture of prevention through advocacy for vaccines.
- To obtain from politicians and policy-makers present at the Summit their support of vaccination and endorsement of the action-oriented declarations.
- To increase advocacy for vaccines and immunization through widespread inclusion of the media in the Summit, preparations for the Summit, and follow-up activities.

Dates and venue

The CVI Secretariat proposed to hold the Summit for Vaccination early in the twenty-first century. A possible venue has not yet been determined, but consideration will be given to cost, geographic considerations, availability of space, communications facilities, and an expressed interest in hosting the meeting from a national government.

Working language

The working language of the meeting will be English. Translation of presentations into a second, or even third language will be made available, subject to the availability of resources.

Meeting participants

Participants critical to the success of the meeting will be selected by the Summit Steering Committee and will be financially supported. The meeting will be open to other participants on a self-funded basis.

Meeting agenda

In preparation.

Funding sources

Possible funding sources for the Summit include the CVI Secretariat, CVI co-sponsors, donors, industry and the host government. A preliminary budget will be prepared allowing the establishment of a small Summit Steering Committee which will finalize the meeting proposal outlined above. □

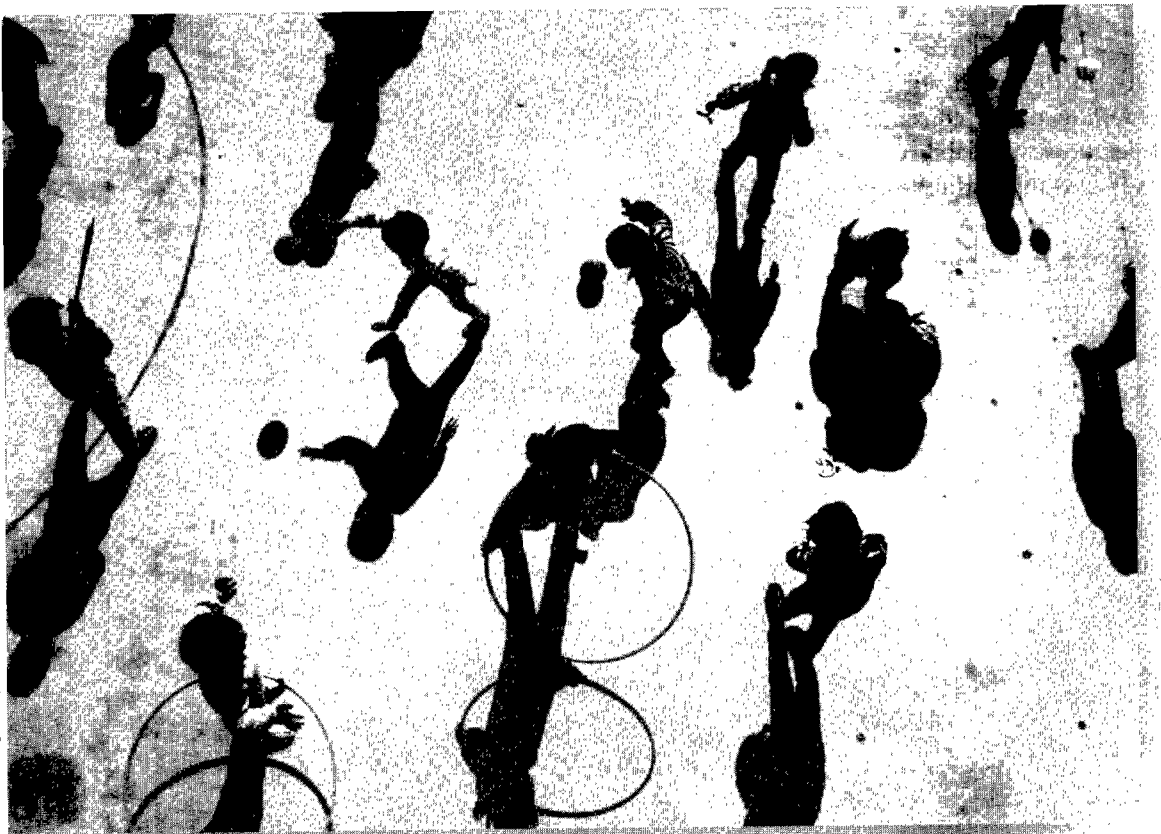


Photo: UNICEF/Roger Lemoyne

The Children's Vaccine Initiative

The Children's Vaccine Initiative (CVI) is a global coalition of organizations from the public, non-governmental and private sectors, including the vaccine industry, working together to maximize protection against infectious diseases through the development and utilization of safe, effective, easy-to-deliver and widely available vaccines.

Launched at the World Summit for Children in 1990, the CVI is co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Health Organization, the World Bank, and the Rockefeller Foundation.

