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Economics of immunization: a guide to the literature and other resources

Vaccines and Biologicals
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Contents

Abbreviations and acronyms

AIDS	acquired immunodeficiency syndrome
ARIVA	Appui au Renforcement de l'Indépendance Vaccinale en Afrique (Support for the Strengthening of Vaccine Independence in Africa)
BASICS	Basic Support for Institutionalizing Child Survival
BCG	bacille Calmette-Guérin (vaccine)
CDC	Centers for Diseases Control and Prevention (USA)
CVI	Children's Vaccine Initiative
DANIDA	Danish International Development Agency
DT	diphtheria toxoid (vaccine)
DTaP	DTP vaccine containing acellular pertussis
DTP3	three doses of DTP
DTwP	DTP vaccine containing whole-cell pertussis
EPI	Expanded Programme on Immunization
EU	European Union
FSP	financial sustainability plan
GAVI	Global Alliance for Vaccines and Immunization
GDP	gross domestic product
GNP	gross national product
HBV	hepatitis B virus
HepB	hepatitis B vaccine
Hib	*Haemophilus influenzae* type b
HIV	human immunodeficiency virus
IAVI	International AIDS Vaccine Initiative
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
LAC	Latin American and the Caribbean

MIC	mass immunization campaign
NIDs	national immunization days
NIP	national immunization programme
OPV	oral polio vaccine
NGO	nongovernmental organization
NORAD	Norwegian Agency for International Development
IPV	inactivated polio vaccine
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PHR	Partnership for Health Reform
REACH	Resources for Child Health Project
R&D	research and development
TRIPS	trade-related aspects of intellectual property rights
UN	United Nations
UNICEF	United Nations Children's Fund
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VII	Vaccine Independence Initiative
WHO	World Health Organization

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1. Introduction

In an effort to make information more readily available to those seeking to increase vaccine coverage worldwide and improve, manage, and deliver immunization services in developing countries, an annotated bibliography was developed. This document is intended as a tool for donor agencies, ministries of health and finance in developing countries, public health institutions and universities, as well as the Global Alliance for Vaccines and Immunization (GAVI). Within the context of immunization financing, this tool identifies literature and web resources on costing, cost–benefit analyses, financing, policy issues, tools, and other related topics. For copies of documents listed, please contact the author or publisher listed in the citation. A contact list of key institutions and individuals working on immunization issues is provided as well.

This document contains the following:

- Background information on immunization financing issues
- Summaries of 87 key articles related to immunization financing
- List of 345 documents primarily from 1995 to the present
- Directory of contacts and web sites for additional information

Please forward additional citations, references and links on immunization financing not listed in this document to:

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2. Background on immunization financing[1]

The issue of immunization financing in developing and transitional countries has become more critical in recent years as some donors have reduced their funding for immunization programmes; as other health priorities, such as HIV/AIDS, compete for limited health funding; and as countries try to increase coverage, to improve immunization safety and to add new, more expensive vaccines such as hepatitis B (HepB) and *Haemophilus influenzae* type b (Hib) vaccines to their national immunization programmes. The immunization financing issue is set to become even more important when vaccines currently in the pipeline, such as rotavirus, *Streptococcus pneumoniae* (pneumococcus) and other new vaccines, hit the market.

A review of existing literature on immunization financing in 1998 indicated that little information existed to guide donors, ministries of health and finance, and NIP managers in improving management and efficiency of immunization programmes, or to develop more effective strategies for the costing and financing of all aspects of immunization services. While the amount of literature on immunization financing has more than doubled in the last five years, information gaps persist on many aspects of immunization costs and financing, especially for middle-income countries not eligible for GAVI funding.

The following sub-sections introduce the main topics of immunization financing, which include immunization costs and cost-effectiveness, financing of immunization programmes, health sector reform, international mechanisms to facilitate immunization financing, and vaccine market.

[1] This background is based on the executive summary of *Review of financing of immunization programs in developing countries* (DeRoeck and Levin, 1998).

2.1 Costs of immunization

The early cost studies from the 1980s showed that costs per fully immunized child varied widely, depending on the delivery strategy used (fixed facilities, mobile services or mass campaigns), the local costs of personnel, and vaccine procurement and distribution. One generally accepted average cost for fixed facilities in low-income countries was US$ 15 per fully immunized child for the traditional antigens of the Expanded Programme on Immunization (EPI)—BCG (Bacille Calmette-Guérin), diphtheria–tetanus–pertussis (DTP), polio and measles vaccines.

Although it was known that the cost per dose of newer vaccines was significantly higher than those of traditional vaccines and presented more of a challenge to developing countries in terms of financing, less was known about the additional operating costs (cold chain, storage, additional service delivery costs, social mobilization, etc.) of incorporating these vaccines into immunization programmes. In general, the magnitude and distribution of total recurrent costs (including personnel costs, vaccines, syringes, transport, cold chain maintenance, and social mobilization) were not well known.

A number of costing and financing studies were conducted in the late 1990s. Partnership for Health Reform (PHR) produced case studies of the costs and financing of immunization programmes in Morocco, Bangladesh (1999), Colombia, Côte d'Ivoire (2000) and Ghana (2001).[2] The Asian Development Bank studied immunization financing in Cambodia, Lao People's Democratic Republic and Viet Nam[3] (1999). In Bangladesh, Côte d'Ivoire and Morocco, personnel time was found to account for over half of total costs followed by vaccines (19–30%). Other recurrent costs, such as transport and social mobilization, accounted for less than 10% of total costs. Capital costs were around 10%. The average cost per fully immunized child was US$ 20–25. The Asian Development Bank, using a slightly different methodology, found that vaccines accounted for 35–54% of total immunization costs in Cambodia, Lao People's Democratic Republic and Viet Nam.

More information on the structure of the costs and financing of immunization programmes in low-income countries is becoming available as countries receiving GAVI/Vaccine Fund support are requested to prepare financial sustainability plans (FSPs) in the second year of receiving funding support. Guidelines for preparing a national immunization programme financial sustainability plan, with standardized methods for costing immunization services, have been developed by the GAVI Financing Task Force to assist countries in developing their FSPs. Among the findings of the first round of FSPs (Cambodia, Côte d'Ivoire, Ghana, Guyana, Kenya, Kyrgyzstan, Lao People's Democratic Republic, Mali, Mozambique, Rwanda) are: total spending on immunization represents on average less than 0.2% of GNP and less than 4% of total health expenditure; and vaccine costs account for an increasingly large part of total immunization costs. This increase is a logical consequence of the addition in national immunization programmes of new products and technologies, such as auto-disable syringes.

[2] See entries 32, 33,34,35,38 and 39 in section 3.
[3] See entry 41 in section 3.

2.2 Cost-effectiveness of immunization policies

Immunization policies compete with other public health interventions for limited budgets both at the national and global level. Within immunization budgets themselves, resource allocation decisions have to be made between different policies and options in terms of expanding coverage or adding new antigens to immunization schedules. Therefore, estimates of cost-effectiveness are essential information for policy makers wishing to allocate resources efficiently. Cost benefit and cost-effectiveness studies generally estimate at what cost public health goals can be reached. Cost-effectiveness studies express results in terms of dollars per disability-adjusted life year (DALY) gained, while in cost–benefit analyses health gains are expressed in monetary terms.

Cost-effectiveness and cost–benefit analyses can help countries make better informed decisions on the inclusion of new vaccines in national immunization programmes, currently the case with hepatitis B and Hib vaccines, as these vaccines are relatively expensive compared to the traditional EPI vaccines. A review of the literature in 2001[4] found hepatitis B immunization to be highly cost-effective in developed countries. However, few studies had been conducted in areas of high endemicity, which include most of the developing countries. The evidence of the cost-effectiveness of Hib in low-income countries is somewhat mixed as the price of the vaccine is still relatively high.[5]

Another issue involving cost-effectiveness calculations is whether and when developing countries should switch from the oral polio vaccine (OPV) to the inactivated polio vaccine (IPV). The former, though safe and effective, causes a (small) number of vaccine-associated polio cases.

Cost-effectiveness calculations are also needed to assess different ways of expanding coverage (routine vs mass campaigns, outreach teams, peer training, channelling). A recent review of the literature[6] found peer training and channelling to have the lowest incremental cost per fully vaccinated child. Outreach teams were found to have higher average costs, but the average costs showed high variability. As expected, mass campaigns had higher average costs per fully vaccinated child than routine immunizations. However, further research is necessary to increase the number and quality, in terms of transparency and generalizability, of the studies.

[4] See entry 2 in section 3.

[5] In 2003, the price to UNICEF, excluding freight, of the monovalent formulation of Hib was around US$ 2.85 compared with US$ 0.40 for hepatitis B.

[6] See entry 20 in section 3.

2.3 Financing of vaccines and immunization programmes

Developing countries have traditionally relied, at least in part, on donor funding to finance their immunization services. This funding has historically been relatively easy to obtain as donors saw immunization as a cost-effective health intervention and more recently as a way to alleviate poverty. However, useful this support is, it does not necessarily encourage countries to increase domestic funding.

The PHR review[7] conducted in 1998 found that more and more countries were financing at least a portion of their vaccine costs and many now have immunization or vaccine line items in their government budgets. In the PHR e-mail survey sample of 78 countries, more than one-third (36%) reported that they financed 100% of their vaccine supply. As expected, there were large regional variations in the level of self-reliance in vaccine financing—while 18 of the countries surveyed in the Latin American and Caribbean (LAC) region (72%) reported that they were self-reliant in vaccine financing, only three countries from the sub-Saharan Africa sample (11.5%) were. Three-quarters of the overall sample of countries reported having a specific immunization programme or vaccine budgetary line item.

Few countries reported financing 100% of their total immunization programme costs. Most countries, including middle-income countries that pay for all of their vaccine supply, still depended, at least to some extent, on donor funding for such programme support activities as training, disease surveillance, cold chain equipment and maintenance, supervision, and social mobilization. Even a relatively well-off country like Brazil received some funding from donors in 1997 for disease surveillance and training activities. However, at least part of this funding from donors, especially in the wealthier countries, may be associated with the worldwide polio eradication campaign or other international disease control efforts.

A number of countries—especially middle-income countries—were financing the introduction of "new" vaccines, including hepatitis B, from government funds. Some countries, including Bhutan, Cameroon and the Pacific island countries, were receiving donor financing for new vaccines. There was also anecdotal evidence that some poorer countries that receive donor financing for traditional antigens buy additional vaccines, such as hepatitis B and yellow fever, with government funds.

Cost recovery for preventive health services in general was reported in only 21 countries in the survey (27%) and only 14 countries (18%) reported cost recovery specifically for immunization services. Two-thirds of the countries reporting cost recovery for immunization services in the survey were in sub-Saharan Africa, where the Bamako Initiative is being implemented, while no country in the LAC region reported its use. Fees per immunization card or per shot were the most common methods reported, especially in Africa. The amount of costs recovered were in most cases unknown, but where estimated were generally low (less than 5% of total costs).

[7] See entry 27 in section 3.

In 2001, a WHO position paper[8] reviewed the policy of international organizations on user fees for immunization and the literature on user fees in health care. After discussion on the pros and cons, it stated that user fees discouraged people from seeking vaccination, that public funding was the most equitable way to finance essential immunization and that essential immunization services should be free of charge.

2.4 The effects of health sector reform on immunization financing

2.4.1 Health sector decentralization

Decentralization varies widely from country to country, and the effects on immunization services differ. Since health reforms are still being implemented, it is difficult to fully assess their effects on the financing of immunization programmes.

According to the literature, some negative consequences of the move toward decentralization of health service delivery on immunization systems are occurring as countries put new management systems into place. To reduce these negative effects, some change is necessary to facilitate the functioning of immunization systems under decentralization. Since decentralization is accompanied by reforms that rearrange financial mechanisms, donors concerned about immunizations must also rearrange their funding mechanisms and behaviour in these countries, for instance, by targeting funding to different levels of the health system, and by involving local governments in determining how to spend donated funds most appropriately.

2.4.2 Private sector/nongovernmental organization participation in immunization service provision and financing

The involvement of non-governmental organizations (NGOs) in the provision of immunization services, at district level, is important in many countries, particularly in sub-Saharan Africa and in Asia. However, the extent to which these NGOs provide additional resources to national immunization programmes or are simply extensions of the government programmes is not known. The specific composition of their clientele (e.g. urban vs rural, better off vs poor) is also not well documented.

The involvement of the private for-profit sector in the provision of immunization is quite low but appears to be growing, particularly in urban areas. However, insufficient information is available on the extent of this involvement, the extent to which previously underserved populations are being served by the private sector, and whether this mechanism of distribution is increasing resources available for immunization services.

[8] See entry 48 in section 3.

2.4.3 Disease eradication initiatives

There is a debate on the impact on national immunization services of supplemental immunization activities such as the worldwide polio eradication initiative and the supplemental measles activities. Earlier studies suggested that while people's knowledge of the benefits of immunization had sometimes increased due to the extensive social mobilization efforts associated with supplemental immunization activities, the level of resources available for routine immunization services might have decreased. A study by PHR[9] found no evidence of decreasing donor funding for routine immunization due to the polio eradication initiative. It also seems that polio supplemental immunization activities have contributed to higher immunization coverage for other vaccines when those antigens were given on national or subnational immunization days. On the other hand, the impact of measles supplemental immunization activities on immunization services has not been evaluated. More research on these issues is required in order to determine the extent of the impact on routine immunization services and how future disease control initiatives can benefit and work hand-in-hand with national immunization services.

2.5 International mechanisms to facilitate vaccine procurement and funding

2.5.1 The PAHO revolving fund, the Vaccine Independence Initiative and ARIVA

Several international mechanisms have been developed to assist countries in increasing their financial contribution for vaccines. The oldest, begun in 1979, is the revolving fund of the Pan American Health Organization (PAHO), which operates on the concept of a pooled common revolving fund and which is able to secure low vaccine prices through large volume contracts with manufacturers. The Vaccine Independence Initiative (VII), which was established by the United Nations Children's Fund (UNICEF) in 1991, sets up an individual revolving fund for each country, which then has access to low-cost, high-quality vaccines through UNICEF's procurement system. Both the PAHO Revolving Fund and the VII allow countries to buy vaccines in local currency and to pay for them only after the vaccine deliveries have been made, thereby eliminating two obstacles—the lack of hard currency and the need to pay for vaccines in advance—that developing countries often face in purchasing vaccines on the open market. To date, all but four countries in the LAC region participate in the PAHO Revolving Fund and those participating have generally reached high and sustainable levels of immunization coverage despite ups and downs in the macroeconomic environment. More than twenty countries (including 12 Pacific island countries) currently have VII contracts. The EU initiative ARIVA (Appui au Renforcement de l'Indépendance Vaccinale en Afrique—Support for the Strengthening of Vaccine Independence in Africa) is currently being implemented in more than 10 Sahelian African countries. ARIVA earmarks EU structural adjustment funding for immunization by requiring the creation of an immunization or vaccine line item in each government budget and provides access to UNICEF's VII.

[9] See entry 80 in section 3.

According to its proponents, ARIVA has resulted in vaccine financing being more secure and having a greater priority among governments in some of the world's poorest countries than has been the case in the past. The initiative has, however, been criticized for targeting the countries least able to pay for vaccines, thereby increasing the likelihood of funds being taken away from other critical immunization or health programme components. Other problems attributed to the programme are the lack of a mechanism to track governments' share of vaccine financing, and the lack of concrete plans to gradually increase the governments' share of financing over time.

2.5.2 The Global Alliance for Vaccines and Immunization

The Global Alliance for Vaccines and Immunization is a public–private partnership dedicated to ensuring that every child in the developing world benefits from access to vaccines. Partners include national governments, UNICEF, WHO, the World Bank, bilateral donors, the Bill & Melinda Gates Foundation, the vaccine industry, public health institutions and nongovernmental organizations (NGOs). Collectively, it serves the purpose of expanding the reach of immunization services; introducing new vaccines; and establishing tools and systems to promote sustainable financing in developing countries.

The Alliance was launched in January 2000 within the context of declining coverage for basic vaccines and slow uptake of new vaccines such as hepatitis B and Hib in developing countries. GAVI and the Vaccine Fund, GAVI's fundraising arm, have to date (July 2003), committed over US$ 1 billion to support national immunization services in the least-developed countries. Through the Vaccine Fund, GAVI provides countries with less than GNP US$ 1000 per capita with grants over a five to eight year period to pay for new vaccines and strengthen their immunization services. There is an ongoing debate on which of the GAVI strategic objectives (expanding coverage, introducing new vaccines, accelerating R&D efforts for vaccines specifically needed by developing countries), should receive highest priority, notably in terms of resources. There are also concerns that the immunization coverage rates achieved as a result of GAVI/Vaccine Fund support will not be sustainable beyond the period of Vaccine Fund support.[10]

[10] Related questions are whether the Hib vaccine should be retained following GAVI support and whether the pentavalent (DTP+HepB+Hib) is appropriate for financial sustainability reasons.

2.6 Market for existing and future vaccines

Vaccine purchases represent an important cost item in immunization services. Consequently, the determinants and evolution of vaccine prices are of special note for anybody interested in immunization financing. The vaccine market is characterized by a limited number of manufacturers and the importance of public sector and UN agency purchases for basic vaccines. Most of the production costs are either fixed or semi-fixed. Procurement and distribution are strictly controlled to ensure that the high safety and quality requirements for vaccines are respected. These and other features of the vaccine market have been described in the literature, but the impact on vaccine prices of such factors as technical barriers to entry and intellectual property rights remains mostly undocumented.

Traditionally, low-income countries have benefited from price tiering and for certain products UNICEF and PAHO have been able to buy vaccines at a fraction of the prices charged in developed countries. This was possible thanks to the fact that there was a demand for the same vaccines in both high-income and poor/middle income countries and there was a willingness of certain suppliers and government customers to accept different pricing for different segments of demand. However, these conditions are changing as immunization schedules of high-income and low/middle-income countries are becoming increasingly divergent. For example, DTwP, OPV and BCG coverage has decreased dramatically in high-income countries following more targeted use of BCG and replacement of DTwP by DTaP (diphtheria–tetanus–acellular pertussis vaccine) and OPV by IPV. On the other hand, these vaccines are still widely used in developing countries. The potential of price tiering for a given product is diminishing as markets diverge.

Of crucial importance is also the question of how the particular features of the vaccine market and the structure of vaccine procurement mechanisms affect research and development incentives for new vaccines and how to encourage vaccine research and development (R&D). Different authors recently contributed to the discussion, some of them proposing push and pull mechanisms, including long-term purchase commitments as a way to create incentives for vaccine R&D. These questions remain largely open to debate since little empirical evidence is available.

2.7 Information gaps

In 1998, PHR identified a number of information gaps in immunization costs and financing. Since then, much more information and analysis has become available. New costing and financing studies have provided updated information on the costs of routine services and the share of domestic funding in low-income countries. Additional costs of incorporating new vaccines such as hepatitis B have been estimated. Nevertheless, some important aspects of immunization remain little known and new questions have emerged, most of which are linked to the impact of GAVI's activities. Current gaps in information on immunization financing include the following:

2.7.1 Vaccine and immunization financing

- The impact of changes in donor funding for vaccines and immunization services and corresponding effects on governments' share of immunization costs, immunization coverage rates, and the overall performance and quality of immunization programmes;
- the impact of GAVI funding on financial sustainability in low-income countries;
- the impact of GAVI on the planning and budgeting of immunization activities in poor countries;
- the impact of other global disease-specific initiatives, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) on immunization financing;
- benchmarks for assessing domestic contribution as well as external funding to national immunization programme financing;
- information on countries' experiences using World Bank or other loans to finance vaccines and national immunization programmes, and the impact of these loans on the long-term sustainability of immunization programmes;
- the impact of adding new vaccines on the financing mechanisms and available funding for immunization programmes overall (including the effect on funding for other immunization programme components and/or health programmes);
- the actual prevalence in developing countries of both formal and informal cost recovery for immunization services (including cross-subsidization from fees for other health services) and the actual and potential rates of cost recovery that they are achieving or could achieve;
- information on who is and is not using immunization services in areas where cost recovery is being implemented, and the impact of cost recovery on the quality and effectiveness of these services;
- information on whether or not cost recovery can be a valuable means of enhancing the sustainability of immunization programmes and under what circumstances, and which specific cost-recovery mechanisms have the most potential for mobilizing additional resources without having a negative impact on utilization; and
- the prevalence and potential for financing mechanisms other than user fees to pay for the costs of immunization programmes, such as prepayment schemes and health insurance schemes.

2.7.2 Effect of changing health sector on immunization financing

- The extent to which flows of funds in decentralized health systems are covering immunization programme costs previously funded centrally, directly by the ministry of health;
- the extent to which, and how resources have been mobilized at the local level for immunization services in countries with decentralized health systems;
- the extent to which the private sector, including both the commercial and the not-for-profit sector, has become involved in immunization service delivery, especially in countries with decentralized health systems, and the extent to which, if at all, participation of the NGO and for-profit sectors lowers the immunization programme costs to the government;

- the impact of sector-wide approaches (SWAps) on immunization and immunization financing;
- the impact of increased private sector participation in immunization service delivery on the equity of access to services, on coverage, and on the quality and safety of services;
- the extent to which community-based health insurance schemes can contribute to the financing of immunization;
- the extent to which polio eradication has affected the availability of resources for routine immunization services, and how disease control campaigns can be designed and implemented to benefit routine immunization programmes and to minimize any negative effects on the management and financing of routine immunization activities;
- the impact of general budget support on the flow of funds and sustainability issues;
- the scope of debt relief initiatives for heavily indebted countries to increase the financing and sustainability of immunization programmes; and
- the effects of poverty-reduction strategies on immunization financing and sustainability.

2.7.3 International mechanisms to facilitate vaccine financing

- The impact of GAVI on the structure of the world vaccine market and the influence of emerging producers;
- the impact of GAVI on vaccine research, intellectual property and technology transfer issues;
- the impact of the increased government share of vaccine financing through the VII, the PAHO Revolving Fund, or the EU initiative on countries' vaccine supplies;
- the impact of these mechanisms on the long-term sustainability of country financing of vaccines and immunization programmes, especially given that the VII and EU initiative were designed for a time-limited period;
- how each of these mechanisms can be improved to minimize vaccine shortages, ensure the long-term sustainability of vaccine and immunization programme financing, and ensure that increased government funding of vaccines does not result in inadequate funding of critical immunization programme components;
- other barriers to the long-term sustainability of country financing of immunization programmes that these mechanisms are not addressing;
- information on countries' experiences with direct procurement of vaccines and under what circumstances direct procurement is more beneficial to countries than participation in one of these mechanisms;
- information on whether or not vaccine wastage and other inefficiencies have been reduced as a result of increased government share of vaccine financing.

2.7.4 Market for existing and future vaccines

- The feasibility of various push and pull mechanisms to promote vaccine research and development in the interest of developing countries;
- the impact of private–public partnerships on vaccine research and development for neglected diseases;
- the impact of the GAVI approach to sharing information about its activities and those of the countries with which it works with the industry; in particular, whether this approach relieves some of the problems linked with demand predictability, production capacity, etc.;
- the role of emerging producers in the world vaccine market;
- experiences with technology transfer to developing countries, including intellectual property rights issues;
- the implications of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement for vaccines; and
- the role of the international community in promoting innovation and protecting intellectual property rights while preserving public health interests and competition among producers.

3. Annotated citations

Articles are organized by five subject areas and alphabetized by author name and may address multiple issues. Annotations are reproduced from original sources if available; others were written by PHR, Miloud Kaddar and Patrick Gaulé.

3.1 Costing, costs, cost-effectiveness

1. **Bennett E.** ***Geographical differences in cost-effectiveness: vitamin A interventions in South Africa.*** **London, Department of International Development, London School of Hygiene and Tropical Medicine, 1999.**

   ***Keywords*: cost-effectiveness**

   This report describes ongoing project work to examine geographical differences in cost-effectiveness through evaluating the cost-effectiveness of vitamin A supplements and food fortification in reducing mortality in children 6 to 24 months of age in South Africa. Five intervention strategies are considered: distribution of capsules to children linked to existing measles vaccine doses, extension of coverage of measles vaccine and vitamin A to 80% of children, fortification of maize to provide 100% of recommended daily allowance for children (produced by large mills), extension of strategy 3 to fortify maize milled by large and small millers, and combination of strategy 1 and strategy 3. The cost-effectiveness of these alternatives for preventing vitamin A deficiency is estimated for South Africa as a whole, in addition to the nine provinces, and the 24 health districts in the Western Cape province. District-level data on the health system and health status is used to examine factors likely to contribute to geographical differences in the cost-effectiveness of other health interventions.

2. **Beutels P. Economic evaluations of hepatitis B immunization: a global review of recent studies (1994–2000).** ***Health Economics,*** **2001:751–774.**

   Keywords: **cost-effectiveness, methodology, hepatitis B**

   A bibliographic search was carried out for economic evaluations of hepatitis B vaccination, published between 1994 and 2000. The results of these studies are then discussed according to the level of hepatitis B virus (HBV) endemicity. Unfortunately, for countries of intermediate to high endemicity very few published studies have been conducted, perhaps due to the fact that necessary data are hard to get. The studies that are available indicate that for the health care payer universal hepatitis B vaccination can be highly cost-effective compared to other interventions. Comparability and transparency of the analyses could and should be improved. Methodological issues such as discount rates and suitability of dynamic versus static analysis are also discussed.

3. **Bloom BS et al. Department of Immunization, Vaccines and Biologicals. A cost-effectiveness analysis of vaccination strategies against hepatitis B.** ***Annals of Internal Medicine,*** **1993, 118(4):298–306.**

Keywords: **HepB, costs, economic evaluation**

Which is the best vaccination strategy against hepatitis B? Four populations have been determined: new-born infants, children under 10 years of age, high-risk adults, and the adult population of the United States. The objective of this study was to identify the clinical and economic arguments in favour of vaccination, with and without preliminary data tracking. The literature on estimations of incidence, and on the effectiveness and side-effects of vaccination, reflects that these issues are widely debated. The authors carry out a quantifiable economic analysis upon which they make the following recommendations: systematic tracking of pregnant women, tracking of new-born infants following vaccination and complete vaccination of children prior to entering school.

4. **Bovier PA, Wyss K, Au HJ. A cost-effectiveness analysis of vaccination strategies against N. meningitidis in sub-Saharan African countries.** ***Social Science and Medicine,*** **1999, 48(9):1205–1220.**

Keywords: **cost-effectiveness**

This analysis evaluates the cost-effectiveness (C/E) of routine vaccination against *Neisseria meningitidis.* Three different preventive strategies are analysed: mass vaccination during epidemics (the current standard of care), routine preventive vaccination and a combination strategy of routine vaccination with mass vaccination during epidemics. A Markov model is used to simulate the epidemics of meningitis in a cohort of 5-year old children and compare these different strategies. The results show that mass vaccination strategy is dominated by the two other strategies. The incremental C/E ratios are US$ 50/Quality Adjusted Life Year (QALY) for the routine vaccination, and US$ 199/QALY for the combination strategy. The C/E ratios are sensitive to: the incidence of meningococcal meningitis, the costs of treating cases, the costs of routine vaccination and the costs and effectiveness of mass immunization campaigns. However, the rank ordering of the strategies is almost never altered. The results of this analysis suggest that mass vaccination in sub-Saharan Africa in case of epidemics should be reconsidered. Routine vaccination against meningococcal meningitis at an early age, with or without mass vaccination during epidemics, is more effective with a C/E ratio within the range of other vaccination strategies currently in place in Africa.

5. **Brenzel L.** ***The costs of EPI: Lessons learned from cost and cost-effectiveness studies of immunization programs.*** **Arlington, VA, REACH Project, John Snow, Inc., September 1990.**

Keywords: **costs, financing, cost-effectiveness, country experiences**

This document is written primarily for field officers and EPI national managers to discuss what has been learned from a decade of EPI cost studies. Section I outlines current knowledge about the costs of national child immunization programmes. Section II provides information about how to conduct a cost-effectiveness study. Section III discusses future directions for the role of cost and cost-effectiveness evaluations in EPI as a whole.

Additional discussion about the cost-effectiveness methodology is found in the appendix. Summaries of REACH cost-effectiveness studies of the EPI in Cameroon, Haiti, North Arcot district in India, Mauritania, Senegal, Sudan, and Turkey are also found in the appendix.

6. **Brenzel L, Claquin P. Immunization programs and their costs.** ***Social Science and Medicine,*** **1994, 39(4):527–536.**

Keywords: **cost-effectiveness, sustainability, EPI**

The Expanded Programme on Immunization made considerable progress in the 1980s towards immunizing the world's women and children. Vaccinations provided through EPI are considered as one of the most cost-effective child survival interventions at a cost between US$ 5 and US$ 10 per child. However, variation exists in the average cost per fully immunized child, depending upon the type of vaccine technology and delivery strategy utilized, the scale of operation, and country and environmental characteristics. Recent evidence on the cost-effectiveness of immunization strategies raises concerns over the affordability of national immunization programmes by governments and highlights the need for continued donor support, identification of other financing mechanisms, or reconsideration of policies aimed toward accelerating and maintaining immunization coverage.

7. **Clemens J et al. Evaluating new vaccines for developing countries. Efficacy or effectiveness?** ***Journal of the American Medical Association,*** **1996, 275(5):1639–1645.**

Keywords: **new vaccines, evaluation**

Despite the profusion of promising new vaccines against illnesses prevalent in developing countries, uncertainties about the balance between costs and benefits of new vaccines have retarded their use in public health practice. Conventional prelicensure trials of vaccine protection exacerbate these uncertainties by focusing on measurement of vaccine efficacy¾the performance of a vaccine under idealized conditions. Vaccine effectiveness trials provide a more pragmatic perspective by addressing the performance of a vaccine under the ordinary conditions of a public health programme, by capturing direct as well as indirect effects of vaccination, and by comprehensively addressing outcomes of public health concern. The use of effectiveness trials should enable more rational triaging of new vaccines into public health practice by resolving speculative debates about practical costs and benefits.

8. **De Champeaux A, Kaddar M.** ***Rapport d'evaluation nationale du programme elargi de vaccination du coût de l'enfant togolais complètement vaccin*****e. [EPI National review report on the cost of fully immunizing children in Togo.] Togo, Ministère de la Santé Publique, Janvier–Février 1991.**

Keywords: **country experience, EPI, costs**

This study is on cost and financing of the national immunization programme in Togo in 1990. The national average coverage rate was estimated at 45%. A distinction is made between EPI-specific programme costs (considering inputs such as vaccines, syringes, needles, supplies, social mobilization for national immunization days, transportation, cold chain equipment and maintenance)

and total EPI costs. Current resources (e.g. personnel, building, overheads) represent 62% of total costs. The government of Togo was paying for most expenditures in the context of heavy external debt. The total cost per fully immunized child is around US$ 8. Financing issues are critical: the government covered only 2% of the additional costs, UNICEF 52%, and the rest was funded by different donors and international organizations (e.g. USAID, Rotary, WHO). The Togo case is an example of a centralized, vertical and ultimately, non-sustainable programme with relatively good short-term performance due to significant external support.

9. **Demicheli V, Jefferson T. An exploratory review of the economics of recombinant vaccines against hepatitis B. The economic aspects of biotechnologies related to human health. Part 1.** ***Biotechnology and medical innovation: socio-economic assessment of the technology, the potential, and the products.*** **Paris, Organization for Economic Co-operation and Development (OECD/GD), 1997, (97)205:105–123.**

Keywords: **HepB, literature review, costs, cost-benefit analysis**

The objectives of the review were two-fold. The first objective was to identify, retrieve and analyse the available published and unpublished studies on the efficiency of the introduction of programmes of yeast-derived vaccines against hepatitis B in developed countries. The second objective was to assess the variability of assumptions upon which such economic models are based and the conclusions reached in those countries. The review included 33 studies addressing issues such as evaluation of vaccinating high-risk populations, evaluation of screening before HepB vaccination, evaluation of different routes of vaccination, and evaluation of combining vaccines in one shot. The review summarizes findings on the incidence of hepatitis B, cost estimates, vaccination costs, and results of cost–benefit analyses.

10. **Edmunds W et al. The cost of integrating hepatitis B vaccine into national immunization programmes: a case study from Addis Ababa.** ***Health Policy and Planning*****, 2000, 15(4):408–16**

Keywords: **cost-effectiveness, methodology, hepatitis b**

This paper describes a method for estimating the additional costs of introducing HebB vaccination into EPI at a national level prior to the introduction of vaccination. The method involved the use of a number of questionnaires to estimate the costs associated with the EPI programme from a large sample of the static clinics as well as from the central sources. Since unit costs were collected along with the quantities of resources and estimates of the capacity for certain facilities (such as refrigerators), the additional cost of introducing HepB vaccine could be estimated largely by extrapolation of the resources used in vaccinating against diphtheria–pertussis–tetanus vaccine. The method is illustrated by a study carried out at the sub-national level, in the city of Addis Ababa, Ethiopia.

11. **Evans DB, Guyatt HL. Human behaviour, cost-effectiveness analysis and research and development priorities: the case of a schistosomiasis vaccine.** ***Tropical Medicine and International Health,*** **1997, 2(11):A47–A54.**

Keywords: **cost-effectiveness, culture and behaviour**

Immunization costs and efficacy depend on a number of cultural and behavioural factors which are largely ignored in cost-effectiveness studies, and these are discussed in this article. Cost-effectiveness analysis has been widely used in the health sector to guide decisions about where scarce resources aimed at disease prevention or control should be funded. In addition, the validity of the behavioural assumptions underlying the economic analysis is rarely considered explicitly. This paper explores the use of cost-effectiveness analysis to set priorities for research using the development of a schistosomiasis vaccine as an example. It then explicitly considers behavioural factors which might affect the accuracy of the calculations. A "product profile" for the new technology is derived, which can be used by developers as a target to aim at. To ensure that the vaccine would be more cost-effective than the currently preferred option for the control of schistosomiasis, chemotherapy based on praziquantel, researchers need a vaccine which has sufficient duration of protection to be delivered as part of the regular childhood immunization programme.

12. **Feilden R.** ***Costs and effectiveness of immunization services in Moldova. Starting the fieldwork.*** **Arlington, VA, BASICS Project, 1996.**

Keywords: **costs, cost-effectiveness**

The objectives of the cost-effectiveness study address the following areas of concern: cost of vaccine, clinicians' practices, vaccine-handling practices, safety of injections, and choice of strategies. This trip report provides information on the preparation of formats on collecting data, agreement on the final sample of rations, training the teams of epidemiologists and paediatricians who would be gathering the data, and the commencement of fieldwork. The author recommends providing a concise field guide along the lines of WHO's Immunization in Practice to specify acceptable vaccine-handling practices, and linking these with appropriate strategies for providing the service.

13. **Hinman A, Irons B. Economic analyses of rubella and rubella vaccines: a global review.** ***Bulletin of the World Health Organization,*** **2002, 80(4):264–270.**

Keywords: **cost–benefits, cost-effectiveness, methodology**

A search was conducted for articles published between 1970 and 2000 that dealt with economic analyses of rubella and rubella-containing vaccines, to investigate whether the incorporation of rubella vaccine into immunization programmes in developing countries is economically justified. For developing countries, five cost-effectiveness analyses and five cost–benefit analyses were found. All these analyses came from the Central America and Caribbean region except two that were conducted in Israel. All cost–benefit analyses had a benefit–cost ratio greater than 1 and the cost-effectiveness studies indicated that rubella immunization was a cost-effective means of reducing the impact of congenital rubella syndrome. However, the methodologies were not

standardized. The data support the inclusion of rubella vaccine in the immunization programmes of both developing and developed countries and indicate economic benefits comparable to those associated with hepatitis B vaccine and *Haemophilus influenzae* type b vaccine. More studies should be carried out on costs for care and immunization using standardized methodologies and locally obtained information.

14. ICCDR/Bangladesh. Summary of project: cost comparison and cost-effectiveness analysis of measles immunisation in Dhaka, Bangladesh. *Health economics and financing programme: research portfolio*. London, Health Policy Unit, London School of Hygiene & Tropical Medicine, 1998.

***Keywords*: EPI, costs, cost-effectiveness, country experience**

The Expanded Programme on Immunization in Bangladesh is focused on six diseases: tuberculosis, tetanus, diptheria, measles, whooping cough, and poliomyelitis. Of these childhood diseases, measles is the major cause of mortality. Each year an estimated one million children die from measles globally, despite the widespread availability of safe and effective vaccines since 1963. The improvement of the immunization coverage in Bangladesh is striking. Coverage increased from 10% in 1988 to 59% in 1993, and was 68% in urban areas such as Dhaka. The aim of the study is to assess the measles component of EPI in Dhaka in terms of a cost comparison analysis, in which the treatment costs averted are subtracted from the cost of measles vaccination in order to calculate the net cost. The study also estimates the additional resources required to progress from measles-control to accelerated measles activities, and the associated gains in measles immunization coverage.

15. Jefferson T, Demicheli V. Is vaccination against hepatitis B efficient? A review of world literature. *Health Economics,* 1994, 3:25-37.

***Keywords:* HepB, literature review, economic evaluation**

This study aims to assess the variability of assumptions on which economic models for the introduction of vaccination against hepatitis B are based. The conclusions reached define a minimum set of methodological standards upon which future economic studies on vaccines should be based. One hundred and sixteen published and unpublished works were gathered through Medline literature searches, consulting private databases, and corresponding with all authors and researchers active in economic evaluation of vaccines. All works were assessed but only those which were original economic analyses were included (90 studies). Principal epidemiological and economic variables were extracted and compared where possible. Rough manipulations were carried out to make the data comparable. Profound variability on the main parameters of the efficiency equation were found. Inconsistencies in definition and study design in 38% of a subset of studies were also found. Little impact on decision-making was detected, which may have been due to uncertain or unclear methodology, as few studies reach valid conclusions. In the future, decisions may be based on biased evidence and scarce resources committed to untested programmes. There is an urgent need to standardize study methods and define a common set of procedures.

16. **Kaddar M, de Champeaux A. Comparabilité et utilité des analyses du coût et de l'efficience des programmes élargis de vaccination en Afrique [Comparability and utility of cost and efficiency analyses of expanded programmes of immunization in Africa].** ***Journal d'Economie Medicale,*** **1994, 12(4):227–238.**

Keywords: **costs, financing**

In the 1980s, EPI in Africa received the top priority in the policies of health and resource allocation from international organizations. In the early 1990s, African EPI programmes showed signs of deterioration. Many questions have arisen about the sustainability of these programmes because of such factors as: increasing prices of vaccines on the international market, financing of the programmes, sustaining technical assistance, etc. This article discusses the range of costs and financing options for EPI programmes based on the experiences of French-speaking Africa. It concludes that for maximum programme efficiency it is important to better integrate EPI programmes into the local context.

17. **Lieu T et al. Analyse coût efficacité de la vaccination contre la varicelle chez les enfants d'âge scolaire et les adolescents : dépistage préalable contre vaccination systématique [Cost-effectiveness of varicella serotesting versus systematic vaccination of school-age children and adolescents].** ***Pediatrics,*** **1995, 95(5):632–638.**

Keywords: **cost–benefit, cost-effectiveness**

By carrying out this important analysis of the advisability of vaccinating children against chicken pox, the authors have devised a strategy comparing costs and benefits. Two decision trees are described: one for children from 6 to 12 years of age, and the other for children from 13 to 17 years of age. Three vaccine policies are also considered: no vaccination, preliminary tracking, and systematic vaccination. Probability calculations are made, taking into account current literature and expert opinion. The costs identified include short-term, average and long-term medical costs and lost working days. This study shows that this vaccination strategy is expensive, but still profitable if done for school-age children and if done in combination with other immunizations. The authors point out that the choice of strategy varies with the quality of the health system and its priorities. Additional empirical evidence must be taken into account in policy formation.

18. **Liu X et al. OPV vs IPV: Past and future choice of vaccine in the Global Polio Eradication Program.** ***Technical report 004 Partnerships for Health Reform plus*****. Bethesda, MD, Abt Associates, Inc., February 2002.**

Keywords: **eradication, cost-effectiveness, polio**

This study estimates the incremental cost of switching from the current oral polio vaccine (OPV) to inactivated polio vaccine (IPV) in developing countries after global polio eradication. Cost of vaccine, cost of vaccination supplies, transportation cost of supplies, cost of sterilization and waste disposal, and cost of training would all increase if countries switched from OPV and IPV. On the other hand, cost of vaccination visits (number of vaccinations per child is less for IPV than OPV) would decrease and cost of vaccine-associated

cases would be eliminated. For all developing countries together, the switch from OPV to IPV would result in total annual cost of US$ 317 million, averaging US$ 2.91 per child. Overall, the switch will need US$ 1 million to avoid any cases of vaccine-associated poliomyelitis paralysis in developing countries. As benefits resulting from the switch will ultimately need to be weighed against the high incremental costs and increased risks, there are reasons to challenge either continuing to use OPV or to switch to IPV post eradication in developing countries.

19. Margolis HS et al. Prevention of hepatitis B virus transmission by immunization. An economic analysis of current recommendations. ***Journal of the American Medical Association,*** **1995, 274(15).**

Keywords**: HepB, evaluation, developed countries**

This study's objective was to evaluate the outcome of immunization strategies to prevent hepatitis B virus transmission. A decision model was used to determine the incremental effects of the following hepatitis B immunization strategies in a birth cohort receiving immunization services in the public sector: (1) prevention of perinatal HBV infection, (2) routine infant vaccination, or (3) routine adolescent vaccination. The study found that prevention of perinatal infection and routine infant vaccination would lower the 4.8% lifetime risk of HBV infection by at least 68% compared with a 45% reduction for adolescent vaccination. From a societal perspective, each strategy was found to be cost saving, but was not cost saving with respect to direct medical costs. The estimated cost per year of life saved was US$ 164 to prevent perinatal HBV infection, US$ 1522 for infant vaccination, and US$ 3730 for adolescent vaccination. The study concluded that routine vaccination of infants in successive birth cohorts to prevent HBV transmission is cost-effective over a wide range of assumptions. While economically less attractive than infant vaccination, adolescent vaccination protects those children who were not vaccinated as infants.

20. Pegurri E, Fox-Rushby J. ***Effects, costs and cost-effectiveness of interventions to expand coverage of immunization services in developing countries: a systematic review of the published literature.*** **London, London school of Hygiene and Tropical Medicine, June 2002.**

Keywords: **immunization coverage, cost, cost-effectiveness**

The review identifies and summarizes the results of 29 interventions aimed at increasing coverage of immunization programmes. Outreach teams showed higher average costs per fully vaccinated child than mass campaigns and both were higher than routine services. However, outreach teams average costs showed wide variations and were significantly influenced by the design (like the employment of community health workers) of outreach strategies and the context (in particular population density) in which they were implemented. The strategies with the lowest average incremental cost per fully vaccinated child were peer training and channelling. Generalizing these results was problematic because of the lack of comprehensiveness and transparency that studies often show in the description of the interventions, evaluation methods and, in particular, in the inputs used.

21. **Resources for Child Health (REACH) Project, 1979–1987.** ***The costs of EPI: a review of cost and cost-effectiveness studies.*** **Arlington, VA, John Snow, Inc. 1988**

Keywords: **costs, evaluation, sustainability**

This document reviews approximately 30 cost and cost-effectiveness studies of EPI as part of the Immunization Sustainability Study (ISS) undertaken by the REACH Project for the Program and Policy Coordination Bureau of USAID. The objectives of this review are to assess the quality and consistency of cost and effectiveness data of EPI and to determine whether these data provide a basis for understanding the relationships between programme costs and coverage levels.

22. **REACH Project.** ***The costs of EPI: lessons learned from cost and cost-effectiveness studies of immunization programs.*** **Revised. Arlington, VA, John Snow, Inc., September 1990.**

Keywords: **EPI, costs, cost-effectiveness**

This document discusses what has been learned from a decade of EPI cost studies. In a time when dwindling resources require that national programmes yield greater coverage levels at less cost, cost-effectiveness analysis is an important tool to assist in decision-making about how to allocate scarce resources. However, some confusion remains concerning the underlying assumptions of cost analysis and the benefits of these studies for programme planning and management. This document was written to shed light on what is known about the cost of EPI as well as to clarify some of the strengths and weaknesses of the methods in use. Section one outlines current knowledge about the costs of national child immunization programmes. Section two provides information about how to conduct a cost-effectiveness study. Section 3 discusses future directions for the role of cost and cost-effectiveness evaluations in EPI as a whole. Additional discussion about cost-effectiveness methodology is found in Appendix C.

23. **Sangrujee N, Caceres V, Cochi S.** ***Cost Analysis of post-polio certification immunization policies.*** **National Immunization Program, Center for Disease Control and Prevention, USA, forthcoming.**

Keywords: **cost, cost-effectiveness, eradication**

Financial costs of three global policy options (Continued use of OPV, OPV cessation with optional IPV, and OPV cessation with universal IPV) were estimated for the time frame 2005–2020. Low-income countries were assumed to follow the recommended option while high-income and middle-income countries were assumed to switch to IPV regardless. OPV cessation with optional IPV, with an estimated cost of US$ 19 820 million, was the least costly option, while the policy option universal IPV had the highest financial costs. However, sensitivity analyses showed that global costs were sensitive about assumptions on the cost of the vaccine. Not taking into account the cost of vaccine-associated cases resulting from continued use of OPV, the break-even price of switching to IPV compared to continuing with OPV immunization is US$ 0.50. In addition to financial costs, risk assessments related to re-emergence of polio will be major determinants of policy decisions.

24. Van Damme P, Beutels P. Economic evaluation of vaccination. *PharmocoEconomics,* 1996. 9(Suppl.3):8–15.

***Keywords*: planning, management, cost–benefit, cost-effectiveness**

With increasing expenditures in health care, interest in the efficiency of certain interventions in healthcare has also increased. Faced with the limitations of the health care budget, budget holders try to find the optimal way of dividing their funds over different health care provisions, without discarding human and medical considerations. One instrument that can help in making such choices and which is advocated in this paper is the economic evaluation. In economic evaluations of vaccinations, different vaccination strategies are defined. The consequences in terms of costs and effects of each strategy are calculated and compared with a reference strategy, which is often the non-intervention strategy, i.e. "no vaccination". According to the way in which the benefit or the output of vaccination—"improvement of health"—is measured, a distinction is made between various methods of economic evaluation: in a *cost-effectiveness analysis*, health gains are measured in natural units (e.g. prevented infections, prevented illness days, life-years gained, etc.); in a *cost–utility analysis*, the quality of the health gains is taken into account (e.g. *quality-adjusted life-year*); and in a *cost–benefit analysis*, health gains are converted into monetary units.

3.2 Financing

25. Batson A. Sustainable introduction of affordable new vaccines: the targeting strategy. *Vaccine,* 1998, 16 (Suppl):S93–98.

***Keywords*: financing, accessibility, market segmentation**

Assuring that existing and new vaccines are available to all children in the world is a global health priority. Despite the clear health need and benefit, many countries have been unable to provide "new" vaccines to their populations. For these countries, the limitation has been the inability of governments to finance the vaccine because of a combination of factors including dependence on donors, donor policy, inadequate recognition by governments of the value of vaccines, and the absolute price of the vaccines. It is economics and not epidemiology which dictates introduction of the vaccine into national immunization programmes. UNICEF and WHO have developed and adopted a framework which differentiates countries based on their capacity to be financially self-sufficient for their vaccine needs. This framework forms the basis of strategies designed to coordinate the actions of governments, donors, agencies, and vaccine manufacturers in order to ensure all countries have rapid access to affordable vaccines. Indicators for the success of immunization programmes include relative wealth of the population (GNP per capita), total market size (GNP) and total population. Countries are plotted on a graph by population and GNP per capita. The third dimension, countries sharing a similar GNP, is then overlaid to form a curve. Countries falling within each curve share common levels of wealth and infrastructure and have similar capacity to be financially self-sufficient.

26. Chunsuttiwat S. Thai EPI and its financing: recent experience. *CVI Meeting on Sustainable Financing for Vaccination Program*. CVI, Geneva, 1999.

Keywords: **EPI, country experience**

Since the commencement of EPI in 1977, it has always ranked among the priority health programmes in Thailand. Over the previous two decades, the programme has been making continuous progress in several dimensions. It keeps adding new vaccines to the immunization schedule. The current immunization schedule offers 11 antigens including hepatitis B and Japanese encephalitis vaccines to preschool children. Immunization coverage has been steadily improving; the survey in 1996 revealed over 90% coverage for all childhood vaccines. Despite high average coverage rates, the programme is currently concerned about and focusing its attention on the underserved and hard-to-reach groups whose immunization status is inferior. Child immunization in Thailand is administered mainly through public health service infrastructure; only 10% of immunizations are provided at private hospitals and clinics. However, the private sector immunization is steadily gaining popularity, especially in urban centres.

27. DeRoeck D, Levin A. *Review of immunization programs in developing and transitional countries. Special initiatives Report 12*. Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., 1998.

Keywords: **costs, financing**

This paper presents a review of selected issues related to immunization financing in developing and transitional countries. Information for this review was obtained through an extensive literature search and through an e-mail survey sent to all UNICEF and PAHO country offices. Information is presented in four main areas: (1) the costs of immunization programmes, with a focus on the costs of introducing additional vaccines; (2) financing of immunization services, including trends in government vs donor funding, financing of new vaccines, and the use of cost recovery for immunization services; (3) the effects of a changing health sector on immunization financing, including the impact of decentralization, the role of the private sector in providing immunization, and the impact of disease eradication programmes; and (4) country experiences with international mechanisms to facilitate vaccine financing, such as the Vaccine Independence Initiative, the PAHO Revolving Fund, and the European Union initiative. In addition to summarizing existing information and lessons learned on the financing and costs of country-level immunization programmes, this paper identifies critical gaps in information on immunization financing. Further information will be obtained through a series of country case studies on immunization financing that the Partnerships for Health Reform Project is conducting in collaboration with WHO and PAHO.

28. **Global Alliance for Vaccines and Immunization (GAVI).** ***Guidelines for preparing a national immunization program financial sustainability plan.*** **Geneva, GAVI secretariat, 2003.**

Keywords: **sustainability, costs, financing**

This document provides information for recipients of Vaccine Fund support and their development partners about the financial sustainability plans (FSPs). FSPs are required of all beneficiaries of Vaccine Fund resources at the mid-point in funding (approximately two-and-a-half years after the first funds are received). The guidelines describe the purpose, suggested content and format, and suggested process for preparation of an FSP. The guidelines also contain annexes and corresponding Excel spreadsheets that facilitate the costing of the immunization programme pre-Vaccine Fund and projecting of future costs and financing of the national immunization programme. The guidelines and corresponding spreadsheets may be downloaded from the GAVI Financing Task Force website (www.gaviftf.org) in English, French, Portuguese and Russian.

29. **Institute of Medicine.** ***'Calling the shots': immunization finance policies and practices*****. Washington, DC, Division of Health Care Services and Division of Health Promotion and Disease Prevention, National Academy Press, 2002.**

Keywords: **financing, vaccine delivery**

Federal, state and private-sector investments in vaccine purchases and immunization programmes are lagging behind emerging opportunities to reduce the risks of vaccine-preventable disease. Although federal assistance to the states for immunization programmes and data collection efforts rapidly expanded in the early part of the 1990s, significant cutbacks have occurred in the last five years, which have reduced the size of state grant awards by more than 50% from their highest point. During this same period, the vaccine-delivery system for children and adults has become more complex and fragmented.

30. **Institute of Medicine.** ***Financing vaccines in the 21st Century: assuring access and availability*****. Washington, DC, Board on Health Care Services, Institute of Medicine, USA, 2003.**

Keywords: **financing, procurement**

The public–private partnership that has formed the foundation for purchasing and distributing vaccines in the United States over the past 50 years is showing signs of erosion. The existing national immunization system has performed well in achieving high levels of immunization for children. But difficult new challenges have emerged, including a growing number of recommended vaccines, higher prices associated with new vaccines, persistent disparities in immunization levels, low levels of immunization for adults with chronic illness, the growing burden of immunization on clinicians, recent shortages in the supply of vaccines and the increasing investment required to license and produce new vaccines.

In diagnosing the problems facing the vaccine system, the Institute of Medicine's Committee on the Evaluation of Vaccine Purchase Financing in the United States recognized that a strong relationship exists between the system for purchasing and administering vaccines and the stability and growth of the US vaccine supply industry. The committee's principal recommendation is the replacement of existing government purchasing programmes with a new vaccine insurance mandate subsidy, and voucher plan. The committee also recommends the initiation of a deliberative process, an evaluation study, and a research agenda to provide data and indicators that can guide future policy and practices with regard to vaccine financing.

31. Jarrett SW, Qi XQ. Financing of child immunisation services in China. *Asia-Pacific Journal of Public Health*, 1988, 2(1).

***Keywords*: EPI sustainability, financing, pre-payment, country experience**

China is accelerating its Expanded Programme on Immunization to reach 85% of children under one year of age in each county by 1990, thereby protecting them against six preventable childhood diseases. With around 20 million births a year, this is a daunting task. This review looks at the financing of child immunization services in China, not in its totality but focusing on the primary care level. In most parts of China, village doctors are responsible for carrying out immunization services in rural areas, where 80% of the population live. Different ways have been tried to pay village doctors for their work, with considerable variations at the local level. Two methods are beginning to create the conditions for long-term sustainability of services: (1) in poorer areas, county subsidies from the regular county health budget provide a regular monthly income for the village doctor; (2) in more economically-advanced areas, a pre-payment plan called the EPI contract, is enjoying considerable initial success in generating parental interest in child immunization and funds for paying village doctors as well as contributing towards the maintenance of EPI operations.

32. Kaddar M et al. *Case study of costs and financing of immunization services in Morocco. Special initiatives report 18*. Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., 1999.

***Keywords*: financing, planning**

The objectives of the study are to estimate the current and future costs of the country's immunization programme, to assist the ministry with programme planning, to provide recommendations to the Moroccan Government on ways to improve its financing strategies, and to draw lessons learned from Morocco's immunization financing strategies for the international health community at large. Financing strategies for immunization have become increasingly important due to Morocco's heavy reliance on external funding through donors such as the World Bank, and the analysis and recommendations in this study are presented in the context of prospects for financial sustainability. Costs and financing data used in the analysis were obtained through government documents and through government and private sector interviews. The financial analysis is based on estimated costs rather than expenditures recorded to provide a more inclusive accounting of costs. The analysis also provides estimates for

projected expenditures for the next five years. The report concludes with a set of options in the areas of programme planning, management, evaluation, research, vaccine procurement and supply, and financing structures to improve the financial sustainability of Morocco's immunization programme within health system reforms and global changes.

33. Kaddar M et al. ***Case study on the costs and financing of immunization services in Côte D'Ivoire.*** **Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., 2000.**

***Keywords*: costs, financing**

The Government of Côte d'Ivoire built a strong immunization programme over the five years prior to the study and saw significant gains in immunization coverage. The objectives of the study are to estimate the current and future costs of the country's immunization programme, to assist the Ministry of Health with programme planning, to provide recommendations to the government and its partners on ways to improve the financial sustainability of immunization activities, and to draw lessons learned from Côte d'Ivoire's immunization financing strategies for the international health community at large. Financing strategies for immunization have become increasingly important to Côte d'Ivoire due to its heavy reliance on external funding through donors such as the European Union. Costs and financing data used in the analysis were obtained from government documents and interviews in the government and private sectors. The study estimates the share of financing by each major funding source, both in terms of the total estimated cost of the programme and the "programme-specific" costs, that is, costs that are incurred specifically for the delivery of immunization services. It also projects expenditures required in the five years following the study to enact a series of improvements to the programme, including the introduction of hepatitis B and the expected gap in funding. This report suggests ways to improve the programme's financing to create a sustainable programme based primarily on country-level resources, including central government allocations, as well as potential new resources.

34. Kaddar M, Levin A. ***Costs and financing of immunization programs: funding of four case studies. Special initiatives report 26.*** **Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., May 2000.**

***Keywords:* cost, financing, sustainability**

This report summarizes and compares the results of in-depth case studies of immunization programme financing strategies in four countries (Bangladesh, Colombia, Côte d'Ivoire, Morocco). The cost analyses indicated that most of the costs of immunization programmes are recurrent, with personnel time accounting for over half of total costs, followed by vaccines (19–30%). Other recurrent costs such as transport and social mobilization accounted for less than 10% of total costs. Differences in the costs of national immunization programmes (NIPs) reflected varying service delivery strategies. Three NIPs used external funding to finance much of the costs of their programmes while the fourth, Colombia, was financed mostly by the government. The percentage of total costs financed by external sources (donors and World Bank loans) is 27%–42%. However, an examination of the

percentage of programme-specific costs (without personnel and building costs) financed by non-government sources shows the role of donor assistance and World Bank loans to be greater, comprising more than three-quarters of programme costs.

35. **Kaddar M, Makinen M.** ***Financing assessment tool for immunization services: guidelines for performing a country assessment. Health reform tools series.*** **Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., 2000.**

Keywords: **financing, sustainability, country assessment**

The immunization financing tool was developed by PHR to meet developing countries' needs for in-depth assessments of national immunization programme costing, financing, and planning issues at the regional and national levels. Following a narrative overview of the assessment process, the immunization financing assessment tool offers a checklist and tables that guide the user through information gathering, estimating the current costs and financing and developing a five-year plan. Findings are intended to help a country's health officials and international donors understand the costs and financing of an immunization, so that they can develop policies to ensure financial sustainability of the existing programme and plan improvements in terms of expanding coverage and adding new vaccines and technologies.

36. **Khaleghian P.** ***Immunization financing and sustainability: a review of the literature. Special initiatives report 40.*** **Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., 2001**

Keywords: **financing, cost-effectiveness, information gap**

This report reviews literature on cost and cost-effectiveness of immunization services. The review, which looks at 170 articles, focuses on published literature, but includes certain grey sources. References date back to the early 1980s, but most date from the mid-1990s, when immunization financing came to be treated as an independent subject. The report considers immunization financing under three headings: the costs of immunization programmes, the financing of the programmes, and the impact of health sector reforms. Each section contains a summary of key gaps in the literature, such as current global data and information on topics such as specific socio-political and institutional determinants of government support, new financing mechanisms such as user fees and risk-pooling schemes and changes in financial patterns over time. The report contains an annex that lists the 170 references.

37. Krasovec K, Connor C. ***Survey of tax treatment of public health commodities. Technical Report 17.*** **Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., 1998.**

Keywords: **tax, cost, vaccine**

This report summarizes the results of a survey of 44 countries on the tax treatment of public health commodities. The survey conducted in 1997 provided a view of which countries had granted tax relief on purchases of any of three public health commodities: vaccines, oral rehydration salts, and contraceptives. Tax status was found to vary more by buyer than by product. In particular, the public sector was most likely to benefit from substantial tax relief. The nature of obstacles to both measuring and achieving the intended impact of tax relief is discussed. Recommendations of the report include extending tax relief to the private sector and either grant exemptions instead of waivers or reduce the administrative burden associated with obtaining waivers.

38. Levin A et al. ***Case study on costs and financing of immunization services in Bangladesh. Special Initiatives Report 21.*** **Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., 1999.**

Keywords: **costs, decentralization, financing**

This study estimates the current and future costs of the country's immunization programme, including the additional costs of improvements to the programme, both to assist Bangladesh in planning its programme and to update and add to the available information on immunization costs of the global community. The Partnerships for Health Reform in collaboration with BASICS/Bangladesh and the Ministry of Health and Family Welfare (MOHFW) of Bangladesh, conducted an in-depth case study on the cost and financing of immunization services in Bangladesh. Cost and financing data for this analysis were obtained through government documents and in-depth interviews with key informants in the MOHFW, the donor community, nongovernmental organizations and international organizations.

39. Levin A et al. ***Case study on the costs and financing of immunization services in Ghana.*** **Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., 2001.**

Keywords: **costs, financing, Ghana**

This study estimates the current and future costs of Ghana's immunization programme, including the additional costs proposed for improvements to the programme, both to assist planning and to inform the international community about global immunization costs. The study provides the total cost of the national programme, including national immunization days (NIDs) and surveillance. In addition, the study provides the annual cost of improvements proposed for the national immunization programme for catch-up campaigns, disease control campaigns, cold chain improvements, and introduction of new vaccines. The following cost savings are proposed: (1) improving the vaccine distribution system; (2) decreasing vaccine wastage; and (3) motivating health workers to increase efficiency.

40. **Percy A, Brenzel L, Waty M.** ***Cost recovery for immunization: a worldwide survey of experience.*** **Arlington, VA, REACH Project, John Snow Inc., April 1991.**

Keywords: **financing, cost recovery, country experiences**

This document presents the results of a comprehensive survey of cost recovery mechanisms for EPI which are currently in place or which have been attempted recently in 103 countries. The survey includes 42 countries in Africa, 37 countries in Asia/Near East, and 24 countries in the Latin America/ Caribbean region. Results of this survey show that a wide variety of cost recovery or alternative financing mechanisms have been tried in many developing countries to raise additional resources for EPI or primary health care. Initiatives in both the public and private sectors are described. The authors recommend that detailed assessments of the most promising mechanisms be undertaken so that these experiences can be shared with other developing countries facing difficulties in financing immunization programmes.

41. **Schwartz J, Loevinsohn B.** ***Financing immunization in Cambodia, Lao PDR, and Viet Nam.*** **Manila, Philippines, Asian Development Bank, 1999.**

Keywords: **cost, financing, sustainability**

This study reviews the current and future financing of immunization in Cambodia, Lao People's Democratic Republic and Viet Nam. Important findings of the financial analyses include the fact that total immunization cost ranged from US$ 0.10 to US$ 0.20 per capita and that Cambodia and Lao People's Democratic Republic contribute only 14% and 3%, respectively, of EPI costs, which contrasts sharply with Viet Nam where the figure is about 60%. It was also found that foreign exchange expenditures for vaccines, injection and cold chain equipment, and technical assistance account for 70–80% of total immunization costs. The study also discusses the financing mechanisms to ensure sustainability of the existing programmes and meet future challenges.

42. **Woodle D. Vaccine procurement and self-sufficiency in developing countries.** ***Health Policy and Planning,*** **2000, 15(2):121–129**

Keywords: **supply, financing, sustainability**

This paper discusses the movement toward self-sufficiency in vaccine supply in developing countries (and countries in transition to new economic and political systems) and explains special supply concerns about vaccine as a product class. It traces some history of donor support and programmes aimed at self-financing, then continues with a discussion about self-sufficiency in terms of institutional capacity building. A number of deficiencies commonly found in vaccine procurement and supply in low-income and middle-income countries are characterized, and institutional strengthening with procurement technical assistance is described. The paper also provides information about a vaccine procurement manual being developed by USAID and WHO for use in this environment. Two brief case studies are included to illustrate the spectrum of existing capabilities and different approaches to technical assistance aimed at developing or improving vaccine procurement capability. In conclusion, the paper discusses the special nature of vaccines and issues surrounding potential integration and decentralization of vaccine supply systems as part of health sector reform.

3.3 Policy

43. Achat H, McIntyre P, Burgess M. Health care incentives in immunization. ***Australian and New Zealand Journal of Public Health,*** **1999, 23(3):285–288.**

Keywords**: financial incentives for immunization, immunization uptake, country experience**

Australia has introduced a nationwide immunization incentive scheme. This two-year programme offers financial rewards to providers and parents to encourage childhood immunization. The objective of this study was to review the use of incentives in immunization uptake in various countries, to identify issues in developing an incentive programme for childhood immunization, and to examine the findings within the context of the Australian scheme. In Australia, the Immunise Australia Program comprises initiatives directed towards general practitioners and parents. The General Practice Immunization Incentive scheme, introduced in 1998, offers cash incentives to general practitioners upon notification to the Australian Childhood Immunization Register and an Outcomes Bonus payment related to the age of fully immunized children attending the practice. Conclusions drawn from the analysis include that both monetary and non-monetary incentives can improve childhood immunization uptake; however, effective incentives require collaboration of key players.

44. Batson A. Assuring affordable hepatitis B vaccine for the world. In: Rizzetto M Purcell et al. ***Viral hepatitis and liver disease.*** **Turin, Edizioni Minerva Medica, 1997.**

Keywords: **HepB, procurement, accessibility, affordability**

Despite the clear health need and benefit, many countries have been unable to provide the hepatitis B vaccine to their populations. For these countries, the limitation has not been the delivery structure¾it has been the inability of governments to afford the vaccine because of a combination of price, donor policy and historical government dependence on donors. Due to the high disease burden of hepatitis B, the existence of an effective vaccine, and the compatibility of delivery with the existing EPI infrastructure, this vaccine is a priority for introduction. All countries could have affordable access to vaccines to protect their children. By using the existing infrastructure more broadly, and by focusing on the priority countries and vaccines, the global community could achieve the maximum health impact with every dollar used. The global community could also ensure a net increase in funds as country budgets in wealthier developing countries expand to take on the responsibility of existing and new vaccines.

45. Batson A. Win–win interactions between the public and private sector. *Nature Medicine Vaccine Supplement,* May 1998, 4(5):487–91.

Keywords: **public/private sector partnership, industry, pricing**

As both the public and private sectors look with increasing interest at vaccines, they are discovering that their efforts are inextricably linked, with the actions of one having significant impact on the risks, costs and goals of the other. Rather than an adversarial relationship, the players are finding, somewhat to their surprise, that open dialogue and tailored strategies can be mutually advantageous. Global availability of an affordable product and adequate financial returns can be achieved simultaneously. This can only occur if the sectors work together to ensure tiered pricing, timely investment in global capacity, and targeted procurement strategies.

46. Bishai D, Suzuki E. The role of public health programs in reducing socioeconomic inequities in childhood immunization coverage. *Health Policy and Planning*, 2003, 17(4):412–419.

Keywords: **immunization coverage, outreach services, equity**

Can intensive outreach services eliminate socioeconomic differentials in vaccine coverage? In 1990, the Matlab Maternal and Child Health/Family Planning Project (MCH-FP) surveyed 4238 respondents in an intervention area that received outreach and 3708 respondents in a comparison area in rural Bangladesh. Interacted multiple regression methods were used to assess the degree to which various socioeconomic indicators predicted the probability of vaccine receipt in each area. Low parental schooling, small dwelling size and female gender were significantly associated with incomplete vaccination in the comparison area, where only the limited government services existed. Residence in the MCH-FP outreach area greatly reduced, and in some cases eliminated, the effects of these socioeconomic barriers to vaccine receipt. Therefore, public health programmes utilizing outreach can reduce prevailing gender and socioeconomic differentials in vaccine receipt.

47. England S. *Options for a global fund for new vaccines.* Geneva, World Health Organization, March 1999.

Keywords: **financing, new vaccines, accessibility**

A global fund for new vaccines is being put forward as one possible part of a system for expanding and improving vaccination. In this paper, five parameters of such a fund are explored: equity, impact, feasibility, sustainability and scope. For each, goals such as access, effectiveness and independence are discussed. This paper includes an analysis of which other goals are compatible and which would involve trade-offs. The goal of coverage is not always consistent with the goal of equity. Goals of efficiency, feasibility, sustainability and focus/simplicity may involve trade-offs with equity. However equity is consistent with efficiency when the practice of efficiency greatly reduces or eliminates the need for rationing of resources. Arguments for greater access include equity, solidarity and social justice. Arguments against access include feasibility and efficiency.

48. England S, Kaddar M. Practice and policies on user fees for immunization in developing countries. Geneva, World Health Organization, March 2001 (document number WHO/V&B/01.07).

Keywords: **user fees, immunization coverage, equity**

This paper recalls the Addis Ababa consensus on the principles of cost sharing in education and health, which among others states that cost sharing should exempt preventive care, in which benefits extend beyond users (e.g. immunization). The paper then reviews the literature related to user fees and immunization financing (annex includes an annotated bibliography). As user fees discourage people, especially the poor, from seeking vaccination, they have a negative impact on both coverage rates and equity. Moreover, they are difficult to administer and usually cover only a fraction of the full cost. The key message of the study is therefore that essential immunization services should be provided at no charge in order to meet public health goals.

49. Fairbank A et al. *Poverty reduction and immunizations considering immunizations in the context of debt relief for poor countries.* Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., 2000.

Keywords: **debt relief, financing, poverty reduction**

There is a strong case for including immunizations as part of poverty reduction strategies for most, if not all, heavily indebted poor countries. Poor health is both a major cause and a result of poverty. Immunizations are among the most cost-effective health interventions and can help break out of the negative cycle of poverty and poor health. The occasion of debt relief offers the opportunity for immunization programmes to be strengthened. The additional resources can be used to increase immunization coverage, to improve the quality of services, to add new antigens and to preserve and ensure the sustainability of the programme. The strengthening of immunization programmes can be expected to contribute to breaking the negative cycle of poverty and ill health.

50. Feilden R, Nielsen OF. *Immunization and health reform: making reforms work for immunization.* Geneva, World Health Organization, April 1998.

Keywords: **decentralization, country experience, service delivery**

This document has been prepared to provide some insights into how quality immunization services can be sustained in a reformed and decentralized health system, especially if integration disbands the vertical EPI programme. This document presents two case studies of countries which have approached reforms in very different ways, and highlights the lessons learned. It is likely that the old systems used for vertical programme must be changed to fit the reformed structures and processes; appropriate solutions will be specific to a particular setting. Reforms are likely to involve operational changes in the way that immunization services are to be managed. Integration of services is often perceived to provide a more cost-effective approach than the vertical programmes. Monitoring and reviews provide ways of assessing the execution of essential functions at the national level and management of immunization services through all levels of the system.

51. **Foster S.** ***Sustaining and improving benefits of immunization within Zambian health reform. September October 1997.*** **Government of Zambia, WHO, UNICEF, DANIDA, JICA, and USAID (BASICS), 1998.**

Keywords: **country experience, decentralization**

To improve availability, access, delivery and quality of an identified package of essential health services, the Government of Zambia has decentralized planning, management, implementation and evaluation of health services to the district level. Reform initiated in 1992 is now functioning in all districts. Based on past Zambian field experience of the Team Leader and the Cold Chain Expert, major improvements in the availability, coverage and quality of the essential services have been and are being achieved. A major strategy of health reform in Zambia involves shifting resources including personnel from the central Ministry of Health to the district level. Although this review was initially planned as a standard EPI review using WHO modules, the format was found to be inconsistent with government policy and was shifted to its current format. As Zambian policy focuses on integrated delivery of services, review format was broadened to delivery of immunization within the framework of preventive service delivery. The review examines vaccine supply, service delivery, communications and health information systems.

52. **Gauri V, Khaleghian P.** ***Immunization in developing countries: its political and organizational determinants. Policy, Research Working Paper series 2769.*** **World Bank, January 2002.**

Keywords: **Political economy, immunization coverage, policy**

This paper uses cross-national social, political, economic and institutional data to explain why some countries have stronger immunization programmes than others, as measured by DTP and measles vaccine coverage rates and the adoption of hepatitis B vaccine. After reviewing the existing literature on demand and supply factors that affect immunization programmes, the paper finds that the elements that most affect immunization programmes in low-income and middle-income countries involve broad changes in the global policy environment and contact with international agencies. Democracies tend to have lower coverage rates than autocracies, perhaps because bureaucratic elites have an affinity for immunization programmes and are granted more autonomy in autocracies, although this effect is not visible in low-income countries. The paper also finds that the quality of a nation's institutions and its level of development are strongly related to immunization rate coverage and vaccine adoption, and that coverage rates are in general more a function of supply-side than demand effects. There is no evidence that epidemics or polio eradication campaigns affect immunization rates one way or another, or that average immunization rates increase following outbreaks of diphtheria, pertussis or measles.

53. Hausdorff WP. Prospects for the use of new vaccines in developing countries: cost is not the only impediment. *Vaccine,* 1996, 14(13):1179–1186.

Keywords: **management, new vaccines, costs**

Global immunization programmes represent a great public health success story. Evidence from every region documents substantial reductions in morbidity and mortality following widespread use of vaccines developed years ago. Development and introduction of new vaccines and vaccine combinations aimed at the industrialized world market are occurring at a fast pace. A number of political and economic factors will influence the rate at which developing country immunization programmes incorporate those new vaccines that could have a major public health impact. Perhaps the greatest determinant of this rate is the extent to which international and bilateral agencies and national governments appreciate the potential value of new vaccines. UNICEF recently issued a new vaccine supply strategy, encouraging countries to become self-financing for vaccine purchases and targeting its funds towards the neediest countries with strong immunization programmes. This article advocates for developing countries and donor agencies to look to the Children's Vaccine Initiative (CVI) and WHO for guidance in determining the relative value of new vaccines and for CVI and others to articulate the value of new vaccines.

54. Khaleghian P. *Decentralization and public services: the case of immunization policy. Research Working Paper series 2989.* World Bank, March 2003.

Keywords: **decentralization, health sector reform, financing**

The impact of political decentralization on childhood immunization is examined empirically using a time-series data set of 140 low-income and middle-income countries from 1980 to 1997. In the low-income group, decentralized countries have higher coverage rates than centralized ones, with an average difference of 8.5% for the measles and DTP3 vaccines. In the middle-income group, the reverse effect is observed: decentralized countries have lower coverage rates than centralized ones, with an average difference of 5.2% for the same vaccines. Both results are significant at the 99% level. In the low-income group, development assistance reduces the gains from decentralization. In the middle-income group, democratic government mitigates the negative effects of decentralization, and decentralization reverses the negative effects of ethnic tension and ethno-linguistic fractionalization, but institutional quality and literacy rate have no effect either way. The study confirms predictions in the theoretical literature about the negative impact of local political control on services that have public goods characteristics and inter-jurisdictional externalities. Reasons for the difference between low-income and middle-income countries are discussed.

55. **Knippenberg R et al. Sustainability of primary health care including expanded program of immunizations in Bamako Initiative programs in West Africa: An assessment of 5 years field experience in Benin and Guinea.** ***International Journal of Health Planning and Management,*** **1997, 12 (Supp.1):S9–S28.**

Keywords: **management, sustainability**

Since 1986, Benin and Guinea have taken on the task of reorganizing their peripheral health systems. Their objective was to improve health system performance despite their former decline due to inefficient management and economic crisis. This paper is an explanation of how, in these two countries, national programmes revitalized the existing health centre network in order to improve the effectiveness and efficiency of health services, while ensuring sustainability and establishing equity mechanisms.

56. **Levine R, Rosenmuller M, Khalegian P.** ***Financial sustainability of childhood immunizations: issues and options, GAVI discussion paper.*** **Geneva, GAVI secretariat, 2001 [draft].**

Keywords: **financing, sustainability, policy**

This paper provides a framework for discussion about what developing countries and development partners can do to promote and measure financial sustainability of immunization systems. After reviewing estimates of the magnitude of current and future financial requirements, the paper describes the key dimensions of financial sustainability and discusses what actions developing country governments and development partners can take to promote financial sustainability. The first dimension of financial sustainability is the efficiency of the supply chain, which includes technical efficiency, efficiency in vaccine procurement and sustained demand. The second dimension is the appropriateness of the funding structure, which consist of mobilizing sufficient reliable financing (for vaccine procurement, labour and other recurrent costs, and capital) as well as ensuring timely resource flows to service delivery points.

57. **Leighton C.** ***Country and international donor financing strategies for sustainability of the EPI in Africa: experience from the USAID Health Financing and Sustainability Project.*** **Bethesda, MD, Health Financing and Sustainability Project, Abt Associates Inc., 1992.**

Keywords: **EPI, sustainability, financing**

Economic and budgetary constraints have forced consideration of the sustainability of EPI in Africa. Recommendations by the World Health Organization for the addition of new and improved vaccines and specific targets for the eradication of polio, elimination of neonatal tetanus and control of measles heighten sustainability issues. The purpose of this paper is to identify key problems related to the financial sustainability of EPI, suggest feasible strategies and options countries can consider to promote sustainability, and identify possible donor roles. It considers sustainability of EPI in the context of new immunization strategies and the changing supply and price factors of the vaccine market. It also addresses these issues in the context of broader African economic conditions and efforts to reform financing of the health sector as a whole.

58. Mahoney RT, Ramachandran S, Xu ZY. ***Financing of new vaccines for developing countries.*** **Seoul, Korea, International Vaccine Institute, 1999 [draft].**

***Keywords*: new vaccines, financing**

The development of new vaccines for important childhood diseases presents an unparalleled opportunity for disease control but also a significant problem for developing countries: how to pay for them. All children no matter where they live and no matter rich or poor should have access to vaccines to prevent needless illness and death. To address this problem, the international community should establish a Global Fund for Vaccines (Global Fund). Allocation of Global Fund to individual countries would be guided in part by a Vaccine Procurement Baseline (VPB) of 0.01% of gross national product (GNP) as an appropriate amount each developing country should devote to its own vaccine procurement. When this amount is not sufficient to procure the vaccines needed by a developing country, the Global Fund would meet the shortfall. The amount required of donors to maintain the Global Fund would be about US$ 430 million per year for both existing EPI vaccines as well as five new vaccines costing US$ 0.50 per dose and requiring three doses per child. Including programme costs, poor developing countries currently spend about 0.13% of GNP on EPI immunizations. The addition of five new vaccines could increase this to about 0.20% of GNP. In contrast, the United States, as one example donor country, spends about 0.035 to 0.07% of GNP for childhood immunization including several new vaccines.

59. Msambichaka K. ***Sustaining immunization efforts under health reforms: challenges for Africa.*** **[CVI meeting.] New York, UNICEF, 1998.**

***Keywords:* sustainability, country experiences**

A number of African countries are implementing health reforms. The aim is to reorganize health service delivery systems to become cost-effective, efficient, affordable and sustainable. Immunization services are part of the cost-effective basic health care package identified by the health reforms. They are still not functioning well in most countries of Africa. They deserve special attention during the health reform process to ensure that the services are improved and sustained. Experiences from Tanzania, Uganda and Zambia are used to identify specific responsibilities of different players in order to ensure that high-quality effective immunization services are sustained in Africa.

60. SAGE. ***What actions will accelerate the introduction of new vaccines?*** **[Background paper for the Meeting of the Scientific Advisory Group of Experts (SAGE), 9–11 June 1998.] Geneva, Global Programme for Vaccines and Immunization, WHO, 1998.**

***Keywords*: new vaccines**

A number of highly effective vaccines are available beyond the six originally recommended for wide use by WHO, but many countries do not use them in their national immunization programmes. The CVI Task Force on Strategic Planning judges these to be "underused" vaccines and recommends actions to bring them into appropriate wider use. It also recommends examination of the utility of other vaccines, such as typhoid, in particular disease-endemic

situations. Many deaths and much suffering and disability could be averted by earlier adoption of these and other vaccines. It is therefore important to identify ways in which the process of new vaccine introduction can be accelerated. An appropriate balance needs to be achieved between extending coverage where it is already high, the launching and timing of eradication efforts, and adding new vaccines to the existing delivery system.

61. SmithKline Beecham. ***First Asia-Pacific regional consultation on economic and policy considerations for the introduction and use of new vaccines.*** **27–29 April 1998. Chiang Mai, Thailand. 1998.**

Keywords: **new vaccines, public/private partnership, financing**

All bodies involved in immunization programmes must plan for the future. It is imperative that long-term planning for new vaccines is undertaken now, and that decision-making for the introduction of such vaccines is based on an informed understanding of disease epidemiology, and of the likely impact and benefit to be derived from the use of such vaccines. This consultation brought together leading experts and policy makers, as well as representatives of international organizations and private industry, and allowed for a broad-based assessment of the opportunities and concerns in Asia and the Pacific Rim in relation to new vaccine introduction and use. Issues addressed included concerns regarding information needs for rationalizing the decision-making process, promoting cooperation and collaboration between public and private sectors, and financing the introduction of new vaccines in a manner which best meets the interests of the consumer.

62. Swanson P. ***Developing benchmarks for financing immunization. Econ Report 25/03.*** **Oslo, Norway, Bill and Melinda Gates Foundation, Econ Centre for Economic Analysis, Oslo, Norway, 2003.**

Keywords: **benchmarks, sustainability, policy**

This report was commissioned by the Bill and Melinda Gates Foundation to advise the Global Alliance for Vaccines and Immunization (GAVI) on the development of benchmarks for financing immunization. The benchmarks are for splitting the cost of an increase in immunization coverage between donors and recipient countries in the "medium term". The report examines several possible methods for developing benchmarks, for identifying "good practice" countries on which benchmarks could be based, and for dividing countries into peer groups for which benchmarks may be tailored. Peer groups are best formed on the basis of per capita income at purchasing power parity. Since donor funding for basic immunization services is comparatively easy to obtain, countries may behave rationally in relying heavily on such funding. It therefore becomes problematic to judge good practice on the percentage of immunization funds that come from a government's own resources. ECON argues that a government could be expected to supply at least the same share of the cost of the basic vaccination package as it spends on the "basic health package" (a notion developed by the Working Group 5 of the Commission on Macroeconomics and Health, World Health Organization, 2001).

63. *Situation analysis: Report on findings of immunization working group.* **Washington, DC, USA, World Bank, February 1999.**

Keywords: **financing**

In March of 1998, the President of the World Bank, James Wolfensohn, hosted a meeting entitled Vaccine Development and Delivery: Leadership for the 21st Century. Motivated by an increased recognition of the value of vaccines, these leaders called for the creation of a working group to prepare recommendations on how to revitalize global effort in immunization. This report calls for a coordinated effort which would look like a modified version of the global coalition, Children's Vaccine Initiative.

64. **GAVI.** ***Addressing financing in a coordinated effort: Strategies to finance the purchase of vaccines and strengthen the immunization infrastructure.*** **Working group of the Global Alliance for Vaccines and Immunization. Washington, DC, World Bank, 1999.**

Keywords: **policy, management, financing**

This report discusses the various options for interventions to ensure that immunization programmes worldwide are sustained and strengthened. These would include new funding mechanisms such as a Global Vaccine Fund, as well as advocacy activities.

65. **SAGE.** ***Financing of new vaccines: what are our options?*** **[Paper presented at the Scientific Advisory Group of Experts (SAGE), Geneva, 9–11 June 1998]. Geneva, WHO, 1988.**

Keywords: **management, financing, new vaccines**

Around two million childhood deaths still occur annually as a result of vaccine-preventable diseases. The most important issue for resolving this looming crisis is the mobilization and allocation of new or additional resources required for the introduction of new vaccines. To overcome past difficulties in financing new vaccines, new strategies need to be introduced. First, a country-based approach is imperative. In order for sustainable vaccine financing to be successful, governments need to be responsible for their individual national immunization programme both financially and technically. Second, while it must be stressed that the ideal would be for countries to finance their recurrent public vaccine costs through their own budgets, the reality is that many countries cannot do so or will have difficulty absorbing the cost of new vaccines. One option for remedying these costs is to use development loans. For infrastructure building, particularly regarding capital expenses, the use of loans can be quite beneficial. In addition, short-term or one-time purchases of vaccines can also be considered as an appropriate use of loan financing. Loans are best used as limited-term measures that enable countries to prioritize and expand their own budget lines for necessary vaccine purchases. They are poorly used if they serve as excuses to avoid this, or if they encourage countries to live beyond their means by supporting unsustainable purchases.

3.4 Vaccine market

66. Ainsworth M, Batson A. *Accelerating an AIDS vaccine for developing countries: issues and options for the World Bank.* Washington, DC, USA, World Bank, 1999.

Keywords: **HIV/AIDS, vaccine investment, vaccine development**

An HIV vaccine that is effective and affordable in developing countries would improve the prospects for reducing the scope of the epidemic, not just in developing countries but across the world. Both public and private investment for the HIV/AIDS vaccine is currently small and oriented toward the needs of the richest countries. In April 1998, the World Bank set up an institution-wide task force to examine ways in which it could help accelerate the development of an AIDS vaccine for developing countries, as one element of its broader programme to combat AIDS. The World Bank's objective is not only to ensure that a vaccine is developed, but also to guarantee the broad and early access of developing countries to a vaccine adapted to their needs. This paper reviews what the AIDS Vaccine Task Force has learned to date about the nature of the problem of under-investment in an HIV/AIDS vaccine for developing countries, and summarizes some of the approaches under consideration. After discussing the market potential for a vaccine in developing countries, the paper outlines various strategies to increase investment. These strategies include "push" interventions (direct support for research, reducing the costs/risks of clinical trials) and "pull" interventions (expanding lending for existing vaccines, providing better information on developing country markets, market assurances).

67. Bishai D, Lin M, Kiyonga C. Modeling the economic benefits of an AIDS vaccine. *Vaccine,* 2001, 20:526–531.

Keywords: **demand, cost-effectiveness, AIDS vaccine**

This paper describes the potential for an AIDS vaccine with a simple economic model. In terms of avoided medical spending, preventing 75% of the AIDS risk for 10 years in one adult male is estimated to be worth US$ 343 in Western Europe, US$ 4.59 in south and south-east Asia, and US$ 2.67 in sub-Saharan Africa. The expected medical savings from a 75% effective vaccine would exceed US$ 25.00 per person for over 700 million people. The mismatch between the public health needs and market forces is highlighted by the fact that, although an AIDS vaccine would save more lives in poverty stricken areas, it would save more money in developed countries. The model can be recalculated to include savings on lost productivity and an "equity perspective" where monetary values for medical spending and lost productivity from Western countries are applied to the whole world.

68. *Immunization financing in developing countries and the international vaccine market: trends and issues.* **Manila, Philippines, Asian Development Bank, 2001.**

Keywords: **supply, price, financing**

The first part of this study gives a picture of the international vaccine procurement and financing mechanisms, in particular the Revolving Fund of the Pan American Health Organization and the Vaccine Independence Initiative of UNICEF. It then describes the main characteristics of the international vaccine market and key factors affecting vaccine prices, including development and production costs, demand, predictability of demand, production capacity, competition and intellectual property rights. Strategies to make vaccines more accessible in developing countries such as tiered pricing and bulk procurement are also discussed. The case of the price history of the hepatitis B vaccine is taken as an example to illustrate the relative importance of these factors.

69. **Kaddar M, Guerin N, and de Champeaux A.** ***Le marché du vaccin et l'avenir des programmes de vaccination en Afrique. Séminaire-atelier, 8–10 Décembre 1992.*** **[The Vaccine Market and the Future of Vaccination Programs in Africa. Seminar Proceedings, 8–10 December 1992]. Centre International de l'Enfance, Paris, 1992.**

Keywords: **EPI, market segmentation, industry, accessibility**

Although accounting for less than 2% of the world pharmaceutical market, the vaccine market has been evolving since 1990. International experts, national EPI managers and vaccine producers participated in a conference on the vaccination programmes in Africa (organized by the International Children's Center); underlined the need to improve the sustainability of the Expanded Programme of Immunization activities and emphasized the necessary but complex analysis of vaccine needs (including stock inventory and the cost of stock losses). The world market is segmented by type of country (industrialized and developing) and by type of product (basic, inexpensive vaccines and new costly vaccines). The level of access to vaccines is strongly determined by economic and financial considerations. This document explains the implications of access for developing countries.

70. **Kremer M. Creating markets for new vaccines: Part I: Rationale. In: Jaffe AB, Lerner J, Stern S, eds.** ***Innovation policy and the economy, Volume 1.*** **Cambridge, MA, Massachusetts Institute of Technologies, MIT Press, 2001.**

Keywords: **vaccine market, R&D incentives, purchase commitments**

This paper describes the market failures affecting the vaccine market and the scope of purchase commitments as a way to create incentives for vaccine research and development. Since there is a tendency for under-consumption of vaccine for a number of reasons, and research for major pandemics is a global public good, private developers lack incentives to pursue socially valuable research opportunities. Purchase commitments may be attractive relative to other ways of rewarding vaccine developers, since they would require no expenses until a vaccine is actually developed and would avoid access problems associated with intellectual property protection. However, the combination of the need to commit large sums, and uncertainty as to whether purchase commitments would actually work, make setting up a purchase commitment difficult.

71. **Kremer M. Creating markets for new vaccines. Part II: Design issues. In: Jaffe AB, Lerner J, and Stern S, eds. *Innovation policy and the economy, Volume 1*. Cambridge, MA, Massachusetts Institute of Technologies, MIT Press, 2001.**

Keywords: **R&D incentives, purchase commitments, supply**

This paper describes how vaccine purchase commitment as proposed in the twin paper "Creating Markets for New Vaccines: Part I: Rationale" could work. For vaccine purchase commitments to spur research, potential vaccine developers must believe that the sponsor will not renege on the commitment once vaccines have been developed and research costs sunk. Courts have ruled that similar commitments are legally binding contracts. Given appropriate legal language, the key determinant of credibility will therefore be eligibility and pricing rules, rather then whether funds are physically set aside in separate accounts. The credibility of purchase commitments can be enhanced by specifying rules governing eligibility and pricing of vaccines in advance and insulating those interpreting these rules from political pressure in the long term.

72. **Mercer Management Consulting. *Economic framework for global vaccine supply: optimal methods to meet global demand. Report for Children's Vaccine Initiative.* Geneva, Children's Vaccine Initiative, February 1997.**

Keywords: **costs, market, industry**

This document is a presentation from the meeting on "The Global Supply of New Vaccines" and provides a synthesis of the Children's Vaccine Initiative's work on the vaccine industry and the economics of the vaccine supply. Included are numerous graphics designed to highlight the major elements in their analysis. A summary of findings is as follows: First, volume effects dominate the cost behaviour of the vaccine industry. Scale and utilization drive fixed cost per dose, learning drives batch yields, and marginal volume has significant value. Second, revenue effects (pricing) are critical to the industry's profitability. Market mix is characterized by low volumes at high prices and high volumes at low prices. If forced to choose, a commercial supplier will opt for low volumes at high prices. However, this choice is not optimal for either public or private customers because for commercial suppliers it reduces available volume and increases costs and for customers it limits availability. The most profitable route for a supplier is to maximize volume, serving all segments of demand at appropriate price points.

73. **Mercer Management Consulting. *Lessons learned: new procurement strategies for vaccines.* [Final report to the GAVI Board, GAVI Secretariat.] Geneva, GAVI, June 2002.**

Keywords: **costs, market, industry**

This study was commissioned by the GAVI Financing Task Force Procurement Subgroup to build a fact base around the global vaccine market including the suppliers, market segments and economics and determine implications for GAVI's procurement strategy. The report is based on a comprehensive review of publicly available data and interviews with suppliers, customers, regulators and experts. It includes text discussion and graphic illustration of

key factors and trends in vaccine economics, such as market growth, demand divergence, product segments, presentation and batch size effects, and producer segments (European and US multinationals, OECD locals, emerging suppliers, developing country locals). The size of the vaccine market, profitability and R&D investment, have all increased significantly in the last 10 years, driven predominantly by high-income country demand. Vaccine production costs are highly volume sensitive and are mostly fixed (60%) or semi-fixed (25%). The recommendations for GAVI include establishing indicators and milestones to measure performance and progress and sharing information on demand, product preference and future needs with industry, unless there is a well-defined reason not to do so.

3.5 General information on immunization financing

74. CVI. ***Sustainable financing for vaccine programmes.*** **[Background paper for the meeting on sustainable financing for vaccination programmes at Labouisse Hall, UNICEF House, New York, 4–5 February 1999.] New York, Children's Vaccine Initiative, 1999. [Meeting report and associated document:** ***A framework for immunization financing*****. New York, CVI, 1999.]**

Keywords**: new vaccines, financing, economic evaluation**

Because of the complexity surrounding immunization financing, it is crucial to develop financing strategies which address the needs of all aspects of immunization programmes. At the CVI Meeting on Sustainable Financing for Vaccination Programmes, a framework was constructed which examines variables in immunization financing. This framework takes into consideration various needs, country types, possible economic and financing interventions, as well as players in immunization programmes. It should serve as a tool that can highlight and make more explicit certain aspects of the complex financing issue to enable effective action.

75. Dietz V, Cutts F. The use of mass campaigns in the Expanded Program on Immunization: A review of reported advantages and disadvantages. ***International Journal of Health Services,*** **1997, 27(4):767–790.**

Keywords**: mass immunization campaigns, planning**

The use of mass immunization campaigns (MICs) has been and remains controversial. To evaluate these campaigns, the authors review the literature relating to their effectiveness, sustainability and cost-effectiveness in controlling diseases and raising immunization coverage levels, and their impact on the subsequent development of routine immunization services. Well-conducted campaigns have increased vaccine coverage levels and decreased disease morbidity and mortality. However, unless infrastructure is improved or campaigns are repeated, gains in coverage levels may not be sustained. Studies suggest that MICs are often not as cost-effective for raising coverage as the delivery of vaccines through routine services, but the use of coverage as the only outcome measure is questionable. Mass immunization campaigns can increase awareness of vaccine and may be appropriate in situations where new programmes are to be initiated. Little information is available on whether MICs strengthen or interfere with the development of routine services. To be successful, MICs require a well-coordinated and planned effort on the part of national authorities with the identification of specific goals, intensive social promotion, and strong management.

76. *Vaccins et maladies virales: plan directeur, 1er rapport*. **Bruxelles, European Commission, 1995.**

Task Force on Vaccine and Viral Diseases: master plan, first report. **Brussels, European Commission, 1995.**

Keywords: **industry market, research**

The mobilization and coordination of research activities on vaccines and viral diseases is one of the eight areas identified by the European Commission in pursuing its regional development efforts among member countries. The report focuses on improved knowledge of viral infections, general infectious diseases, as well as general financing issues. This report also presents the guidelines of the programme in describing the status of the European and global vaccine market, and identifying the needs and priorities for future research.

77. **Freeman P.** ***The PAHO revolving fund: History operations and contributions to speeding vaccine introductions.*** **[An information paper for the Children's Vaccine Initiative.]**

Keywords: **management, financing, procurement**

This paper describes the strategy of the Americas region for improving immunization programmes and for the introduction of new vaccines, emphasizing how the Revolving Fund is employed towards those ends. When established, the Fund's objectives were limited to more traditional procurement and financing tasks. The Revolving Fund is one component of the overall strategy of procurement to sustain immunization financing activities. Many outside the Americas region have not realized the explicit management of this mechanism by PAHO to accelerate systematic uptake of vaccines; when and where cost effectiveness can be demonstrated. This paper describes the history, operations and strategy of the Fund. Evaluation of programme effects from the perspective of the countries served exceeds the scope of this presentation.

78. **Global Alliance for Vaccines and Immunization (GAVI).** ***Immunization financing options*****. Geneva, GAVI Secretariat, 2002.**

Keywords: **sustainability, costs, financing, debt relief, SWAps**

Immunization Financing Options are short, user-friendly briefing sheets that outline options for financing national immunization services. Principally intended for policy makers in ministries of health, finance and planning and investment, the briefing sheets bring together up-to-date knowledge about the major advantages and drawbacks of available financing options. Financing options covered include: general revenues at national and subnational levels, project grants, debt relief proceeds through HIPC II, sector-wide approaches, national budget support, Vaccine Fund support, user fees, cross-subsidies, health insurance, national trust funds, and revolving funds. The briefing sheets also introduce key concepts related to the financing of immunization services, such as the economics of vaccine production and pricing.

79. **Kaddar M et al.** ***Training manual vaccines: financing and management.*** **Paris, International Center for Children and the Family, 1998.**

Keywords: **management, procurement, and financing**

This training manual aims to strengthen the capabilities of immunization programme leaders to negotiate and organize the central procurement, optimal management and distribution of vaccines at intermediary and peripheral levels. It is divided into four parts. Part one, entitled *Vaccine Economics*, works to enable participants to understand the specific economic features of vaccine as a "product" and to understand the characteristics of the vaccine market and its recent evolution. Part two, named *Supply Factors*, strives to help participants understand the characteristics of world supply and demand for vaccines and to identify supply factors, and sources and methods of financing. *Procurement*, the third part, is intended to facilitate and improve the effectiveness of procurement. This section aims to enable participants to do the following: estimate their needs as a function of different strategies; identify procurement opportunities on the international market; and facilitate steps to seek out, select, and negotiate with suppliers. The fourth and final part, entitled *Distribution* is designed to enable participants to make management methods and distribution systems more efficient in order to lower costs.

80. **Levin A, Jorissen J.** ***Impact of the Polio Eradication Initiative on donor contributions to routine immunization.*** **Bethesda, MD, Partnerships for Health Reform Project, Abt Associates Inc., March 2001.**

Keywords: **financing, routine immunization, eradication**

While the polio eradication initiative has been highly successful in lowering the number of polio cases worldwide, questions have arisen about the impact of the initiative on the functioning and financing of health systems as a whole and routine immunization more specifically. This study looks at funding trends among international organizations and donors, and the impact that their funding of polio eradication activities has had on their funding of routine immunization activities. The study findings indicate that while some short-term decreases in donor funding for routine immunization appear to have taken place as polio eradication initiative activities were introduced and accelerated, on the whole, donor funding for routine immunization support does not appear to have decreased.

81. **Maceira D et al.** ***Analysis of international mechanisms supporting immunization programs: the Pan American Health Organization revolving fund.*** **Bethesda, MD, Abt Associates Inc., December 2000.**

Keywords: **bulk purchasing, supply, financing**

This study describes the PAHO revolving fund and examines its performance. Data were collected through a review of literature, interviews of the Fund's staff and surveys of country officials and suppliers. The PAHO Revolving Fund is a bulk procurement mechanism that helps reduce the cost of vaccine purchases for Latin America and Caribbean countries. Apart from cost and price considerations, the PAHO Revolving Fund also offers other advantages in terms of quality control and payment terms to user countries. From the producers' perspective, the PAHO Fund serves as a point of access to the

vaccine market in LAC countries, especially in the introduction of new and combination vaccines. However, the suppliers would prefer to negotiate directly with LAC's more populous countries and to be able to implement tiered pricing. From the countries' perspective, the PAHO Fund guarantees vaccine quality and reliable access to vaccines.

82. Madrid Y. The introduction and use of new vaccines in the public and private sectors. *Country report: Thailand.* Geneva, World Health Organization, 1988 [draft, 27 July].

Keywords: **private/public sector partnership, HepB, affordability**

This study examines the factors which influence the early uptake of new vaccines in developing countries with a focus on the role that the private sector may have on public sector decisions to incorporate these vaccines into national immunization programmes. The study examines the past experiences concerning hepatitis B and *Haemophilus influenzae* type b vaccine adoption in developing countries. Thailand is one of three countries in which a pilot study was conducted (the other two are Morocco and Zimbabwe). Despite its importance, the private sector has not been a direct driver of new vaccine integration in the public sector, although it has been supportive of such efforts. The integration of HepB vaccine in Thailand's EPI programme can be said to have been driven by a combination of the development of a perceived need and political will. With regard to the establishment of need for HepB vaccine, the academic community had a key role. Thailand's experience highlights that the affordability of new vaccines is an issue which results in delays in the public sector integration even for a developing country with a relatively high GDP per capita, good economic prospects, a strong public immunization programme, knowledge of disease burden, and adequate political will.

83. Mahoney RT, Maynard JE. The introduction of new vaccines into developing countries. *Vaccine*, 1999, 17(7–8):646–52.

Keywords: **financing, procurement, new vaccines**

The development and introduction of new vaccines is a costly and time-consuming process. Unfortunately, those most in need—individuals in developing countries—are the last to receive these powerful disease-preventing products. From the time a vaccine is first licensed in a developed country to the time most of the poor in developing countries have access to the vaccine can be 20 to 30 years. This delay is unacceptable. There is a great need to reduce this time span. This paper examines five ways of reducing the time span: establishment and dissemination of disease burden data and of cost effectiveness computations; vaccine introduction trials and effectiveness evaluations; establishment of an international consensus on recommendations for vaccine use; assurance of adequate and competitive vaccine supply; and creation of funding mechanisms to supply vaccine to countries unable to finance their own procurement. Each of the five is essential and achieving success on all five will require a heightened level of international effort and coordination.

84. Milstien J. ***Local vaccine production: issues of quality and viability.*** **Geneva, Children's Vaccine Initiative, 1999.**

Keywords: **vaccine supply, cost, local production**

A large proportion (measured in terms of doses) of the traditional vaccines used in the national immunization programmes of developing countries are produced domestically (local production). In 1992, as part of the activities of the Task Force on Situation Analysis of the Children's Vaccine Initiative, WHO staff began a study of the characteristics of local vaccine production in developing countries under the auspices of CVI. Since that time, CVI has carried out 13 full-scale vaccine supply assessments and over 30 smaller assessments in developing nations around the world. The survey revealed numerous problems with the quality, cost and reliability of the vaccines produced by these manufacturers as well as the manufacturers' inability to effectively manage epidemiological, organizational and technological changes. The survey also pointed to a set of factors that appear to be necessary for long-term viability. These factors should enable governments and donors to maximize the returns of their technological and financial support by focusing it on the producers that are most likely to be successful. As the study demonstrates, local production is a viable option only for meeting a developing country's vaccine needs when it is well supported both politically and financially. However, the potential disadvantages of relying on local manufacturers are significant, and must be carefully understood and addressed in order to ensure a reliable stream of high quality vaccines.

85. Mumford EA et al. ***Reproductive health costs literature review. Working paper series no. 3.*** **Washington, DC, POLICY Project, Futures Group International, 1998.**

Keywords: **cost-effectiveness, costs, literature review**

After the International Conference on Population and Development held in Cairo in 1994, reproductive health and the preventive and curative services that could assure it in developing countries became a key objective by more than 180 signatory governments. However, it was left unclear what the cost of this expansion was and how it would be financed. To fill that cost-estimation gap, the authors reviewed 160 publications issued between 1970 and June 1997, most of them about the time of the Cairo conference. The studies highlighted in this paper offer some quantitative data on the costs of reproductive health services identified as part of the Cairo agenda. In this review, cost data are reported for eight categories of reproductive health interventions: family planning, safe motherhood programmes, maternal/infant nutrition and immunization, obstetric care, abortion/post-abortion care, STIs/HIV/AIDS, reproductive cancers, and miscellaneous gynaecology. The review of family planning cost data is treated differently from other reproductive health interventions. For the seven non-family-planning reproductive health elements, there were about 75 examples (29 studies) of unit cost data. We found only 17 instances of cost-effectiveness estimates (i.e. quantitative relations established between costs and health outcomes) in 15 studies. Furthermore, there were only six studies that referred to inter-disease measures of health outcomes, such as disability-adjusted life years, producing 16 cost-effectiveness estimates. This review recommends that

"filling the gaps" should be based on local information needs, and that issues of quality, access and integrated service delivery require closer attention. In addition, the ongoing debate about the existing measure of health outcomes suggests that alternative methods for comparing health interventions merit attention. Finally, collecting the cost information available in developing countries would be useful both to local decision makers and others involved in setting priorities and allocating resources for health services.

86. Van Damme P, Kane M, Meheus A. Integration of hepatitis B vaccine into national immunisation programmes. ***British Medical Journal,*** **April 1997:314.**

Keywords**: HepB, costs, developed countries**

Hepatitis B is a major public health problem even though safe and effective vaccines have been available for over 10 years. Because hepatitis B infection is largely asymptomatic with long-term complications occurring after many years it has not received the attention it deserves. Strategies to immunize those at high risk have failed to control the disease. Delegates to the World Health Assembly of the World Health Organization recommended in May 1992 that all countries should integrate hepatitis B vaccination into their national immunization programmes by 1997. Some Western European countries remain unconvinced that the burden of disease warrants the expense of universal vaccination. However, epidemiological data and economic evaluation show that universal hepatitis B vaccination is cost effective in countries with low endemicity and that it will control hepatitis B, reinforcing the necessity for action.

87. World Health Organization. Expanded Programme on Immunization (EPI): The Social Science and Immunization Research Project. ***Weekly Epidemiological Record,*** **September 1998, 73(37):285–288.**

Keywords: **EPI, management, culture and behaviour**

The Social Science and Immunization Research Project is organized as a multinational activity with funding from the governments of Denmark and the Netherlands. This article is a summary of general recommendations that were formulated by researchers from the country teams, in collaboration with the representatives of international agencies and other partners. While the success in immunization achieved so far has been considerable, a social science perspective should provide valuable new insights into how the missing 20% or more can be reached. Social and behavioural research at community, national and international levels can provide a better understanding of what is needed to get more public support for immunization. The studies have shown that immunization coverage levels are the result of a complex interaction between demand and supply factors within specific sociocultural contexts and administrative and organization cultures. Of particular importance is the observation, valid in all the countries studied, that serious damage is being done to the programme by the poor interaction between staff and clients.

4. Bibliography

The citations annotated in part three and other references of interest are listed below. Articles are categorized according to key topics, but many address multiple issues. Full text of articles for which electronic versions are available can be found at the following web address:

http://www.who.int/vaccines-access/financing/references.html

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5.2 Internet resources

Organization	www address Description
Allied Vaccine Group	www.vaccine.org Allied Vaccine Group is a web ring created to facilitate access to reliable, science-based information about the economic and health benefits of vaccines and immunization. Along with links to member web sites, the homepage of the web ring contains an engine that allows a simultaneous search of member sites for vaccine-related information. Current members of the web ring are: The American Academy of Paediatrics; Bill and Melinda Gates Children's vaccine program at PATH; The Immunization Action Coalition; The National Network for Immunization Information; Parents of Kids with Infectious Diseases; The Vaccine Education Center at The Children's Hospital of Philadelphia; and the Vaccine Page.
Centers for Disease Control, National Immunization Program	www.cdc.gov/NIP/ This site offers a large number of vaccine resources and links for the general public, health care professionals, media and partners.
Children's Vaccine Program at PATH	www.childrensvaccine.org/html/immunization-resources.htm An online library of documents on all aspects of immunization, including immunization financing and advocacy. There are links to the web sites of a wide range of organizations involved in immunization programmes, vaccine research and production and promotion of safe injections.
GAVI (Global Alliance for Vaccines and Immunization)	www.vaccinealliance.org GAVI's web page provides a list of links to vaccine-related organizations, publications and events. Of particular interest are a summary of recent studies on vaccine cost-effectiveness and a research briefing on the impact of improved health on economic growth.
The Vaccine Fund	www.vaccinefund.org The Vaccine Fund was launched in 1999 to address the needs of vaccines and immunization in the world's 75 poorest countries. It provides financing for immunization services and for purchasing new and underutilized vaccines against diseases such as hepatitis B, yellow fever, and *Haemophilus influenzae* type b. Http://www.vaccinefund.org/en/publications/annual_report_2002.pdf *The Vaccine Fund 2002 report.*
Immunization Action Coalition	www.immunize.org Contains a list of free educational brochures for patients and health workers on vaccinations. Many brochures inform on the value of immunization but a wide range of vaccination-related topics are covered. Also of note is the *Directory of immunization resources* (2002), which lists immunization-related resources of all kinds (web sites, newsletters, books, videos, etc.)

Organization	www address Description
International Federation of Pharmaceutical Manufacturers Associations (IFPMA)	www.ifpma.org IFPMA represents the research-based pharmaceutical industry and other manufacturers of prescription medicines, worldwide. It is the main channel of communication between this sector of the industry and the World Health Organization as well as other international organizations that are concerned with health-related issues. The Federation also has a central role in the exchange of information within the international industry, and in the development of position statements on matters of policy.
Sabin Vaccine Institute	www.sabin.org The Sabin Vaccine Institute is a non-profit organization that promotes rapid scientific advances in vaccine development, delivery and distribution worldwide. Sabin Vaccine Institute publications include: *Global vaccine shortage: The threat to children and what to do about it* (2003); *Moving beyond the barriers: making new vaccine techologies available in the developing world* (2002) and *Vaccines for developing economies: Who will pay?* (2000).
International Vaccine Institute	www.ivi.org The International Vaccine Institute was founded on the belief that health in developing countries can be dramatically improved by the development, introduction and use of new and improved vaccines and that these vaccines should be developed through a dynamic interaction among science, public health, and business. This site includes news and information on vaccine research for a wide range of infectious diseases from cholera to AIDS to anthrax.
Pan-American Health Organization	www.paho.org/english/ad/fch/im/Vaccines.htm PAHO's division of vaccines and immunizations works towards improving the criteria for adoption of policies governing immunization programmes and to promote the establishment of effective national surveillance programmes as well as delivery, development, and production of high quality vaccines in the region. The page provides access to health statistics for the Americas and PAHO's publications, information on support to immunization programmes and news.
Partnerships for Health Reform plus (PHRplus) Project	www.phrplus.org Provides access to all published PHR Reports, including several on immunization financing. The site also includes a bibliographic database that cites books, papers, grey literature, videos, CD-ROMs and journal articles related to health sector reform and the work of PHR. The database contains over 5000 entries, primarily from 1990 to the present and can be searched by title, author, publisher, organization, date, region, language and subject. To facilitate access to PHR constituents around the world, ordering information for documents is provided with each entry as much as possible.
Rotary International	www.rotary.org This site contains links to RI's PolioPlus project and allows text searches of international immunization projects.

Organization	www address Description
TECHNET (Technical Network for Logistics in Health)	www.acithn.uq.edu.au/Vvm/index.html Provides a forum for professionals to discuss issues and ideas leading to concrete action for improved implementation, quality and management of immunization programmes. The forum encourages members to participate by providing contributions based on their own experience and expertise.
UNICEF	http://unicef.org The UNICEF homepage contains a reliable search engine, links to publications and research and numerous references to UNICEF's involvement in immunization programmes. UNICEF vaccine-related publications include *State of the world's vaccines and immunization*, *Progress of nations* and *Vaccines for children: Supply at risk*.
USAID Global Health Immunization Programs	www.usaid.gov/pop_health/cs Provides an overview of USAID's Child Survival programmes and links to publications on the various topics. The page includes a section on USAID immunization programmes in developing countries
BASICS (Basic Support for Institutionalizing Child Survival)	www.basics.org BASICS II is a USAID flagship project to improve child health. It works in collaboration with public health officials in developing countries and other international organizations and provides technical assistance to countries' priority health programmes. The web site offers online publications and a bibliography related to sustaining immunization efforts.
The Vaccine Page (Vaccine News & Database)	www.vaccines.com This site offers up-to-the-minute vaccine news provided by Yahoo. It also includes links to official vaccines sites in Australia, Canada, USA, Italy, Denmark, New Zealand, Pakistan and the United Kingdom as well as a directory of vaccine resources.
International AIDS Vaccine Initiative (IAVI)	www.iavi.org The International AIDS Vaccine Initiative is a global organization working to speed the development and distribution of preventive AIDS vaccines. IAVI's work focuses on four areas: mobilizing support through advocacy and education; accelerating scientific progress; encouraging industrial participation in AIDS vaccine development; and assuring global access.
World Bank	http://www.worldbank.org/vaccines Provides information on World Bank support to immunization programmes and links to partners and selected vaccine-related sites. *Immunization financing options: A resource kit* is a joint World Bank, WHO and GAVI paper that gives an overview and comparison of financing options.
World Health Organization ***Note**: WHO's website is updated continuously—the links listed here are subject to change at any time.*	http://www.who.int/vaccines http://www.who.int/vaccines-documents/catalogue.pdf provides summaries and links to WHO vaccine-related documents, including several on immunization financing and costing.

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

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

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

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

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

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

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

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