

**VACCINE INTRODUCTION AT COUNTRY LEVEL;
A CASE STUDY IN MALAWI**

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June 2008**



**Thesis submitted as a part of the
Master of Philosophy Degree in International Community Health**

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Acknowledgements

I would like to extend my heartfelt thanks to all those who helped me complete this research and who guided me through the process of this master thesis. First, I would like to thank my supervisor Kristin Ingstad Sandberg for introducing me to the topic of GAVI and immunization, and for patiently leading me through the writing of this thesis. Not only has she been an excellent supervisor, but also a mentor and an inspiration, with constant expressed believe in my ability to complete this research, and encouraging and motivating interest for the topic. She has impressed me with the rapid and detailed response to my questions. I would also like to thank Steinar Andresen at Fridtjof Nansens Institute, for interesting discussions, and for taking the effort to give new and useful feedback on this research concerning the analytical framework. Without the assistance of the University of Malawi and Professor Kenneth M. Maleta, the field work would have ended much sooner than expected. Thank you for the much needed contact. The fieldwork was financially supported by Arnfinn and Lise Heje's foundation, and I am grateful for the support.

This thesis could not have been completed without the important field work in Malawi, and the field work could not have been completed without the help from my father John Eie at NCA and Ragnhild Seip at the Norwegian Embassy. They introduced me to policy makers in Malawi, and through their professional and social network, led me into a world of knowledge, humour and frustration. Without them, this thesis would not be possible.

I would also like to take this opportunity to thank all the people whom I contacted in Malawi, Geneva and Norway. Their knowledge is impressive, and even more so, their dedication to their work. In spite of tight schedules they took their time to answer my questions, or to guide me to other persons who could provide me with important information.

Last, but not least, I would like to give my deepest thanks to my husband for putting up with me through the good and bad times during the work with this thesis. He has been patiently listening, constantly motivating, and irresistibly expressing his believe in me, and he made the field work in Malawi unforgettable.

Abstract

The aim of the thesis was to assess whether global strategies to introduce new vaccines result in new practices at country level and to find out whether implementation of the new vaccine requires changes in the existing immunization programme in Malawi. Malawi's decision making process leading to the application for support GAVI is seen as an important part of these objectives. The participation of the actors and their relative influence, the information flow including access to data on long and short term costs and benefits, and the main topics for discussion for the actors taking part in the process, were at the outset central topics in order to answer the main objectives illustrated above, with the use of semi-structured interviews, and available documents as a research method. Malawi is one of the poorest countries in the world, with high HIV/AIDS prevalence and a substantial amount of the population being undernourished. They started their EPI programme in 1976, and they introduced Hep B and Hib in 2002. The EPI programme now contains measles, DPT, HepB, Hib, polio, and BCG. According to the Financial Sustainability Plan from Malawi from 2004, the total programme cost increased significantly by over 200%, the initiation of the GAVI support (including the measles campaign carried out that year). An article reviewing hospital surveillance data for acute bacterial meningitis from Blantyre district, published in 2006, concludes that there is an urgent future need now for a sustainable routine infant immunization programme including a less expensive vaccine and new financing strategies. Despite the meager resources, the Malawian Ministry of Health has, according to this report, recognized the importance of infant Hib immunization and applied for bridge funding from the Vaccine Fund to allow it to continue routine infant Hib and Hep B vaccination. The government will during 2006 contribute to approximately 20% of the total cost of pentavalent vaccine. Given the tremendous number of other health priorities the country is facing it is unlikely that the Ministry of Health will be able to afford these costs despite the recognition of the vaccine benefits. This study traced the factors affecting the implementation of new vaccines and the effect of the introduction on the existing immunization programme. Like environmental problems, many health problems are international, their causes and consequences cross political borders. This is evident when it comes to infectious diseases, and in order to lift focus, and set the results in a greater perspective, the analytical framework of regime studies was applied. The study indicates that the decision to introduce the new vaccines was not based on cost-effective data and data on disease burden, but rather on the fact that Malawi was eligible for support, and the vaccine was available for free. The

introduction of SWAp seems to influence the policy context to a larger degree than the introduction of GAVI, as the donor community and the UN agencies already had a substantial funding responsibility in the health sector also before the introduction of the new vaccines. A somewhat unexpected finding was that the discussions concerning the new vaccines are still going on, and the challenge of the financial sustainability and the remaining high price of the pentavalent vaccine is substantial for the EPI programme.

1 Introduction

The topic for this master thesis became an interest for several reasons. In the Bachelor degree in Development studies, the topic of globalisation, trade agreements, and the need for developing countries to create a “development space” in order to become a part in the international trade on their own premises, and to get the space to find and define their own needs, were presented. During the first semester in Master of Philosophy of International Community Health, lecturers representing the Global Alliance for Vaccine and Immunization (GAVI) gave us interesting knowledge of the concept of public private partnerships, and new efforts to provide the children of the world with equal access to vaccination. In an effort to find a research topic in this field, Professor Gunnar Bjune acted as an intermediate in getting in contact with Kristin Ingstad Sandberg, who was completing her PhD study on GAVI's effort to speed introduction of new vaccines. The PhD study focused on the positions and behaviour of global actors. Kristin Ingstad Sandberg is also a research coordinator in what is referred to as the SUM-MEDIC project which started spring of 2008, where the implementation of strategies to introduce new vaccines and the capacities of national health system will be explored further (1). This case study will be a pilot study for a part of the SUM-MEDIC research project.

Very often the introduction and expanding use of vaccines follow a typical pattern. They are first introduced in the private market in industrialized countries, with low quantities and high prices. As quantities grow, they are introduced to the public market integrated into the public health policies of industrialized markets, with a lower price to the public market than to the private market. At this time the vaccine is also introduced to the private markets of the developing countries at intermediate prices, which partly compensates for the loss of customers who previously were a part of the private market of the industrialized countries. Finally, the vaccine becomes used in general, with massive purchases at low prices in the public markets of developing countries, directly or through international procurement agencies such as for example the United Nations Children's Fund (UNICEF) (2). The vaccines must be introduced into the different countries on the countries' own premises, and adjusted according to the countries' own vaccination programmes. With the new public private partnerships like GAVI, the financing part is supposed to be eased, although this might just be solved on a short term basis. From the PhD study it was shown that even though the financial bottleneck was solved, there were still problems in getting new vaccines into

low-income countries. The study indicated two diverging positions among GAVI partner agencies on new vaccine introduction. One argument was that many country level immunization programmes are too weak to absorb new antigens, and on the other hand the argument was that introduction of new vaccines through combination vaccines does not place additional stress on the health system (1). This is a case study that aims to get an understanding of what influenced the government's decision making process in the introduction and adoption of new vaccines in Malawi. The focus for this study is the Haemophilus Influenzae B and Hepatitis B vaccines which Malawi introduced with GAVI support in 2002. The study focuses primarily on the decision making process during the years 1998-2002 concerning the adoption of the vaccines to the national immunization programme, but also includes the discussions on financial sustainability that followed until 2005.

The main objectives of the study are developed in accordance with the objectives for the SUM-MEDIC research project (Appendix 9). This project has as an ambition to study vaccine demand and coverage at different levels; from the global to the national and local levels. The part that this study relates to, concerns the interface between the global and national level, studied through processes of new vaccine implementation. Like environmental problems, many health problems are international, their causes or consequences cross political borders. To combat these problems requires coordination among states. When widely accepted principles and norms govern behaviour, it can be called an institution or a regime. Like in international environmental commitments there are many factors influencing the international health commitments as well. Therefore research aiming at tracing cause and effect can be difficult (3). As an analytical framework, however, regime studies lift focus from the programmatic and technical capacities at country level, to its interface with the global enabling environment (4). The analytical approach is adapted from environmental regime studies, and this adaptation demands a certain adjustment and justification of objectives. The different concepts used in the objectives will be clarified further in section 3.3 concerning the analytical framework and study design.

From the outset, the research question for the case study was twofold; Do global strategies to introduce new vaccines result in new practices at country level?; Does implementation of the new vaccine require changes in the existing immunization programme?

From regime implementation studies, the main research issues that follow are:

- To identify political and institutional factors that affect implementation of new vaccines
- To study the role of international norms on new vaccine introduction in national decision-making processes
- To study whether problem solving capacities of countries and international partner agencies can explain performance on new vaccine introduction
- To trace the actual decision-making processes, taking into account the following explanatory factors:
 - The actors' relative influence in the process
 - Facilitation of adequate information flows
 - Access to data on long and short term costs and benefits
 - Toleration of dissent

The method used to obtain the results is qualitative in depth interviews and review of documentation from meetings during the time of discussion. Documents from Malawi Ministry of Health (MoH), Global Alliance for Vaccine and Immunization (GAVI), University of Malawi, and others are also part of the data.

In the following chapters, chapter 2 will aim at giving the reader some background knowledge and will give a short presentation of some of the already existing literature concerning this topic, together with information of the major stakeholders in immunization, including information concerning Malawi. Chapter 3 will give a presentation of the methodology and theoretical framework used to obtain the results, together with the study design. In chapter 4 the results of the case study will be presented and in chapter 5 the results will be discussed and analysed. Chapter 6 will give a conclusion and recommendations for further studies.

2 Background

This case study covers many aspects which could need an extensive description and discussion on their own, something the limited size of this thesis will not allow. Instead, some short clarifications will be made of the main concepts this case study is concerned with, and how they are used in relation to this topic. In order to get the necessary background knowledge this chapter will give a short presentation on some of the already existing literature concerning this topic.

2.1 The process of new vaccine introduction

Published literature concerning the decision making process at country level is scarce. However, some articles suggested to be relating to this topic will be presented in the following. There is also so-called grey literature¹, concerning this and relating topics, some will be included in the following presentation while just giving the information of the existence of others.

An article concerning the introduction of the Hep B vaccine in Taiwan and Thailand, gives some interesting knowledge concerning what influences government adoption of vaccines in developing countries. The countries concerned are both considered as middle income countries, and they were some of the first countries to adopt the vaccine, several years after it became available in 1984, but before the WHO's endorsement in 1992. This article suggests that vaccine cost and political will is given as the two most often cited considerations when it comes to introducing new vaccines, but shows that although price was a critical constraint in Thailand, it was not so in the case of Taiwan, to a degree which is not explained simply with reference to its higher income. Disease burden, programmatic feasibility, proactive role of the medical association combined with an already strong EPI programme were all common supporting factors for the two countries. The differences were, in addition to the sensitivity to price, the international support, being critical to Thailand and entirely absent in Taiwan. The potential for local manufacturing was important for the decision making in Taiwan, but only played an indirect role in Thailand. The article underlines the importance for both countries of the policy making environments that were in part open to multiple inputs and actors and at

¹ Grey literature or grey papers is in this case study literature written for Universities or Organizations, only published in their own organization or on the internet

least partly evidence based. This is far from typical, particularly in the developing world, due to “weakly institutionalized processes of policy making as well as power and resource asymmetries between donors bringing much needed finance, on the one hand, and country health and finance ministries on the other” (2, page 12). The article underlines the need for further studies on the policy process concerning the adoption of new vaccines (2). Their analysis of the policy process is also particularly interesting because the introduction processes studied took place before the development of GAVI.

Another article, published in 1999, is concerning the experience of introducing the Hib conjugate vaccine in the non-industrialized world. The decision-making process, the mode of introduction, the effectiveness, and the impact on the immunization programme of the vaccine were evaluated for the countries of Qatar, Uruguay, Chile and Kuwait. The countries had introduced the vaccines quite recently, the first country in 1993, and the last one in 1997. The article outlines the decision making process as the area where it was most difficult to obtain objective information. The results from the study indicated, however, that the introduction of the vaccine was initiated by the Ministry of Health (MOH), with the scientifically accepted disease burden data being a key factor together with the severity of the disease. The major concern to be dealt with in the decision making process was, for three of the four countries, the price of the vaccine. Although the cost of the vaccine has declined gradually and continues to do so, according to this article, it remains the single largest obstacle to wider use in most of the world. The authors recommend further studies especially concerning the process leading to the decision to adopt a new vaccine (5).

In an article concerning policy analysis a defined framework for the introduction of vaccines in developing countries is given. This framework lays out five essential overlapping and complementary elements of successful introduction of vaccines in developing countries. These elements are measurement of disease burden and computation of vaccination cost-effectiveness, conduct of large-scale vaccine introduction trials, establishment of international and national consensus on need for the vaccine along with recommended practices for use, the assurance of adequate and competitive supply and the creation and sustenance of funding mechanisms for procurement of the vaccine. It gives the case of the introduction of Hep B vaccine in Indonesia as an example. The policy analysis was conducted to support a model immunization programme on the island of Lombok. The issues were anticipated and dealt with systematically and in advance rather than addressed reactively as they arose. The article

outlines the need for further research on policy analysis in order to enhance health in developing countries (6).

The limitations of sustainable introduction of affordable new vaccines have been the governments' inability to finance the vaccines due to several factors, according to an article by Amie Batson, published in 1998. These factors include dependency on donors, donor policy, and inadequate recognition by governments of the value of the vaccine, and, for some countries, the absolute price of the vaccine. Taking the example of the Hep B vaccine, this article suggests that it is the economics and not epidemiology which dictates introduction of the vaccine into national immunization programmes. The article outlines a framework developed and adopted by WHO and UNICEF, to evaluate a country's capacity to be financially self-sufficient in immunization, using relative wealth of the population, total market size, and total population. The details will not be presented further here, but based on this framework, the article suggests price elasticity, or tiered pricing of vaccines, which means different prices for different markets based on each market's capacity to afford the vaccine. As donors has expressed grave concerns about the financial feasibility of introducing new vaccines, the segmented markets with appropriate tiered prices could provide a possibility for handing off the financial responsibility of immunization programmes to governments, and to enable all countries to have rapid access to new vaccines (7).

A paper published by Save the Children, describing the country level experiences of applying for support from GAVI in Tanzania, Mozambique, Ghana and Lesotho, GAVI was generally seen as a positive development in all four countries as it renewed focus on EPI where the vaccine preventable diseases had dropped down the priority list. However, all four countries experienced pressure to make rapid decisions and in some cases were subject to unreasonably tight deadlines in the application process. The new initiative also had to fit alongside pre-existing commitments and priorities, and the MoH staff was not able to make immediate changes to systems at the delivery level, such as reporting systems, retraining staff and new record cards. In the countries included in this study the Inter-Agency Coordinating Committee (ICC) was dominated by donor and MoH staff whose main interest was in EPI. They focused on GAVI criteria and were less concerned about how GAVI would fit into wider programmes of work within SWAp processes. Bilateral donors expressed concern that GAVI was re-verticalising donor support to health, and that it was overextending limited capacity, among other things. Other findings from this study were that the likely impact of GAVI will be

highly dependent on the capacity and performance of the current health systems. In Ghana and Mozambique where district level assessments were conducted, they had major difficulties in recording and reporting valid and reliable data on immunization coverage. As increased coverage is one of GAVI's targets, there is a risk that this places excess emphasis on reporting and monitoring of quantitative data, which could be manipulated so as to increase rewards. The report questions the reward systems for global health, which is also an argument in Hardon and Blume's article presented later in this study, including the argument that there is a risk with this system that funds are used to raise the overall coverage rather than to address some of the inequities within the country. A notable finding in this study is the apparent lack of discussion and co-ordination around future financing, involving major donors at the country level. The arguments put forward is that the different Ministries of Health have been dependent on external support for a long time and therefore remain pragmatic in anticipating that funds will eventually follow the plans and priorities of the sector. As donor commitments are usually set for one or maybe two years, it is understandable that they welcome a five year commitment. The cost of sustaining such commitments after the five years becomes a challenge to the health sector and to the international community as there seems to be an assumption by the Ministries of Health that the costs will be picked up by donors or international organisations (8).

In an article on Immunization in Developing Countries, Gauri and Khaleghian try to explain why some countries have stronger immunization programmes than others using the vaccine coverage of DPT and measles together with the adoption of the Hep B vaccine as a measure. The explanation they find is that broad changes in the global policy environment and contact with international agencies, together with the quality of a nation's institution and its level of development, are strongly related to immunization coverage and vaccine adoption in low income countries. It also shows that national coverage rates are more a function of supply-side than the demand effects. The paper outlines the importance of the exchange of professional knowledge, autonomy for public health managers, the quality of national institutions, and the involvement of international agencies in raising immunization coverage rates. In order to increase the effect on the demand side the paper suggests larger and more sustained efforts to motivate people to get vaccinated (9).

Further studies belonging to the area of grey literature is an unpublished policy study on factors influencing the adoption of new and underutilized vaccines in developing countries,

by Brooks, Cutts and Walt(10), together with a study concerning the same topic done in Bangladesh, Phillipines and Uganda by Judtith Justice (11), and a study on the introduction and use of new vaccines in the public and private sectors, using Morocco, Thailand and Zimbabwe (12) as examples. These will not be described further due to the limit of the size of the thesis, but only mention their existence if further reading should be desired.

2.2 Haemophilus Influenzae B, Hepatitis B and vaccine cost-effectiveness

This is not a case study on the diseases caused by Hepatitis B and Haemophilus influenzae type B, or on technical aspects of the vaccines which could prevent them. The medical details on the anatomy physiology of the diseases they cause, the treatment, or how they are prevented by the vaccine will therefore not be explored here. Instead, this is a case study concerned with the political discussions and the decision making process which took place prior to the introduction of the vaccine. In order to get a broader understanding of the topic however, there will be short clarifications of the two vaccines and the diseases they cause.

Haemophilus influenzae type B (Hib)

Hib is a bacterium estimated to be responsible for some three million serious illnesses and an estimated 386,000 deaths per year. It is commonly found in the noses and throats of healthy individuals and is spread by exhaled droplets. From there it can invade the bloodstream and cause infection and disease in other parts of the body. Most commonly it causes meningitis and pneumonia mainly in children under the age of five and more rarely septic arthritis (an inflammation of the joints), septicemia (blood poisoning) and epiglottitis (swelling of the epiglottis; piece of cartilage at the back of the tongue that closes off the windpipe when swallowing). But- these diseases can also have other causes. In developing countries pneumonia accounts for a larger number of deaths than meningitis, although Hib meningitis have mortality rates several times higher than is seen in developed countries and leaves 15 to 35 % of those who survive with permanent disabilities such as mental retardation or deafness. The vaccine has been available since the 1990's. However, the Hib disease is difficult to diagnose, and the price is seven times the cost of the original DPT vaccine. WHO therefore, recommends it "where resources permit its use and the burden of disease is established". This was from the position paper from WHO in 1998 (13). There is a new position paper from WHO from 2006, however, that advocates clearly the desirability of Hib use in all countries

(14). The testing of Hib from blood specimen (pneumonia) or spinal-fluid specimen (meningitis) needs sophisticated laboratories, and the disease may still be masked because antibiotics were given before the samples were taken (15).

Hepatitis B (Hep B)

Hepatitis means inflammation of the liver, and the most common cause is infection with one of five viruses, called hepatitis A, B, C, D, and E. All of them can cause acute diseases, but Hep B is the most serious type of viral hepatitis and the only type causing chronic hepatitis. In most of the developing world (including sub-Saharan Africa) most people become infected with Hep B during childhood, and 8% to 10% of people in the general population become chronically infected. About 90% of infants infected during the first year of life and 30% to 50% of children infected between 1 to 4 years of age develop chronic infection. The risk of death from Hep B related liver cancer or cirrhosis is approximately 25% for persons who become chronically infected during childhood. The Hep B virus is transmitted by contact with blood or body fluids, and is 50 to 100 times more infectious than human immunodeficiency virus (HIV). The most common ways of getting infected with Hep B are from mother to baby at birth (perinatal), child-to-child transmission, unsafe injections and transfusions and through sexual contact. WHO recommended all countries to add Hep B vaccine into their national immunization programmes in 1991(16).

Cost-effectiveness

In a statement from the World Bank in connection with the first introductions of vaccines at the very beginning of GAVI, the president of the World Bank at the time, Mr. James Wolfenshohn states that "Immunization is one of the most cost-effective health interventions....we know immunization to be a sound investment.....The link between health and wealth is a strong one" (17). Cost effectiveness is a central concept when talking about immunization, and its definitions and calculations could be discussed extensively. Due to the limitations of this thesis, this will not be done here. Some definitions of the concept will be given however, and a clarification of how it is meant to be used in this case study. According to WHO; "Immunization is undoubtedly one of the most cost-effective health achievements of modern times. It protects against the long-term effects of a disease on a person's physical and mental well-being and thereby the ability to complete education or training and carry out work. This protection entails un-measurable individual and societal benefits in terms of earning capacity, productivity and growth. In other words, immunization

prevents death and disability at a fraction of the cost of treatment, to the benefit of both the individual and the society as a whole. Effective health policies and related expenditure must be seen as an investment, not a cost. Good health boosts economies while illness drains them” (18). A review article concerning the economic aspects of vaccines and immunization, indicates that in the 162 articles carried out on economic evaluations of vaccines from 1969-1998, consistently show that immunization is an excellent investment, highly cost-effective, and usually cost-saving for vaccines that are currently recommended for universal use (19). The article is published in 1999, but takes into considerations that although prices of newer vaccines are higher than prices of traditional vaccines, they are still highly cost-effective. It also elaborates on the issues of cost-benefit and cost-effectiveness. When seeking to evaluate if immunization is worthwhile, several techniques are used. Cost-benefit analysis requires assigning a monetary value to all costs and all benefits of a policy or programme. The benefits are calculated by estimating the total cost of disease in the absence of intervention and subtracting the total costs of residual disease occurring with the programme. The cost of the programme include vaccines, vaccine administration, costs of dealing with adverse events and other programme costs such as public education. Benefits and costs can be direct (e.g. cost of medical care or indirect (e.g. time off from work to care for a sick child). If the benefit divided by cost ratio is greater than 1.0, the intervention is considered to be cost saving. In cost-effectiveness analysis, the question is how much it costs to achieve a particular outcome, and no attempt is made to assign a value to the life or illness. Interventions are considered cost-effective if the cost per year of life saved is less than, or equal to, the per capita gross domestic product. It is particularly useful when comparing several strategies to achieve a single effect. A specific form of Cost-effective analysis is cost-utility analysis, where outcomes are reduced to a common denominator such as the quality-adjusted life year (QALY) or disability adjusted life year (DALY). This makes it possible to compare problems with different outcomes, such as illness and death versus prolonged disability. The definitions used in this article will also be used in this case study. There are striking differences between the UNICEF prices for traditional vaccines and the prices of the newer ones. In general, the newer generations of vaccines are much more complicated and expensive to develop and produce and are protected by intellectual property rights. In addition, research and development costs have not yet been recouped and with the development of the biotechnology more and more possible avenues for research and development are opening. Both the hepatitis B and Hib vaccine are highly cost-effective in developing and developed countries, according to this article, but the question is whether they can be afforded (19). Cost-effectiveness is thus

used both as a political argument about the value of vaccines, and as a tool to calculate if the adoption of a new vaccine into a national immunization programme is justified from an economic and public health perspective. In the latter case, the calculations depend on information about disease burden and projected vaccine prices. Good information on these two factors was one of the challenges facing GAVI when it started vaccine-introduction processes in 2000 (19).

2.3 The role of GAVI in relation to new vaccine introduction

GAVI was created in 1999 to give greater access to the benefits of immunization. It is an Alliance of public and private resources, consisting of research institutes, pharmaceutical industry, non-governmental organisations, donor-and recipient countries, the Gates foundations, UNICEF, WHO, and the World Bank. One of the main goals of GAVI is solving the problem of delays in introduction of new vaccines to low-income countries, but also to strengthen the existing immunization systems. Prior to GAVI, new vaccines took on average 15-20 years before they reached the children in the developing world, and this gap threatened to grow, as more new vaccines were about to be introduced in the market. An expansion of the market for new vaccines could stimulate manufacturers' further investments in products for low income countries, and also contribute to bring down the prices of the vaccines. The GAVI partner agencies took on different areas of responsibility towards new vaccine introduction, according to their comparative advantage (4). GAVI is not a UN-led initiative. It is governed by a board of 16 (also given as 15 in other literature, depending on if the Vaccine Fund is included as a member of the board) institutional members, including 5 (this number is also given as 4 in other literature) permanent members and 11 rotating ones. The permanent seats are occupied by the Bill and Melinda Gates Foundation, the Vaccines Fund (not mentioned as a member in other literature), WHO, UNICEF and the World Bank. The 11 rotating seats represents developing countries (2 seats), developed countries (3 seats), NGOs (1 seat), developing country industry (1 seat), developed country industry (1 seat), foundations (1 seat), technical health institutes (1 seat), and research and academia (1 seat). Creating an independent secretariat outside the UN meant to avoid delays in plan implementation associated with UN bureaucracies. The emphasis on the introduction of new vaccines made the industry willing to participate in the GAVI Alliance. The conditions for the industry participation were outlined at the first GAVI Partners meeting in the Netherlands in 2000. The conditions included a guarantee for 'reasonable prices', support for a credible and

sustainable market, respect for international property rights, a tiered pricing system including safeguards against re-export of products back from developing countries to high-priced markets and a prohibition on compulsory licensing (a legal option included in the international trade agreement on intellectual property rights (TRIPs), granting a licence to a third party without the consent of the patent holder, issued on various grounds including public health, giving the patent holder a compensation) (20).

According to a GAVI commissioned evaluation of the Accelerated Development and Introduction Plan (ADIPs), GAVI had no coherent vaccine supply strategy in 2002, where the supplies of the preferred vaccines for delivering the Hep B and the Hib antigens in the tetravalent and the pentavalent combination were severely limited with only one manufacturer for both of them. UNICEF Supply Division was procuring vaccines pre qualified by WHO. The supply constraint was exacerbated by delays at country level with placing orders and setting up introduction plans which led to a mutual distrust between the multinational manufacturers and GAVI. Increasing the industrial capacity for the GAVI market seemed therefore an unlikely possibility at the time. This created further a market imbalance; where UNICEF as the only buyer was working to obtain the lowest possible prices for countries, while the one seller in the absence of competition, saw no need to lower prices (14). The intention in GAVI, one global partner representative said, was that the different members of the Alliance should concentrate on what was their comparative advantage. WHO had a normative (determining norms or standards) function while for example UNICEF had more of the logistics and vaccine purchase and distribution; the World Bank took care of the funding and so on (i7.GPR).

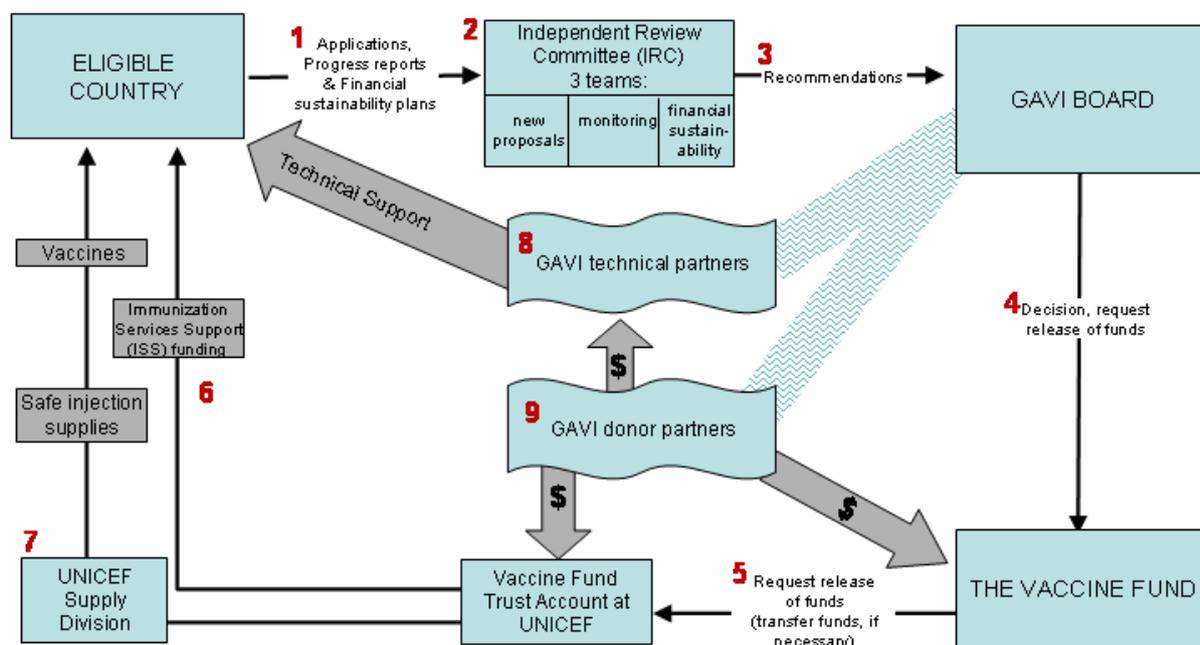
2.3.1 The introduction strategy

In GAVI phase 1²(2000-2005), the strategy for introduction of new and under used vaccines was to provide the vaccines for free for the first five years of support, without demanding any co financing from the recipient countries. After the five years, the market forces were expected to drive the prices down in the market, enabling countries, and the donor community to be able to incorporate the vaccine costs in their own health budgets (4). During these first five years the Alliance has committed over 1.2 billion dollars (the numbers

² GAVI phase 1; The term used to describe GAVI policies and priorities during its initial 2000-2005 period

vary in the literature, up to 1.5-1.6 billion US\$) and disbursed over 480 million US\$ to 71 of the 75 eligible countries.

The GAVI application and country support process can be illustrated in the following figure (21).



Only countries with an annual GNI/capita below \$1000 are eligible, and immunization services support (ISS) is provided to strengthen immunization and health systems based on the immunization coverage. With reported immunization coverage above 80%, the country is not eligible for ISS support (22). The three basic conditions for support for eligible countries, adopted by the GAVI Board October 4th 2000 were in phase 1:

1. A functioning Inter-agency Coordination Committee or equivalent collaboration mechanism
2. A recent assessment of immunization services
3. A multi-year plan for immunization

In addition countries are expected to follow safe immunization procedures and have plans to improve safety if there is room for improvement (23).

Inter-agency coordination committee (ICC)

According to GAVI the Inter-Agency Coordinating Committee (ICC) is a key coordinating mechanism for immunization services in developing countries. They are usually chaired by the Ministry of Health. Members of the committee include development partners such as the

World Health Organization, UNICEF, nongovernmental organizations, and donor governments (24).

At each step of the application and monitoring processes pictured above, GAVI requests countries to submit a number of forms and documents.

These include:

Annual progress report

One of the conditions for continued support from GAVI is an annual progress report. All countries receiving support from GAVI must submit annual progress report to the monitoring team of the Independent Review Committee. This committee assesses the report and provides recommendations for approval to the GAVI board (24).

Financial Sustainability Plan

The Financial Sustainability Plan (FSP) describes the governments approach to mobilise and use resources to support medium and long term immunization objectives. The countries were requested to submit their FSP to GAVI at the mid point in their period of support during the first phase of GAVI. The FSP is now integrated into the comprehensive Multi Year Plan required for every application for support (24).

Multi Year Comprehensive Plan

The comprehensive multi-year plan for immunization (cMYP) is a key planning and management tool for national immunization programmes which addresses global, national, and sub national immunization objectives and strategies, and evaluates the costs and financing of the programme. This is now in line with the WHO-UNICEF Global Immunization Vision and Strategy (GIVS) 2006-2015. A cMYP is required along with the standard proposal form when applying for GAVI support. The cMYP replaces the Financial Sustainability Plan” (24).

Bridge financing

The GAVI Board has agreed to provide so-called ‘bridge-financing’ to those countries which used GAVI resources to introduce the more expensive combination vaccines (DTPHepB, DTPHep-B-Hib) in Phase 1. This was worked out as a solution at the end of Phase 1, when recipient countries and their health aid donors were not able to take over the costs of new vaccines, as GAVI had planned initially. It is a concept of co-financing with the receiving countries and donor agencies, where the aim is for GAVI to gradually phase out. The feasibility of co-financing will depend upon the willingness and ability of country governments and other donors to contribute to vaccine costs. The exact mechanics of bridge financing are now being developed but they will entail extending support to those countries

which will gradually contribute their own resources to co-finance vaccine procurement (25). According to the HLSP evaluation looking at the Hib vaccine introduction picture in 2005, it was recognized that since the price of the pentavalent vaccine had not gone down, and countries yet had to fully implement financial sustainability plans, there would be a need to extend the vaccine financing, and the Bridge Financing concept was introduced. For some of the countries that had incorporated the Hib vaccine into their immunization programme, this decision was not necessarily sustainable after the financing from GAVI ran out (14).

2.3.2 The role of WHO and UNICEF in relation to immunization

The success of the eradication of smallpox, led WHO to create the Expanded Programme on Immunization (EPI) in 1974, and later, UNICEF to set the Universal Childhood Immunization goal (UCI). They were both dedicated to establishing routine immunization services in every country to protect children from 6 vaccine preventable diseases: diphtheria, tetanus, pertussis, measles, poliomyelitis and tuberculosis, and focused on creating demand and establishing the basic delivery infrastructure (7). UNICEF served as the leading donor in most developing countries and procured and supplied the projected amount of vaccines needed. WHO acted as a technical partner, providing most of the training materials and assistance in information systems, cold chain storage, disease surveillance and evaluation (20). WHO and UNICEF were recognized as key agencies in GAVI through their expanded programme on immunization (EPI), UNICEF being the vaccine procurement agency, financed through the Vaccine Fund, and WHO the lead agency in terms of surveillance, demand forecasts, and guiding countries in their selection of vaccines and vaccine presentation. This is also illustrated in the figure above, where WHO will give the technical support illustrated in point 8 in the figure and UNICEF supply division being responsible for the procurement of the vaccine financed through the vaccine fund at point number 7 in the figure above. According to GAVI, WHO should also assist in disease burden studies and effectiveness trials to assess the importance of new vaccines at country level. The World Bank were responsible for the financing issues, including the financial sustainability plan, and the developing-country governments were responsible for the multi year immunization plan, to coordinate the external inputs and to assure contributions from government budgets. The advocacy for new vaccines was allocated to the Children's Vaccine Programme (CVP) (4).

WHO and UNICEF have in cooperation produced a 10-year immunization framework: the Global Immunization Vision and Strategy (GIVS), for the years 2006–2015. This framework

aims to expand the benefits of immunization to all people so that immunization contributes to the Millennium Development Goals (MDGs), global security and cancer prevention. In addition to this WHO's role is to provide technical support to countries, in terms of assisting with the design, financing and implementation of strengthened sustainable national immunization programmes (26). According to WHO, on the issue of immunization, the organization is responsible for supporting and facilitating research and development, ensuring the quality and safety of vaccines, developing policies and strategies for maximizing the use of vaccines, reducing financial and technical barriers to the introduction of vaccines and technologies, and supporting countries in acquiring the skills and infrastructure needed (13). According to GAVI, the GAVI Alliance depends on WHO's guidance on technical issues. WHO, along with UNICEF, plays a key role in supporting countries in their application for GAVI funds, and the following implementation and monitoring of GAVI-related immunization activities (27).

2.4 Malawi

2.4.1 Country facts

Malawi is a land locked country with Lake Malawi covering 20 % of the surface area. The country is divided into three regions, the Northern, the Central and the Southern region, which in turn are divided into 28 administrative districts. The population was projected to be 12,757,883 in 2006 (28). The country has a low life expectancy, decreasing from 41.8 in 1970-1975 to 39.6 in 2000-2005. The GNI/capita in US\$ is 160, the GDP/capita is 667 US\$ (GDP per capita is PPP adjusted) (29).

2.4.2 Health, disease and immunization in Malawi

An unpublished study from the University of Malawi from 1997 concerning the constraints, proposed improvements and sustainability of Expanded Programme on Immunization (EPI) in Malawi, can give important information on how the vaccination programme worked prior to GAVI and the introduction of the new vaccines. The study is a result of key informant interviews. The results from this study suggest that several factors have already disrupted or may threaten to disrupt the existing supply system for vaccines. These are the over-dependence on donors; the cash budgeting system and financial uncertainty; the unavailability

of vaccines at the central Vaccine Stores; logistical problems such as lack of storage, transport and equipment; inaccessibility of some areas due to poor road infrastructure, especially during the rainy season; and lack of clear and unequivocal Government commitment towards EPI. In order to improve and sustain the current immunization coverage rate levels, the study recommends the Malawi Government to have the commitment to make immunization a priority and take over from the donors the procurement and distribution of vaccines. The donor support should be solicited, and government funding assured. They also recommend that community participation must be strengthened, together with the operations research, the improvement of the IEC activities, the cold chain system, the transport and infrastructural system and the staffing. Another constraint mentioned by the respondents in this study was the lack of relevant data for decision making (30). It is reasonable to assume that the people interviewed in this case study are in some of the same positions as the people interviewed in the study mentioned above. Although the results can not be compared directly, having the results of this study in mind, it can indicate if there has been a change in the immunization programme after the introduction of GAVI and the new vaccines.

Health system

The health services in Malawi are provided by three agencies; the Ministry of Health (MOH) provides 60 % of service delivery, the Christian Health Association of Malawi (CHAM) provides 37%, and private institutions provide 3% of the health care. The health delivery system is divided into 4 levels; the central hospital level, the district hospital level, the health centre level, and the community based outreach care. All institutions provide the Expanded Programme on Immunization (EPI) services (28). The Ministry of Health (MOH) has created a cost effective package of health services, the Essential Health Package (EHP) to achieve the goal: *“to raise the level of health status of all Malawians by reducing the incidence of illness and occurrence of premature deaths in the population”* (31, page 10). It focuses on vaccine preventable diseases, malaria, adverse maternal and neonatal outcomes including family planning, tuberculosis, acute respiratory infections, acute diarrhoeal disease, sexually transmitted infections, schistosomiasis, nutritional deficiencies, eye ear and skin infections and common injuries. The EHP was costed at 17.5 US\$ per capita per annum in 2002. The health centre is the first level of contact between community health services and the formal health sector. Some cannot provide the EHP however, as they are only served by dispensaries or maternity units. At the community level the Essential Health Package (EHP) is delivered through Health Surveillance Assistants (HSA). Their activities include advocacy and health

promotion, home visits, village clinics, and meetings with communities, and the inspection of public facilities. The Government of Malawi has targeted a ratio of 1 HSA to every 1000 people, but the current ratio is 1 to 2600 people. The lack of human resources in the health sector is substantial. Many district hospitals do not have doctors. The vacancy rate for nurses was 59% in public sector and 77% at CHAM facilities; the average vacancy rate for doctors at both facilities was 62% (28). The EPI programme was a vertical programme in the Ministry of Health until the discussions of sector support came along, which led to the Sector Wide Approach (SWAp). The definition of a vertical programme used in this thesis, is a disease specific programme, planned by the central ministry and financed through earmarked funds. Implementation is managed through programme-specific vertical structures within the existing health system: drugs and other resources are usually procured through a parallel process; health workers are also often dedicated exclusively to programme-related activities; and, programme supervision and monitoring procedures are independent as well (32). The Sector Wide Approach (SWAp) provides a framework and environment that facilitates cooperating partners and government to work together for health development. The key strategies here are increasing the availability and retention of staff in the health sector, providing adequate volumes of drugs and medical supplies at all service delivery points, providing essential medical equipment at all health facilities, implementing infrastructure development, improving routine operations at the service delivery level to deliver EHP and other health services, and developing appropriate policies, systems, and standards to support central and district operations (28).

Disease

The infant mortality rate in Malawi is 76 per 1000 births and the under-five mortality rate is 133 per 1000. Malawi is number 165 out of 177 countries on the human development index (33). The maternal mortality rate is one of the highest in the world at 984 deaths per 100 000 births in 2004. Only 57% of deliveries took place in health facilities. The HIV/AIDS prevalence is 12 % at the age group 15-49 years (2005), and 34% of the population is undernourished (2001-2003) (28, 34).

Malawi's major burden of disease is characterized by infectious or communicable diseases due to conditions such as malaria, HIV/AIDS, tuberculosis, sexually transmitted infections, diarrhoea and acute respiratory infections (ARI). Acute respiratory infections, diarrhea and malaria are major causes of childhood mortality. These conditions are worsened by the poor

nutritional status of children, where 49% of the children under five are estimated to be malnourished and stunted (28).

Immunization

The Expanded Programme on Immunization (EPI) was initiated in Malawi in 1976 as a pilot programme, and was fully operational in 1978. Malawi was one of the first 13 countries in Africa who got their proposals approved for a five-year support on the introduction of new vaccines from the Global Alliance on Vaccines and Immunization (GAVI). The EPI currently offers measles, DPT-HepB+Hib, Polio and BCG vaccines to children under 1 year of age and the tetanus toxoid vaccine to pregnant women and women of child bearing age. The new vaccines of Hep B and Hib were introduced in 2002. All children who received 1st and 2nd dose of DPT restarted, while those who completed the three doses of DPT were not eligible because they had already completed the recommended schedule for DPT (35).

The immunization coverage in Malawi has been above 85% since 1989, except from the year 2000 and 2002. The drop in the year 2000 can be attributed to factors such as the global shortage of polio, BCG and DTP vaccines due to manufacturers' problems (35). The drop in 2002 might be explained by the shift in reporting system due to the introduction of the new vaccine (i5.CR). The DTP3, Hep B and Hib coverage was above 90% in 2005 and 2006. The Malawi reported coverage numbers and the WHO-UNICEF estimates correspond in these numbers. The immunization coverage differs among the district however, with 31% reporting DTP3 coverage greater or equal to 90%, 54% of the districts report the DTP3 coverage to be between 80-89% and 15% reporting DTP3 coverage from 50-79%. The proportion of districts not reporting or reporting coverage of less than 50% was zero. In this report, the number of districts is given as 26, in the annual report of the work of the Malawi health sector; the number of districts is given as 28. Nonetheless, the numbers given says that 69 % of the 26 districts, reported a DTP3 coverage of less than 89%, and it is therefore difficult to see that the overall coverage, given as reported coverage from Malawi and estimated coverage from WHO-UNICEF, can be 99% (28, 29).

In the 2004 Malawi Demographic and Health Survey the overall number of children fully vaccinated by 12 months is given as 64 %. In a report from Centre for Social Research at the University of Malawi in the Zomba region, the number of children fully vaccinated by 12 months of age in 2004 is given to be 51%. In some of these reports, the methods for collecting these numbers are given, and for some of them they are not. The point here is to show that

the numbers differ according to where they are found and how they were obtained. The reader should have this in mind in the discussion of whether the introduction of new vaccines results in new practices at country level, or if it requires changes in the existing immunization programme (36, 37).

SWAp

Moving towards Sector-Wide Approaches (SWAp) was a stated policy decision arising from the May 2000 Consultative Group (CG) meetings between the government and development partners. The aim was to establish several joint processes in terms of planning, funding and procurement and monitoring and review, and they wanted to adopt a *single plan of action* for the sector as a whole to implement. A broad range of stakeholders including development partners and NGOs was brought onboard to implement this plan, with the overall process being driven by government (35).

An evaluation of SWAp in several developing countries, initiated by Swedish International Development Cooperation Agency (SIDA), and worked out by Institute for Health Sector Development (HLSP) in 2003, have the following definitions on SWAp:

“The sector wide approach defines a method of working between government and development partners, a mechanism for co-ordinating support to public expenditure programmes, and for improving the efficiency and effectiveness with which resources are used in the sector. All significant funding for the sector supports a single sector policy and expenditure programme, under government leadership, adopting common approaches across the sector and progressing towards relying on Government procedures for all funds”.

The report has included Malawi in the countries evaluated, although Malawi was one of the countries in its introduction process at the time of the evaluation. The major concern for most countries about activities outside the SWAp were the new global initiatives, with GAVI as one example, in terms of the levels of funding to be received, and the management of those funds outside the SWAp. Malawi and Burkina Faso report that monies from global initiatives are expected (Malawi was due to receive huge inflows, according to this evaluation at that time), however that they have been taken into account in SWAp design (Malawi) and so are not seen as a problem for the SWAp (38). According to GAVI, the aim was for SWAp to have considerable efficiency and equity gains for Malawi’s health service. Efficiency will increase as the transaction costs of utilizing and monitoring various sources of financial support fall, and joint planning ensures that duplication of service provision is minimized. Equity will

improve as stakeholder coordination and resource allocation become systematic. There will be some short-term risks to vertical service delivery structures, such as the immunization programme, as the SWAp develops. There will have to be a careful process of change management to ensure that individual MoH “success stories” (such as the EPI programme) are not eroded as the overall health system improves its performance (39).

2.4.3 Hib and Hep B in Malawi

There is a study done in 1996-97, before the Hib vaccine was introduced, where clinical and demographic data were collected on all children from the age one day to 14 years, with the diagnosis of bacterial meningitis (BM). The study was done in Blantyre, at Queen Elisabeth Central Hospital. Data was collected prospectively for one year. It was found that 2.7% (267 out of 9847 children) of all paediatric admissions at the hospital were found to have BM, and of them: 83% were under 5 years of age, 61% under 1 year of age, and 23% under one month (= the neonatal period). Haemophilus influenzae type b (Hib) was the causative organism in 21 % of the cases in the post neonatal period. The other causative organisms in this period were Streptococcus pneumoniae (27%) and Salmonella typhimurium (6%). Hib was not a causative organism in the neonatal cases. The overall mortality was 40%, and the outcome was worst in the salmonella infections particularly the neonatal salmonella BM with the case fatality of 89% (8 of 9 cases). Coma on presentation worsened prognosis, and 15% of the survivors had sequelae on discharge. One of the conclusions in the study was that vaccination against Hib infection would have reduced the number of meningitis cases by 16% and death due to the disease by 17%. It also suggests that earlier access to adequate health care and awareness of BM in a malaria-endemic area would reduce mortality and morbidity (40).

In 2006, an article is published where cases of acute bacterial meningitis from 1984-1991 at Royal Liverpool Children’s Hospital in Liverpool, UK, and from 1996-1997 at the Queen Elisabeth Central Hospital in Blantyre, Malawi, are compared. The results from this study demonstrate a marked difference. The mortality rate in Blantyre is in this article given as 41 %, and over five times that in Liverpool with 7% mortality. Children with meningitis present later in Blantyre, and tend to be sicker, more anemic, more malnourished and more likely to be unconscious and have a history of seizures. Some of the difference in mortality is also due to different organisms causing meningitis, but mortality was higher in Malawian children even when compared with Liverpool children infected with the same organism (for example

Hib 43% vs 6%). Other potentially contributing factors to the higher mortality include HIV, malnutrition, and poorer access to medical care. Malaria can have some of the same symptoms as meningitis and therefore also cause a delay in hospital admittance. The article states that conjugate vaccines could decrease mortality from meningitis in Malawi, but gives no published numbers on this, but states that the data presented suggests that Hib vaccine could have prevented up to 25% of the cases of meningitis at the hospital and 17% of the deaths due to the disease (41).

An article reviewing hospital surveillance data for acute bacterial meningitis in Blantyre district (children age 1-59 months admitted during 1997-2005), following the Hib vaccine introduction during 2002, show a decrease in Hib meningitis incidence rates (20-40/100 000 to near zero) among all residents, despite no change in pneumococcal meningitis incidence rates. The study was a review of hospital surveillance data for acute bacterial meningitis in Blantyre district Queen Elisabeth Hospital, among children 1-59 months. At the time the Hib vaccine was introduced, WHO established the paediatric bacterial meningitis surveillance network (WHO PBM), and data from the WHO PBM surveillance site at Queen Elisabeth Central Hospital is used for this evaluation as well as historical data from the hospital collected before vaccine introduction. The report describes difficulties in obtaining the date for when vaccines were given, so the analysis was conducted from 2003 onwards when all children would have had the opportunity to be vaccinated (Recorded cases for earlier years from 1997-2002). The report states that Hib vaccine is highly effective in a country where health care resources are poor, and the burden of HIV is high, but because of reduced ambulance availability, some cases might have died before reaching the hospital, and children presented at the health centres were given first dose of AB, before the lumbar puncture at the hospital. These factors might have influenced the results of the study. Despite the meager resources, the Malawian Ministry of Health has, according to this report, recognized the importance of infant Hib immunization and applied for bridge funding from the Vaccine Fund to allow it to continue routine infant Hib vaccination. The government will during 2006 contribute to approximately 20% of the total cost of pentavalent vaccine. But- by introducing this vaccine, together with the Hep B vaccine, in the routine immunization programme, the total vaccine cost per year for the government of Malawi increases from approximately 600,000 US\$ to 6,000,000 US\$ per year (based on 3.3 US\$ per dose), according to this article. Given the tremendous number of other health priorities the country is facing it is unlikely that the Ministry of Health will be able to afford these costs despite the recognition

of the Hib vaccine benefits. It concludes that thus Hib vaccine is clearly effective in reducing Hib meningitis; there is an urgent need for innovative financing strategies for the world's poorest countries including a less expensive vaccine that preferably is delivered in a multivalent form (42).

An article concerning the seroprevalence of Hep B and C and HIV in Malawian pregnant women, published in 1998, before the introduction of the Hep B vaccine, concludes that Hep B and C infections are highly endemic in Shire Valley in rural Malawi. Fifty HIV-positive and 100 HIV-negative samples were selected randomly from 153 HIV-positive and 443 HIV-negative women delivering in hospital. 16% of the HIV-positive mothers and 12% of the HIV-negative mothers were chronic carriers of Hep B. The findings showed that Hep B and C were highly prevalent in this rural area of Malawi and the figures obtained are in agreement with figures from other highly endemic areas. The exposure to the Hep B infection seemed to occur early in life (43).

A study doing serological and molecular screening for viruses in blood donors from Ntcheu district, published in 2001, one year before the vaccine was introduced, shows that among 159 blood donations 8.1% was Hep B carriers. The study also concludes that HIV-1³, Hep B and Hep C infections are highly endemic in Malawi. The numbers are lower than in the study mentioned above, but the study from the blood donors also states that it is generally admitted that screening blood donors tends to provide a lower estimate of viral marker prevalence than is found in the general population, as blood donors represents a younger and healthier group within the general population (44). A study done among male workers at a sugar estate in Malawi in 1998, investigated associations between HIV-1 prevalence and herpes simplex virus 2, hepatitis C virus, and hepatitis b virus infections, and showed among other findings, that the prevalence of Hep B infection was 16.9% among HIV-positive persons and 14.4% among control subjects who were HIV-negative, indicating high levels of acute or chronic Hep B infections in this population. These prevalence estimates are consistent with estimates reported among rural Malawian pregnant women but are slightly higher than those reported among Malawian blood donors. The study says further that the high prevalence of Hep B and Hep C are troubling because they indicate high future rates of chronic Hep B and Hep C complications (45).

³ HIV-1 is the virus that was initially discovered and termed LAV. It is more virulent, relatively easily transmitted, and the cause of the majority of the infections globally

3 Methodology

3.1 Choice of method

This research is concerned with why the decision was made of implementing the new vaccines in Malawi, how the decision was taken, and what results the implementations of the new vaccines have given. The intention for this thesis is to look into the decision making process of Malawi in deciding to implement the new vaccines. Case studies of organizational decision making have long been one of the most important strategies by which researchers have investigated organizational behaviour and improved their theoretical understanding of that behaviour (46). There are many definitions of case studies. For Thomas et al. a case study “... is often an account and an analysis of particular events and decisions, and can be used to illuminate a decision or set of decisions, why they were taken, how they were implemented, and with what result” (47). According to Yin “(T)he essence of a case study , the central tendency among all types of case study, is that it tries to illuminate a decision or set of decisions: why they were taken, how they were implemented, and with what result” (48, page 12). Case studies are the preferred strategy when “how” and “why” questions are being posed, when the investigator has little control over events and when the focus is on a contemporary phenomenon within some real life context. This definition, however, sites the topic of decisions as the major focus, and although it makes it all “fit nicely” into this research it is not enough to define what a case study is all about. The case study is a research strategy covering the logic of design, data collection techniques, and specific approaches to data analysis (48). Using case studies might be a challenge, however, because there are few methodological guidelines available compared to many other types of research (46). Several methods can be used in case studies; the use of secondary data and data analysis, structured surveys, review of documents, and semi structured interviews. The first methods can be characterized as quantitative methods, and often answer questions of what, how many or how often. The quantitative approach look for consistent behaviours or ‘laws’, which then can be applied to sets of similar examples. Document reviews can be both qualitative and quantitative, depending on the information. An interview, on the other hand, is in essence a qualitative methodology, asking the questions of how and why. This is often used to investigate causality directly by looking in detail at how the causal process works within particular cases (47). In his book, “Interviews- an introduction to qualitative research interviewing”, Kvale describes an interview as “a conversation where the outcome is a co production of the interviewer and

the subject”. He defines it further saying that “the qualitative research interview attempts to understand the world from the subject’s point of view, to unfold the meaning of people’s experiences, and to uncover their lived world prior to the scientific explanations” (49). A qualitative research should increase the complexity, not reduce it (50). Kvale uses Webster’s definition of a conversation as; “an oral exchange of sentiments, observations, ideas, opinions”, and he compares different types of conversations, calling the qualitative interview a professional interchange, or a professional conversation. This study relies primarily on semi-structured interviews and document reviews, and is as such a qualitative study. It applies what George and McKeown calls the process-tracing approach where the decision-making process is the centre of investigation, and where the process of constructing an explanation is much like the construction of a web or network. The growth of the web orients the search for new pieces (46). A similar approach in the health literature is found in the area of policy analysis. This is a process of looking back at why and how a policy made its way onto the agenda and whether or not and why it has achieved its goals (51). Stakeholders are in this setting described as “individuals and groups with an interest in an issue or policy, those who might be affected by a policy, and those who may play a role in relation to making or implementing the policy – in other words, actors in the policy process” (51, page 177). Identifying the stakeholders who are, or have been, involved in a political process, requires the judgement of the analyst (51).

The sources of information used in this case study, are documents and key informant interviews. (The results included are the documents and meeting minutes received from different sources during the field work in the autumn of 2007, together with the in depth interviews done in Malawi, Switzerland, and Norway.) The documents are in the form of the proposal from Malawi to GAVI for support, the meeting minutes from the meetings prior to the writing of the application, the annual progress reports from Malawi, annual reports from the Ministry of Health in Malawi, and documents from GAVI found on the internet and received during the visit to GAVI in Geneva. The interviews were conducted during a 3 months field work in Malawi. In order to document the persons contacted, and the information given in the day-to-day work with the research during the field work, a record of events and observations was written on a daily basis. This was also in order to keep track of all the persons contacted, who they were, and whom they referred me to (Appendix 7).

3.2 Identifying stakeholders and challenges in collecting data

In the book *Making Health policy*, health policy interviews are said to be of a special nature. They are sometimes called elite interviews, and they pose special challenges. It might be difficult in recruiting respondents, as they may worry about how the results might be used, they might be very busy and have less time to give interviews, and they might be able to only talk about official policy issues, that might as well could have been obtained using policy documents(51).

In this thesis, identifying the stakeholders in the implementation process in the introduction of new vaccines was of great importance. Moreover, the number of people directly involved in a decision-making process is often limited, depending on the breadth of involvement of stakeholders and civil society. As a starting point the application sent from the Malawi government to GAVI was used, together with the snowball technique using the contacts already established in Malawi. There was also a published working paper on the constraints, proposed improvements and sustainability of the EPI programme in Malawi, where the authors of the paper were identified as people of interest for this study. This implied having a few individuals to approach when the research started, and through them identify further informants who then in turn identified others. Some of the stakeholders identified as participants in the process had moved out of the country, and three of them agreed to answer the questions per mail. However, one of them withdrew after the questions were posed, and one answered only very limited to the questions. Although the persons considered to be of interest was listed beforehand, there was still the challenge of finding them, interviews were refused for different reasons, and those who at the starting point were assumed to be able to give useful information in some cases did not do so in the end, requiring other informants.

One of the limitations of data collected through health policy interviews is that the persons interviewed do not necessarily give information about what the persons actually think or do. The information is about what they say. The importance and the relative influence of the actors taking part in the process, is not possible to judge, other than judging the influence of the organizations they were representing. It is important to mention here, that some of the persons, who were working for the international organizations, were Malawians, and whether they answered in accordance with their organization at the time or in accordance with their nationality is difficult to judge. When the different persons were asked to participate, they

were asked if they took part in the process or if they had knowledge considering the process although they did not take part themselves. This might have excluded more people than necessary, but the interviewer found it necessary for the persons to define this on their own part. It is believed that an interview with a person who is *convinced* having taken part in, or having knowledge about, this decision making process, would create only limited answers of interest. This suggests that it was important that this was defined and decided by the stakeholders/participants themselves. Whether the person had taken part or not in the process, or had knowledge of the process without actually taking part in the meetings where the new vaccines were discussed, was therefore the persons themselves were let to define, not the interviewer. If the persons contacted said they did not have the knowledge, the interviewer accepted this with no effort of persuasion. The persons ending up taking part in this study however, seems to be the key persons taking part in the decision making process.

The challenge in relation to the interviews mentioned by all, were the time span since the meetings and the decision had taken place, and that it therefore could be difficult to recall the content of it all. Some asked for the questions in advance, and some did not. This is a lesson learnt for the author however, and the interviewer would have encouraged the interviewees to receive the questions beforehand in order to make the most of the interviews, if the field work should have been done all over again. The reason for not doing this for all the interviews however, was the perception that the persons to be interviewed were very busy and their time taken for the case study should be limited to the interview itself.

One consideration before going to the field was that the topic for this research could be sensitive, in regards of questioning the introduction of the new vaccines at a time where it is evident that the prices of the vaccines has not dropped as hoped and the financial challenges are prominent. However, the respondents gave little impression of this and it was the impression that they talked freely during the interviews, although the situation was limited by time, as they all had very tight schedules. When the time for the field work was going towards the end, the circle of people was closing in. The different persons the interviewer had been in contact with referred to each other and to the same people who had already been interviewed. It is the impression of the author, therefore, that although finding the people to interview could pose some challenges, the key persons for the purpose of the study, were the ones who actually took part.

One important consideration seen in the aftermath of the fieldwork, however, is that with the results in hand, the impression is that the decision making process is still going on. The process has not ended. With this information in hand during the field work, the persons judged as taking part in the decision making process would have been different as this would also include the persons working with immunization today. Some of the persons taking part in this study are by coincidence working with immunization also today, but with the judgment described above; this would also have influenced the content of the questions asked and the group of people approached.

More time than expected also needed to be used in getting a research permit from the Ministry of Health in Malawi. An ethical clearance from Norway was not necessary, and unfortunately, the information that a research permit was needed was not in the hands of the author before arriving in the country. An application could only be submitted on certain dates and the Ministry of Health needed several weeks of considering the application. The advice from several key informants was not to contact the persons of importance for the interviews before this research permit was in hand, in order to avoid unnecessary offence. However, this had to be done in the end, in order to be able to interview the “right” people during the time schedule laid out for the field work (Appendix 1).

From the outset, there were around 20 names on the list of persons who could be of interest to this case study. After arriving in Malawi, it became evident that many of these persons were no longer in the country, and new names were added to the list that was not mentioned in the applications or any of the reports in hand. The principle made for the time in the field was to contact all the people whose names were given to me, and trust them if they said they had knowledge of the process, and also if they said they did not. Although the list of persons interviewed became considerably shorter than first anticipated, it is believed that the key persons who worked with immunization in Malawi at that time, and who also work with immunization in Malawi today, were available and answered to the questions extensively. The persons interviewed were asked to give their verbal consent before the interviews started (Appendix 2).

To increase the understanding of the topic and the validity of the results, three meeting minutes from the period the Malawi government and the international organisations through the ICC committee, are also being used. There are other meetings described in the application

from Malawi, and there have been made extensive efforts from the EPI manager in the Ministry of Health in Malawi to get hold of these minutes, but unfortunately this was not possible. The three minutes that are used, are described in the application as the most important ones (Appendix 8).

3.3 Analytical framework and study design

In the GAVI effectiveness paper by Sandberg and Bjune, (1) this framework on vaccines and immunization has been used with the rationale arguing the need for a political perspective on global health governance without reinventing the wheel. As a pilot for part of the SUM-MEDIC research project, this study makes an effort of applying the analytical framework from studies of environmental regime implementation to the introduction of new vaccines at country level. In a paper by Sandberg and Bjune, the national circumstances between and within countries suggests that there is no single way for a country to put its international commitments into practice. Like environmental problems, many health problems are international, their causes or consequences cross political borders. To combat these problems requires coordination among states (3). When actors decide to coordinate their actions to solve a problem, they need to agree on a solution, and the implementation will depend on each partners will and ability to adhere to the agreement. Regime studies looks at how cooperation works in practice. Regimes can influence the behaviour of partner agencies and members, they are not actors in their own right, and the effects following regimes are changes in partner's interactive decision-making. This can be considered outcomes of regimes (4).

There are many factors influencing the behaviour and effectiveness of international commitments; the nature of the problem at hand, configurations of power, the nature of commitments, linkage with other objectives and issues, exogenous factors, public concern, and national and international organizations. International institutions are established principles and processes for making decisions and can therefore lead to more effective international cooperation. Institutions can be looked upon not only as organisations but include arrangements for cooperation, sets for informal and formal rules prescribing roles and responsibilities, and do not act on their own, as organizations do (4). They are sometimes equated with regimes, and are often used interchangeably. Like in international environmental commitments there are many factors influencing the international health commitments as well. Therefore research aiming at tracing cause and effect can be difficult (3). The political

challenges arise once you move away from a situation where actors share the same preferences, interests and values about an issue. Regimes can also affect actors differently, because actors have different perspectives from which they judge costs and benefits and because the material consequences can differ. The cooperation can also be determined by the institutions problem solving capacity, which can be defined as the extent to which the institutional set up can provide incentives for partners to adjust. This is further decided by the institutional setting, the distribution of power or authority among the actors involved and the persuasion and skills within an institution exercised by leaders or experts (4).

The assumptions this analytical framework (and the experiences on vaccines so far) create is that as a global institution, GAVI will ease cooperation among partner agencies in countries' decision making processes on new vaccine introduction. GAVI partner agencies and stakeholders in Malawi are likely to see new vaccine implementation differently. Therefore, their will and ability to adhere to GAVI agreements is likely to differ.

The study objectives, as presented in the introduction, formed the basis of an interview guide in order to ensure consistency and reliability in the interview situation. This also served as a guide to structure information from documents. The interview guides were adjusted according to which stakeholders were being interviewed. Thus, the global partner representatives had slightly different interview questions guiding the interview, than the country representatives from Malawi (Appendix 3, 4, 5, 6).

The objectives set for this research, give room for interpretations. For further ensuring consistency and validity of information it is important to define variance on key variables. The concept of 'new practices at country level', for example, will not only be concerned with the technical part of vaccination, but will also include the new financial aspects of the immunization programme, and is seen as if the existing immunization programme had to go through extensive changes in order to make the new vaccines "fit in" to the original EPI programme. This will also apply when the topic of 'changes in the existing immunization programme' are being discussed, where changes can be defined as "to make different in some particular" (52), in this case make the EPI programme different from what it was experienced to be prior to the introduction of the new vaccines of Hep B and Hib. However, these variables were left open to interpretation by interviewees, and therefore not given a strict definition. In this way, the interview guide sought to mirror environmental implementation

studies in key aspects, yet keeping some variables wide, and thus be open to the possibility that the data on Malawi and new vaccines might reveal new insights into the policy process

The concept of problem solving capacity is borrowed from Sandberg et al where they in their studies use Miles et al's clarification of the concept where problem solving capacities are the tools available to an institution to direct and adjust collaboration. This capacity is conceptualized as *power*, *persuasion*, and the *institutional setting*. Power, or authority on the part of individuals or actors, can be an effective tool in situations where there is a big difference in actor's positions. Power may be the ability to influence issues important to one self (autonomy), or the means to influence others. Power can also be an informal source of leadership. Studies of environmental regimes show for instance that the less formal authority is vested in a secretariat, the more important are informal sources of leadership. The institutional setting is the operating procedures for reaching decisions. One can view institutions as a framework that regulates access to the decision-making table, and the kinds of problems that are decided upon. In this way, the design of regime may influence actor's willingness to agree on what to do and how to do it, merging diverging positions into collective decisions about solutions (4). The concept of regime will be discussed further in chapter 3.3.

The term adequate can be defined as "sufficient for a specific requirement", according to the Merriam-Webster Online dictionary. The specific requirement in this case study could be seen as the decision making process taking place, where the optimal goal is that the process ends with an informed consent, where sufficient and adequate information was provided and received concerning the different topics being discussed. The concept was, at the outset of the interviews, not given a strict definition. It was seen as most appropriate to let it be defined by the stakeholders involved in the process and learn if they experienced the information flow satisfactory according to their expressed or not expressed need for information (52). Norms could be defined as a principle of right action binding upon the members of a group and serving to guide, control, or regulate proper and acceptable behavior (52). In the GAVI-effectiveness paper, the prevalence of a disease within a country or region is said to be the key information that for national governments can justify the introduction of new vaccines. This information demonstrate the extent to which the disease targeted by the vaccine is a public health problem, and thus informs if immunization will be cost-effective and bring public health gains. Such studies are a norm in middle- and high income countries and with the Hib-

vaccine, this was increasingly also advocated as a norm for decision-making processes in low-income countries (4). In this case, the norm is not a binding principle of action, but more of a guiding one.

Norms can be seen as implicit rules underlying cooperative behaviour and regularity of behaviour, or a tool for coordination. Norms can also be defined as “standards of behaviour defined in terms of rights and obligations” (53). Norms can also be explained in the following “a variety of norms serve to guide the behaviour of regime members in such a way as to produce collective outcomes which are in harmony with the goals and shared convictions that are specified in the regime principles” (54).

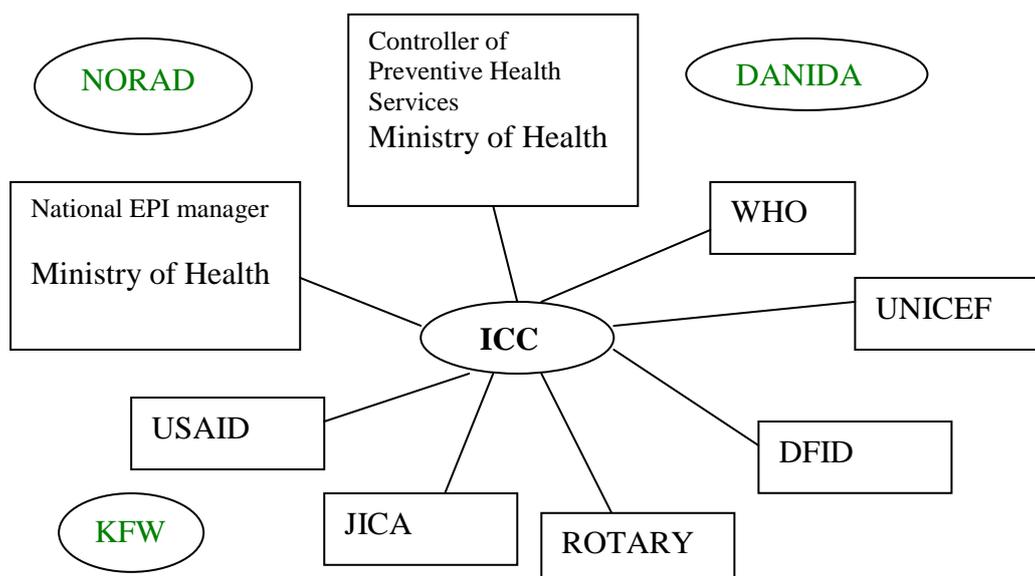
The interviews were recorded and transcribed immediately after they were done. As English is the official language in Malawi, an interpreter was not necessary. The respondents were informed on how the information given would be used and that the respondents would be kept anonymous, and as already mentioned, they were asked of their informed consent before the interview started.

4 Results

In the following chapter, the results from the field study will be presented. Many actors and organizations are involved in this case study. The ICC committee, which was one of the starting points for the mapping of the stakeholders, will therefore first be presented. In order to keep track of important moments in the decision making process, a chronology over the decision making process will follow, with an explanation of the importance of the different moments in time. The chapters following the chronology, are organized in accordance with the study objectives and the interview guide, although some chapters have been put together in order to give a more organized presentation. The persons interviewed are classified and referred to according to the following; Country Representatives (CR), In Country Partner Representatives (ICPR) and Global partner Representative (GPR). The “i” with the following number is for the author to identify the interviewees.

4.1 The stakeholders

The members of the ICC committee in Malawi at the time of application for the support from GAVI are illustrated below.



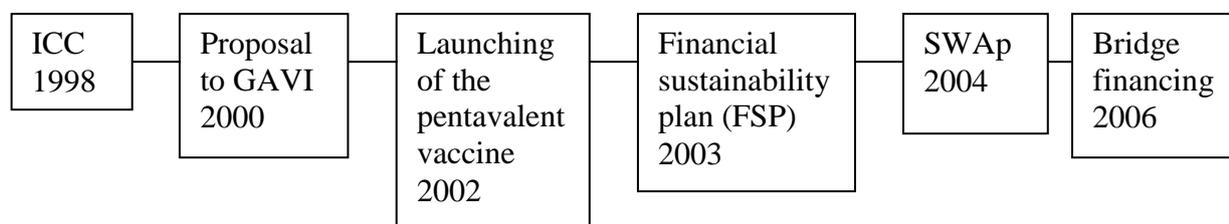
In the meeting minutes from the meetings prior to the application was sent, the actors taking

part in the discussions expressed the desire to include more stakeholders in the process, specifically mentioned; DANIDA, KFW, and NORAD, also outlined in the figure above, although not “attached” to the ICC. These were accordingly also of interest for this case study, however, the first two did not take part in any of the meetings prior to the application sent according to the meeting minutes obtained, and the latter was reluctant to be interviewed.

4.2 A chronology over the decision making process.

The results from the interviews suggest that a few main actors in the different steps of this process are more or less the same throughout the process, and many of them are also working with topics related to immunization today. It was also discovered information which indicates that the decision making process is a continuous process which is still going on, as the funding of the immunization programme in Malawi is not secured for the time after the GAVI support, and the prices of the vaccines are still relatively high.

There were different moments pointed out by all the respondents as important happenings which had and still has, influenced the process. In order to clarify to the reader the concept of these moments and when they took place, a time line is presented with a justification of why these moments were important in the decision making process.



The establishment of the Inter-Agency Coordinating Committee (ICC)

The date of the constitution of the ICC committee in Malawi is given as 29th April 1998. It was established as a permanent committee which should assist in decision making for the overall functioning of the Expanded Programme on Immunization (EPI). The background for the establishment was the need to follow up the polio eradication immunization days and to focus the efforts in the control of measles. The donors and Ministry of Health suggested the following be members of the committee WHO, UNICEF, the Department for International development (DFID) in UK, ROTARY, Japan International Cooperation Agency (JICA), United States Agency for International Development (USAID), the Norwegian Agency for

Development Cooperation (NORAD), Ministry of Health (55). With the exception of NORAD, these are also the members who constituted the ICC committee and who composed the application sent to GAVI.

One interviewee says the following of how the ICC committee was established on the basis of all EPI partners and who they were;”*and you could be an EPI partner if you were a donor, or if your contribution was funding or technical assistance*” (i9.ICPR). The respondents were not able to remember exactly when and how the process of taking in the new and under used vaccines started, but the ICC committee was mentioned by several to be the starting point, although they did not give any date or year of its establishment. Several of the respondents knew of the Hep B vaccine, and some of them had heard of the Hib vaccine although this was referred to as the “new vaccine” in the cases it was mentioned. One country representative said the ICC committee was established in order to support the polio eradication, and that ICC was not set up for GAVI, but that GAVI strengthened the operational and functionality and seriousness of the ICC. (i4.ICPR). The meeting minutes attached to the proposal to GAVI states more specific the time line here, as referred to above (55).

The establishment of a proposal to GAVI from Malawi

The GAVI proposal for Malawi was sent in February 2000, and it was approved from GAVI September 1st, 2000. Malawi launched introduction of the new vaccine (DPT-HepB+Hib) on 29th January, 2002. The country has given in an annual progress report every year since 2001 (the report from 2007 is still not on the GAVI website) (55, 56).

One of the country representatives refers to the beginning of the writing of the proposal as the actual beginning of the decision making process (i2.CR). Several of the respondents refer to the WHO annual meeting with the EPI management as the place where the news about the possibilities of receiving support for new and underused vaccines came up. Apparently, it was then discussed further in the MoH, before the information was presented at the ICC meetings. The time was stated to be late 1999 or early 2000 (i3.CR). According to one central informant, the proposal was written by MoH, then endorsed by the ICC committee, and then sent to GAVI for approval (i2.CR).

The establishment of the Financial Sustainability Plan

The request for a financial sustainability plan seems to have been important for new and further discussions concerning the future financing of the immunization programme in

Malawi. The pilot for the first financial sustainability plan from GAVI was established in 2003. The eligible countries were asked to give in their financial sustainability plan in the mid term of the period of support, and Malawi submitted their first financial sustainability plan in 2003 (55, 56). One country representative describes the introduction of the Financial Sustainability Plan in the following:

“(...)Initially there were no major arguments, until maybe, 2 or 3 years later, yes, when we got a communication from GAVI that we were supposed to write a financial sustainability plan, implying that oh, we went into something very expensive without knowing how we would manage that. So some people were saying that we wish we had started that discussion right at the beginning so that we could see the implications.” (i2.CR)

Several of the country representatives mentioned that the request from GAVI for a financial sustainability plan came as some sort of a surprise. Most of them said that the discussion of sustainability, both as a concept and as a challenge for the country, were not discussed in any detail during the decision making process, but it nevertheless came up as a substantial issue during the interviews. This will be discussed further in the next chapter.

Another description of how the financial sustainability became an issue is cited below:

“Now in those days, the initial days of course the cost was not really an issue, because government and countries saw more the positive consequences of introducing a new vaccine to the children of their own country, but there were very little regards to the cost implications to that. But now two years later or three years later GAVI began to worry what’s going to happen next, because GAVI is a good initiative.” (i4.ICPR)

The establishment of a Sector Wide Approach (SWAp)

Although the establishment of a Sector Wide Approach (SWAp) happened after the new vaccines were introduced, it can be seen as an important moment for the future financing of the EPI and the vaccines given in the country. The concept of SWAp was only in its planning process when the discussion of applying for the new and underused vaccines was taking place. One country representative said it was a discussion going on about SWAp at the same time as the discussion about the immunization programme. SWAP was to a large extent another way of organizing the funding for the health sector. As the new vaccines were free of charge for the first five years, the concept of funding was not discussed and therefore not the concept of SWAp, according to the same respondent. One country representative talked of SWAp as:

“(…)…the feeling at that time was that if major issues relating to EPI were put in Swap (….) it would be a problem. So that the organisations that were putting funds in, said (….) the funding should be set aside for EPI, but I think there was quite some discussion on that, because the ministry wanted all the funds in one pot, and some organisations said no. It takes quite a long time for government to give funds to departments that require assistance, so the feeling was that the EPI would get the funds directly from donors, of course passing through the ministry of health, but it would be like special funds for EPI(….) not all organisations were willing to put their money to the Swap basket at the time, it was quite an issue, others said no, what we will do is we will just buy into what is in the basket, I mean what the plans of the Ministry have made, and say, we are going to support this, funds will go directly to that.” (i1.ICPR)

One country representative had taken part in the discussion of SWAp in the ministry and gave more information concerning what the discussion was all about. He talked of SWAp as an operationalization of the EHP and said that SWAp is basically one shared goal where EPI featured heavily.

Seen in retrospect, now that the concept of SWAp has existed for a while, the EPI programme still has remained a priority for the Ministry of Health, according to one country representative;

“(…) the issue has just come in about two years ago. The issue of Swap, and the procurement of the vaccines, it’s just recent that we want to incorporate it into Swap. But when we were introducing the new vaccine it was purely known as a program issue.” i5.CR).

Another country representative expressed the concern they had because the SWAp concept would implicate that it would be the government who should purchase the vaccines, and no longer UNICEF who had done it for years, and this was to a certain extent a worry in the discussion.

Some respondents expressed concern that the introduction of SWAp would have negative effects on the EPI programme, which until this time was seen as a well functioning vertical programme, but that SWAp could have effect on the awareness of the financial side of vaccination as well;

“(…) efforts are still being settled on all the issues but also the Ministry does realise that EPI is also a major component of the serving of the child, because if it did not, then since the SWAP started we could have had no vaccines. So on top of all the other priorities that we had, it still recommends that EPI is also one of the key issues that had to happen. Before

SWAP, for someone to know how much it would cost, because the funding would just come from the DFID and then go, so the people would just see the vaccine, but now they actually see how much they have to bring out of the basket, outside, but it has always been prioritised and that's why I think it has really been successful.” (i3.CR)

The bridge financing

Some of the respondents talk of the bridge financing as a topic that came up when the request came from GAVI for the eligible countries to give in a financial sustainability plan. There was a discussion concerning whether Malawi would be able to start contributing a certain amount and then increasing it successively until GAVI could finally phase out, or if they should make an effort to be able to pay one certain amount and then stick to that flat out, and then rely on the prices of the vaccines declining. One country representative dated this discussion to be taking place around 2004 (i3.CR, i5.CR). The concept of bridge financing, or co-financing became an issue in Malawi as the support came to an end towards 2006, and the Government has so far committed to an annual contribution of 20 % of the total cost of the pentavalent vaccine, beginning 2006. The national health delivery systems will be strengthened to ensure high national immunization coverage. Therefore, continued financial support from partners is still required in order to sustain the provision of the pentavalent vaccine and for strengthening of the health delivery systems (57).

“(…) the program is heavily donor dependent. Until last year when the government at least contributed something, because of the bridge financing, the government contributed about 1 million, so this time around, this year we have contributed around 500 000, close to 500 000 US\$.” (i5.CR)

One alternative outlined by one country representative was to go back to the previous programme, without giving the Hep B and the Hib vaccine, if the funding of the vaccine is ending. This is described further in the next chapter. Another in country partner representative describes the changes as follows:

“We learned a little bit from our experience. GAVI phase 2⁴ has been designed with two major changes in the process, number one; it's not five years it's ten years,(…) because we learned, we got burned, and we learned that to expect the prices to tumble from a monopoly

⁴ GAVI Phase 2: Starting in 2006 GAVI will likely follow a somewhat revised set of policies to reflect experiences gained in phase 1 and evolving priorities and adaptations. The contents of phase 2 policies and priorities are still being defined.

position in as little as five years was unrealistic.(...) prices tumbling when there are two manufacturers, and eventually three four or five, in a ten year period, gives us a better chance of being right this time. And number two; vaccines are not free anymore. There is co-finance, co pay price which has been attached to those new vaccines, which is, admittedly, symbolic, it's not very much money, 30 cents a dose, but we feel that, critical, that Ministry of Health and Ministry of Finance, establish a budget line for this vaccine today, when they start receiving this vaccine from GAVI, so that when that GAVI support ends, they have already been accustomed to going to the treasury including a budget line, so that it doesn't... The shock is when you go from zero to something, but it's not so bad when you go from this something to that something (...)." (i9.ICPR)

4.3 The organization of EPI in Malawi and the entrance of GAVI

4.3.1 The EPI programme

All the respondents talked about the EPI programme in Malawi as a successful programme, and the country representatives and the in country partner representatives were very proud of what they had achieved. Some reasons for the success were said to be that the EPI programme did not have so many partners and that it was a vertical programme in the Minister of Health, and therefore was very independent of the other programmes going on in the ministry. It was also said that because they could manage the programme with the use of health surveillance assistants (HSA) instead of nurses and doctors in many areas, the health workers crisis did not hit them as hard as in many other areas of the Ministry of Health. Another reason mentioned by one in country partner representative for the success of the immunization programme, was that after a while this programme functioned very well. Donors would in general like to put their money, and names, into something successful, so that their organisation can show that their money is being useful, and so the donor community was eager and willing to put money into the programme.

When the persons involved in this study were asked which factors had contributed to the high immunization coverage given, the importance of Health Surveillance Assistance (HSA) was again mentioned by almost all the respondents as an important explanation. The EPI programme has also been successful in explaining the importance of immunization to the mothers in the district, or the social mobilization, as one of the country representatives called

it, and they have been able to build faith in the programme. Malawi's outreach activities were also mentioned as contributing factors, because it makes the walking distance for the mothers shorter. It was also mentioned that Malawi very rarely had stock outs of the vaccines, so the mothers did not experience the situation of reaching the health care facility and then the vaccines were not there. The fact that the vaccines are free of charge was also said to be important. One in country partner representative gives three main contributing factors to the high immunization coverage; strong leadership from the government, the role of the Health Surveillance Assistance, and the donor coordination around the interagency coordinating committee lead by the Minister of Health. Another country representative explained it by the dedicated EPI manager, with good support in MoH, strong district structure and generous funding from the donors, as the main contributing factors for the current immunization coverage.

According to all the respondents, UNICEF was the major procurement agency for the vaccines, although some mentioned that this was now changing, and that the MoH was in the process of taking over. When UNICEF procured the vaccines, the funding would go directly to UNICEF one country representative said. The funding as it is now will go to the government who will do the procurement, while the EPI will take care of the transportation of the vaccines to the districts. The Central Medical Store was, during the field work in Malawi, going through some reformations so the organising of the procurement was not all clear according to one of the country representatives. This was also described as an effort to try to move away from using UNICEF as the main procurement agency, to a situation where the Ministry of Health buys the vaccines directly from the manufacturer, and put it under Central Medical Store. The same country representative said they had never experienced any stock outs of vaccines. Another country representative mentioned that the BCG had been stock out once, but that this was due to a problem world wide, not for Malawi only. One country representative expressed concern on how the Ministry of Health was going to manage the procurement after the introduction of SWAp, and that direct procurement from the manufacturer could be a challenge. The factors of greatest concern, he said, were the continuous funding of the vaccines, adequate logistics for procuring the vaccines, and people trained in actual procurement; the expertise to see it through. One in country partner representative said that transport is and will be the most important factor that have or may disrupt the existing supply system.

4.3.2 The entrance of GAVI

Implementation of new vaccines at community level

Several of the country representatives and the in country partner representatives said the new vaccine did not affect the existing immunization programme very much, or that little change was required. The effects mentioned by two central persons in the process, were that there was a need for new training guides to facilitate the training, and with the help of the health education unit, come up with some publicity material, and also a chart showing how the new vaccine fitted in the already existing programme.

“At community level there was the IEC, Information, Education, and Communication, to get the information about the new vaccination out to the community so they would not be confused.” (i6.ICPR)

It was also important to make sure the health workers understood that they were now giving five antigens, not only three. A new EPI manual was published with the introduction of the new vaccine, and with the help of GAVI the syringes were changed from reusable, to non reusable or disposable syringes. The same country representative called the introduction a smooth transition, as the new pentavalent vaccine fitted well into the existing immunization programme. One country representative talked about the reporting system also being changed with the introduction of the new vaccines, explaining the drop in the reported immunization coverage in 2002.

“The practical doing was no change, it was nothing, it was the same thing, we were giving three doses to a child, in fact people didn’t notice anything, no change, the same thing, the only change for us, maybe the size of the vial, that’s all, this time around it’s small, but there isn’t much.” (i5.CR)

Representatives from GAVI had in many ways the same answers to this question, but also mentioned improvement of the cold chain system as something that had to be done at community level. An in country partner representative sums it all up in the following;

“I mean it takes about six months to get ready to introduce a new vaccine, you have to reprint the vaccination cards, prepare all your monitoring systems, you have to check your cold chain to make sure you have space to accommodate, to train your health workers, information packages for the general public, and for the public health community as well, cause you need, doctors, nurses, everybody must be on your side and behind it, hmm...you know by the time you receive the vaccine and send it out to the districts and get ready for day one, we used to

recon about six months. So, technical agencies like WHO we would concentrate on making sure the government was ready. That was our concern.” (i9.ICPR)

Consequences for the national health system

This was a question several of the respondents from all groups, found hard to answer, and the question could also be interpreted in different ways. One central person in the Ministry of Health said that there were hardly any consequences for the national health system, because that was the job of the Ministry of Health, to make sure the new introduction did not create chaos in the system. He explains this further by saying that in order to avoid this, you need to know the system well, and because they applied for the pentavalent vaccine only, they did not have to make any big changes. Asking the mothers to come for new shots would have shaken the system, and therefore the ministry tried very hard to avoid this, and applied for the pentavalent vaccine. Two other country representatives pointed at the reduced incidence of Hib meningitis after the introduction of the new vaccine as positive consequences for the national health system.

“Well in Malawi, really, EPI really didn’t have much impact in health systems, because coincidentally Malawi has more urgent issues to be solved from an instant point of view, and that was HIV/AIDS, and because EPI delivery system is so specific that you can actually, and this is demonstrated, you can actually make it work without the system work, because it is so specific, you need a cold chain, the vaccines has got the cold chain, you need the specific vaccine, you have the injectable vaccines, the oral vaccine, so this is one of the examples, and good examples in the world, that you can have a very successful vertical program, EPI, without a system functioning above, and Malawi demonstrates that.” (i4.ICPR)

GAVI; the organisation now and before and how to reach agreements

One global partner representative explained the history of GAVI as follows; there was strong criticism towards WHO and UNICEF for not taking responsibility when it came to new and underused vaccines and little had happened in the vaccination area since the 1980’s. To achieve results quickly, and efficiently, a new Alliance was created, were the partners should have the responsibility to do the tasks, and that the Alliance should only have a small secretariat, and no offices in countries; no country representation. It started out with one man and 50% secretary work, and during the first year, built up to five professionals, and three-four secretaries. They were based in the basement of UNICEF, and had a banc account of 750 million US\$ from the Bill Gates foundation. There was pressure on the Alliance to choose a

few pilot countries, and scale up their immunization programme first, but this was rejected by the starting group of GAVI, they wanted to have a quick scale up for all the countries who were defined as the poorest countries in the world with a GNP per capita below 1000 dollars a year. During the first year of GAVI's existence, they had approved the proposals from 50 countries, and when the results began to show, it was the Gates foundation that suggested prolonging the programme. The intention was to make the GAVI Alliance redundant. The criteria for being an eligible country have more or less stayed the same during GAVI's existence according to this respondent. There was in the beginning a discussion concerning how the different members of the Alliance should be organised. One reason for this was because the mandate an organization has on a global level, can be different from what they have on a national level. The role and responsibility of the members of the Alliance is according to the role of their so called comparative advantage and this has not changed to any extent since the start.

WHO and UNICEF are described as the main actors in the ICC by one of the global partner representatives, and they are also two of the principal partners in GAVI, according to one of the in country partner representatives. WHO and UNICEF are the two agencies that run the decision making body that directs GAVI and therefore the information distributed by GAVI must be harmonised and consistent with WHO and UNICEF. He further states:

"(...) and therefore information distributed by GAVI must be harmonised and consistent with WHO and UNICEF, and I think it is. I've never seen an example where there's any significant discrepancy, and I can't think of any example, they go to some trouble to make sure it's all... And don't forget GAVI doesn't have field staff, WHO has people in the field, UNICEF has people in the field, GAVI doesn't have, they only have its staff here, you just met them, they don't have any field workers. They go to countries, but they don't have people there who, you know, could possibly develop a different message, I couldn't see how that would be (...)"
(i9.ICPR)

One in country partner representative said that WHO is governed by the ministries of health in the member state countries, who forms the general assembly, which determines the work of the executive board in Geneva. The ministries of health wanted WHO to be an active partner in GAVI, and the member states will drive the agenda, according to this in country partner representative. Another global partner representative emphasized the communication between GAVI and the eligible countries, that the GAVI secretariat should not communicate directly

with the country, but that the main communication should go through WHO and UNICEF, so that the responsibility to communicate with the countries on technical issues were done by them. GAVI only did the communication concerning the application.

As of how the organization works when it comes to the applications they receive, the following was explained by one global partner representative; the country, with the help of the partners of the Alliance, develops the proposal. The proposal goes directly to the GAVI secretariat, the secretariat is organizing a review of the independent review committee, and the independent review committee is answering directly to the board that will eventually approve if the independent review committee is recommending for approval. The independent review committee has technical assistance from WHO. This was necessary in the beginning of GAVI, when there was a concern that the introduction of new vaccines would undermine the polio eradication, so WHO was requested to establish a team to pre assess the proposal which was submitted by the country and give technical advise about whether the country was giving the right considerations to the polio eradication activities, vis-à-vis the activities for the introduction of the new vaccines. There were also other pre assessments done like injection safety, availability of vaccines, and financial sustainability plans. In order to elaborate on how the GAVI Alliance has changed, he further says that in the beginning GAVI did not ask many questions to the counties on injection safety, then they started to ask the countries to give in documentation on this, then they started giving injection safety support, only for three years, and most of the countries continues to have a focus on this after the three years have ended, some also expand it to the entire health sector. According to this global partner representative the requirements of GAVI will keep modifying by building on what is the capacity the way it is developed in the country.

Advocacy

It was said by one in country partner representative that tonnes and tonnes of advocacy was done for the new vaccines, in terms of websites and publications. Another global partner representative specified it further by saying that it was important for GAVI to make sure the countries knew that the vaccines were available, that they knew of the recommendations from WHO and the World Health Assembly.

GAVI's contribution to immunization in Malawi

As one mentioned earlier, GAVI's contribution could be the strengthening of the functionality, operationality and seriousness of the ICC. Other than that, WHO's Reaching Every District (RED) approach was mentioned, because the percentages that are not reached for immunization, is often not reached because the places they live are difficult to reach. One of GAVI's major contributions was mentioned as the support for infrastructure for immunization services. The possibility to increase the reward for every additional child vaccinated in order to increase the immunization coverage, was also talked about as a solution. The issue of health system strengthening could also be a contribution from GAVI; *" (...) then there is the system of health system strengthening (HSS), you know there are so many barriers in the immunisation which are not restricted to immunisation, and the root of those barriers are belonging to the system, the health system, so the issues of having initiated giving these countries the possibility to address those barriers for sure will have an impact on the actual consolidation on the immunisation programme, to make it stronger and able to achieve what now it becomes much more difficult to achieve."* (i8.GPR)

When asked if the position of the immunization programme in Minister of Health and Population had changed before and after GAVI, one respondent answered that the volume of the focus has changed, being more focus on it now than before, but the reason for this he said, was more due to the increased focus on the Millenium Development Goals (MDG) than the existence of GAVI, although GAVI had helped increasing the focus in the decreasing of meningitis cases. Another one said, the attention of the programme had increased because of the increased cost of the immunization programme after the introduction of the new vaccines. The concept of SWAp was also given as a reason for the increased attention on the cost of the programme. Several country representatives said the position of the programme in MoH had more or less stayed the same.

"So in some countries the GAVI have had a stronger impact than others, in Malawi apart for the supplies and financing, in terms of planning and seriousness of EPI, there's no change" (i4.ICPR).

Major concerns in introducing new vaccines to Malawi and other developing countries

The concern emphasized by one global partner representative in introducing new vaccines to developing countries in general, was the dependency on GAVI and the donor support, and gave this as the reason for GAVI to introduce the concept of co-payment, where the countries

are required to contribute a small amount for each vaccine, already from the start. He calls this a lesson learnt from GAVI, in order to make the countries plan for the time when GAVI is longer giving support. Another concern expressed by the same person, was the management of the vaccines, the improvement of the cold chain, and the procurement and distribution of the vaccines. Another in country partner representative talks about the system barriers as the major concern in introducing the vaccines to developing countries. These are, according to him, the barriers out there that prevent vaccination from rising. He says further that GAVI ran a study on system barriers in Malawi where they found no system for vehicle maintenance, and the same time learning that the outreach programmes are very transport dependent. If you don't have adequate transport, or drivers, or fuel, then you have a problem reaching every district. This respondent also mentioned the shortage of health staff in the country as a major concern.

The plan of action for the Malawi health sector, for 2001-2005, also mentions the challenge of religious groups such as Apostolic Faith and Zion who do not allow their members to receive immunization. During the rainy season some areas are also impassable, which denies the children in these areas to complete their immunization in time (58, 59). In the Malawi annual report of the health sector for 2006/2007, the main challenge is said to be the procurement of the vaccines through the SWAp mechanism (28). The procurement and distribution of the vaccines and the improvement of the cold chain was also mentioned by one of the global partner representatives. All the reports mentioned above, mention the shortage of health staff as a major challenge, although this is not a problem for the immunization programme alone, it goes for the whole health sector. This was also mentioned by one of the in country representatives. The system barriers that prevent the coverage from raising is also mentioned by one in country representative as a challenge, and Malawi had their proposal to GAVI for strengthening immunization system support approved in June 2007.

4.4 Political and institutional factors affecting implementation of new vaccines

4.4.1 The influence of the actors

Participation and personal influence

The participation of the stakeholders was very much decided through the ICC committee and the members of this committee were as stated earlier in this chapter, the main EPI contributors. It was the Ministry of Health who chaired the ICC committee. All the respondents in this case study were involved in the process at the time the decision to apply for the pentavalent vaccines came about, although not all of them had participated in the meetings in Malawi. When asked about their own personal influence some of them found it difficult to be the one to judge their own personal influence or performance. The possible personal influence came out as a factor when they were asked of the reasons for success in the EPI programme, as their names and the role they played were mentioned as one contributing factor. Here the respondents did not mention themselves, but were mentioned by other respondents.

The stakeholders' relation, role and interaction

At the time of discussion concerning the new and underused vaccines, the SWAp was not yet on the agenda. The Malawi government and the international community had therefore not started the so called basket funding, and the different stakeholders had different roles according to what they could provide; their comparative advantage. JICA provided equipment to the cold chain and also funding after a while. The role Ministry of Health was more in terms of policy and directions in terms of how that policy can be properly implemented using the instructions and structure of the ministry. The EPI programme was said to be looking after all the immunization given in the country, looking for surveillance issues, looking for measles cases and neonatal tetanus cases, and take care of the National Immunization Days (NID), among other things. They are also responsible for the information, education, and communication (IEC), and to keep up the awareness of immunization in the community. The USAID was to a large extent responsible for the system strengthening programme, and provided also technical assistance. WHO supported the national programme in capacity building, development of annual and period work-plans, surveillance strengthening and partial funding for routine immunization activities. UNICEF called their role instrumental, and they took care of the purchase and procurement of the vaccines. According to the country

representatives, the ICC relies a lot on the EPI programme management technical working group.

“EPI does not have very many partners because they are already performing very well..., but the few partners that are there, they are already so much involved in such a way that their participation is adequate enough for the country.” (i2.CR)

The process and the interaction between the different stakeholders is described further by one country representative:

” So what is happening is that instead of having a wide achievement with technical people discussing issues to inform policy, at the technical level we rely on guidelines from WHO. So these meetings that we are talking about they were organised by WHO. So whatever we get as a new direction in terms of what to adapt or adopt, we discuss it, we just go for a meeting and ask the District Health Officers (DHO’s) and the other partners to participate, within the EPI program, so there is a discussion. What that discussion comes up with, conclusions, maybe adapt the guidelines or the generic guidelines, then ones we have adapted, the EPI program goes ahead with the preparation on how these guidelines should be implemented, in terms of what has to be procured, what has been changed, what has to be developed in training management and the like, so that transverse into a package. Now it is the package of what has to be done and how much money is required to do what has to be done, that goes to the ICC. Now the ICC includes all the partners like the donor partners, , DFID, USAID, NORAD, the UN bodies , that is participating in the EPI, to discuss, first of all to look at what we have agreed on activities to influence, to manage the change, or to manage the diversion of the new guidelines, whether we have done it in such a way that it will be cost effective. It is not a question of whether we will do it or not, it’s a question of whether it is done in such a way that it is cost effective....(...)...the next thing to be doing till we meet again, is to look at the financial mobilisation, how much will come from government, how much will come from....so we put that figures on the left column, the donors on the top column, and then whatever amount they put on each one of the activities, we know which are the gaps. So using that approach we have been very, very successful,” (i2.CR)

When it comes to the actual proposal for the funding from GAVI, the Malawi government was said to be the owner of the proposal, and one of the requirements from GAVI was for the proposal to be developed in close cooperation with the ICC committee. The final signature is

always from the Minister of Health, but as was said during one interview, a signature from the health minister without the signature of WHO and UNICEF would not be good.

GAVI and WHO

One country representative said WHO provided the information needed concerning the new vaccines. A global partner representative gave one example of the cooperation between GAVI and WHO:

“(…)in the past we had technical assistance from WHO on the issues of polio, particularly at the beginning, just at the beginning of GAVI, there was a concern that the introduction of new vaccine would have minimized the whole of polio eradication which was actually still a concern in most of the countries, so WHO was requested to establish a team that could pre-review, or let me say, it’s not correct the word pre-review, but pre assess the proposal which is submitted by the country and give a technical advise about whether the country was giving the right considerations to the polio eradication activities, vis-à-vis the activities for the introduction of the new vaccines, so that was one of the issues that was relevant for them.”
(i8.GPR)

On the question of whether this role had changed before and after GAVI, one in country partner representative explained it in this way; WHO is a sort of cooperation designed by the workers, WHO is governed by the ministries of health of the countries, the 90 member states who form the general assembly which determines the work of the executive board with the headquarters in Geneva. The ministries of health wanted the WHO to be an active partner in GAVI, and it is, so you know, the member states still drive the agenda (i9.ICPR).

4.4.2 Toleration of dissent

One of the questions asked during the interviews were if there had been a lot of discussions when the meetings took place concerning whether the vaccines should be integrated in the immunization programme or not. This was denied by most of the respondents. In fact, all except from one said they all agreed it was a good idea, and if there were any discussion, it was more concerning the practical side on how to implement the new vaccines.

4.4 The role of international norms on new vaccine introduction

An important part of the standards of behaviour or norms in the vaccine introduction process is the exchange of information and technical advice between WHO and countries, and between GAVI and countries, and the presence of information expected to be part of the decision-making process.

4.5.1 Facilitation of adequate information

Although the term adequate in this case study can be seen as sufficient information provided and received concerning the different topics being discussed in the decision making process, the concept was, at the outset of the interviews, not given a strict definition. It was seen as most appropriate to let it be defined by the stakeholders involved in the process and learn if they experienced the information flow satisfactory according to their expressed or not expressed need for information. On the topic concerning adequate information, the respondents are asked where the information came from, what kind of information Malawi asked for, what kind of information Malawi was asked to provide and information between GAVI and countries, and the responsibilities of WHO in that setting.

From the WHO point of view, the important information for them to receive from the country was information concerning if the government was ready to introduce the new vaccine. The respondents talked about the need for information as different now, and in phase 1. In phase 1 the important information for GAVI to give to the countries were concerning what a good application was all about, and what were then criteria for support (i7.GPR). On the question concerning where the information came from, most of the respondents answered WHO and UNICEF. The information concerning the specific application from Malawi was given from GAVI, and also offered on request if needed. It was also mentioned that some information came from within the EPI programme, especially the official national statistics, and information concerning the national immunization days.

One of the global partner representatives said the important thing was that the countries were aware of which vaccines were available, and when it came to Hep B, to make sure the countries were aware of the recommendations from WHO that the World Health Assembly had made a declaration that every country, except for a very few, were recommended to take

in the Hep B vaccine. This was a bit different for Hib, as the recommendations concerning this disease were built on the rapid assessment⁵ of the disease burden. (This has changed however, with new recommendations from WHO advocating the desirability of Hib use in all countries (14). He also mentioned that it was important for GAVI to receive the plan of the countries vaccination programme. It was more important to know of the different constraints in the system which could be a potentially obstacle for the immunization coverage, than of the disease burden, he said. (i7.GPR). Another global partner representative said that WHO had now come out with a general recommendation concerning the Hib vaccine as well, without having any information on disease burden. (i8.GPR). The respondents were not clear on what kind of information Malawi asked for, instead they answered yes on the question of if the information flow was adequate and sufficient. When representatives from GAVI was asked what information was important for them that the countries were provided with, they answered that it was important that the countries knew of the criteria for support, and how to write a good application. After phase 1 had started, it was further important for GAVI to receive a progress report, financial sustainability plan, and a multiyear comprehensive plan in order to get information on the long term immunization plan for the countries involved. (i8.GPR)

To give in a plan for the introduction of the new vaccines was also some of the information the country representatives said they were asked to provide for GAVI. The national annual vaccine requirement was also mentioned by another global partner representative as important information from the countries to GAVI. In the meeting minutes in the application to GAVI, the ICC members suggest that more details and clarifications for GAVI should be made available (55).

Concerning the information flow between GAVI, WHO and UNICEF, one global partner representative describes it this way:

“(...) all countries are sending by the 15th of April, normally, they are expected to submit to the regions and then from the regions to the head quarters, they call it joint reporting form, whereby they report how many children they have vaccinated or which vaccines against the target population and so on, so we base ourselves on this report, because our partners, main partners, WHO and UNICEF who are in the country will be the best agencies to verify what

⁵ Hib Rapid Assessment Tool is used to quickly obtain data on the size of Hib disease burden. It is used by setting the number of Hib meningitis cases against the whole population in the district under age 5, to give an estimate of the incidence of this condition.

they are talking about in the joint reporting form and what they are raising in the annual progress report, if they actually match or not. (...) when the independent review committee verifies when receiving the annual progress report, one of the ways of verification is to see the consistency of these data with what has been written in the joint reporting form. The annual progress report is from the country, and the joint reporting form is from WHO and UNICEF.” (i8.GPR).

An important part of information, one in country partner representative emphasized, was that the country had set up mechanisms to check for adverse events following vaccination. This was something that WHO concentrated a lot, according to this respondent (i9.ICPR).

One global partner representative said that today, the two important parts of information that is important for GAVI to give to the countries is that the eligible countries should be aware that there is a cost involved in applying for new vaccines, it is no longer as it was at the start of GAVI, that they get a donation for free for the first years. Secondly, it is important for GAVI to receive information on how the countries are planning on renewing and maintaining the cold chain system, so that by the time they will introduce the new vaccines they will be able to have the sufficient capacity to accommodate that vaccine and to manage it properly and to the standard criteria (i8.GPR).

Data on disease burden

There were few data on disease burden available from Malawi prior to the application was sent to GAVI. The respondents had different opinions of whether the data on disease burden were there or not at the time of the application, and also whether the data they had were of importance for the application. Several of the respondents mentioned that the data of Hep B were the general recommendations from WHO, and one also mentioned that Hib had been studied by WHO in neighbouring African countries, and that these data also could be applied for Malawi. There was a general recommendation from WHO and the World health Assembly that Hep B should be given to all children world wide, except for a few countries, and one global partner representative said there was also a recommendation from WHO that Hib should be given to all children. This was confirmed by another global partner representative who said that GAVI saw Hib as a big problem especially in Africa, and that GAVI had taken the initiative to do the rapid assessment of Hib in some African countries, and this was decisive in order to decide whether to take it in or not in some countries. In some countries

these data were not considered. In the application sent to Malawi, no data on disease burden were given, and the rapid assessment for Malawi had not been done.

When asked about the disease burden on Hep B and Hib, all the respondents agreed on the fact that there were few data, and that these data had not been important for the decision to send in an application to GAVI. The data they had, had been obtained independently of the decision to apply for funding, there had been by coincidence, according to a country representative, a study done on blood donors on Hep B in Lilongwe, which showed a prevalence of 8-10%, and Welcome Trust had been doing their own studies in Blantyre, on bacterial meningitis, where they had data from five years back, which showed that Hib was accounting for many of the bacterial meningitis cases. These studies are presented in chapter 2.4.3 and are mostly from the time before the introduction of the new vaccines. (41, 42, 43, 44, 45). One in country partner representative emphasized that there were no “data” on disease burden, only projections.

“We didn’t, to be honest, we didn’t spend a lot of time on that issue, and the countries weren’t asking a lot of questions. It was...in the public health community it was I think it was widely understood, that liver cancer is the first cause of cancer mortality in most of Africa, therefore if these guys have a vaccine to prevent it; it must be a good thing. That was largely...Hib was even more difficult, because there was even less information about burden of disease. And, of course, you know Hib produces meningitis and pneumonia, and it’s very difficult...it’s very complicated to estimate what proportion of overall meningitis is due to Hib and what proportion of overall pneumonia is due to Hib, we do have some rough figures on that, but again, it’s pretty much estimates.” (i9.ICPR)

4.5.2 Access to data on costs and benefits

On the question if the persons involved in the decision making process had access to data on long term costs and benefits, most of the respondents answered no, they did not have these data available. One of the in country partner representatives answered a clear yes, sure, on the questions on if the data on long and short term cost and benefit was available, but did not elaborate on this further. Most of them said they did not have the data on this, and that especially the cost was something that came up when Malawi was asked to give in their financial sustainability plan, half way through the first five years. When the subject of cost and benefit came up during the interviews, the discussion of sustainability also became a part of this question. This will be a topic later in the result chapter and will therefore not be

elaborated further here. One in country partner representative said, that in the overall strategy for health, the immunization of the world's children is considered the most cost effective intervention that can be done, and that the problem is that immunization is not given the right level of resources which was expected to be received. This, he argues, is because the curative part of the health sector has had priority over the preventive part, and that when talking about cost-effectiveness, the curative part is very costly, and maybe more so than the preventive one. (i8.GPR)

It was strongly believed, one in country partner representative said, that the massive increase in demand for the new vaccines would convince the manufacturers to allow the price to decline, increase the competition from other manufacturers and thereby reduce the cost. This has happened to the Hep B vaccine, where he gives the price of the vaccine to be 25 cents, declining from 100 dollars a dose in the 1980's.

4.6 Issues raised by the respondents

What is written in the previous chapters were the main issues raised in the interviews, but it was not, however, most of the respondents major concerns. During the question of whether there was a lot of discussion during the meetings prior to the writing of the application the answer was no. However, several of the respondents elaborated further on this later in the interview, and when asked of the major challenges in implementing the pentavalent vaccine, some main issues came to the surface.

4.6.1 Sustainability

According to GAVI's own evaluation of phase 1, contrary to their expectations, a five year period was insufficient for vaccines to become affordable and for government budgets to adequately expand to finance them. Some GAVI partners also believe that providing vaccines for free, contributed to weak national decision making. When some of the "early-adopter" countries were faced with having to finance the vaccine through national and partner/donor resources, it became clear that they had introduced Hib vaccine without first reviewing the evidence and deciding that it was a national priority" (60).

One in country partner representative said that the discussion of sustainability is now the most difficult part of the whole exercise. Several respondents started answering the question of sustainability by giving their definition of the concept of sustainability. Sustainability could be defined as the ability of the country to continue its immunization program in the absence of external support (61). One says that no government in the developing world has the money to finance all the interventions that has presently been financed with external money, so sustainability becomes more of a question of who's going to pay, the donors, the government or the users of the services. Now, if donors want to sustain the new vaccines introduced in Malawi, they have to continue pumping money, according to this in country partner representative. Malawi is genuinely poor, so in countries like Malawi, he says, donors have no other option. Another global partner representative said that sustainability is not the same as self sufficient. Sustainability, he says, is when the economic development has reached a gross national product of above 1000 US\$, and they will be able to finance the new vaccines. This was contradicted however by another in country partner representative. A global partner representative said that sustainability is not the same as self sufficiency, but as the possibility for local resources both from the government and from other resources in the country. One country representative says that the issue of sustainability is just an excuse for not introducing new ideas. One global partner representative answered that until Malawi had experienced some economic development, the possibilities for them to take over their immunization programme, and make it sustainable, is an illusion. He further says that when they achieve a gross national product of above 1000 US dollars, they will be able to finance their own vaccines. One country representative emphasized the fact that the immunization programme in Malawi is heavily donor dependent. The issue of sustainability, therefore, was often talked about in connection with the commitment of the donor, and the continuous funding from the donor community. The sustainability depended on if the donors would be available to provide funds for procurement of the vaccines (i1.ICPR). One country representative says further that when the question came from GAVI on how Malawi could sustain their immunization programme, a programme that had increased it's cost by 90 % because of the new vaccines, the Malawi government answered that this would not be possible for them to sustain, and that if this was a criteria they would go back to their original immunization programme.

“What we would just tell them that actually the diseases can come back and they can restart as a major problem, but for the sake of what we will explain; we are no longer able to procure the additional vaccine which were in the same volume, because of financial

problems. The partner who was there before has decided to discontinue in supporting it.”
(i2.CR)

One country representative said there was little discussion on funding at the start of the process, the vaccines were coming for free so there were no major headaches about funding, and the challenge and discussion of sustainability came up when Malawi were asked to give in their first financial sustainability plan, mid way through the first five years of support, and that it was at this point they discovered how expensive the vaccines really were when comparing it to other vaccines in their immunization programme.

“(…)so we had to be open in our discussions, for Malawi this is what it could mean because maybe had we known it would be this expensive although it is very good for the children, we would have waited and worked with GAVI properly, but this was like a support which had come in and we knew we needed it so who would say no.”(i3.CR)

The same respondent says it was a good thing they started to talk of the financial issues, because by that time the assumption was that the prices would come down but it was discovered after the first phase that they'd really never dropped.

“(…) we are hoping for the best as we move on, because a country like Malawi with a lot of other health problems would not be able to pay that sort of cost, so it is a good thing to have the discussion of co payment with WHO and GAVI” (i3CR).

The alternative of going back to the old immunization programme was also mentioned as a solution, talking about it as a disaster for the Malawi children.

All the respondents emphasized that the cost of the vaccines and financial sustainability was not really an issue in the initial phase of the discussions, there were little regards to the cost implications. One in country partner representative said that a government like Malawi at the time of the introduction was not really prepared to fund the vaccine that would cost them 5 dollars, with the total health expenditure being 10 dollars. As time went on the issue of sustainability came up, because “everybody” had begun to worry, the countries who had implemented the vaccines in their immunization programme, and GAVI. As the respondent said, very few countries in the world will be able to cover the 5 or 6 dollars that the original vaccines are costing. When the respondent goes into the question of challenges for Malawi in implementing the immunization programme, the issue of sustainability comes on again. He says that Malawi has for the first time had a positive economic growth, and if the trend

continues they might expect higher levels of income to the government and thereby higher levels of finances to the health sector, but unless that happens, it is difficult to see how they will pay the price. He says further that immunizing the children is a part of the Millennium Development Goals, which GAVI is also backing, and he gives the numbers on this by saying that achieving the MDGs will cost approximately 60-80 dollars per person. This is not possible to do for Malawi alone.

As mentioned earlier, the issue of financial sustainability through a financial sustainability plan raised the question of how Malawi was going to handle the situation after the GAVI support had finished, and how much they would be able to contribute. Several country representatives presented the responsibility between the Malawi government and GAVI like this; Malawi should be able to pay a fixed contribution, which was given to be 1 million dollar per year, and then GAVI should manage two things; to contribute the remaining amount of money, and to negotiate on price reduction. Another country representative said the request from GAVI was that the Malawi government should start contributing a certain amount and then increase, but the Malawi government and the Ministry of Health said they could only manage a certain amount flat out. They were expected to pay 20 cents per dose, which this respondent gives to be around 400 US\$ per year.

From GAVI's point of view, the financial sustainability plan was partly introduced to make the countries aware of the issue of the vaccines having a value, they have a cost, and to encourage the countries to start giving something. One global partner representative said the original plan for GAVI was to give support for five years, but then the Alliance became so popular, and the market forces started to have an influence on the Alliance, and this increased the resources, and thereby the possibilities for the Alliance to extend their support to 15 years. The plan was still to have reduced prices by competition from several pharmaceuticals, also in the developing countries, according to this respondent. Another one explained this prolonged support by the influence of co payment, if the countries contribute with a certain amount, GAVI will be able to give support to that country for a longer time. One in country partner representative calls the introduction of the financial sustainability plan an interim measure to begin to accustom the countries to the idea that the price shock at the end of phase 1 might not be quite as light as we thought it was going to be.

4.6.2 Vaccine prices and co-financing

The description of the situation and the “discussion” concerning the price is described in the following:

“This was GAVI phase 1, so there was no what we call co-finance.... it was free. So when everybody turned to me as a technical, sort of, advisor, and said; ”What do you think....?”, I said; “ Go for the all in one, what have you got to loose?.... So I said, if supply is available, there were one or two supply issues around at the time, but if supply is available, why not go for the all in one? There is no pain for the country at all, there was no price.”(i9.ICPR).

The price of the vaccine determines whether the vaccine is in or out, it’s all or nothing, it does not determine coverage, one in country partner representative said. There was not done much in terms of cost and benefits assessments, according to this respondent. One global partner representative said the price reduction of the vaccines have been much slower than expected, even though the price of the tetravalent vaccine has been reduced by 50%. He expresses disappointment with UNICEF in not being able to negotiate the prices further down. One global partner representative said that GAVI played a role in the marked, in the sense that if they increase the vaccine demand, it will challenge the manufacturer, which again will give a drop in the vaccine prices. At the end of the 1990’s, the expectations were that the decline in prices would have happened more quickly than what has shown to be the case, one in country partner representative said. He takes it further by saying that the vaccines should not have been free of charge in the first place, and calls it a bad calculation. It was too easy to take a free vaccine and not worry about the future, although Malawi thought about the future more than some countries and quite early in the process started discussing the concept of sustainability. It might have been better to have a symbolic charge to begin with, he says. All the respondents expressed optimism when talking about the future possibilities of having a price reduction of the vaccines.

“We should never have given the free vaccines..... Well, I think it was a, it was a, a bad calculation. It was too easy to take a free vaccine and not worry about the future, and all though Malawi did think about the future perhaps a little bit more than some countries, some countries never questioned sustainability, they said, “free vaccines?, we’ll take it!”(..)We have learned that lesson, phase 2...you know, any organisations that learns from its mistakes is doing a good job, GAVI has learned, we are doing it differently now.(...)There’s no point in blaming anyone, nobody was responsible it just happened, but it’s possible that if some of us with much more extensive field experience, had been consulted and had had an opportunity to

really influence the policies, we might have realized that it would be better to have a symbolic charge for the vaccine". (i9.ICPR)

One in country partner representative emphasized the expectations of the prices of the vaccines coming down, he talks about the dollar vaccine and the penny vaccine, and the message was at the time of the introduction, that by the time the GAVI support finishes, the vaccines would have become a penny vaccine. The biggest issue at the beginning of the discussion was how to make the country ready for the introduction of the vaccine, from a technical point of view, and although the issue of sustainability was raised, he says, the countries were told not to worry, because the prices would come down.

"... cause that's the trouble, you know, a little bit like private investment, you know, the guys tell you, this investment is going to earn you money, you know, they don't know, based on previous trends they should, but the future can't be foretold, and the same thing is true for these vaccines, the vaccines prices, all indications are, that all the necessary components are in place but the vaccines should drop in price, because of this and this and this, but, will it actually happen?" (i9.ICPR)

5 Discussion

The overall targets for this case study were twofold; to assess whether the introduction of Hep and Hib had influenced the immunization practices in Malawi and if the implementation of the new vaccines required changes in the existing immunization programme in the country. The aim was to trace the decision making process, and find out more of whom participated and what factors affected this process and the decision of introducing the pentavalent vaccine.

Certain topics evolved during the interviews as the essential subjects of discussion, which suggests some main findings of the study. These are therefore accordingly, set as the main topics for this chapter. It is important to recognize that this study did not measure the respondents actual behavior in the process, instead the findings represents the respondents *perception* of these factors, together with documentations concerning the same area of discussion. The information given in the interviews could thus be about their opinions, even what they think is the right thing to say, not necessarily what they have done.

5.1 The policy context

The specific role of international agencies towards the national immunization programme did not change much with GAVI, but the policy context changed with the transition to the Sector Wide Approach (SWAp), as SWAp is a way of securing equity of funds to the health sector, and the financing issue of the immunization programme is a prominent issue in the discussions in the health sector. Hence, the introduction of SWAp changes the context for the discussions, although it did not develop as a result of the new vaccines in EPI programme. At the time of the introduction of the new vaccines, the EPI was a vertical programme, which is said by one of the country representatives, to be one of the reasons for its success. Malawi submitted their first Financial Sustainability Plan in 2003, and one year later the establishment of Sector Wide Approach (SWAp) was launched. Both factors increased the focus on the financial issues in the discussions.

5.1.1 The position of the EPI programme in the Ministry of Health

In the Malawi application sent to GAVI in 2000, the National Vaccine Supply Strategic Plan is attached where the EPI programme is called one of the priority programmes Ministry of Health (55). At the outset of this case study the position of the EPI programme in Ministry of

Health before and after the introduction of the new vaccines, seemed to be an interesting aspect of the discussion in order to try to find out if this had any consequences in the national decision making process. The results gave diverging answers and explanations, those who said there had been an increased focus explained it by the increased focus on the Millennium Development Goal, and the increased cost of the vaccine, and those who said there was no change in focus, did not give any further explanations for this. The EPI programme had already dedicated personnel, and the programme was by many called successful. It was a programme in the Ministry of Health which “everybody” was very proud of, and it was known in the donor community, in GAVI and in Malawi for its success. The existing and strong EPI programme was also given as supporting factors for the introduction of new vaccines in Thailand and Taiwan (2). It was expressed concern however that with the introduction of SWAp, the EPI programme could be suffering from competing programmes. The SWAp mechanism had only been existing for three to four years at the time of the interviews, so the effect of it was yet to be seen to its full extend., but also in the article from the University of Malawi before the introduction of GAVI, the lack of clear and unequivocal government commitment towards the EPI programme is mentioned as a possible contributing factor that has already disrupted or may threaten to disrupt the existing supply system for the vaccines. In order to improve and sustain the current immunization coverage, they recommend the Malawi Government to have the commitment to make immunization a priority (30).

5.1.2 Role and relation of stakeholders

All stakeholders in the process talked of Malawi as heavily donor dependent. As GAVI is more or less an Alliance constituted by the same actors already present in the country, with the private industry as an additional member, the difference in the stakeholders influence before and after GAVI can be difficult to judge. Like in international environmental commitments there are many factors influencing the international health commitments as well, and tracing cause and effect can be difficult.

The actors, whom ended up taking part in the study, can be considered to be health policy makers influencing health policy on different levels in the Malawi health system. In Munira and Fritzen`s article, the roles and the relative strengths of the actors is said to be depending on the context of the policy making. Seen in relation to regime studies, some of the factors

that can affect the behaviour and effectiveness of international commitments is the configuration of power, and the public concern. It should be reasonable to say that the relationship between the different actors in the field of immunization is between actors of unequal power. Money, expertise, professional norms, and moral norms are all sources of power (62). According to the book *Poverty, AIDS and Hunger*, by Ann Conroy, international estimates suggest that providing comprehensive health care requires investments of at least US\$35 or US\$ 40 per capita. The Malawi Government estimates that the Essential health Care Package would cost US\$22 per capita, but the budget for the Ministry of Health provides less than US\$10 per capita, and it says further that it will be impossible to improve the health status of Malawians unless human resource and financial constraints are addressed urgently and comprehensively (33, page 46). In the annual report for the health sector for 2006-2007, it is found that from 1998/99 to 2004/05, the total expenditure on health has increased from 12 US\$ to 20 US\$ per capita, and of the 22 US\$ necessary for the delivery of the EHP, the government and donors provided 16.9 US\$ (28). The exact numbers on how much the donor community is providing is not given in this literature, but it is reasonable to assume that if Malawi contributes less than 10 US\$ of the total amount of 22 US\$, it can indicate the importance of the role of the donor community in financing the health sector. As money can be a source of power this can also influence the role and interaction the donor community have with the Malawi government when it comes to decision making processes in the health sector.

In periods where the prominence of the issue is rising, the decision making is more likely to be dominated by senior political figures, but in what they call “bureaucratic-politics-as-usual” times, the technical personnel of different kind, are more likely to play a prominent role (2). In the case of Malawi, the people who had taken part in the process were of different character. There were senior and relatively prominent people representing the Ministry of Health, and other less prominent people, also in the donor community. Whether or not they answered strictly to official policy issues, is difficult to judge as the policy documents are few. The time span since the actual discussions had taken place was said to be a challenge for all the respondents. This could make the recall of details in the process more difficult, and make the memories more selective.

The role and the interaction of the participants in the process in this case study, was very much a result of the organization they represented at the time. In GAVI, the UN agencies are

no longer the leaders, and the donor countries and agencies hold the majority vote (20). However, it now has to cooperate with other stakeholders through GAVI. Many would argue, and particularly within WHO, that WHO is still the lead agency on vaccines and immunization at the global level. One could ask if the WHO influence is different in countries. The persons interviewed in Malawi referred to WHO as an important stakeholder in GAVI and together with UNICEF seen as the main actors in the ICC and one of the principal partners in GAVI. One in country partner representative said that WHO and UNICEF are the two agencies that run the decision making body that directs the Alliance, and that the information distributed by GAVI must be consistent and harmonized by WHO and UNICEF. The role of WHO in GAVI has not changed very much since the development of the Alliance, according to the interviews in this case study. On the other hand, there is literature concerning the complicated process of the creation of the Alliance, where the cooperation of WHO and UNICEF and the Alliance is described as somewhat difficult. In order to get GAVI off the ground, it was essential to bring WHO into the centre of the Alliance. WHO had been criticized for not being able to take the necessary steps, and take charge of the topic of immunization. WHO talks about being sidelined of vaccines in the 1990's, and did not feel the ownership in this area. This literature also talks of a continuous tension between the goals and operation of the GAVI and the interests of its principal partners. It says further that those who staff the GAVI infrastructure are constantly made aware of the ambivalence felt by both UNICEF and WHO toward the Alliance, and the ongoing danger of losing their interest and cooperation (2, page 243). None of the respondents expressed knowledge of any tension between any of the stakeholders during the decision making process. This might have been because there was none, or because they did not want to reveal this information. In a GAVI initiated evaluation, the constitution of GAVI with the diverse groups of organizations might possibly have been the biggest challenge to the initiatives in doing their work, because they are accountable to many interests (14). One of the global partner representatives in this case study also talks about the criticism towards WHO and UNICEF for not taking responsibility when it came to new and underused vaccines, and said that little had happened in the vaccination area since the 1980's. He explains that the GAVI Alliance was created in order to achieve results quickly and efficiently. The point here is to underline the fact that the working of the Alliance is depending on the cooperation between its partners, and in trying to identify the political and institutional factors that affect the implementation of new and underused vaccines, WHO and UNICEF play a major role. It is reasonable to assume that the fact that the role of WHO and UNICEF has been subjects of discussion to this extend that is described

in the literature and in the interviews, especially in the early days of the Alliance, also influences the working of the Alliance, and the decisions made. According to Sandberg et al, there are at least two diverging positions in GAVI in whether to concentrate on new vaccine introduction or to concentrate on a wider set of objectives including strengthening health systems. In a global health perspective, the question being, should it prioritize basic services to everybody, or using new science and technology quickly? This study suggests that these diverging positions within the Alliance also affected the introduction of Hib vaccine globally. Initially, partners in GAVI united on a vision of securing equity in global immunization programmes through access to new technology. Equity could mean both an imperative to achieve fairer distribution of new health technologies globally, and a fairer distribution of overall health in a given country. Regime effectiveness studies have shown that the interplay between politics and knowledge can fuel the differences in underlying values which results in divergent positions in what an initiative seeks to accomplish. When there exists differences in interests, uncertainties might be more difficult to overcome, and might also fuel the already existing difference (4).

International regimes very often come to an agreement that establishes specific rules, commitments and decision making procedures. The implementation will depend on each partners will and ability to adhere to the agreement (4). With the assumption that the board of GAVI is dominated by donors and Northern representatives as it is according to Hardon and Blume, the ownership of the agreement might be distributed differently among the stakeholders, and thereby maybe also the commitment to the agreements.

5.2 A smooth transition

Adding the two vaccines to the already existing immunization programme, was technically a smooth transition for the Malawi EPI due to the choice and approval of the pentavalent vaccine, the EPI being a “strong” vertical programme with dedicated personnel at the time of the introduction, and close communication with the WHO regional office. In discussing if global strategies to introduce new vaccines result in new practices at country level and “new practices at country level” is seen as if the existing immunization programme had to go through extensive changes in order to make the new vaccines “fit in” to the original EPI programme, the findings from this case study show that few new practices had to be introduced.

Most of the respondents' referred to the practicalities of the immunization programme when discussing whether or not the implementation of the new vaccines required changes in the existing immunization programme and with the approval of the pentavalent vaccine, only minor changes had to be done. This was also one of the reasons given for applying for the pentavalent vaccine, given by the country representatives, and the in country partner representatives; that the pentavalent vaccine would require minimal changes in the existing immunization programme.

There had to be done some changes in their Information, Education and Communication (IEC) programme concerning the new vaccines introduced, the vaccine was delivered in a bigger vial, and a slight increase in the fluid given to the child, but the time for the injections remained the same, and it was still only one shot for the baby. If new practices at country level also include the financial side of the immunization programme, the answers are different. The remaining relatively high prices of the new vaccines, has caused new practices in the sense that the original financing system for vaccines is no longer sufficient for the new programme, and new discussions concerning priorities in the health sector has followed.

One of the findings in this case study was that during the meetings concerning the introduction of the new vaccines, there was very little discussion going on. One of the hypothesis before going to the field, was that this topic would have caused a lot of discussion, as the cost of the vaccines are relatively high, the GDP per capita in Malawi is low, and the competing priorities in the Malawi health sector are many. Some of the respondents called it a smooth transition, others said there was little to disagree on. Malawi had for quite some time wanted the Hep B vaccine, but could not afford it, and when they learned of the GAVI Alliance, and the possible windows for support with the possibility of having the vaccines for free for five years, they applied, and the application was approved. It is important to notice here however, when later in the interview the question of financial sustainability came up, all the respondents answered extensively, and all of them said that the issues of future financing, what would happen after the five year support ended with the future pricing of the vaccines, were not brought up during the discussions before the application was sent to GAVI.

There were still some challenges posted concerning the new immunization programme. In the Malawi Plan of action for 2000, and in their five year plan of action for 2001-2005, many of the same challenges are listed. This include amongst others establishing a budget line for the

procurement of the vaccines, soliciting funds to procure Hep B, soliciting long term continued external support, monitoring of routine immunization and identifying low coverage areas, the infrastructure concerning transport, funds and infrastructure for cold chain activities, shortage of EPI stationary, and under reporting of neonatal tetanus cases. As a general comment to the issue of new health interventions, Muraskin points out that a situation like this is aggravated by the fact that health workers have so many different jobs to do. Every new program comes along with great enthusiasm but then it crests and retreats (63). Again, many, and almost all of the respondents mentioned the financial aspect of the immunization programme as one of the major challenges in implementing the programme.

5.3 Information

The decision to introduce the new vaccines was not based on information on burden of disease or cost effective data. The information leading to the decision to introduce the vaccines was the information of the development of GAVI, and with it, a window where Malawi was eligible for support, and the information that there was a possibility to have the vaccines for free.

In one of the concept papers for the SUM-MEDIC research project it is indicated that in the implementation of environmental agreements, implementation can be difficult due to the perceived relations between costs and benefits among implementation agencies. Costs are up front, concentrated and certain, while benefits are long-term, uncertain and diffuse (64). In the case of Malawi and the introduction of new vaccines, this situation is almost the opposite, where the long term cost is posed to be one of the biggest challenges for the future implementation. Although immunization can give long term benefits, the data showing the certainty of the effects of the vaccines are not available, due to lack of disease surveillance, and studies of efficacy and efficiency of the pentavalent vaccine in the Malawi population. In assessing the information flow during the decision making process, this case study aimed at tracing the content of the information important to the different stakeholders taking part. The information outlined as important for GAVI to receive from Malawi was that they knew of the eligibility criteria for support, and that they had the necessary information in order to complete their application for support from GAVI. The eligibility criteria were outlined, and the information concerning if Malawi met these criteria were easily obtained through official UN websites. One important criteria of information concerning the eligibility, is the

immunization coverage in the country. The official information on immunization coverage was available for GAVI before Malawi sent their application. Malawi answered to the criteria for support for the introduction of new vaccines, with reported immunization coverage above 80%, but as mentioned in chapter 2.4.2 the information obtained concerning the immunization coverage numbers for and within the country varies. This challenge is also discussed in the study from Save the Children, where difficulties in obtaining valid and reliable immunization coverage data were seen as a challenge in both Tanzania and Mozambique (8). According to Hardon and Blume, the reliance on immunization coverage rates as performance indicators overlooks the absence of reliable health information systems in most countries applying for support, as well as problems in calculating coverage. Prior to this case study, the data on immunization coverage were obtained from the WHO, and the curiosity when developing the questions, was related to the information obtained by Malawi and the donor community that lead to the decision to introduce the new vaccines, rather than to how the immunization coverage numbers were obtained, and the reliability of the numbers. Taken into consideration the importance of the immunization coverage in getting support from GAVI, this could be a topic for further studies in Malawi, as the qualitative method and the objectives for this study do not cover this.

One of the international norms on new vaccine introduction could be the information on disease burden. In the study from Thailand and Taiwan information on disease burden was found as a supporting factor in the introduction of new vaccines (2). This was also the case in the study from Qatar, Uruguay, Chile and Kuwait, where the key factor for the introduction of the Hib disease was the disease burden data and the severity of the disease (5). Mahoney suggests in the article concerning policy analysis that measurement of disease burden data and computation of vaccination cost effectiveness, are important elements of successful introduction of vaccines (6). Data on disease burden can raise the public concern, and could together with information on cost-effectiveness raise the level of information, leading to valuable knowledge on how the implementation of the new vaccines would require changes in the existing immunization programme in terms of future financing. Although some studies showed a relatively high prevalence of Hep B and Hib, one of the in country partner representatives emphasized that there were no data on disease burden in Malawi, only projections. In the application from Malawi to GAVI, there is given a budget summary for proposed activities where disease surveillance is given attention and where the need to quantify the burden of the problem of Hep B and Hib in Malawi is expressed (55). As stated

in the evaluation report by HLSP, unclear data on disease burden could mean a weak message on the desirability to incorporate the vaccine from WHO and a weak demand forecast as demand and need in countries with unclear disease burden could not be quantified. Without a clear disease burden the impact of the vaccine would be difficult to document, and therefore the countries could envision to drop the Hib vaccine once the support from GAVI ran out (14). This has already been outlined as an alternative by the Ministry of Health in Malawi. When the interviewees were asked if they found the information flow adequate during the decision making process, they all answered yes. Later in the interviews it became apparent that information concerning the issue of sustainability and what was going to happen after the five years of support was missing. With this knowledge in hand, one can ask if the information flow still can be considered adequate. Thus, the need for information seemed to change after the application was approved and the new vaccines were introduced, with the lack of information concerning the price of the vaccines and the issue of who is going to pay after the five years of support have finished, were areas where more information was needed according to all the stakeholders interviewed. The need for information on cost effectiveness and disease burden data was not expressed to the same extent. The issue for GAVI was to introduce vaccines quickly and effectively, and the issue of sustainability was not on the agenda then. It was important to change the picture that the issue of raising the immunization coverage in the poor parts of the world was not working very quickly. When the question came up of what would happen after the five years, the answer from GAVI was that this would be looked upon at a later stage; the important thing now was to get a quick scale up of the introduction and implementation of new and underused vaccines (i7.GPR). Regimes can affect actors differently because actors have different perspectives from which they judge costs and benefits and because the material consequences can differ. It was important for GAVI to achieve a quick scale up of the new vaccines. This was also important for Malawi, but more important the information on how the immunization programme should be sustained and how the changes in the material consequences for the existing immunization programme should be handled in the future. This leads us to the next finding in the case study.

5.4 The time frame and financial sustainability

5.4.1 The time frame

In trying to trace the actual decision making process, one of the findings of this study indicates that vaccine introduction processes do not start and end with country decisions to take the vaccine into the national immunization programs. They span over time, and decisions on global versus national financing may follow several years down the line, and with it, the discussion on whether to keep the Hep B and Hib vaccine in the existing immunization programme.

The time frame for the decision making process is closely connected to the issue of financial sustainability, and these two findings might be hard to separate, although an effort will be done to do so in the following. The two chapters might overlap slightly in order to cover both topics.

When time is mentioned in other studies as a challenge to the process, the relatively short time limit for the application process is discussed, and not so much the time frame for when the decision making process starts and ends, although it is possible to think that the short time for the writing and submission of the application also can influence the content of the discussion. If the stakeholders have the feeling of limited time during the discussion it might be possible that the most complex topics will not be discussed in depth, or that it might give less time to search for possible challenges and problems concerning the implementation in the future. In the study by Save the Children (Starling M. et al, 2002), all countries experienced pressure to make rapid decisions and were in some cases subject to what they call unreasonable tight deadlines in the application process. The study does also mention however, the risk of withdrawing the combination vaccines from the immunization programme due to the possible lack of funding, but suggests that this might be too politically sensitive to do for the governments. In addition to the susceptible risk of changes in the epidemiology in a population by withdrawing a vaccine which have been given for some years, the financial sustainability issue might also interrupt the basis for the agreement, or what was set at the outset as widely accepted principles and norms which should govern the implementation process, or the agreement, of new vaccine introduction, and thereby risking that the implementation of the new vaccines into the original immunization programme is no longer

successful. Regime studies looks at how cooperation works in practice, and changes in partners interactive decision making can be considered outcomes of regimes. As the five years of support was moving to an end in Malawi, the financial challenges became more apparent, and with it, the possibility of a political challenge where they move away from a situation where the actors share the same preferences, interests and values about an issue (4). A somewhat complicating issue in this situation is that although the decision making process is still going on; the countries have to keep the programme performing in order to get support.

The assumption prior to this research was that the decision making process had already happened, and the process ended with the launching of the new vaccines into the new immunization programme. This was not the case for Malawi. The vaccines were incorporated into the immunization programme, but the health policy makers are still discussing how to keep them in the programme, mainly due to the financial sustainability issue, and as already mentioned, removing them from the programme was outlined as an alternative. This is an important finding for many reasons. Methodologically, this influenced both the content of the questions asked during the interview, and the approach of possible actors taking part in the process. With this knowledge now at hand, more, and other, actors could have been a part of the research, as the health policy makers working with immunization from the beginning of the discussions until today, would be of great interest. This would also have motivated a greater interest in the issue vaccine prices and financial sustainability at the outset of the research, both as a topic for discussion with the stakeholders, and for further discussions concerning possible solutions and financing mechanisms, and how the stakeholders perceive future introduction of new vaccines. Some of the actors already interviewed were a part of the immunization programme today however, but this was a coincidence in the research, not a result of a deliberate approach.

GAVI has now recognized that their original policies regarding the introduction of new and under used vaccines was based on incomplete information and erroneous assumptions. Based on this experience, there is now a general consensus that countries must have an appreciation of the costs and financing of new vaccine introduction at the outset, not mid way through the process, as was the case in phase 1. Increased predictability of future expenditure on vaccines is important for countries and for manufacturers, to ensure adequate supply and affordability in the long term. This was hindered in phase 1 as the basic predictions GAVI used were unrealistic (63, page 263). According to Muraskin`s report, the implementation of new

vaccines should be integrated with, and subordinated to, broader systems objectives. As outlined earlier in this thesis, Malawi has many contending health issues on the agenda. Muraskin argue that the introduction of the vaccines should be determined by its effect on the overall mission of strengthening the entire health system, with the vaccine Alliance (and others) helping in keeping the focus on the importance of immunization. In order to achieve sustainable immunization programmes there should be built strong foundations that will support the lasting achievements (63). Hardon and Blume argue that GAVI run the risk of creating health inequities in the poorest countries, which they have prioritized for support. Seeing these arguments in perspective, Malawi has to have a continuous priority process, where the immunization programme is one of many contending programmes in Ministry of Health. The finding in this case study, therefore, that the decision making process is still going on, might not be so surprising. The introduction of SWAp can also have contributed to this situation, as the EPI programme is now integrated into the health sector as a whole, sharing the common resources, instead of being a vertical programme with its own funding mechanisms. One of the differences in the discussion now, is that the vaccines are already implemented.

5.4.2 Financial sustainability

An important and unexpected finding in this case study will be given attention in the following chapter. In trying to summarize it; there was little discussion concerning whether the new vaccines should be implemented in the immunization programme or not. The discussion came later when it became apparent that GAVI funding would cease after five years and the price of the vaccines had not dropped. The discussion about the new vaccines is tied to financial sustainability and the uncertainty about prices.

Interestingly, Malawi Ministry of Health, do not see financial sustainability as being self-sufficient, but as the ability for the donors to finance the programme in the future. The immunization programme in Malawi is heavily donor dependent. This case study suggests that the sustainability of the immunization programme depended on if the donors would be available to provide funds for procurement of the vaccines (i1.ICPR).

Prior to GAVI and the introduction of the new vaccines, the Malawi Government already had a future policy and work plan for their immunization programme, referred to as the five year

plan, or the Malawi Multi Year Plan, and therefore only needed to revise this when the request came from GAVI for a Multi Year Plan. The plan was attached to the application sent to GAVI in 2000, together with the statement that the EPI Unit planned to produce a 5 year Plan of Action later in the same year. However, at the time of the introduction, Malawi was not really prepared to fund the vaccine that would cost them around 5 dollars, with the total health expenditure per capita being 10 dollars (i2.CR). The stakeholders involved in the discussions concerning the introduction of new vaccines to Malawi, were aware of GAVI's plan for support for five years. The challenge was that there was no clear plan for what was going to happen *after* the five years, and this was not brought up as a topic for discussion during the decision making process. The Malawi Government sought advice, and the advice they received from WHO was to go for the new pentavalent vaccine, as they all believed the prices of the vaccines would be reduced and therefore more affordable for the countries after the five year period. The price of the vaccines did not drop as expected, and the issue of what was going to happen came up almost half way into the five year period of support in Malawi's case, with the request from GAVI for a financial sustainability plan. This request is seen as the starting point for the discussions concerning the financing issues, and the time when Malawi became aware of the price of the new vaccines. The new pentavalent vaccine was already introduced, and it was expensive. It is reasonable to assume, that Malawi's possibility to influence on vaccine prices is very low, and with the high donor dependency, the government's influence on future finances is at least limited. The power and the capacity to meet the challenge of financial sustainability of the immunization programme, could then be limited to the alternative of withdrawing the pentavalent vaccine from their immunization programme.

From GAVI's point of view it was important to introduce the idea of the vaccines actually having a price, therefore the financial sustainability plan, and thereby encourage the countries to give something. The introduction of the financial sustainability plan was interim measures to begin accustom the countries to the idea that the price shock at the end of phase 1 might not be quite as light as it was thought to be. The concept of financial sustainability and what could increase the countries possibilities of being able to sustain their own immunization programme is complex. An argument for what makes the long term commitment a challenge is given by Muraskin; "Provision of five years worth of vaccine free and subsequently expecting 100% transition to national government and partners is impractical... even if a given vaccine is not a national priority, an offer of free vaccine for five years is difficult to refuse,

therefore initial country uptake is not an accurate measure of long term commitment” (63, page 263). It is believed, that the responsibility concerning the question of what is going to happen after the five years should be shared by all the stakeholders who took part in the process. WHO gave advice to go for the pentavalent vaccine, and strongly believed that the prices was going to decline, Malawi had been waiting for a financial opportunity to introduce the Hep B vaccine, and took the advice. The issue of financial sustainability was not raised to any extent during the decision making process by any of the stakeholders. One reason could be lack of ownership to the programme with the new vaccines provided for free.

The study from Save the Children showed that the lack of consensus in terms of future financing beyond the five year time frame was stark. It is argued that for Ministries of Health, for so long being dependent on external support, remain pragmatic in anticipating that funds will eventually follow the plans and priorities of the sector, and as time frames for donor commitments usually is one or two years, a five year commitment is welcomed. Consistent with the findings from the case study in Malawi, the lack of discussion and co-ordination around future financing, involving the major donors at the country level, was a notable finding (8). Gauri and Khalegian argue that donor presence at country level tends to strengthen EPI, but slow the adoption of new vaccines (9). Unfortunately, neither the persons from DFID or NORAD, or other major donors to the health sector of Malawi who was involved in the discussions at the time, were able to take part in this case study, and therefore no conclusions can be drawn from a donor perspective on the future financing of the new immunization programme in Malawi.

In Munira and Fritzen`s article it is emphasized that a challenge in a large number of countries in the developing world is the power and resource asymmetries between donors bringing much needed finance on the one hand, and the country health and finance ministries on the other (2). As we have seen from the regime studies, the configuration of power may influence the behavior and effectiveness of international commitments, and more so when the actors no longer share the same interests and values about an issue (3, 4). An effect of continued relatively high prices of vaccines could result in the continued discussions and uncertainties of the ability for Malawi to sustain the new vaccines in their immunization programme, and with it, reduce the effectiveness of the agreement from 2000 to do so. The explanations for the persistent relatively high prices of the vaccines were mainly the marked forces not yet having had the necessary effect on price reduction, with too few manufacturers of the pentavalent

vaccine in the market. It was also mentioned that UNICEF played a role in negotiating price reduction, and did not manage to do this sufficiently. In a regime implementation perspective, the global enabling environment, which in this case could be the market forces or price negotiations, and which should act as a positive force in order to make the implementation of new vaccines effective and successful, is reduced. The agreement and commitments set at the start of the implementation of the new vaccines in the original EPI programme in Malawi, might have been perceived differently from the different stakeholders taking part in the decision making process, without the stakeholders being aware of the mismatch in the understanding of the agreement. Another explanation could be that the knowledge of the mismatch was present, but together with the expectations that these challenges will be solved during the years to come, before the support from GAVI ended, all the stakeholders agreed on the fact that the continued high prices of the vaccines became a somewhat unexpected challenge towards the end of GAVI phase 1. Whatever the reason, one of the effects of the high price of the vaccine is continued discussions around the original agreement to introduce the vaccines, and this might also possibly affect the international cooperation concerning new vaccines. Increased tension and disagreement among the stakeholders concerned with immunization, and the coordination of action concerning the international commitment to combat infectious diseases might become less effective, but the result can also be more discussions, increased knowledge, and thereby increased awareness concerning this global challenge. If the latter becomes the case, the agreements on solutions, and the implementation of the actions might have a better chance of success. In the article concerning the policy analysis for the introduction of vaccines in developing countries, the creation and sustenance of funding mechanisms for procurement of the vaccine is said to be one essential element for successful introduction (6). This is consistent with the study from Malawi from 1997, prior to GAVI, where the over dependency on donors and the financial uncertainty is already expressed as a factor that may disrupt the existing supply system for vaccines (30).

It has also been argued by Hardon and Blume that donor dependency for the procurement of the vaccines is being reinforced under GAVI. GAVI was able to generate resources for wide scale introduction of the new, more expensive combination vaccines, and have in a relatively short time developed mechanisms to process and approve developing countries requests for support to obtain the new vaccines. However, they also express concern for the sustainability of the current GAVI supported immunization programmes in developing countries, and the possibilities for an increase in the disparities in access to vaccines, as the countries might be

unable to sustain the supply of new and improved vaccines if the global resources flow diminishes. GAVI has been addressing the sustainability and equity issues however, and although they are 'learning by doing' and making mistakes, the Alliance is proving to be a dynamic coalition (20).

The issue of future financing of the immunization programme was, and still is, an increasing concern for all the stakeholders involved in the process. Of the political and institutional factors that affect the implementation of new vaccines in Malawi, financial sustainability and vaccine prices are two of the most important ones. Had the five year period been absolute, the capacity for Malawi and the stakeholders in immunization for problem solving would have been very limited. This is not the case however, as GAVI is extending their support, and the donor community is discussing new financing mechanisms for immunization.

6 Conclusion

The findings from this case study were not as expected. One hypothesis was that there would have been extensive discussions concerning the introduction of the new vaccines at the time the decision was taken. This was not the case. At the same time the fact that the issue is still being discussed was an unexpected finding. With the knowledge obtained through interviews and documents, this research suggests that from the technical perspective, the introduction of the new vaccines went smoothly. Looking at it from a public health perspective, there are underlying challenges concerning the immunization programme and the Malawi health system that have prevailed since before GAVI. Seen from a political and financial perspective, the decision making process around the introduction of the new vaccine is complicated and ridden by high uncertainties. The questions one can ask is what responsibility the Malawi Government has to continue their commitment to increase and sustain immunization coverage, and to what extent can private foundations which provide a large proportion of funds for such efforts, be held accountable.

The performance based support encouraged by GAVI and the reliance on immunization coverage rates as performance indicators might be based on at least varying, and maybe also the wrong assumptions. The health information systems in many countries applying for support from GAVI might not be reliable. In the case of Malawi, this is not fully explored, and no conclusion can be drawn about the immunization coverage numbers given, but-given the variety in numbers obtained in this case study, it might at least be questioned. The health information system and how the immunization coverage numbers are obtained might be a topic for further studies in Malawi, together with possible prospect study on the new financing mechanisms of GAVI, how it will work, and who ends up paying the bill if the prices still do not decline as expected, together with other new vaccines waiting for implementation. This would probably demand for quantitative research as well as qualitative.

In order to lift focus, and see the global and international enabling environment concerning the introduction of new vaccines in Malawi, the analytical framework became a useful guidance in understanding and analyzing the results of this study, and in giving an important perspective to the subjects which evolved. However, the concept of applying the framework of regime studies , is still quite new, and few other studies where this is applied in analyzing the implementation process of vaccines are available for comparison.

Due to limited data, it can be difficult to draw any conclusions on whether global strategies to introduce new vaccines results in new practices at country level or whether implementation of the new vaccine requires changes in the existing immunization programme. Nevertheless, issues evolved which could suggest useful directions for further research concerning international agreements in global health, and for the further implementation of the vaccines in Malawi's immunization programme. One lesson learned is that the decision making process to not end with the as the new vaccine is included in the immunization programme, and this should be taken into consideration in future studies as this will have effect on who and how the topic is approached. The practical introduction of the pentavalent vaccine went smoothly and the introduction of SWAp had a somewhat greater influence on the policy context than did the introduction of the new vaccines the effect of its existence will not be seen to the full extent yet. This study has also given an indication of the importance of further studies on burden of disease and cost effectiveness. The topics vaccine prices and financial sustainability were not a part of the objectives at the outset of this thesis, and were also new and unexpected findings in this study. Although not entirely new, it is the impression that these findings can give useful information for further studies concerning the same topic, in Malawi or other countries for comparison. One lesson could be to extend the time frame for the process, and thereby include more stakeholders including persons in Ministry of Finance and the donor community, as the financial aspect of immunization seems to be of great importance. With the cost of the vaccine now becoming a big issue, the focus on the disease burden has increased. As GAVI is now entering its phase 2, where vaccines are no longer given for free and the issue of co financing has been established, it could be interesting to see if this has an effect on the perception of the importance of the information on disease burden in the future implementation of new vaccines in Malawi.

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