What influences government adoption of vaccines in developing countries? A policy process analysis

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Abstract

This paper proposes a framework for examining the process by which government consideration and adoption of new vaccines takes place, with specific reference to developing country settings. The cases of early Hepatitis B vaccine adoption in Taiwan and Thailand are used to explore the relevance of explanatory factors identified in the literature as well as the need to go beyond a variable-centric focus by highlighting the role of policy context and process in determining the pace and extent of adoption. The cases suggest the feasibility and importance of modeling ‘causal diversity’—the complex set of necessary and sufficient conditions leading to particular decisional outcomes—in a broad range of country contexts. A better understanding of the lenses through which government decision-makers filter information, and of the arenas in which critical decisions are shaped and taken, may assist both analysts (in predicting institutionalization of new vaccines) and advocates (in crafting targeted strategies to accelerate their diffusion).

Keywords: Hepatitis B vaccine; Vaccine introduction; Policy analysis; Developing countries; Taiwan; Thailand

Introduction

The 20th century saw tremendous advances in vaccine technology and, in the last two decades primarily, its broadened application to health problems afflicting the poor throughout the world (World Bank, 1993). The expanded program for immunization (EPI) package of vaccines alone is estimated to have saved approximately 20 million lives in the past two decades (UNICEF website, 2006). Yet the process of diffusion of these vaccines has been far from even, as countries with different priorities and access to resources adopt and sustain vaccines to different extents. Differences in mortality and morbidity rates across even similarly situated poor countries were quite pronounced by the late 1980s, due largely to the different extent to which these countries had adopted and successfully implemented the ‘basic’ EPI package of vaccines (Wang, 2002; Wilkinson, 1992).

What determines the pace at which countries move to incorporate emerging vaccines with potentially great positive health impacts into their vaccination programs? Given the dynamism characterizing vaccine development, this question is highly relevant and important. A better understanding of the lenses through which government...
decision-makers filter information, and of the arenas in which critical decisions are shaped and taken, may help us anticipate the diffusion of new vaccines, and help advocates craft targeted strategies to influence their adoption (Batson, 1998; Vaccine Alliance, 2006; Walt & Gilson, 1994).

This paper examines the process by which adoption of one important vaccine—that for Hepatitis B—took place in two middle-income countries, Taiwan and Thailand. These countries were in the first wave of countries to adopt the vaccine into their mass immunization schedules, several years after the vaccine became available in 1984, but before the WHO’s endorsement in 1992. It asks, what were the factors that led to early adoption in these cases? Were these countries highly idiosyncratic, or were there important common factors at work? Beyond shedding light on the two cases, the purpose of this paper is to present a framework that can be used as a starting point for the more systematic modeling of the decision-making dynamics underlying vaccine adoption in developing countries. We have labeled this a ‘policy process’ approaches because of the salience of the sequencing and policy context in which critical decisions are made.

Beyond ‘cost’ and ‘political will’ in explaining uptake: the case of Hepatitis B

Government decision-points in vaccine development

The introduction and expanding use of vaccines follow a typical pattern (Vandersmissen, 2001).

During a period of early demand, the vaccine is launched in the private market of industrialized countries, with low quantities and high prices. It is subsequently integrated into the public health policies of industrialized markets. As quantities grow, a multi-tiered price structure appears, with supplies to the public market at a lower price than sales to the private market. The loss of the customers who previously were part of the private market of industrialized countries is partly compensated for by new introduction of the vaccine in the private markets of developing countries, usually at intermediate prices. Finally, the vaccine becomes generally used, with massive purchases at low prices in the public markets of developing countries, directly or through international procurement agencies such as The Pan American Health Organization (PAHO) and The United Nations Children’s Fund (UNICEF).

The premise of this paper is that the pace of the process shown in Fig. 1 is shaped by decisions that occur in the interface between the private sector market and government adoption into standardized packages of immunizations, such as EPI. The factors underlying government decisions in this area are complex, and in general under theorized; but the two most often cited considerations are vaccine cost (Batson, 2005; Mahoney & Maynard, 1999) and, as a residual category, political will (Catford, 2006). It is generally feared that even vaccines with favorable cost–benefit ratios at high prices will not go into general use until prices drop considerably, a process that may take up to 20 years or more.

Fig. 1. Traditional vaccine market development (adapted from Vandersmissen, 2001).
(Vandersmissen, 2001). Where high-income countries can potentially benefit from the vaccine, they will generally lead the wave of adoption, while in very low-income countries, adoption may be subjected to the binding constraint of price (McGuire, 2003), awaiting foreign funding and initiatives. This may help explain the limited interest in the literature given generally to the government decision-making process in the presence of this ostensibly binding constraint. Middle-income countries are potentially the most unpredictable in terms of where they will fall in any sequence. With their greater (and often increasing) discretionary expenditure as compared with low-income countries, and the often growing sophistication of health policymaking networks, adoption may occur at a more intermediate point in this process.

The case of Hepatitis B in middle-income countries

Cost has certainly played a role in the diffusion process of the Hepatitis B vaccine, commercially available since 1982 and globally recommended since 1991. Unlike other vaccines used in national EPIs (immunization programs), which have always been in the public domain, this vaccine was both controlled by active patents and introduced into the public sector at a fairly early stage in its production lifecycle. At the time of the recommendation for global introduction, the vaccine price had dropped from over US$50 to roughly US$3 per dose, yet even at this level the full series (three doses) of HB vaccination cost more than 10 times all the other EPI vaccines combined, putting it out of reach for public use (Batson, 1998). At present, The GAVI Alliance continues to support countries introducing new and underused vaccines such as Hepatitis B vaccine, as even the current price of US$1.5 can strain health budgets in low-income countries (WHO, 2006; GAVI Alliance, 2006).

Fig. 2 shows the progress of Hepatitis B vaccine uptake in different countries since it first became available in 1982. Each star in the chart represents a country that has included the Hepatitis B vaccine

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**Fig. 2.** Hepatitis B vaccine uptake by country status, 1982–2004 (data from WHO and the World Development Indicators 2004).
into its national immunization program, listed according to the year of vaccine adoption. The evidence is consistent with a hypothesis that cost is a critical factor: the median time to adoption of the vaccine is 11 years for high-income countries, 15 years for middle-income countries and 20 years for low-income countries, respectively.

Yet clearly cost serves poorly as the sole variable predicting uptake. Some affluent countries only adopted the vaccine well after 1997, the WHO’s target for universal adoption. And a number of countries at the lower income brackets decided early on to integrate the new vaccine. Indeed, several middle-income countries were among the earliest adopters of the vaccine, integrating the antigen into their existing national immunization programs.

The Hepatitis B vaccine is thus a good example of the uneven diffusion process of new vaccines—with and without donor support—in developing countries. This unevenness exerts a cost in terms of lives lost to preventable disease; and the difficulty in predicting uptake and the mistaken assumption (usually implicit) that cost is the sole important factor—may well lead to missed opportunities for the targeting of advocacy efforts. The question is, what factors will influence this process? Does the literature help us to predict where and how it may happen?

Methods and empirical strategy

To further unpack the factors at work in the Hepatitis B case, we reviewed a broad swathe of literature on vaccines in which factors predicting uptake are mentioned directly or implicitly. We found that this literature, as described below, suffers from two basic shortcomings. First, it generally has not considered systematically what comparative methodologists call “causal complexity” (Ragin, 1987, 2000), which simply means that rather than a particular explanatory variable having a consistent impact on the dependent variable of interest—such as government adoption of a vaccine—this impact may vary depending on the configuration of other variables in the case context. There is thus no consistent formula that will predict adoption; rather, mapping different ‘causal pathways’ (Fritzen, 2000)—i.e. different combinations of explanatory factors that lead to a similar outcome may prove more fruitful for the purpose of drawing out the implications of limited, comparative case study evidence for future cases.

A second shortcoming of the literature lies in its neglect of issues of policy process and context; thus, we draw selectively on some core theories in the public policy literature in our delineation of key relevant variables in the framework below. We also highlight political context in the conclusion of the paper.

The framework is applied to data on the Taiwan and Thailand cases that were developed from two sources. The first is a thorough review of published sources—some of them quite extensive and detailed—providing a descriptive account of adoption in the two countries. These were compared and contrasted with nine expert interviews conducted, in person and via email, from among government officials, medical association members, and the pharmaceutical sector in the two countries. The intention was to view the adoption process from multiple stakeholder viewpoints so as to improve data quality and achieve a more grounded analysis of the stakeholder dynamics that are at the core of our conceptual framework.

Hypothesized factors predicting uptake

Despite its importance, this question of how to predict vaccine uptake remains only lightly researched in the literature on the role of vaccines in the public health systems of developing countries. The focus in the literature has instead been on issues such as system capacity and sustainability (Salisbury, Beverley, & Miller, 2002), socioeconomic determinants of individual access to vaccines, vaccine cost-effectiveness (Glennerster, Kremer, & Williams, 2006; Stanton, 1994) and financing strategies (McGuire, 2003)—all of which have generated kernels of speculation about the factors that may be at work in vaccine adoption. While there have been few attempts to assess the relative importance of different factors in particular cases, three categories of factors can be elaborated on in individual cases in order to assess the combination of factors leading to a particular outcome: vaccine characteristics, health systems characteristics, and policy process and context.

Vaccine value characteristics

Vaccine-related factors that can influence uptake include the disease burden targeted, safety and performance, and cost-effectiveness. Disease burden
Vaccine safety and performance is a second factor. Most countries have mentioned safety, low rates of side effects and vaccine performance as key criteria in considering introduction of a new vaccine. Decision-makers in one survey (DeRoeck, Clemens, Nyamete, & Mahoney, 2005) required evidence of vaccine safety and effectiveness in the local population before considering use in the public sector, even for vaccines already licensed locally and used in the private sector. Minimum acceptable performance levels for a number of countries for vaccines such as typhoid fever, shigellosis and cholera included a minimum protection length of 5 years and efficacy rates ranging from 75% to 85%; in some countries, the latter figure increased to 90% for government use. (Hepatitis B vaccine compares relatively favorably in this regard, with an efficacy level of 75–95% against chronic infection, and duration of immunity of 15 years after the primary series of injections (WHO, 2002).)

A final factor is cost-effectiveness. The economic impacts of a disease and potential cost savings effectuated by vaccine coverage have featured prominently in discussions about the need for enteric vaccines (Griffiths, Hutton, & Pascoal, 2005). Evidence of cost-effectiveness of vaccines—as opposed to treatment—has been cited by informants in Thailand, India, Bangladesh, Pakistan, and Vietnam, as critical to convincing government decision-makers to finance public sector use of a new vaccine (DeRoeck et al., 2005).

Taken together, these factors suggest that a new vaccine is more likely to be adopted when the burden for the relevant disease is high; decision-makers are convinced the vaccine meets acceptable standards of efficacy and safety; and when cost-effectiveness is assessed to be high.

**Health system characteristics**

A second category of explanatory factors predicting vaccine uptake focuses on how the proposed vaccine fits into health delivery systems of a country. One variable that has attracted much interest by analysts is programmatic feasibility, broadly signifying the level of ease with which a vaccine can be added to existing service delivery networks (Dasgupta & Priya, 2002; Duma, 1995). Programmatic feasibility may be affected by a range of issues such as: the timing of immunization schedules, including whether a birth dose is recommended; impact on cold chain capacity; the proper mix of single/multi-dose vials; the number of injections per visit; vaccine security; whether it may negatively affect the uptake of other antigens in the existing program; possibility of local vaccine production (Woodle, 2000); and cost (Wittet, 2001). In addition, personnel requirements necessary to delivery a new vaccine influence potential cost of the program immensely.

As noted above, vaccine price has been mentioned as one of the most important factors in influencing decisions to introduce a new vaccine, often second only to the issue of disease burden (Mahoney & Maynard, 1999). Yet at least one study, focusing exclusively on middle-income countries, has found that vaccine prices may not be the major driving factor, especially when it comes to vaccines that are in combination form; it points out that many of the poorer countries among the middle-income countries included in the study have been paying premium prices (Milstien, Munira, & McKinney, 2003). Price may best be considered in terms of both affordability, i.e. as a percentage of national health budgets—and in conjunction with other factors such as perceived impact and policy context.

**Policy actors, process and context**

As noted above, few papers examine the process by which decisions to incorporate vaccines into national health systems are made, despite the obvious relevance of this literature to explaining or predicting adoption outcomes. Instead, ‘political will’ is often deployed as a residual concept masking a host of potential factors at work; to help unpack and operationalize the notion of ‘political will’ as an explanatory factor (Catford, 2006), this paper draws on some well-established approaches in the policy process literature, including the Sabatier and Jenkins-Smith’s Advocacy Coalition framework (1999), Kingdon’s framework for policy adoption (1995), and Grindle and Thomas’ framework for contextualizing specifically developing country policy environments (1991). Concepts are borrowed very selectively in this paper, and the concluding
section notes additional areas where the policy literature may be fruitfully exploited for understanding vaccine adoption.

**Actor interests and interactions.** A variety of actors, both inside and outside a predictable core, must interact in ways to influence the adoption of a vaccine (Walt & Gilson, 1994). The first, most obvious actor is what policy analysts sometimes refer to as ‘sovereigns’ (Jenkins-Smith & Sabatier, 1994), the government authorities governing the health sector who ultimately determine strategies and allocate scarce resources. Other groups are appropriately seen as attempting to influence them. These include the second group, the scientific/medical grouping, which must form a consensus on the medical value and level of scientific evidence associated with a new vaccine, and advocate for it in policymaking circles. For this group, the availability of scientifically presented evidence regarding vaccine value characteristics, including the existence of pilot studies and trials, are likely to be critical. Formal recommendations by bodies such as the WHO are often critical in both reflecting and shaping medical community consensus, and in influencing governmental decisions.

Third, the role of the public and non-health interest groups is also important to analyze. The public, via the media or non-governmental associations, may or may not push politicians and physicians to take action to address a perceived health problem via a vaccine. Public support might be gauged by looking at the visibility of the media treatment of the vaccine issue over time. Local and/or international drug manufacturers who may benefit from vaccine adoption may be mobilized to support adoption. As a result, the feasibility of local production of a vaccine would be an important consideration in determining the political forces pushing for adoption (Clemens, 2003; Muraskin, 1996; Woodle, 2000).

A fourth type of actor is the ‘policy entrepreneur’ (Kingdon, 1995), typically either government officials or prominent researchers who decide to ‘own’ the vaccine issue by pushing consistently and creatively for the articulation of specific proposals timed to the policy adoption cycle (Duma, 1995).

**Decision-making process and context.** Mention of policy entrepreneurs leads to the issue of process and context. One prominent approach to explaining the circumstances surrounding policy adoption focuses on the convergence of three factors or “streams” onto a defined decision-point, at which time a ‘policy window’ is said to open (Kingdon, 1995):

- Government officials fix attention onto a particular problem, from among a huge and shifting number of alternative problem choices, that may arise on their agenda through various “focusing events” such as crises, disasters or the availability of a new, high-profile study (p. 112).
- Specific, actionable proposals or policies are “generated, debated, redrafted, and accepted for serious consideration” (p. 143); and
- The politics of an issue, which may be influenced by “swings of national mood, election results, changes of administration, changes of ideological or partisan distributions in Congress, and interest group pressure campaigns”, for instance, promote proposals to high-agenda status, where they may or may not be acted on (p. 162).

The context of policy-making plays a critical role in determining the roles, and relative strength, of the actors noted above. To borrow a pattern reported in other sector contexts, in periods in which the prominence of the issue is rising following an epidemic, decision-making is more likely to be dominated by senior political figures concerned with the political impacts and perceptions, whereas in ‘bureaucratic-politics-as-usual’ times, technical personnel concerned with some mixture of the technical costs and benefits, and the bureaucratic turf issues, are more likely to play a prominent role (Grindle & Thomas, 1991). In addition, the weight given to the scientific evidence, and the evaluation of the political and technical risks involved in vaccine adoption, may be influenced by the sequence of international adoption. This is especially true at the bookends of the sequence: the cues that countries at the early phases of international adoption will be sensitive to are likely to be different from those at the end, for instance (Mahoney & Maynard, 1999).

The above considerations orient our examination of contextual and process-oriented variables affecting the governmental adoption of vaccines. We now turn to such an analysis as applied to two middle-income countries, Taiwan and Thailand. It is based on three sources: extensive interviews with a range of governmental, non-governmental actors and international actors in 2005; a review of secondary documentation from the countries’ Ministries of
Health; and published accounts of adoption in these contexts.

Results

Taiwan

Taiwan in the early 1980s was considered a high endemic country for liver cancer; nearly half of all male and one in every seven female in Taiwan were likely to develop cirrhosis or hepatoma (Republic of China (ROC) Department of Health (2004)). Studies conducted on the population in the 1960s and 1970s revealed the association between these diseases and the hepatitis B virus (HBV) infection (Huang & Lin, 2000). Evidence showed that over 9000 people annually died of hepatocellular carcinoma, liver cirrhosis or chronic liver disease, while more than 80% of hepatocellular carcinoma cases and liver cirrhosis in Taiwan were related to chronic HBV infection. Scientists then discovered that the HBV infection in Taiwan occurred early in life and at very high rates; and that perinatal infection led to chronic liver diseases in 90% of those affected, emphasizing that the mother-to-infant transmission was the main route of HBV transmission in Taiwan. These facts convinced health advocates of the need to reduce the disease burden and prevent the further spread of this deadly virus.

In 1984, Taiwan became the first country in the world to adopt the vaccine into its national immunization program, only 2 years after it became commercially available—a major step for a country that had only in recent years reached the status of an industrialized state. The policy decision and process that lead to it, however, was certainly not effortless.

At the time, several groups of scientists in Taiwan had closely observed and studied the spread of the Hepatitis B virus and its related diseases. They joined forces to lobby the government by putting forward the following conclusions (personal communication with M. H. Chang):

- that there was a high prevalence of Hepatitis B carriers in Taiwan, and that 90% of these carriers were likely to suffer from liver cirrhosis;
- that the liver cancer caused by the Hepatitis B virus has proven to be mainly transmitted through vertical infection, from mother to child, directly during but not prior to parturition;
- that the transmission/infection needed to be interrupted during the first 24h of life by giving the vaccine to new-born infants.

The assessment of the researchers was that the adoption of Hepatitis B vaccine would depend on strong political support from senior policymakers given the highly centralized, hierarchical decision-making process of the government (and the health department itself). The President of Taiwan at that time, Y.S. Sun, was in the process of articulating a policy of advanced health care as part of a general push in the area of science and technology, with a vision to tapping into and adopting leading global technologies in a range of fields. The president’s vision was influenced by, and associated with, J.T. Lee, who in 1984 held the title of Minister without portfolio. These scientists thus targeted Lee in their advocacy efforts; and gaining his support, the government decided to form a committee in mid-1984 under the Department of Health to study policy responses, sponsor further scientific research, and conduct a pilot immunization program for Hepatitis B.

Lee proved an essential supporter of the process (personal communication with D. S. Chen). One role he played was to defend the vaccine-piloting phase from various attacks, such as opposition to conducting trials targeted at infants. Lee hosted an international Hepatitis conference in Taipei resulting in a unanimous conclusion that a clinical trial of the Hepatitis B vaccine was indispensable for Taiwan, and that the focus of such trials should be on children at high risk.

Since the vaccine had just been launched, the price offered in the international market to date had averaged US$12 per dose, more than the cost of the basic EPI vaccines combined. There were two vaccines qualified and ready in the market, one from Merck and the other from Pasteur. The Department of Health decided to purchase from the latter, which had agreed to give Taiwan license to produce the vaccines locally—an important political consideration that figured in policy debates surrounding early introduction; and which agreed to the price of US$4 per dose in part to use Taiwan as an example for other countries to follow. To fund the vaccine, the government in Taiwan simply absorbed the cost within an already expanding health budget, which from 1980 to 1990 increased from 3.3% to 4.2% of Taiwan’s GDP (a trend that has continued into the present decade (Republic of
China (ROC) Department of Health, 1997). For the first 2 years, vaccines were purchased through Pasteur’s parent company; by the third year, local production was enabled, a factor which, together with the favorable results of the initial targeted phase, helped convince the government to expand provision of the vaccine, at no user cost, to all infants in 1986 (personal communication with D.S. Chen).

A striking aspect of Taiwan’s case was the lack of direct international support to the health sector generally, and specifically for the introduction of the Hepatitis B vaccine. Some analysts have suggested that this fact actually spurred Taiwan to take its pioneering role, as politicians and health officials believed favorable international commentary could benefit them and the country in different ways (personal communication with Mark Kane). Some Taiwanese officials have asserted their pride at being the first country to introduce, and successfully adopt, the Hepatitis B vaccine into its national immunization program over 10 years before the recommended target from the World Health Organization—the same organization that does not grant membership to Taiwan (Chan, Lee, & Lo, 2004).

Fig. 3 and its accompanying notes summarize the broad sequencing of government decision-making in Taiwan; compiled from various expert interviews as well as literature reviews.

Notes to accompany figure: initiators and role

(1) Scientists conduct clinical trials and studies conducted on liver cancer prevalence in Taiwan, and (2) in coalition lobby government, which (3–4) forms a National Committee to oversee pilot program and assess policy options, which (5) conducts pilot program and assesses favorably the possibility of local production, leading to (6) the formal launch of Taiwan’s national immunization program for Hepatitis B in 1984.

Thailand

Thailand was among the earliest countries to adopt the Hepatitis B Vaccine into its routine immunization schedule; Thailand’s case in particular is also interesting given that although officially a middle-income country, its GDP per capita in 1992 was, according to one measure, only 19.3% that of Taiwan (Republic of China (ROC) Industrial Development, 2006). In 1992, the population chronic carriage rate of HBV was 8–10% and hepatocellular carcinoma was the most common cancer-related cause of death. Most virus transmission occurred during childhood and about two thirds of neonates were infected by the age of 3 months. Hepatitis B vaccine was integrated into Thailand’s EPI in 1992, supported by a pilot project which demonstrated that immunization reduced chronic HBV carriage in children under 5 years by at least 80%. A national Hepatitis B vaccination coverage rate of over 90% was subsequently achieved using a monovalent product with the first dose given at birth (Chunsuttiwat, Biggs, Maynard, Thammapormpilas, & Prasertsawat, 2002).

The process that propelled Hepatitis B to a relatively high public policy priority was a collaborative...
effort. It involved at different stages the Ministry of Public Health’s (MOPH) Department of Communicable Disease Control (CDC) (spearheaded by Dr. Vinij Assawasena, the Director General of the CDC, and Dr. Piroj Ningsanon, the MOPH’s Permanent Secretary), the Thai Medical Association, the pharmaceutical industry and the media, with an internationally-supported Task Force eventually playing an important catalytic role (Muraskin, 1995; personal communication with Somsak Lelekha supplemented by anonymous peer reviewer). The manner in which this process played out highlights the shifting influence of scientific and programmatic evidence as well as shifts in lead actors driving advocacy efforts.

A critical step in the early deliberative process exploring the possibility of mass vaccination was the formation, in late 1985, of the National Hepatitis B Committee. It comprised some 20–30 experts from different institutes, associations and government departments, to be chaired by the Director General of the CDC. Some observers felt that the size of the committee retarded initial evidence collection by increasing the costs of bureaucratic coordination (Muraskin, 1995). For example, internally the decision-making of the committee was subject to bottlenecks of centralization. Any recommendations emerging from its membership had to be screened and approved by the committee head before they could proceed to a higher level in the Ministry to then be presented to the Minister of Public Health, who would then be responsible for coordinating advocacy efforts (Muraskin, 1995).

The MOPH conducted initial policy discussions regarding potential mass vaccine in its initial year. It also facilitated early efforts that included the CDC itself, the medical association, and pharmaceutical companies to engage the media through public talks and interviews to raise awareness of the Hepatitis B virus, highlighting the high toll taken by the disease in Thailand. While these early efforts suggested that the Hepatitis B agenda had potential, the Committee’s leadership was convinced that political support could ultimately only be clinched if more persuasive scientific and cost-related evidence could be mobilized.

Towards this end, the Committee moved slowly—but with hindsight systematically—to build the evidentiary basis needed to win political support for an eventual mass immunization program. In 1988, the MOPH launched a cost-effectiveness study, comparing the option of a mass immunization program with the alternative, selective vaccinations for high-risk groups. The study found the former to be both more economical and effective, primarily due to the anticipated difficulties in identifying and achieving acceptable coverage rates within high-risk groups (Van Damme, Kane, & Meheus, 1997). Earlier studies had also estimated the Hepatitis B carrier rate in Thailand at as high as 10%, with 3% due to perinatal infection (mother-to-child) and the rest involving horizontal infection. Such findings convinced scientists that in order to lower the endemicity it was essential for the government to emphasize prevention through mass vaccination for infants. The most persuasive message to convey to policymakers through the Committee, they found, was that most liver cancer patients were carriers, and thus that preventive measures would enable them to significantly lower liver cancer morbidity and mortality rates (Poovorawan et al., 2001). The fact that the efficacy of the vaccine itself had been proven in the private market by that time was also highlighted.

Price remained a critical remaining consideration for both many Committee members and government officials, and was perceived to be an important barrier to the adoption of a mass campaign. Yet the growing scientific consensus behind mass immunization noted above coincided with the emergence of increased international support for its operations and financing. Specifically, a PATH-affiliated team—the International Task Force for Hepatitis B, supported also by the Australian International Development Assistance Bureau (AIDAB), and the Thai Red Cross Society—launched a mass immunization pilot project in two provinces, and initiated the funds to purchase the vaccine for this purpose. The project, which concluded in 1991, successfully demonstrated that the Hepatitis B vaccine could be operationally synchronized with the basic EPI package without creating a parallel system, a feat deemed critical in winning the support for nationwide immunization among several senior Ministry of Public Health officials (Muraskin, 1995; Wittet, 2001).

The Task Force also helped the government negotiate prices and assisted them in selecting the most affordable alternatives. The Task Force’s initial enthusiasm for local production—which proved unsuccessful in the end—contributed to a stronger negotiating position for the government vis-à-vis international suppliers, helping to push the price down significantly to US$1 per dose.
With a choice between two vaccine alternative types—plasma derived and recombinant—Thailand’s Ministry of Public Health opted for the lower-priced plasma-derived vaccine, produced by the Korean Green Cross Corporation (KGCC)—to the reported consternation of larger private pharmaceutical companies. Interestingly, once the government had decided to implement a nation-wide immunization program for Hepatitis B, the Ministry’s aggregate health budget was increased specifically to fund the program (personal communication with Somsak Lolekha). In these ways, the International Task Force served as an external catalyst among the many members of the National Hepatitis B Committee (Muraskin, 1995).

Thus, the initial impetus for mass immunization that had emerged from the National Committee in the mid-1980s was finally adopted as a national policy that includes the Hepatitis B vaccine into Thailand’s routine immunization program in 1992, some 7–8 years after its initial public debate. It was clear that the 4-year pilot project’s success was a critical factor that convinced the government that the vaccine adoption was indeed feasible, even with its mid-term results (Chunsuttiwat et al., 1997). Thailand’s case in turn proved to be a strong spur to the World Health Organization in issuing its 1992 recommendation for universal Hepatitis B vaccination in developing countries (Poovorawan et al., 2001). Fig. 4 summarizes the broad sequencing of government decision-making in Thailand.

**Notes: initiators and roles**

(1) Scientists, supported by media and pharmaceutical companies present scientific evidence and successfully capture public attention, which leads
(2) Ministry of Public Health to prioritize the vaccine and establish
(3) a National Committee to review options, assisted by
(4) an International Task Force, which performs multiple support functions, leading to
(5) government adoption of the vaccine into routine EPI schedule.

**Conclusions**

The case of the introduction of Hepatitis B in these two middle-income countries can be used to reflect both on the broad set of determinants of government vaccine adoption and on the methods necessary to gain a deeper understanding of the process underlying adoption. On the most basic level, we can examine the similarities and differences in the policy process by which the two countries reached the same ultimate outcome (early adoption). In each country, fixed characteristics (such as the disease burden being experienced around the time of adoption) combined with core and non-core actors to frame decision-points for the use of scientific evidence. Table 1 lays out in summary fashion the presence and absence of some of the factors predicted to be facilitative of vaccine adoption.

Fig. 4. Thailand’s process prior to introduction (compiled from expert interviews and literature review).
adoption posited in section three above, and their presence and absence in the two country cases. The case studies suggest some important commonalities in the countries’ experiences. Both shared a high disease burden from the Hepatitis B virus, which set the stage for the articulation of political and/or social demand for its prevention. In both countries, the demonstration of programmatic feasibility through pilot projects was an important impetus to winning support from technical elites in the ministries. And central to both was the proactive role that medical associations played, which used the growing scientific evidence and epidemiological studies to advocate for adoption of the new vaccine in policy and indeed political circles. This combined with an already strong and well-performing EPI and centralized health system (particularly in Taiwan), were all supporting factors in the process.

But striking differences were evident as well. The most important differences lay in the different constellation of those actors outside the core circle of government officials and the medical associations, including the local and international pharmaceutical industry, international donors, and the media. International support—critical to Thailand, absent entirely in Taiwan—was a most obvious critical difference. The potential for local manufacturing was an important supporting factor in the decision-making calculus in Taiwan, but in Thailand played only an indirect role in negotiations over price. Sensitivity to vaccine price differed too. Price was a critical constraint in Thailand until international support and a far lower marketed price came into play, whereas Taiwan was relatively price insensitive to a degree that is not explained simply with reference to its higher income. Taiwan presented evidence of a critical role being played by ‘policy entrepreneurs’, while in Thailand no highly visible individuals drove proposals towards a decision.

Thus Thailand and Taiwan present two related but distinct pathways to the same ultimate outcome of early adoption. What light do these two cases shed on broader issue of the determinants of vaccine adoption in developing countries? There are potentially huge implications to understanding the process better, since the success of efforts to incorporate new vaccines into the regimen clearly hinge on the ability to persuade policymakers to invest both in the initial uptake and long term institutionalization of vaccines (Hardon & Blume, 2005; Mrazek & Mossialos, 2003; Tangcharoensathien et al., 2001). We have known for some time that such factors as political will, resources and institutional capacity are important determinants of the success of the EPI effort (Catford, 2006; Clemens, 2003). But the ability to predict and systematically explore these factors still eludes us.

This study is no more than a first step towards reopening the question of policy processes underlying vaccine adoption as a field of inquiry warranting greater attention. In moving towards a sustained research agenda in this area, two broader aspects of our findings warrant attention.

The first concerns methodology. The study sheds light on the methodologies that will be important to the further development of this research agenda. A classic approach to predicting uptake would involve the construction of databases of cross-national variables predicting uptake—indicators of the kind explored in section three above—followed by econometric analysis; the aim of such analysis

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<th>No.</th>
<th>Factors</th>
<th>Taiwan</th>
<th>Thailand</th>
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<tr>
<td>1</td>
<td>High disease burden</td>
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<td>Programmatic Feasibility</td>
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<td>5</td>
<td>Important role played by:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Role of the medical association</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td></td>
<td>b. Local manufacturers</td>
<td>Present</td>
<td>Not present</td>
</tr>
<tr>
<td></td>
<td>c. International support</td>
<td>Not present</td>
<td>Present</td>
</tr>
<tr>
<td></td>
<td>d. Role of media</td>
<td>Not present</td>
<td>Present</td>
</tr>
<tr>
<td>6</td>
<td>Sensitivity to price</td>
<td>Not present</td>
<td>Present</td>
</tr>
<tr>
<td>7</td>
<td>Policy entrepreneurs</td>
<td>Present</td>
<td>Not present</td>
</tr>
<tr>
<td>8</td>
<td>Other countries already using the vaccine?</td>
<td>Not present</td>
<td>Present</td>
</tr>
</tbody>
</table>

would in general be to quantify the incremental impact of any of the variables while holding all others in the equation at their mean value. While such a variable-centric approach has not yet been conducted and may be feasible, our findings suggest it is unlikely to cast much light on the critical issues of policy context, process, and stakeholder configurations. It is likely that the primary variables at work are triggered and impact on decisional outcomes in complex combinations with other variables; this is the hallmark of ‘causal diversity’ that forms a core assumption of the present study, and one borne out by the case analysis. Such causal combinations that will be highly difficult to model give limited sample sizes in cross-country analysis (Parashar, 2005).

More promising, therefore, will be methodologies that attempt to model sets of necessary and sufficient conditions indicating distinct causal pathways towards the same outcome, of the type pioneered by Ragin (1987, 2000). Such ‘qualitative comparative’ and ‘fuzzy-set’ analysis will require the construction of a greater range of qualitative case studies using comparable categories of analysis (such as those suggested in section three). These can – and will certainly need – to extend beyond the middle-income country range, and should include cases of late or non-adoption as well as the early adopters explored in the present paper.

An important challenge facing this type of comparative method will be the establishment and justification of appropriate boundary conditions underlying an assessment of the ‘presence’ or ‘absence’ of different factors. Sensitivity and fidelity to the case narratives in this work will be vital, since without grounded comparisons the actual modeling of causal conditions will prove meaningless. In doing so, it is important to note that the coding of variables will be based on the relative rather than absolute values for variables in the cases; for example, the comparative lack of a high-profile policy champion in the present study’s Thailand case does not imply that passionately motivated individuals played little role; indeed, their presence among other places on the International Task Force was indeed very important (Muraskin, 1995). Likewise, few if any countries will be oblivious to price considerations in vaccine adoption, but countries will vary in their degree of price sensitivity, as they did in the present study.

A second set of considerations concerns the contested, political context of vaccine adoption described in this paper’s framework. The adoption process described in our cases underlined the importance of policy-making environments that were in part open to multiple inputs and actors, and at least partly evidence based. But this condition is far from typical in a large number of countries, 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. Recognition of the political context of policy-making underscores the need for eclecticism in conceptual approaches—which will need to draw on theories of as bureaucratic politics (Brinkerhoff & Crosby, 2002; Grindle & Thomas, 1991) as well as policy transfer and learning (Rose, 1993) in future studies. It also highlights the necessity of care in interpreting findings besides those provided by sound epidemiological studies (the latter often critically lacking in developing countries); those seeking to influence the adoption process will not be able to follow a variable-centered ‘cook-book’ of conditions or methods facilitating adoption. But the emphasis placed in the current study on the dynamics of the policy process, coupled with its approach to making the modeling of explanatory frameworks dependent to a greater extent on local conditions, may point towards a research agenda rich with practical implications.

Disclaimer: The views and opinions expressed in this article are those of the author and does not reflect the official position of The Global Fund to Fight AIDS, Tuberculosis and Malaria.

References


