J HEALTH POPUL NUTR 2004 Sep;22(3):322-330 © 2004 ICDDR,B: Centre for Health and Population Research
ISSN 1606-0997 $ 5.00+0.20

The Importance of Engaging Policy-makers at the Outset to Guide Research on and Introduction of Vaccines: The Use of Policy-maker Surveys

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ABSTRACT

Face-to-face surveys of policy-makers and other influential leaders are a useful tool to identify, at an early stage, (a) major issues regarding the introduction of a new vaccine, (b) persons and groups in a country who play a major decision-making or influential role in the introduction of vaccines, (c) potential obstacles to the introduction of vaccines, and (d) data-needs of policy-makers to overcome these obstacles. By surveying the opinions and beliefs of those who will make or influence decisions on whether to introduce a new vaccine, these studies can help ensure that research activities respond to the needs of policy-makers in countries endemic for the target diseases. These surveys can also inform vaccine-introduction strategies by identifying financially and politically feasible means of distributing, targeting, and financing the vaccines. This paper describes the methodology used in conducting such surveys and discusses methodological issues. It also presents lessons learnt from two policy-maker surveys carried out in several Asian countries in regard to new-generation vaccines against cholera, typhoid fever, and shigellosis; and future vaccines against dengue fever/dengue haemorrhagic fever.

Key words: Vaccines; Immunization programmes: Health surveys; Cholera; Dysentery, Bacillary; Typhoid fever; Asia

INTRODUCTION

Why conduct policy-maker surveys?

Increasingly, the public sector is creating large research programmes to accelerate the introduction of new vaccines in developing countries. In recent years, multi-million dollar programmes have been created to develop and introduce a variety of vaccines. Examples include a meningococcal conjugate vaccine targeted for children in sub-Saharan Africa (1), a paediatric dengue vaccine (2), rotavirus and pneumococcal conjugate vaccines geared towards children in developing countries (3), a malaria vaccine (4), improved vaccines against Japanese encephalitis, and new-generation vaccines against cholera, typhoid fever, and shigellosis (5).

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These research efforts should lead to the availability of a greater number of safe, effective, and presumably reasonably-priced vaccines in the marketplace in the coming years. However, as more vaccines become available and as each research programme tries to convince countries to introduce its target vaccine, resource-constrained governments will not be able to take up all desired or presumably needed vaccines. The past two or three decades have seen the development of a number of vaccines sorely needed in developing countries, including vaccines against hepatitis B, *Haemophilus influenzae* type b (Hib), and Japanese encephalitis (for Asia). However, many national immunization programmes have not introduced these vaccines because of their perceived high cost, uncertain disease burden in their country, or other factors. As more vaccines enter the international market, countries will be forced to set priorities for vaccines and disease-control activities based on sound data and financial realities.

However, just what are the disease-control priorities of policy-makers in developing countries and how do various upcoming vaccines fit in with these priorities? How do policy-makers determine these priorities and what specific information do they use to do so? Is, for instance, disease burden always the major determinant in setting priorities? What other factors or data influence decisions to introduce a new vaccine? What is the decision-making process that different countries use regarding the introduction of new vaccines and who makes and influences these decisions? What are the major barriers to the introduction of vaccine and how can they be overcome? Are there criteria for cost and performance of different vaccines that decision-makers consider critical or even a pre-condition to considering their use? And if they do decide to introduce a certain vaccine, what introduction and financing strategies are they considering, if not full-scale introduction of free vaccine through the national immunization programme?

While policy-making is not always a rational process, answering these questions early in the formulation of vaccine-research programmes may improve the odds that a research programme will actually lead to the introduction of a vaccine in a country, that the people most in need of the vaccine will receive it, and that its use and financing will be sustainable over the long term.

One way to begin answering these questions is to conduct face-to-face surveys with key policy-makers and other opinion leaders in the target countries during the design or early implementation phase of the research programme. By initially surveying the opinions and beliefs of those who will actually make decisions on whether to introduce a new vaccine, these studies can help ensure that the research activities, including vaccine development, respond to the needs of end-users of data—that is, policy-makers in countries endemic for the target disease. Policy-maker surveys can provide valuable data to inform the research agenda, advocacy plans, and actual introduction of vaccine by determining the likelihood of a new vaccine being introduced in a country, identifying key decision-makers and centres of influence, identifying obstacles to the introduction of vaccine, determining the data and other requirements needed to overcome these obstacles, and identifying vaccine-introduction strategies that are most likely to succeed in a sustainable fashion. Unlike more comprehensive stakeholder analyses or political mapping exercises, policy-maker surveys are relatively rapid assessments to initially identify key issues and critical players. They can also serve as an initial step in the process of policy dialogue with country-level policy-makers and influential leaders concerning the introduction of new vaccines.

The International Vaccine Institute (IVI) has conducted policy-maker surveys for two of its research programmes: the Diseases of the Most Impoverished (DOMI) Programme, which is aimed at accelerating the use of new-generation vaccines against cholera, typhoid fever, and shigellosis (which include already licensed oral killed whole-cell cholera vaccines and injectable typhoid Vi vaccine) and the Pediatric Dengue Vaccine Initiative (PDVI). This paper discusses the methodological issues and provides lessons learnt and illustrative findings from both DOMI and dengue fever policy-maker surveys. The DOMI survey was carried out during November 2000–June 2001 in all seven Asian countries participating in the programme (Bangladesh, China, India, Indonesia, Pakistan, Thailand, and Viet Nam). The dengue survey was conducted in mid-2002 in four dengue-endemic Southeast Asian countries (Cambodia, Indonesia, Philippines, and Viet Nam) (6).

METHODOLOGICAL ISSUES AND CHALLENGES

Survey methods

The DOMI and dengue fever policy-maker surveys were conducted during country visits of four and eight days respectively. Interviews were held on a one-on-one basis or in group meetings of up to eight participants. It was felt that only through face-to-face interviews could we address in any depth the broad range of issues that were identified for exploration. While written questionnaire or telephone surveys could be used for supplementing the interviews, these methods alone would be less conducive to probing respondents in depth to gain more than a superficial understanding of their perceptions, attitudes, and beliefs. Face-to-face interviews are also likely to yield a higher response rate, especially from high-level policy-makers, than are telephone surveys, or written questionnaire.

Topics of interview

To guide the interviews for each survey, a comprehensive question guide was prepared. The guides were

based on key issues influencing the introduction of new vaccines, identified from a review of prior studies of the uptake of new vaccines in developing countries (7-11) and from the research and clinical experience of the researchers or their colleagues. The questions examined perceptions, beliefs, and opinions of informants regarding:

- scope and seriousness of the target disease(s)
- level of priority of controlling the disease
- quality and accuracy of the existing surveillance data and reporting systems
- effectiveness of the current prevention and treatment methods
- need for and interest in vaccines compared to other prevention or treatment methods
- criteria and preferences for vaccines against the target disease
- experiences to date with the target vaccines (for the DOMI survey)
- preferred or feasible strategies for the introduction of vaccine, including distribution channels, scope and targeting of immunization, vaccine sources, and financing
- data needs to inform decision-making regarding the introduction and use of vaccine.

Appropriate informants were also asked detailed questions about their country's immunization programme, the policy process involved in past introduction of new vaccines, licensing of vaccine and regulatory procedures, local vaccine-production capabilities and future plans, and other relevant issues.

Techniques of interview

The question guide consisted entirely of open-ended questions, allowing for a semi-structured qualitative interview format. This format was felt to be more appropriate for interviewing high-level informants and for creating an informal atmosphere conducive to the free expression of ideas than highly-structured interviews using a close-ended questionnaire. This method also allowed for probing and clarification of responses and facilitated the identification of new issues or facts to explore. A two-person team conducted the interviews for the DOMI survey and one or two person(s) were interviewers for the dengue study.

Interviews and meetings averaged one to two hour(s) in length and ranged from 45 minutes to more than three hours. A number of informants gathered data ahead of time and some, especially in China, received the question guide in advance and had it translated to prepare for the interviews.

Selection of interviewees

The list of persons and groups to be interviewed in each country was developed with the guidance of the researchers and input from local collaborators who arranged the interviews. The goal was to meet as many key persons and groups as possible in the given timeframe who make or influence decisions regarding disease control, immunization programmes, local development and production of vaccine, and vaccine introduction.

For both DOMI and dengue vaccine studies, the types of persons interviewed included the following:

- Ministry of Health officials, including department heads of communicable disease control, preventive medicine, planning or finance; and programme managers of the national immunization programme and the specific disease-control programme in question (e.g. diarrhoeal disease, dengue)
- Ministry of Finance officials
- Directors of large public-sector children's or infectious disease hospitals
- Presidents and officers of professional associations (e.g. national paediatrics and national medical associations)
- Leading academics and researchers from universities and research institutions, including members of National Vaccine Advisory Committees
- Health officials from selected local governments
- International technical agency officials (e.g. WHO).

High-level health officials, such as Vice Ministers of Health and Directors General, were also interviewed in several countries for both the surveys. Several national and local-level politicians were interviewed in the Philippines for the dengue study and in Viet Nam for the DOMI survey. Since new-generation vaccines against cholera and typhoid fever are already on the market and other newer-generation vaccines are well

under development, interviews for the DOMI survey were also conducted with representatives of: national regulatory authorities, local vaccine producers, and private-sector vaccine suppliers (in four countries).

Seven to 16 interviews or meetings were conducted for the DOMI survey in each country, involving 19-29 participants per country. In total, 165 informants took part in 86 interviews or meetings in the seven countries combined. The four-country dengue survey involved 10-13 interviews/meetings per country, for 48 meetings with 91 participants.

A key issue that arises is whether or not the sample of informants in each country was representative of the country's major decision-makers and influential leaders as a whole and whether some critical players were not interviewed. This is especially a concern regarding informants from local-level health authorities, since only a few localities were represented in each country. The samples of informants could also over-represent those with a particular interest in the target disease or vaccine. To ensure that the prevailing views and beliefs of policy-makers in many countries—at least at the national level—were tapped, in all countries we interviewed individuals who were identified by the researchers, by local collaborators, and by other informants as key decision-makers or influential leaders regarding immunization programmes and vaccines. Nonetheless, while the best attempt was made to meet as many relevant individuals as possible, it is likely that key decision-makers in some countries were missed. To address the issue of lack of representativeness of local government informants, responses were analyzed by type and level of informant, allowing us to separate out the responses of the local health officials from those of central-level policy-makers.

Analysis of results

A complete set of notes from the interviews was transcribed and organized by topic area and by person or group interviewed. From these notes, country-specific summaries for the dengue study and detailed country reports for the DOMI survey were prepared.

As with all qualitative research, there is the risk that responses of the researchers, due to their biases or language barriers, misinterpreted informants. To minimize misinterpretation, the researchers probed the respondents for details, asked for clarifications, and often summarized their interpretation of the informants' responses to ensure accuracy. The country reports or summaries were sent to the project collaborators in each country for feedback and corrections to further validate the findings. Revisions to the summaries or reports were made based on the feedback. Additional feedback was solicited from the informants themselves, who received country-specific summaries of the findings. While several project collaborators provided feedback to the reports or summaries, few responses were received from the informants.

LESSONS LEARNT FROM POLICY-MAKERS SURVEYS IN ASIA

What factors influence disease-control and vaccine priorities?

When asked which factors figure most into setting priorities for disease-control activities and selection of vaccine, the informants invariably cited disease burden as the number one consideration. Indeed, the top priorities cited by the informants and declared in official reports, such as tuberculosis, malaria. and acute respiratory infections, are often diseases with the highest estimated disease burden in these countries. Diseases with growing incidence, such as HIV/AIDS and dengue fever/dengue haemorrhagic fever (DHF), were also of great concern to the informants. However, judging from many of the infectious disease concerns and priorities, several other factors, besides the magnitude and growth of disease burden, are also in play in determining these priorities. There was a near consensus on the importance of dengue fever/DHF and interest in future vaccines in the four countries surveyed, while concern for enteric diseases in seven countries (two of which overlapped with the dengue survey) was more mixed, despite the likely higher mortality rates from enteric diseases than from dengue in these countries [shigellosis, typhoid fever, and cholera cause an estimated 1.8 million deaths per year worldwide compared to an estimated 30,000 for dengue/DHF (12-15)]. Of the enteric diseases, concern was generally higher across countries for typhoid fever than for shigellosis or cholera, despite the considerable uncertainty of the true burden of all three diseases in these countries. And the expressed interest in cholera vaccines among national-level policy-makers was higher in some presumably low-incidence countries (Thailand and China) than in several countries considered to be cholera-endemic (e.g. Bangladesh,

Pakistan, and Indonesia). Other factors influencing priorities that explain some of these discrepancies appear to be the following:

- **Occurrence of epidemics.** Diseases that occur throughout the year are less likely to attract the attention of the medical and public-health communities, politicians, and the media than epidemic diseases, such as dengue/DHF, although the former may cause considerably higher overall mortality than the latter. In several countries, the public increasingly blames national and local political leaders for not doing enough to prevent dengue epidemics, thus increasing politicians' concern about and awareness of the disease.
- **Burden on hospitals.** Diseases that place a large burden on hospital facilities, staff, and finances, such as dengue/DHF and typhoid fever, are more likely to be uppermost in the minds of policy-makers than diseases that are largely treated on an outpatient basis or that generally consume fewer hospital resources.
- **Limited or dwindling treatment options.** The lack of a specific treatment for DHF and the difficulty in managing the disease—which can cause sudden death—engender considerable concern and even fear among practitioners. Growing rates of antibiotic resistance of typhoid fever in many countries and the need to treat it increasingly with expensive newer-generation antibiotics, such as ciprofloxacin, contribute to the growing concern about this disease. The perceived need for typhoid vaccines appeared more urgent to policy-makers in countries that must import and pay high prices for ciprofloxacin than in countries where the drug is locally made and relatively inexpensive. In contrast, the generally lower level of concern about cholera and interest in new-generation cholera vaccines among national-level policy-makers in several endemic countries was due, in large part, to their perception that the widespread use of oral rehydration therapy has made the disease largely manageable and has reduced mortality due to cholera to the point where they feel a vaccine is no longer needed.
- **Economic considerations.** The high and rising costs of treating typhoid fever, due to growing antibiotic resistance, and the economic costs to families resulting from loss of work to care for a child during long recovery periods, appeared to be key factors contributing to growing concern of policy-makers for the disease and interest in new-generation typhoid vaccines. In addition, the expressed interest in cholera vaccines among several central government policy-makers in China and Thailand stemmed more from their fear of the potentially devastating impact of reported outbreaks of cholera on their growing economies (e.g. on tourism and food export industries) than on any expected epidemiological impact of a vaccine.
- **Perceived risk across social classes and in urban areas.** Policy-makers appeared to have heightened awareness of and concern about diseases, such as typhoid fever and dengue/DHF, which are perceived to affect all socioeconomic classes than diseases, such as shigellosis and cholera, which predominantly strike the poor. The prevalence of typhoid and dengue fever in urban areas—the centres of political power and the media—also appears to contribute to their heightened concern about these diseases.

These findings indicate that, although disease-incidence and mortality data can be critical in informing the disease-control and immunization priorities of policy-makers, these priorities cannot always be predicted based on disease-burden data alone.

Who influences policy regarding vaccine introduction in Asia?

While Ministries of Health are normally crucial in the decision-making process for the introduction of new vaccines and often play the role of initiator, other individuals and groups in both public and private sectors in Asian countries play a key decision-making, influential or catalytic role that can ultimately make the difference between vaccine uptake and no uptake. These groups and individuals must, therefore, be targeted for any activities to disseminate research results and promote the introduction of new vaccines.

In most countries surveyed, professional societies, such as national paediatrics and national medical associations, play an important role in developing national immunization guidelines and schedules, promoting private-sector use of new vaccines, and providing guidance to national immunization programmes. Reportedly, these

associations played a critical role in convincing the managers of immunization programmes in several Asian countries to add hepatitis B vaccine to their infant immunization schedule. In one study, they were also found to be key promoters of the introduction of Hib vaccine in four 'early adopting' countries (16). Leading academics and researchers can also be key opinion leaders, especially when they serve on national immunization committees, which in several countries play a major advisory role in government decisions regarding vaccine introduction. And as local producers of vaccines in several countries increasingly take the initiative in developing new vaccines or acquiring new vaccine technologies, their role in influencing the introduction of vaccines becomes more important. This is especially true in cases where local production drives the prices of vaccines down to the point where governments are more willing to consider their use.

Other government ministries and agencies besides the health ministry can have an important impact on vaccine introduction decisions and must be taken into account in devising advocacy strategies. These include: planning and/or finance ministries and other government entities, such as Parliament, which must approve funding for the introduction of vaccine. In one country, nation-wide use of a vaccine began when a local public-health leader convinced the Planning Commission to fund limited introduction of a vaccine through a non-regular budget, bypassing the health ministry, which opposed adding the vaccine to the national immunization programme. In some countries, science and technology ministries can serve as critical catalysts to local production of new vaccines by providing financial support for research and development and for start-up firms. This was the case with the local development of recombinant hepatitis B vaccines in India.

Finally, as governments decentralize in more and more countries, state, provincial or municipal governments are assuming an increasing policy-making role, as they gain the ability to initiate and finance health interventions on their own, including the introduction of new vaccines.

Likely trends in vaccine introduction and financing strategies

As more and more vaccines enter the market, patterns of targeting, distributing, and financing these vaccines will likely differ from those used for traditional EPI vaccines which, in most countries, are provided by national immunization programmes administered and financed by the central government. These likely changes are due to the limited human and financial resources of often over-burdened national immunization programmes and the likely higher prices of newer vaccines compared to the basic EPI vaccines. Based on the DOMI and dengue policy-maker survey results, introduction strategies that may be deployed for these and perhaps other newer vaccines include the following:

- **More limited scope and targeting of vaccination**

  Use of several newer vaccines may increasingly be limited to higher-risk groups and geographical areas, especially for vaccines against diseases that are concentrated in certain populations or areas. For example, several Asian countries have suggested targeting food workers and refugees for vaccination against enteric diseases as a cost-effective means of controlling these diseases. Targeting for cholera vaccine was also suggested for populations in high-incidence areas, fishermen, the poor, prisoners, and others in confined settings, and during floods and other natural disasters. Suggested targets for typhoid vaccine included urban school-age children, slum residents, and soldiers. This strategy requires solid disease-burden data from different parts of the country, disaggregated by geographic area, age group, and other demographic characteristics.

- **Increased role of the private sector in the introduction and distribution of vaccines**

  Several governments in Asia increasingly view the role of the private sector in immunization not as limited to serving a tiny, wealthy elite, but as an integral part of a comprehensive vaccine-introduction strategy. This is especially the case in countries with vibrant private health sectors, such as India and Pakistan, and for vaccines, such as typhoid Vi, with a potentially large demand among the middle classes and urban dwellers. Policy-makers in these countries view private-sector distribution of vaccines as means to:

  - demonstrate public demand for a vaccine, which some national immunization programmes increasingly require before considering public-sector use;

- provide vaccines before the public sector is able to do so. Innovative strategies of distributing hepatitis B vaccine to large numbers of people in India and Pakistan in partnership with vaccine companies, medical associations, NGOs, and local governments have demonstrated that private-sector distribution can reach beyond small elites. These collaborative public-private efforts have included large-scale immunization camps using discounted vaccine, school-based campaigns, and programmes to distribute discounted vaccine at public-sector health facilities; and
- provide vaccines for free to the poor via the public sector, while encouraging those better-off to obtain the vaccine in the private sector. This 'dual channelling' approach was suggested in both India and Indonesia as a potential cost-containment strategy for the introduction of newer vaccines, such as new-generation enteric vaccines.

- **Increased role of decentralized governments in providing and financing new vaccines**

  As countries decentralize their health systems, the introduction of new vaccines could increasingly be initiated and financed by local governments at the state, province, district or municipality level. This is already true in China, where the provision and financing of the basic EPI vaccines and the decision to provide any non-EPI vaccines rest with provincial governments. Some states in India have also begun to introduce new vaccines, such as hepatitis B, measles-mumps-rubella, and Japanese encephalitis, on their own. Introduction and financing by local governments is especially likely for vaccines against diseases considered largely regional, such as cholera in India, and diseases for which local governments feel strong public pressure to control, such as dengue/DHF in Indonesia and the Philippines. Possible sources of decentralized government financing include user-fees, with exemptions for the poor; local government budget allocations; and donor funding.

Key data requirements of policy-makers

Based on the findings of both the surveys and the expressed data needs of informants, information that can most assist policy-makers in making decisions regarding introduction of new vaccine includes the following:

- **Evidence of disease burden.** National or local government decision-makers will not be convinced to introduce and fund a new vaccine without compelling data demonstrating need. Such data can also be powerful in convincing local vaccine producers of the potential demand for a vaccine, which they may require before investing in development, testing, and production of the vaccine. In several countries, informants argued that data must be gathered from different parts of the country to provide a national picture of disease incidence to develop a national strategy and to identify high-risk areas and populations for targeting immunization.
- **Local data on safety, effectiveness, and impact of vaccine**. Policy-makers increasingly require in-country data demonstrating safety, immune response, and epidemiological impact of a vaccine on their local population before deciding to include the vaccine in a country's immunization programme. This is true even for vaccines, such as typhoid Vi, for which clinical trial data from other countries exist. The interest of policy-makers in local data is due to the potential differences between populations in immune response, endemicity of the disease, and ecological factors. This information can best be provided through controlled demonstration projects that also provide data on the programmatic feasibility of administering the vaccine through the existing public-health infrastructure—data that can be crucial to policy-makers in making decisions on whether or not to introduce a new vaccine (17). Such demonstration projects can also act as catalysts to stimulate political will for the wider vaccine introduction (10).
- **Local data on cost savings and cost-effectiveness of vaccination**. Economic data to demonstrate potential savings in treatment costs from vaccination and to measure the cost-effectiveness of immunization versus other preventive measures are increasingly viewed as critical to set vaccine priorities and to convince budgetary decision-makers to approve funding for the introduction of a vaccine. Data on vaccine cost-effectiveness are especially needed, given the higher prices of most newer and upcoming vaccines compared to traditional EPI vaccines. In the case of new-generation enteric

vaccines, cost-effectiveness data may be critical to inform vaccine-uptake decisions, given their moderate protection levels (e.g. ca. 60% for oral cholera vaccine and ca. 70% for typhoid Vi) and the stated preference of many policy-makers for more permanent solutions, such as improvements in water and sanitation, over immunization. These data can most efficiently be gathered during vaccine-demonstration projects described above.

CONCLUSION

Policy-maker surveys can be a useful and relatively rapid means of gaining the perspective and insights of key groups and individuals at the country level who make or influence policy decisions regarding the introduction of new vaccines. There are, however, a number of limitations to such surveys. These include the difficulty in ensuring that all key decision-makers are included and the difficulty in obtaining sufficient feedback on the findings and conclusions from respondents for validation. Like all surveys, they also capture a moment in time. This can especially be limiting with policy-maker surveys, since changes in governments can result in changes in key decision-makers and in programme priorities. Rapidly changing circumstances and new phenomena, such as the recent epidemics of SARS and bird flu, can also quickly change the disease-control priorities of governments.

Given these limitations, policy-maker surveys are most appropriate as a means of initially identifying key issues, such as factors influencing decisions regarding vaccine introduction, misconceptions regarding targeted diseases and vaccines, other obstacles to vaccine introduction, and the specific types of data that can have the greatest potential impact on policy decisions. They are, therefore, best viewed not as a definitive or final policy analysis, but as one of a series of activities to inform the design of vaccine research programmes, information dissemination, and advocacy activities.

ACKNOWLEDGEMENTS

This work was supported by the Diseases of the Most Impoverished (DOMI) Programme, funded by the Bill and Melinda Gates Foundation.

The policy-maker surveys described in this paper were designed with the assistance of Dr. John D. Clemens, Dr. Richard Mahoney, and Dr. Jacqueline Deen of the International Vaccine Institute (IVI), Seoul, Republic of Korea. The surveys were conducted for the DOMI Pro-gramme by the lead author and Andrew Nyamete of IVI. Dr. Jacqueline Deen participated in the dengue survey in the Philippines.

The authors wish to acknowledge the assistance of local collaborators who arranged the interviews and meetings in each country. For the DOMI surveys, they were: Dr. Wanpen Chaicumpa and Pramuan Tapchaisri, Faculty of Tropical Medicine, Mahidol University, Thailand; Dr. Cyrus Simanjuntak and Dr. Narain Punjabi, U.S. Naval Medical Research Unit No. 2 (NAMRU-2), Indonesia; Dr. Dang Duc Trach (deceased) and Dr. Do Gia Cahn, National Institute of Hygiene and Epidemiology, Viet Nam; Dr. Zulfiqar Bhutta, Aga Khan University, Pakistan; Dr. Subrata Routh, Dr. Ziaul Islam, Dr. Sukumar Sarker, and Dr. Shaikh Shahed Hossain, ICDDR,B: Centre for Health and Population Research, Dhaka, Bangladesh; Dr. N.K. Ganguly and Dr. K.K. Singh, Indian Council of Medical Research, and Dr. S.K. Bhattacharya, National Institute of Cholera and Enteric Diseases, India. The authors are also grateful to Dr. Zhi-Yi Xu, Senior Scientist, IVI, for arranging and participating in the interviews in China.

Local collaborators for the dengue surveys were: Mr. Norman Nacpil in the Philippines; Dr. Nemia Sucaldito, Department of Health, The Philippines; Dr. Rita Kusriastuti, Chief, Arbovirosis Subdirectorate, Ministry of Health, Indonesia; Dr. Nguyen Dang Vung, Senior Programme Officer, Health Policy Unit, Ministry of Health, Viet Nam; Dr. Ngan Chantha, National DHF Programme Manager in Cambodia, and Dr. Chang Moh Seng, WHO Office, Cambodia.

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