Sociobehavioural Research Methods for the Introduction of Vaccines in the Diseases of the Most Impoverished Programme

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ABSTRACT

Participation in vaccination campaigns worldwide, particularly the Expanded Programme on Immunization, has increased significantly in recent years. However, there remain multiple and integrated behavioural, sociocultural and political-economic barriers to vaccination. The Diseases of the Most Impoverished (DOMI) Programme has undertaken shigellosis disease-burden studies and oral cholera and typhoid Vi polysaccharide vaccine trials in seven Asian countries. As part of these projects, sociobehavioural studies have been undertaken to determine the potential demand for vaccines for these diseases and the obstacles and enabling factors that may affect acceptance, delivery, and use of vaccines. A theoretical model of acceptance of vaccination and a triangulation of qualitative and quantitative methods have been used for fully elucidating the range of issues relating to vaccination for shigellosis, cholera, and typhoid fever. In this paper, the theoretical and methodological basis of the DOMI projects has been reviewed in a context of current sociobehavioural research on the acceptability and desirability of vaccination.

Key words: Vaccination; Research design; Dysentery, Bacillary; Cholera; Typhoid fever; Asia

INTRODUCTION

Health-seeking can be conceptualized as an ongoing life-long process that includes both behaviours to cure or seek relief from specific symptoms or illnesses and behaviours to avoid symptoms and illnesses. The latter may include a range of activities, such as engaging in exercise, consumption or avoidance of certain foods, and/or use of traditional or biomedical preventive practices, e.g. vaccinations. These behaviours, however, Correspondence and reprint requests should be addressed to: occur within dynamic sociocultural and political-economic contexts, which (re)construct social roles and responsibilities, ideologies, and practices through dayto-day activities and interpersonal relationships.

A range of models have been developed over the past several decades to further understand the interactions of variables as they affect individual health-seeking processes. These include a range of 'behaviourist' models, such as the Health Belief Model (1), the Protection Motivation Theory (2), and the Stages of Change Theory (3). These behaviourist models of health-seeking, however, often neglect the context of actions of an individual and the complex relationships among individual, sociocultural and political-economic conditions. These models are primarily based on a western industrialized concept of medicine and individual action, including cost-benefit analysis. Alternatively, political

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economic theories, including feminist and critical theory, incorporate the limitations on choices and actions of individuals through the social construction of groups (e.g. race, gender) and within specific institutional infrastructure (4,5). While the political economic theories provide a framework for expansion of understanding the health-seeking processes beyond behaviours of individuals, they have also been criticized as too deterministic, with insufficient attention to individual and group initiatives and resistance (6).

In recent years, sociobehavioural health studies have used a number of behaviourist and cultural and political-economic theories to account for decision-making of individuals regarding vaccination. These studies have included perceptions about and acceptability of existing vaccines (7) and hypothetical vaccines, e.g. HIV, human papillomavirus (8-10). Among the behaviourist studies, a number of variables, which can be categorized as 'disease'- or 'vaccine'-related, emerge as potentially salient to the decision-making process for vaccination. In terms of perceptions about and attitudes towards the preventable disease, such variables as perceived severity of the disease or characteristics of the disease (11) and vulnerability to the disease (12) have been recognized as contributing to acceptance and use of vaccination. Vaccine-related variables have included 'comfort and confidence' in vaccine (9), general positive attitudes towards immunization (13), perceived benefits and risks of vaccination (14), cost of vaccine (15), and characteristics and delivery of vaccine, e.g. number of injections (16,17).

Other vaccine-acceptance studies have relied more on a sociocultural and/or political-economic framework. In some of these studies, such variables as client-healthcare provider communication and healthcare infrastructure are delineated as important to acceptance and participation of individuals in vaccination programmes or campaigns. In a study of British parents who refused MMR and/or meningococcal C vaccines for their children, poor communication and inadequate information from healthcare providers was one reason for these decisions (18). In a qualitative study in Britain, both 'confidence and trust' in healthcare providers and exposure to media information about the safety of MMR vaccine influenced the vaccine decision-making process of parents (19). Similarly, among Italian mothers, their satisfaction with information about immunization affected their acceptance of MMR and pertussis vaccines (13). A

survey of healthcare providers regarding influenza immunization for adults and the elderly found that inadequate or ineffective outreach methods were an obstacle to recruiting patients for vaccination. In addition, perceived burdens on the healthcare infrastructure and time and labour of providers affected immunization rates (20). In a retrospective study of adult influenza and pneumonia immunization in the United States, a number of social and economic conditions predicted rates. These included ethnic group, education, and income of individuals and availability of health insurance (21).

In recent years, the Expanded Programme on Immunization (EPI) campaigns in non-industrialized countries have significantly increased rates of immunization in many areas, and vaccination is becoming a routine part of child healthcare (22). In a study of the effectiveness of communication efforts during vaccination campaigns in Mexico, Pérez-Cuevas et al. found that 83% of mothers interviewed were aware of the campaign and approved of messages (23). In addition, these mothers actively sought immunization, e.g. going to publichealth clinics to receive vaccines, rather than more passive participation, e.g. waiting for home visits. Nichter has defined 'active demand' for vaccination as "adherence to vaccination programs by an informed public which perceives the benefits of and need for specific vaccinations", and 'passive demand' as "acceptance of vaccinations by a public which yields to the recommendations and social pressure...of health workers and community leaders" (24:330).

A range of barriers to vaccination, however, continue to exist both within EPI campaigns and in relation to vaccines available outside EPI and for older children and adults. Streefland et al. discuss these barriers from the perspective of changing national healthcare infrastructure, increases in disease burden, e.g. HIV, broader political and economic changes and instability, and sociocultural meanings attached to vaccination by leaders, healthcare providers, and parents (25). These studies conducted in Bangladesh, Ethiopia, India, Malawi, the Netherlands, and the Philippines integrate local culture and meanings ("local vaccination cultures") within the larger national and international healthcare infrastructures and immunization programmes and campaigns. Streefland expands on Nichter's concepts of active and passive demand and discusses 'acceptance' (a more passive demand), 'social demand' (both for more and better vaccination services), and 'non-acceptance'.

The latter includes three categories: (a) those willing to go but unable to attend for logistical reasons; (b) those who simply refuse to attend because of logistic or delivery issues; and (c) those who question the need for vaccination.

Both current and historical contexts need to be considered in looking at acceptance and use of vaccination. Thus, in a retrospective study of local reactions to a public-health campaign for a tetanus vaccine in Cameroon, a rumour that the vaccine caused sterilization was analyzed in relation to communication, local 'response' to foreign technologies, and historical and extant relations between the local vaccination site and the state (26). In an analysis of EPI and childhood immunization in Asia, Nichter considered a range of variables to assess the desirability of vaccine, including household economics and healthcare decision-making, the infrastructure of national health services and conditions of health workers, local political dissent, and distrust between ethnic groups (24).

VACCINATION STUDIES OF THE DOMI PROGRAMME

Theoretical overview

All of these recent studies support the need for an integrated and dynamic framework within which to analyze acceptance and use or refusal of vaccination for a particular disease. The International Vaccine Institute's DOMI (Diseases of the Most Impoverished) Programme, supported through the Bill and Melinda Gates Foundation, includes disease-burden studies and vaccine trials in Bangladesh, China, India, Indonesia, Pakistan, Thailand, and Viet Nam. The disease-burden studies have focused on shigellosis and include surveillance of diseases, cost of illness, and sociobehavioural studies of perceptions of disease, use of healthcare, and desirability of vaccine (27). The vaccine trials are assessing the effectiveness of the Vi polysaccharide typhoid vaccine (28) and an orally-administered bivalent (anti-O1 and anti-O139) cholera vaccine (29). The sociobehavioural research associated with the trials includes qualitative methods and pre- and post-trial household surveys.

The sociobehavioural studies were undertaken to provide in-country policy-makers with data on perceptions and attitudes regarding the specific diseases, and demand for vaccines, as well as to provide data which would help increase participation in vaccine trials, and faciliate future introduction of vaccines for the target diseases. In addition, these projects provided a unique opportunity for cross-country analysis of perceptions and attitudes regarding these enteric diseases, and experiences and expectations regarding vaccination. Table 1 provides a summary of studies by country and disease.

The research for the sociobehavioural studies has focused on addressing three key issues elicited through discussions with local and national policy-makers in each country. These issues include: (a) What is the potential demand for vaccines for the target diseases (shigellosis, typhoid fever, cholera); (b) What is the current use of existing preventive control measures and demand for future control measures in the community; and (c) What are the potential obstacles and enabling factors that may affect acceptance, delivery, and use of vaccines?

The model for these studies is one that emphasizes dynamic relationships among individual, culture, social structure, and political-economic conditions. The vaccine-acceptance model has integrated variables from other health belief and health-seeking behaviour models with sociocultural theoretical concepts. These concepts include gender construction and how the roles and responsibilities of men and women in a household affect decision-making regarding healthcare-seeking, including use of vaccines. The model also considers dynamic ways in which people use multiple health belief systems (e.g. biomedical, traditional), and the means through which these systems are reproduced, altered, revised, and resisted.

In relation to the target diseases, variables assessed include: (a) perception of disease severity; (b) perception of self and other's vulnerability to the disease; (c) perceived causes of the disease; and (d) perceived availability and efficacy of preventive measures and treatments. In relation to vaccination, variables include: (a) perceived purpose of vaccines; (b) perceived efficacy of vaccines; (c) perceived risks and benefits of vaccination, e.g. risk of adverse effects; (d) costs of vaccination; (e) desired characteristics of vaccines; and (f) vaccine-delivery logistics. The disease and vaccine variables are inter-related. For example, if a disease is not perceived to be very serious, side-effects of vaccine may be a greater concern. In addition, the relative importance of each of these variables will be related to experiences of individuals with the disease, vaccinations, and the health system. Furthermore, these individual experiences

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	Bangladesh	China	India	Indonesia	Pakistan	Thailand	Viet Nam
Cholera	Household survey		Oral cholera vaccine trial, including qualitative rapid assessment and pre- and post- vaccina- tion house- hold sur- vey	Qualitative rapid assessment and house- hold survey			Household survey
Typhoid fever		Vi vaccine trial, including qualitative rapid assessment and pre- and post- vaccination household survey	Vi vaccine trial, including qualitative rapid assessment and pre- and post- vaccina- tion house- hold sur- vey	Vi vaccine campaign, including qualitative rapid assessment and pre- and post- vaccination household survey	Vi vaccine trial, includ- ing qualita- tive rapid assessment and pre- and post-vacci- nation household survey		Vi vaccine trial, includ- ing qualita- tive rapid assessment and pre- and post-vacci- nation household survey
Shigellosis	Disease- burden study, including qualitative interviews and house- hold survey	Disease- burden study, including qualitative interviews and house- hold survey	-	Disease- burden study, including qualitative interviews and house- hold survey	Disease- burden study, including qualitative interviews and house- hold survey	Disease- burden study, including qualitative interviews and house- hold survey	Disease- burden study, including qualitative interviews and house- hold survey

 Table 1. Sociobehavioural studies by country and disease

will be embedded in the context and reflective of household conditions and larger social, political and economic conditions (Fig.).

Ethics

The national ethics review boards of the local governments and the World Health Organization, Switzerland, approved the studies. Interviewers were trained in ethical research and obtaining consent. Written consent was obtained from all participants.

Research methodology

In the development of the research methods and instruments, the project needed to balance a need for specific local data to provide the maximum benefit for introduction of vaccines within sites with a need for comparable data across sites. A research methodology was designed for both shigellosis disease-burden studies and vaccine trial studies through workshops and meetings. These meetings included members of the DOMI Social Science Task Force, study coordinators, and local scientists from each study site. In these workshops, drafts of interview guides and instruments were developed. These guides and instruments were modified to be culturally and site-specific, but retained a structure based on those factors identified as important to future cross-site analysis, e.g. severity of disease and vulnerability.

To obtain data that would adequately address the complexity of factors affecting acceptance of vaccine in a specific population, multiple methods were employed (Table 2). In both disease-burden studies and vaccine trial studies, qualitative data-collection methods included open-ended, semi-structured interviews with

Sociobehavioural research methods in DOMI project

residents, leaders, and healthcare providers. Open-ended interview allows for respondents to answer the question in the language and context which 'makes sense' to him/her. Using interview guides, semi-structured aspect of interview provides for flexibility in asking questions, while the guides provide a means of ensuring that all topics are adequately covered for each interview. Flexibility also allows for an iterative approach so that each interview can build on data obtained in previous interviews.

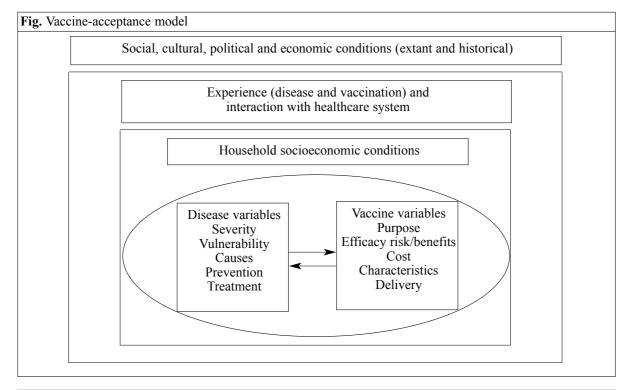


 Table 2. Theoretical variable domains and research methods for shigellosis disease-burden studies and typhoid fever/cholera vaccine studies

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Variable domain	Shigellosis disease-burden studies	Typhoid fever/cholera vaccine studies				
Political-economic Sociocultural	Qualitative interviews with local leaders, healthcare providers, and residents	Rapid-assessment qualitative inter- views with local leaders, healthcare providers, and residents				
Healthcare infrastructure and experience/interactions with healthcare providers	Qualitative interviews with healthcare providers and residents Case studies Household survey	Rapid-assessment qualitative interviews with healthcare providers and residents Pre-and post-trial surveys				
Household dynamics	Qualitative interviews with residents Vignettes (variations by age and gender) Household survey	Rapid-assessment qualitative inter- views with residents Pre- and post-trial surveys				
Disease-related variables (severity, vulnerability, causes, prevention, and treatment) Vaccine-related variables (pur- pose, efficacy, risk/benefits, cost, characteristics, and delivery)	Qualitative interviews with local leaders, healthcare providers, and residents Household survey	Rapid-assessment qualitative inter- views with local leaders, healthcare providers, and residents Pre- and post-trial surveys				

Both biomedical and traditional healthcare providers were interviewed. In this instance, the health system was defined after Kleinman (30) as a dynamic system, including all components with which an individual interacts in his/her healthcare-seeking process. Both formal and informal leaders were included as appropriate to the particular site. Finally, residents were selected based on local demographics to ensure that a range of ethnic and/or economic groups were included.

Qualitative interviews were conducted using the interview guides. These guides included questions which addressed the three key policy questions and the multiple variables at both individual and sociocultural and political-economic levels. Table 3 provides sample questions and probes used in Hue City, Viet Nam, for typhoid fever resident interviews.

For shigellosis disease-burden projects, vignettes were also included in semi-structured interviews. The vignettes were developed to elicit hypothetical health care-seeking behaviours of respondents based on symptoms of shigellosis. These vignettes varied by gender and age of the person exhibiting symptoms and also varied across sites to reflect cultural differences. By varying gender and age within sites, we hoped to determine the potential differences in healthcare-seeking practices for household members, e.g. daughters, sons, elderly, wage-earners. Table 4 provides sample vignettes and probes used in Nha Trang City, Viet Nam.

Also, as part of these disease-burden projects, case studies were conducted. Case studies were a series of open-ended, semi-structured interviews with individuals or family members of individuals who had either confirmed or suspected shigellosis diagnosed by the commune health centres and private practitioners. The interviews were conducted as soon after onset of illness as was feasible and at 3, 6, and 12 months. The interview guides for the case studies included targeted questions to assess the sequence of healthcare-seeking behaviour

 Table 3. Typhoid fever resident interview guide. Sample questions, probes, and rational, rapid assessment, Hue City, Viet Nam

Question: Can you name different types of illnesses in which individuals suffer from persistent fever, headaches, abdominal discomfort, or physical malaise?

Probes: What are the different terms for these illnesses? What other symptoms may be associated with these illnesses? Rational: To determine if people recognize typhoid fever as a distinct illness. Do they recognize various symptoms associated with typhoid fever? What terms/language do they use in relation to typhoid fever? How do they categorize typhoid fever in relation to similar illnesses? How could this affect population demand for vaccine and understanding what the vaccine protects against?

Question: How severe is typhoid fever?

Probes: What complications can occur from typhoid fever? Are these complications different for different groups (e.g. children/adults, men/women)?

Question: Who is most likely to get typhoid fever? Why?

Probes: Do you feel that your children are susceptible to typhoid fever? Do you feel that adult members of your household are susceptible? Why or why not?

Question: How prevalent is typhoid fever in your community?

Probes: How has this changed over the past 5 years? 10 years? Why do you think typhoid fever is more or less prevalent now than in the past? How much of a problem is typhoid fever compared to other illnesses for children (adolescents, adults) in your community?

Rational: These questions help determine perceptions of the severity, vulnerability, and prevalence of typhoid fever now and in the past, which may affect demand for vaccine and/or use of vaccine for particular age groups

Question: Have you or other members of your household received vaccines in the past?

- Probes: Who has received vaccines? Do you remember the different vaccines received (what diseases they prevent)? Where did you go to get those vaccines? Did the person who received the vaccine had any sideeffects? What were the side-effects? What questions or concerns did you or other family members have about the vaccines? Would you recommend for others in your family to receive those vaccines? Why or why not?
- Rational: To provide information on real previous experiences with vaccinations and vaccination campaigns, and how positive or negative past experiences may affect desire and demand for the typhoid fever vaccine

from onset of symptoms through possible sequelae from the disease. The case studies were also designed to obtain data on household dynamics in relation to decisionmaking during illness, perceptions of interfacing between the patient and/or his/her family with representatives from the health system, and perceptions of efficacy of various treatments used over the course of illness. The local research team primarily collected qualitative data for both disease-burden studies and vaccine trial. Members of the DOMI Social Science Task Force (SSTF) provided technical assistance in modifying the crosssite interview guides and training of interviewers. The latter included training in qualitative interviewing techniques, ethical research, and logistics. At some sites, the

Table 4. Sample vignettes, shigellosis sociobehavioural study, Nha Trang, Viet Nam

- 1. Hang is a 48-year old mother-in-law who lives with her son, his 22-year old wife, and their two small children. She has been having abdominal pain since yesterday morning and loose stools since last night*
- 2. It is now late afternoon of the next day, and her diarrhoea has become bloody and she has a fever*
- 3. It is three hours later. Now her son has developed abdominal pain and diarrhoea. She remains with fever, and her stools continue to be bloody*
- Hoa is a three-year old girl. For two days she has had 8-10 watery stools per day, but otherwise has not been acting sick*
- Now it is the next day. Her stool has become scantier, but has blood and mucous in it. She has a fever. She wants to lie down and is tearful*
- 3. The next day Hoa is no better. In fact, she looks very pale and is hardly talking at all*
- 1. Thanh is a 28-year old man. He lives with his wife, their five-year old daughter, their one-year old son, and his parents. Thanh works at night at a local factory. His wife runs a small food-selling business. Yesterday morning, after returning home from work, he started to have abdominal pain and loose stools*
- 2. This morning he continued to have abdominal pain and had bloody stools*
- 3. By late afternoon, his abdominal pain is worse, he continues to have bloody stools, and he has a fever*

*Probes (asked after each addition to the vignette) What do you think is the problem? Is there a name for this condition? What is a possible cause of this problem? Would she (you) do anything to treat herself (the child)? If so what? What other options for treatment might she (you) consider? At this point, would she (you take the child) to go anywhere for care? If so, where? Why? If not, why not? Who would be involved in deciding what should be done at this point?

For the sociobehavioural studies on typhoid fever and cholera vaccine, a qualitative rapid assessment was conducted. Rapid assessments are often used as precursors for surveying development and implementation and have been used for addressing varied health issues, including drug abuse, malaria, sexually transmitted diseases, diarrhoeal disease, water and sanitation, and nutrition (31,32). The rapid assessment also included open-ended, semi-structured interviews with salient individuals in the community, including leaders, residents, healthcare providers, and educators. The rapid assessment, however, included fewer interviews conducted over a shorter period (generally 2-3 weeks), thus minimizing the degree to which new information could be incorporated into questions for future interviews. Rapid assessments were used for these studies due to time limitations and the need to collect both qualitative data and pre-trial survey data prior to vaccination.

SSTF member assisted in data collection, particularly during the pilot phase. The pilots of the instrument provided an opportunity for the interviewers to gain field experience and to obtain feedback regarding the research instrument. This feedback was an important component of the process to refine the wording of questions and ensure the accuracy of translation.

The qualitative data served two purposes. First, these data were important in terms of primary information about health beliefs relating to the particular disease (shigellosis, typhoid fever, cholera), perceptions of availability of current preventive measures (e.g. adequate supply of clean water), experiences and beliefs about vaccines, healthcare-seeking behaviours, and perceptions of local health services. These interviews also provided data from the perspectives of healthcare providers regarding perceptions of the target diseases, experience with delivery of vaccine, anticipated demand for new (hypothetical or actual) vaccine, perceived need in the community for such a vaccine, and anticipated barriers and facilitators to delivery of vaccine. Interviews with community leaders provided the researchers with information regarding their perceptions of burden of a particular disease, current community preventive measures, perceived need for vaccination and their perceptions of local community demand, and broader sociocultural barriers and facilitators to delivery of vaccine.

Second, the qualitative data were an important source of information for the development of the survey instruments and their local modifications. These data provided local staff with information for the surveys about the health system, traditional prevention methods and treatments, traditional beliefs regarding the cause of disease, and local health information sources, e.g. for prior vaccine campaigns.

For the sociobehavioural studies on shigellosis, a close-ended, household survey instrument was developed and initially piloted by researchers at ICDDR,B: Centre for Health and Population Research at the Bangladesh site. The final survey framework was distributed to the other sites and modified accordingly to ensure that the survey was culturally specific and addressed issues raised during the qualitative phase at that particular site. In addition to the Bangladesh pilot, pilot-testing of the instruments was conducted at each site to ensure the cultural validity of the survey items and response categories.

Specific variations between sites included: (a) choices for prevention and treatment of shigellosis based on local traditional beliefs regarding the causes of the disease; (b) options for healthcare-seeking and reasons for using specific health options; (c) options for obtaining information about a hypothetical shigellosis vaccine; and (d) places and times for possible delivery of vaccine.

At all the sites, the surveys included scales and/or items for each of the five disease and six vaccine variables, demographic and socioeconomic information about respondents and households, and items relating to healthcare-use patterns.

The surveys were delivered one-on-one in homes of respondents. Households were randomly selected from local census data, and eligible participants included household members aged 18 years or above. The majority of respondents were household heads or their spouses. At each site, between 500 and 562 residents completed the survey. Data for the disease-burden surveys were entered at the research sites and analyzed locally (27, 33,34). However, these data were also sent to West Virginia University, where they were compiled and recoded to conduct cross-site analysis. These analyses included multiple logistic regression analysis to identify variations and similarities in regional correlates for acceptance of shigellosis vaccine for both adult and child recipients.

Both pre- and post-trial household surveys were implemented for the typhoid fever and cholera vaccine trial. Households were randomly selected from the census data collected as part of the vaccination trial. The same respondent was asked to complete the pre- and post-trial surveys. In some sites, additional respondents completed the post-trial survey due to extensive in- and out-migration. Sample size at each site was calculated to be 500 assuming an attrition rate of 10-15% between pre- and post-trial surveys.

The pre-trial survey was modified from the shigellosis survey to be relevant to the specific disease (typhoid fever, cholera) based on rapid assessment data. In addition, the pre-trial survey was implemented in conjunction with an economic study on willingness-to-pay survey. The pre-trial surveys were implemented to assess pre-vaccination knowledge about and attitudes towards the target disease (typhoid fever or cholera), healthcare-seeking in response to symptoms indicative of these diseases, and experience, knowledge, and attitudes towards the specific vaccines to be included in the trials (typhoid fever Vi and oral cholera). The pretrial surveys also provided data prior to vaccination regarding what information people wanted to know about the vaccine, media through which to effectively convey that information, and possible barriers to participation.

The post-trial survey included questions from the pre-trial survey for pre/post comparisons in responses regarding beliefs about the specific diseases, perceptions of vaccination in general, and future demand for typhoid fever Vi and oral cholera vaccines. The posttrial surveys also included questions about participation in and logistics of the trial and informational campaigns. These survey included items on who did or did not participate in the trial, reasons for deciding to participate or not to participate, satisfaction with information about the trial, satisfaction with trial logistics, and concerns about the trial. The post-trial survey provided important information on actual participation in the vaccination trial as opposed to data (collected with the pre-trial survey) on hypothetical willingness to participate.

As with the qualitative research, major part of data collection for the quantitative studies was completed by local staff with the DOMI Social Science Task Force providing training and technical assistance.

DISCUSSION

The introduction of new vaccines and successful expansion in the use of existing vaccines (both within and beyond EPI) demands data from an integrated body of knowledge about individual, sociocultural and politicaleconomic factors. The DOMI Programme has undertaken to develop and implement sociobehavioural studies in conjunction with the shigellosis disease-burden studies and cholera and typhoid fever vaccine trials to further elucidate barriers and facilitators to acceptance and use of vaccine.

At the individual level, it is important to obtain data regarding people's perceptions and knowledge about the target disease, particularly as many people do not have any direct experience with those diseases for which vaccines are available (35). While this is most true for individuals living in industrialized countries, there are often significant differences in disease exposure within non-industrialized countries. Certain diseases, such as cholera, may be perceived as a disease of the poor or the 'underclass' and, therefore, those not identifying with these groups may resist participation in a vaccination or prevention campaign (36). HIV and other sexually transmitted diseases are stigmatized because of 'behaviours', e.g. promiscuity, and 'groups', e.g. intravenous drug users, often associated with these diseases. Individuals may resist vaccination for reasons of feeling not-vulnerable because they perceive themselves to be outside the risk group and/or not participating in certain behaviours. In the current studies, findings include residential or economic groups who feel less vulnerable to a disease, such as shigellosis, because they either feel that the infrastructure is sufficient to prevent spread and/or that they are personally able to avoid the disease due to their own efforts, e.g. installation of hygienic latrines and use of boiled water (34).

In terms of acceptance of a particular vaccine by individuals, information is needed about perceptions, knowledge, and experience with vaccination. Individuals may be more likely to state acceptance of a vaccine in a hypothetical situation than in reality, and studies are, therefore, necessary both before and after vaccination trials and campaigns. As Streefland (25) has pointed out, there are different reasons why people may refuse to participate in vaccination. Only through pre- and posttrial or campaign surveys can 'refuses' be categorized in terms of reasons for non-acceptance and intention to participate in future vaccination programmes. In the typhoid fever study in Viet Nam, individuals refused to participate in the trial for multiple reasons, including individual concerns regarding perceptions of health and condition of their child (e.g. my child is too weak or too small), larger concerns regarding the vaccine itself, including adverse effects from the vaccination, and broader social-political concerns and resistance in relation to the source of the vaccination programme, and/or the implications of a vaccine trial, e.g. fear of 'experimentation'. Each of these different reasons would need to be addressed in future vaccination campaigns to ensure a well-informed community, more active participation, and broader vaccine coverage.

The stability and political-economic support for the existing healthcare infrastructure and effective healthcare provider-client communication are crucial to successful vaccination campaigns. Data from healthcare providers and community leaders are essential to understanding their perspectives on barriers and facilitators to delivery of vaccine. It is also necessary to understand perspectives and knowledge of healthcare providers about the target disease and their perceptions of need for a particular vaccine. In these studies, healthcare providers were generally supportive of vaccination intentions, but also expressed concern regarding competing demands on their time and resources.

Finally, as vaccination in general becomes more acceptable as a preventive measure against a wide array of diseases, it is necessary to study situations and settings where a campaign has been less successful and to better understand the 'hard-to-reach' populations, e.g. those who outright reject a particular vaccine. Future research needs to continue to define and refine levels of acceptance of different vaccines in various settings to better design outreach efforts and educational materials. All of this demands data not only on characteristics of individuals in relation to disease and perception and knowledge about vaccine, but also on household dynamics and experiences of the general populations, leaders, and healthcare providers with disease and vaccination. In addition, extant and historical data are important for the general healthcare system, and the general social-economic-political context of health, illness, and access to healthcare.

Through the DOMI Programme and other recent research, theoretically-based methodological protocols are being developed and implemented for further knowledge about acceptance and use of vaccination. While many policy-related decisions regarding vaccination are made on a country-by-country basis, these studies can provide frameworks that are useful in articulating commonalities and differences between and within countries as existing vaccine programmes expand and new vaccines become part of the public-health arena.

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REFERENCES

- 1. Harrison JA, Mullen PD, Green LW. A metaanalysis of studies of the Health Belief Model with adults. *Health Educ Res* 1992; 7: 107-16.
- Floyd DL, Prentice-Dunn S, Rogers RW. A metaanalysis of research on protection motivation theory. J Appl Soc Psychol 2000;30:407-29.
- Prochaska JOP, Velicer WF, Rossi JS, Goldstein MG, Marcus BH, Rakowski W *et al.* Stages of change and decisional balance for 12 problem behaviors. *Health Psychol* 1994;13:39-46.
- 4. Harrison F. Racial and gender inequalities in health and health care. *Med Anthropol Q* 1994;8:90-5.
- 5. Rapp R. Risky business. Genetic counseling in a shifting world. *In*: Schneider J, Rapp R, editors.

Articulating hidden histories: exploring the influence of Eric Wolf. Berkley: University of California, 1995:175-89.

- 6. Morgan L. The importance of the state in primary health care initiatives. *Med Anthropol Q* 1989;3: 227-39.
- Rhodes SD, Hergenrather KC. Using an integrated approach to understand vaccination behavior among young men who have sex with men: stages of change, the health belief model, and self-efficacy. *J Commun Health* 2003;28:347-62.
- Zimet GD, Mays RM, Winston Y, Kee R, Dickes J, Su L. Acceptability of human papillomavirus immunization. *J Womens Health Gend Based Med* 2000;9:47-50.
- Van De Ven P, Bartholow B, Rawstorne P, Crawford J, Kippax S, Grulich A *et al.* Scaling HIV vaccine attitudes among gay men in Sydney, Australia. *AIDS Res Hum Retroviruses* 2002;18: 1333-7.
- Kahn JA, Rosenthal SL, Hamann T, Bernstein DI. Attitudes about human papillomavirus vaccine in young women. *Int J STD AIDS* 2003;14:300-6.
- Mays RM, Sturm LA, Zimet GD. Parental perspectives on vaccinating children against sexually transmitted infections. *Soc Sci Med* 2004;58:1405-13.
- Zimet GD, Liau A, Fortenberry VD. Health beliefs and intention to get immunized for HIV. J Adolesc Health 1997;20:354-9.
- Impicciatore P, Bosetti C, Schiavio S, Pandolfini C, Bonati M. Mothers as active partners in the prevention of childhood diseases: maternal factors related to immunization status of preschool children in Italy. *Prev Med* 2000;31:49-55.
- Ramsay ME, Yarwood J, Lewis D, Campbell H, White JM. Parental confidence in measles, mumps and rubella vaccine: evidence from vaccine coverage and attitudinal surveys. *Br J Gen Pract* 2002; 52:912-6.
- Sansom SL, Barker L, Corso PS, Brown C, Deuson R. Rotavirus vaccine and intussusception: how much risk will parents in the United States accept to obtain vaccine benefits? *Am J Epidemiol* 2001;154:1077-85.
- Liau A, Zimet GD. The acceptability of HIV immunization: examining vaccine characteristics as determining factors. *AIDS Care* 2001;13:643-50.

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- Harrington PM, Woodman C, Shannon WF. Vaccine, yes; injection, no: maternal responses to the introduction of *Haemophilus influenzae* type b (Hib) vaccine. *Br J Gen Pract* 1999;49:901-2.
- Smailbegovic MS, Laing GJ, Bedford H. Why do parents decide against immunization? The effect of health beliefs and health professionals. *Child Care Health Dev* 2003;29:303-11.
- Evans M, Stoddart H, Condon L, Freeman E, Grizzell M, Mullen R. Parents' perspectives on the MMR immunisation: a focus group study. *Br J Gen Pract* 2001;51:904-10.
- Doran T, McCann R. Obstacles to influenza immunization in primary care. *J Public Health Med* 2001;23:329-34.
- Kamal KM, Madhavan SS, Amonkar MM. Determinants of adult influenza and pneumonia immunization rates. *J Am Pharmacists Assoc* 2003; 43:403-11.
- 22. World Health Organization. Department of Vaccines and Biologicals. Pt. I. Immunization challenges. *In*: State of the world's vaccines and immunization. Geneva: World Health Organization, 1996:1-16.
- 23. Pérez-Cuevas R, Reyes H, Pego U, Tomé P, Ceja K, Flores S *et al.* Immunization promotion activities: are they effective in encouraging mothers to immunize their children? *Soc Sci Med* 1999; 49:921-32.
- Nichter M. Vaccinations in the third world: a consideration of community demand. *In*: Nichter M, Nichter M, editors. Anthropology and international health: Asian case studies. Amsterdam: Gordon and Breach, 1996:329-66.
- Streefland P, Chowdhury AMR, Ramos-Jimenez P. Patterns of vaccination acceptance. *Soc Sci Med* 1999;49:1705-16.
- Feldman-Savelsberg P, Flavien TN, Schmidt-Ehry B. Sterilizing vaccines or the politics of the womb: a retrospective study of a rumor in Cameroon. *Med Anthropol Q* 2000;14:159-79.

- Kaljee LM, Thiem VD, von Seidlein L, Genberg BL, Canh DG, Tho LH *et al.* Healthcare use for diarrhoea and dysentery in actual and hypothetical cases, Nha Trang, Viet Nam. *J Health Popul Nutr* 2004;22:139-49.
- Griffin GE, editor. Clinical profile of a typhoid Vi polysaccharide vaccine. *BioDrugs* 2001;15(Suppl 1):1-27.
- 29. Trach DD, Cam PD, Ke NT, Rao MR, Dinh D, Hang PV *et al.* Investigations into the safety and immunogenicity of a killed oral cholera vaccine developed in Viet Nam. *Bull World Health Organ* 2002;80:2-8.
- Kleinman A. Patients and healers in the context of culture: an exploration of the borderland between anthropology, medicine, and psychiatry. Berkeley: University of California Press, 1980. 427 p.
- Rhodes T, Fitch C, Stimson GV, Kumar MS. Rapid assessment in the drugs field. *Int J Drug Policy* 2000;11:1-11.
- Utarini A, Winkvist A, Pelto GH. Appraising studies in health: using rapid assessment procedures (RAP). Eleven critical criteria. *Human Organ* 2001;60:390-400.
- Blum LS, Nahar N. Cultural and social context of dysentery: implications for the introduction of a new vaccine. *J Health Popul Nutr* 2004;22:159-69.
- 34. Kaljee LM, Genberg BL, von Seidlein L, Canh DG, Thoa LTK, Thiem VD et al. Acceptability and accessibility of a shigellosis vaccine in Nha Trang city of Viet Nam. J Health Popul Nutr 2004;22: 150-8.
- Obaro SK, Palmer A. Vaccines for children: policies, politics and poverty. *Vaccine* 2003;21:1423-31.
- 36. Nations MK, Monte CG. "I'm not dog, No!": cries of resistance against cholera control campaigns in Brazil. *In*: Inhorn MC, Brown PJ, editors. The anthropology of infectious disease: international health perspectives. Amsterdam: Gordon and Breach, 1997:439-82.