

Assessment of Relevant Cultural Considerations is Essential for the Success of a Vaccine

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ABSTRACT

This paper explores applications of social science research to international vaccine development and implementation. The paper discusses examples of vaccine-implementation controversies, suggesting that many of these issues could have been avoided with a greater focus on cultural issues regarding perceptions of disease, vaccination, and health services. The paper also discusses the relationship of theory-based behavioural interventions with the development of an overall vaccine strategy and examines experience of growing vaccine research with regard to perceptions of medical decision-making, acceptable practices, and authority and how these perceptions impact vaccine usage. The importance of social science in the ethical conduct of research is also discussed.

Key words: Perceptions; Social sciences research; vaccine development

INTRODUCTION

The triumph and the controversy surrounding the smallpox-eradication programme doubtlessly have served as the cornerstones for thousands of public-health lectures, symposia, and manuscripts over the last several decades. A search for literature on 'smallpox eradication' in PubMed produced almost 400 entries. Not only the forerunner of vaccinology, the smallpox vaccine was the first—and to-date remains the sole—agent associated with the 'annihilation' of a disease (1).

However valuable the lessons learnt from the smallpox campaign were—that a vaccine could be produced to reduce the incidence and severity of disease and that a disease could be eliminated with the systematic introduction of a vaccine—some of the to-date unlearnt lessons

from the smallpox-vaccination era are equally important. Notable among these lessons is the dependence of a vaccine programme on behavioural change and, therefore, public acceptance. The Compulsory Vaccination Act 1853, also known as 'the Poor Act', simultaneously inaugurated state-mandated smallpox vaccination, the perception of state intrusion into private life, and the seeds of the successful Victorian anti-vaccination movement in Great Britain (2,3). However well-founded on epidemiological principles it may have been, mandated smallpox vaccination for targeted individuals was seen as an extreme example of class-based legislation and resulted in a rejection of compulsory vaccination as a kind of political tyranny (2). In how many countries, over how many diseases has this drama of well-intentioned but misunderstood policy regarding vaccine strategies been played out over the last century? The answer to prevention of a repetition of missteps of the smallpox-eradication programme lies not in learning a specific lesson of creation of a vaccine programme but rather in the broader lesson of the need to design vaccine programmes to be acceptable within the local culture and society. The success of an individual vaccine is as dependent on fit of the vaccine programme with the local community as it is on the biomedical and

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technological construction of the vaccine itself and epidemiology of the disease in that country.

The notion of introducing a new vaccine without antecedent biomedical and epidemiological research is virtually inconceivable. Vaccinology will achieve new levels of success when the importance of preparatory behavioural and anthropologic research is likewise considered integral to the introduction of new vaccines. Several issues fundamental to the success of a vaccine programme are discoverable through systematic behavioural and ethnographic research and the application of basic behavioural principles, including the use of explicit theories of behaviour and behavioural change in designing vaccine strategies. Issues amenable to discovery through social science research include understanding the perception of need, the process of medical decision-making and considerations in vaccine delivery, and the development of vaccine programmes which are consistent with local ethical considerations.

FORMULATING A VACCINE STRATEGY: THEORY-BASED BEHAVIOURAL INTERVENTIONS

The biomedical principles directing the development of new vaccines have advanced dramatically over the past decades. Technological approaches to vaccine development that were acceptable or even 'state-of-the-art' two decades ago would not be considered by today's vaccine developers. Likewise, the behavioural principles directing the development of vaccine campaigns have advanced dramatically over the last two decades, fuelled to a great extent by the discoveries accompanying prevention efforts for the global HIV epidemic (4). Behavioural change is critical to the success of any vaccine programme. This axiom is applicable to programmes using the existing vaccines with high rates of efficacy. It will be all the more important as it is applied to newer vaccines, such as HIV vaccines, whose protective efficacy is anticipated to be lower than that resulting from most traditional EPI vaccines (5-8). Just as biomedical researchers follow biological models in the development of new vaccines, models of behaviour and behavioural change need to be applied to the development of strategies around the introduction of a vaccine. These models of behavioural change explicitly articulate the presumed mechanisms by which the changes in behaviour will be brought about. As such, these models guide the development of behavioural change interventions

accompanying vaccine campaigns. Currently, the most commonly-applied models—social cognitive models (9,10), models employing concepts from diffusion theory (11), and models based on individual readiness to change or adapt new behaviours (12)—were developed and have been used primarily in western cultures (13,14). However, where investigators have sought to assess their applicability to non-western settings in Africa (14,15) and Asia (16), the models of behavioural change have generally been shown to be consistent with local decision-making regarding behaviour. It is possible that, over time, new models will be developed that are specifically designed for these settings—or that as our globe becomes smaller, prevailing models will be altered and become even more acceptable. Whether we retain the same models or develop new ones, there is little doubt that merging of the biomedical and behavioural worlds in vaccine programmes will become normative—and that vaccine campaigns will become increasingly successful as a result.

Understanding perceptions of need

Perceptions of disease

"Knowledge, attitude, and perception surveys" have become so standard during the last quarter century that virtually all public-health researchers are aware of the interest in, if not the importance of, perception of disease. It is widely recognized, with some supportive evidence, that individuals who perceive a disease to be severe and to which they perceive their children or other loved ones to be vulnerable are more likely to seek protective action against that disease (4). At the same time, public-health researchers concerned with diarrhoeal diseases have recognized that perceptions of severity and causation of disease are inextricably entangled with its local names and categorization. Thus, for example, a culture in which there are many recognized types of dysentery—each with a distinctly different name—may view each stool variation as a different and unrelated disease, or even in some cases, as 'normal' variations (17,18). Just as some members of western society may regard 'teething diarrhoea' or 'teething fever' as an innocent or unavoidable happenstance of growth, so too may other cultures recognize certain illnesses (diarrhoea, cough, malnutrition) as 'normal' variations of the life-cycle (19). It is difficult to even conceptualize concepts of 'severity' or 'vulnerability' in the context of a condition that is considered 'normal'. That is, despite what the occasional parent

may think, what meaning is there to "a severe case of adolescence" or "vulnerable to becoming an adult?" A single disease with many clinical manifestations, such as HIV or *Shigella* dysentery, may not be recognized within a community as a single disorder (or even as a disorder) with a wide continuum of signs, symptoms, and/or severity, but rather as multiple, unrelated states of health and disease. Likewise, just as the medical profession understands that, for certain illness, such as pertussis, age influences the vulnerability of an individual to a disease and/or the severity of the disease in that individual, so too do local cultures make these assumptions. However, the local perceptions may differ from the scientific perception. For example, while in China young children and the elderly were repeatedly identified as especially vulnerable to dysentery, pregnant women were never cited as a vulnerable group (9). Thus, a simple assessment of perceived severity and vulnerability of disease may not adequately inform a vaccine campaign. Rather than excusing vaccine researchers from the obligation to conduct preparatory behavioural research, these observations underscore the need for thoughtful social science inquiry designed to reveal subtle but important perceptions of categorization, severity, and vulnerability of disease.

Perceptions of vaccines

In most societies, the population will have had significant experience with vaccination and, therefore, will hold opinions regarding the intrinsic value of vaccines, including an opinion as to whether, overall, they represent something 'good' or 'bad'. Indeed, vaccines are viewed with enormous variation. In China, vaccines are widely accepted by the public as 'good', with individuals expressing an easy acceptance of new vaccines because of their generally good experience with existing vaccine programmes (9). Although there is a great variation within the continent, in many parts of Africa, vaccines are well-regarded; in fact, even adverse reactions do not impugn the reputation of vaccines. A local reaction to a vaccine may be perceived as evidence that it is working, and a severe reaction may be blamed on the vaccinator rather than the vaccine itself (20). However, in other cultures, vaccines may be viewed as harmful, or, in extreme cases, as the means to achieve coercive or evil ends. In the Philippines and in other developing countries, tetanus toxoid has been viewed as causing infertility (21,22). In the United States and parts of Europe, many individuals believe that measles vaccine contributes to autism (23), and in Great Britain, public

concerns regarding pertussis vaccine as a cause of mental retardation raged from 1974 through 1986 (3). Concerns regarding hepatitis B vaccine and its association with demyelinating disease in France resulted in France's suspending its adolescent hepatitis B vaccine programme in 1998. While the programme was subsequently reinstated, the acceptance of vaccine remains low (24). Likewise, one's willingness to pay for a vaccine again varies as a function of disposable wealth, perceptions of severity and vulnerability of disease, perceptions of effectiveness of vaccine, and as a matter of cultural expectation. In China, there was greater willingness to pay for vaccines for the very young and the elderly than for older children and young adults (9). Vaccine characteristics, such as cost, perceived efficacy, duration of protection, and route of administration, may also impact on the acceptance of vaccine (9,20).

Understanding how medical decision-making occurs

Perceptions of authority

Every country has a history. Part of this history is the relationship among the state, the medical profession, the media, and the health of the people. The introduction of a new vaccine occurs in the context of perceptions and realities of these historical relationships. As seen with the introduction of mandatory smallpox vaccination in Great Britain, understanding these relationships will impact greatly on the success or failure of a vaccine campaign.

Vaccine campaigns may succeed and may fail independent of whether vaccination is compulsory or encouraged. Viet Nam, with compulsory vaccination not only for the EPI vaccines, enjoys enormous enthusiasm for its vaccine programme. Like Great Britain in the post-smallpox era, the Netherlands has adopted a system that can be defined as 'promotive' in which the Government and health officials encourage but do not demand immunization; the country enjoys high rates of vaccination (3,20). In general, in the United States, there has been relative acceptance of compulsory vaccination for school enrollment with corresponding high rates, at least at the time of school entrance. Whether the vaccine is required appears to be less important to its success than local/national expectations regarding the relationship between the state and immunization practices. Countries in Asia, Africa, and South America vary widely with regard to compulsory vaccine practices but, in general, the presence or absence

of a policy appears not to be the defining factor in the success of a vaccine programme (25).

While a society may reject the state as the authority figure with regard to vaccination, this does not mean that all authority figures will be rejected in this regard. For example, the American Indians in Alaska enjoy high rates of immunization despite a history of distrust between the indigenous peoples and the United States Government. This recent success has been credited, in part, to the active role and stance taken by local (respected) civic groups, community leaders, and tribal health facilities (26).

In other settings, accustomed to high-level government decision-making, such as the Derg regime in Ethiopia, the smallpox-eradication programme was mandated and accomplished in a very short time (20,27). This discussion is not intended to make a value judgement on one or more approach(es) but rather to acknowledge that achieving the final product of a high level of vaccination, different strategies work in different settings.

Understanding how vaccine should be delivered

Perceptions of local systems

Certainly, there is a great advantage from delivery of a new vaccine through the existing public-health systems—if the systems are well-perceived by the intended recipients of the vaccine programme. There are ample contemporary examples of the failure of vaccine or health-delivery programmes as a result of using systems that, despite having been designed to provide services for the targeted population, fail because of poor public perception. These are not new lessons. For example, over a century ago in Argentina, the anti-tuberculosis programme failed in large measure because the prevention and treatment facilities established for the working poor were shunned by them and only used in desperation (28).

Perceptions of acceptable practices

One of the reasons posited for the success of the WHO/UNICEF EPI global campaign has been its uniformity: the same vaccines against the same diseases targeting the same high-risk groups across the globe. At the same time, it is equally true that EPI varies greatly by local culture and social influences. In parts of Bangladesh and Pakistan, male vaccinators may not be able to deliver tetanus toxoid to women—or may do

so only through a curtain in which the limb alone is exposed to the male (20). In India, the caste system may dictate where vaccines can be delivered and by whom (20). Failure to recognize these important cultural mandates results in programmatic failure. For example, in India, women and children of differing castes could not access vaccination delivery which was situated in the home of women of a different caste. Once considered an anathema to routine vaccine delivery, catch-up campaigns were first introduced in Latin America and now have become mainstream in all countries in the Americas, including the United States (29).

Perceptions of incentives

Incentives, whether for recipients or for healthcare workers, may be well-received. For example, in Great Britain, a significant increase in vaccination rates has been attributed to incentives. However, in other settings, incentives may be viewed as bribes, raising the suspicion that a problem exists with the vaccine (20).

Perceptions of use of authority

There is a great variation in the perception of decision-makers with regard to vaccine promotion and decision-making. In some countries, such as China, much of health decision-making occurs at a local or communal level, rather than at the family or individual level. In these settings, there is confidence that if a vaccine is recommended, it is a good thing (9). By contrast, among a substantial segment of the population in Great Britain, some European countries, and part of America, there is greater skepticism about relying on judgements of public-health authorities (3,23,30). This differing perception of credibility of the medical profession is complex, defying simple explanations or characterizations. In some situations, it may be global (e.g. rejection of modern health) or even religion-based, but in other cases, it appears to be limited to vaccines or even to specific vaccines.

Creating an ethical vaccine programme

Most researchers would fully champion the general principle that ethical considerations are of paramount importance in the conduct of international research, especially research in developing nations. Ethical edicts and guidelines are designed especially to protect the most vulnerable; arguably, substantial proportions of the population of some developing countries are 'vulnerable' for social, economic, educational, or health reasons (31).

Championing a general principle and agreeing on its application in individual situations are not synonymous. The wide divide concerning basic tenets in ethical considerations among researchers, ethicists, and populations has become painfully evident in the aftermath of the medical debates surrounding placebo-controlled trials involving less-expensive alternatives to zidovudine in Africa. Rather than holding zidovudine as the 'standard of care' (and, therefore, the appropriate control for subsequent treatment evaluations) after it had been demonstrated in the United States to dramatically lower rates of neonatal HIV infection, researchers instead argued that a placebo-control was appropriate since the Africa-based population would not have had access to zidovudine outside an experiment (32). In the absence of social science research prior to the conduct of vaccine-efficacy and implementation studies, it may be difficult to achieve many of the precepts of ethical conduct of research. Before exploring but a few of many ethical issues which need to be addressed as part of vaccine research, it might be helpful to first reflect on the scaffolding of western concepts of bioethics. It could be argued that two largely non-overlapping perspectives dominate western conceptualizations (31) and help us understand the passion and inability to come to an acceptable compromise in the zidovudine controversy. 'Utilitarian' bioethical formations argue that individual actions and public policy should maximize 'good' for the greatest number of people. A trial of a vaccine that holds great promise for many individuals and a study design that enables the most rapid determination of efficacy of this vaccine, while harming the fewest, would be supported by this philosophical approach. 'Deontological bioethics' argues that all actions should be in accordance with treating people not as a means to an end, but towards maximization of each individual (33). 'Common good' is, therefore, not a compelling, nor even an acceptable argument. A trial of a vaccine holding great promise but with the possibility of harming an individual or subjecting them to a treatment that was less than what they could potentially have had would be unacceptable.

Neither of these perspectives is 'correct' or 'better', rather they are two dearly-held perspectives that will result in individuals viewing certain research designs as ethically acceptable or unacceptable. While there has been much debate about the need for an international code of ethics versus a local code in research in developing countries (31), the discussion might more

appropriately focus on the need for both an international code and a local code. Ultimately, research conducted in a local environment needs to be understood by the references applicable in that culture. For example, while western bioethics underscore the importance of individual decision-making—indeed this is the cornerstone of informed consent—in societies where decision-making is made at the commune or community level, such an emphasis may well leave individuals unprotected. For, in western society, while there may be a 'gate' at the community level (be it a physician's office, hospital, county health officer, etc.), there will be a second gate at the individual or parent level. As noted earlier in this document, this right of refusal is exercised with vigour in many countries even for established vaccines; physicians are not viewed as "the ultimate gate-keeper" (30). In countries where decision-making occurs at the community level, if researchers do not openly discuss all the consequences, both biological and social, with the community leaders to enable them to contemplate the effect on all members of the community, our western notion of informed consent will ill-suit the needs of individuals within that community. That is, while it would seem that a western concept of informed consent would be offering individuals greater protection than what they might otherwise receive, in fact, it may offer them less protection than their current systems. Many researchers working in developing countries have noted the high acceptance rates among the population. While there are many possible explanations for this phenomenon, one of them may be that the western informed consent does not well serve the needs of individuals who live in communal decision-making societies.

Independent of the issue of different organizing philosophies of individual and societal relationships, the issue of 'therapeutic misconception' is especially perplexing among individuals with limited education, a larger percentage of whom will reside in developing countries. Assessments of personal risk even after vaccination are difficult for most individuals and will be especially problematic as the public-health world moves to the use of vaccines that are less effective than the traditional EPI vaccines and possibly to vaccines that confer protection not to the vaccinee but to those with whom he or she has contact (6-8). Social science research would help adequately inform vaccine research regarding these and other equally important ethical considerations.

CONCLUSION

The successful introduction of vaccines requires attention to behavioural and cultural issues, including the perception of need, process of medical decision-making, and considerations in vaccine delivery. Understanding of these issues will be greatly facilitated through social science research, including use of articulated models of behavioural change, which will also facilitate the creation of vaccine programmes that address local ethical considerations. Clinicians, epidemiologists, public-health experts, biomedical researchers, and social scientists are all needed in the development of effective vaccination programmes.

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