New Decade of Vaccines 5

Addressing the vaccine confidence gap

Heidi J Larson, Louis Z Cooper, Juhani Eskola, Samuel L Katz, Scott Ratzan

Vaccines—often lauded as one of the greatest public health interventions—are losing public confidence. Some vaccine experts have referred to this decline in confidence as a crisis. We discuss some of the characteristics of the changing global environment that are contributing to increased public questioning of vaccines, and outline some of the specific determinants of public trust. Public decision making related to vaccine acceptance is neither driven by scientific nor economic evidence alone, but is also driven by a mix of psychological, sociocultural, and political factors, all of which need to be understood and taken into account by policy and other decision makers. Public trust in vaccines is highly variable and building trust depends on understanding perceptions of vaccines and vaccine risks, historical experiences, religious or political affiliations, and socioeconomic status. Although provision of accurate, scientifically based evidence on the risk–benefit ratios of vaccines is crucial, it is not enough to redress the gap between current levels of public confidence in vaccines and levels of trust needed to ensure adequate and sustained vaccine coverage. We call for more research not just on individual determinants of public trust, but on what mix of factors are most likely to sustain public trust. The vaccine community demands rigorous evidence on vaccine efficacy and safety and technical and operational feasibility when introducing a new vaccine, but has been negligent in demanding equally rigorous research to understand the psychological, social, and political factors that affect public trust in vaccines.

Published Online
June 9, 2011
DOI:10.1016/S0140-6736(11)60678-8

See Online/Comment
DOI:10.1016/S0140-6736(11)60765-4,
DOI:10.1016/S0140-6736(11)60766-6, and
DOI:10.1016/S0140-6736(11)60710-1

This is the fifth in a Series of five papers about the new decade of vaccines

Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, London, UK (H J Larson PhD); **Department of Paediatrics, College of Physicians and Surgeons, Columbia University, New York, NY, USA** (Prof L Z Cooper MD); **National Institute for Health and Welfare (THL), Helsinki, Finland** (J Eskola MD); **Department of Paediatrics, Duke University, Durham, NC, USA** (Prof S L Katz MD); **Government Affairs and Policy,**

Introduction

Tremendous progress has been made in the development of new vaccines, along with increasing access to new and underused vaccines in the lowest income countries. But, vaccines—often lauded as one of the greatest public health interventions—are losing public confidence. Some vaccine experts describe the problem as a "crisis of public confidence"[1] and a "vaccination backlash".[2]

Public concerns about vaccine safety and vaccine legislation are as old as vaccines themselves—dating back to the anticompulsory vaccination league against mandated smallpox vaccination in the mid-1800s.[3,4] Some common concerns shared by the antivaccination groups of the 1800s and those of today are related primarily to arguments against mandated vaccination, or imposed vaccine schedules. But current antivaccination groups have new levels of global reach and influence, empowered by the internet[5] and social networking capacities allowing like minds to rapidly self-organise transnationally, whether for or against vaccines.[6] These groups reach people who are not necessarily against vaccines, but who are seeking answers to questions about vaccine safety, vaccine schedules, changing policies, and the relevance of some new, and old, vaccines. Vaccines evoke concerns different from other health interventions because many healthy people need to be vaccinated to achieve a protective public health benefit.

Several factors drive public questions and concerns: perceptions of business and financial motives of the vaccine industry and their perceived pressures on public institutions—such as during the H1N1 influenza response; coincidental rather than causal adverse events that are perceived as vaccine related; challenges in management and communication of uncertainty about risks[7] (including serious, albeit rare, ones); less risk tolerance for vaccines given to those who are healthy than for drugs given to treat an illness; scepticism of scientific truths, which later become untruths, or amended truths as new research becomes available;[8] elitism of a group of people that believe they should not risk vaccination of their child if enough other children are being vaccinated; and, in some cases, outright non-acceptance of scientific evidence such as in the case of antivaccine movements that persist in the belief that autism can be caused by thiomersal or the measles,

Key messages

- Public concerns about vaccines are not merely about vaccine safety, but are also about vaccine policies and recommendations, vaccine costs, and new research findings.
- Public decision making related to vaccine acceptance is complex and is neither driven by scientific nor economic evidence alone, but is also driven by a mix of scientific, psychological, sociocultural, and political reasons, all of which need to be better understood.
- The internet and new forms of social media have not only allowed for rapid and ubiquitous sharing of information—and misinformation—but have also allowed new methods of self-organisation and empowerment of newly founded online communities that argue against or for vaccines.
- Although communication of positive, evidence-based information about the safety of specific vaccines and their benefit–risk ratios to the public is crucial, communication alone will not stop public distrust and dissent against vaccines.
- Levels of public trust in vaccines are highly variable and context specific. To sustain or restore confidence in vaccines, a thorough understanding is needed of the population's—or subpopulation's—specific vaccine concerns, historical experiences, religious or political affiliation, and socioeconomic status.
- Core principles to be followed by all health providers, experts, health authorities, policy makers, and politicians include: engagement with and listening to stakeholders, being transparent about decision making, and being honest and open about uncertainty and risks.

Johnson & Johnson, New Brunswick, NJ, USA; (S Ratzan MD)**; and Journal of Health Communication, Washington, DC, USA** (S Ratzan)

Correspondence to: Dr Heidi J Larson, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT, UK
heidi.larson@lshtm.ac.uk

mumps, and rubella (MMR) vaccine, despite an abundance of scientific evidence that shows no causal effect.[9,10]

Although communication of candid, evidence-based information to the public about the safety of specific vaccines and their benefit–risk ratios is crucial, this information alone will not stop public distrust and dissent against vaccines. Public decision making related to vaccine acceptance is not driven by scientific or economic evidence alone, but is also driven by a mix of scientific, economic, psychological, sociocultural, and political factors, all of which need to be understood and taken into account by policy and other decision makers.

We discuss factors in the changing global environment that have precipitated what some in the specialty of climate change call "an erosion of trust",[11] caused by a small minority of climate change sceptics. The vaccine community faces similar challenges. We examine key determinants of trust, with specific examples in which public distrust undermined vaccine acceptance and interrupted immunisation programmes, and, then, what was done to restore trust. Finally, we outline ways to improve public trust including future research and actions that can be taken now.

***Panel 1*: Framework for analysing the development of public concerns about vaccines**

Prompters of public concern

Adverse events after immunisation—generally, such events that occur locally are stronger prompters of rumours, but an event reported in a distant location is also a possible prompt; publication of new research;[12] new recommendations or policy change (eg, removal of thiomersal from vaccines in the USA, stopping hepatitis B vaccination in schools in France); new products (ie, introduction of new product or change of current product source or product packaging); political motivations (ie, purposefully spreading rumours to undermine the government, other providers, or producers of the vaccine)

Factors that sustain public concern

Global spread of vaccine-related rumours; frequency of rumours (eg, occasional rumours *vs* persisting and strengthening rumours); media reports that amplify any prompter of public concern; historical bad experience that lowers public trust (eg, Pfizer's Trovan trial was perceived to cause childhood deaths in Nigeria, inadequate public information about the bovine spongiform encephalopathy outbreak in UK, dishonesty about HIV-infected blood supply in France);[13] socioeconomic marginalisation (ie, populations that have historically been marginalised with lower access to health services are less trusting of authorities); previous existence of self-organised community groups that can repurpose their experience to address vaccine concerns (eg, women's groups organised to question and stop human papillomavirus vaccine project in India[14])

Outcome and effects

Vaccine refusals (individual or group level); vaccine withdrawal (this can be a prompter of rumours and a consequence of rumours); vaccine-preventable disease outbreaks (eg, measles, pertussis, poliomyelitis)

The changing global environment

Background

Many proposed explanations exist as to why vaccines are questioned by the public, what exactly is being questioned, and what can be done to restore public confidence. One common perception is that waning public trust in vaccines is because vaccines have become a victim of their own success—whereby they have been so effective for prevention of disease that more attention has now been focused on the potential risks of vaccines than on the risks of the now less prevalent diseases they prevent. In high-income countries, lack of familiarity with vaccine-preventable diseases is present in the health-care community (eg, nurses, physicians, and others that administer vaccines),[6] many of whom are too young to have seen these illnesses.

Increased public questioning of vaccines in low-income countries, where vaccine preventable diseases are still prevalent, point to other underlying reasons for public distrust or dissent besides the absence of vaccine-preventable disease (panel 1). These reasons can be cultural, religious, or sometimes economic or political, as in the case of the polio vaccination boycott in northern Nigeria, where marginalised communities asserted their voice by refusing or challenging government-driven initiatives.[15]

Vaccine safety

Another perception is that vaccine safety is the primary concern of the vaccine-questioning public. Although vaccine safety is clearly important, and certainly the most monitored and addressed concern by national immunisation programmes and international organisations such as WHO and UNICEF, safety is not the only concern a growing number of individuals, communities, and even governments have about vaccines. Other concerns include affordability and relevance of new vaccines in different settings. Furthermore, the issue of vaccine safety is now being viewed in the framework of individual genetic predispositions to harm, raising fears that adverse events after immunisation are expressions of uncommon genetic susceptibilities.[16]

Diversity of vaccines

In the past decade, the global vaccine industry has mushroomed in terms of the number of companies involved and products in development. From 1995 to 2008, the number of vaccine companies that sought to create or manufacture vaccines doubled to 136, as did the number of prophylactic vaccine products in

 Published online June 9, 2011 DOI:10.1016/S0140-6736(11)60678-8

development to 354.[17] The list of WHO prequalified vaccines now has 202 products from different manufacturers targeted against 20 infectious agents,[18] and the US Food and Drug Administration (FDA) list of vaccines available for immunisation in the USA consists of 72 products.[19] Most of these products are variations and combinations of vaccines that have existed for years, and thus are not really new, but the range certainly seems complex and confusing to both recipients and providers of vaccines.

Although the growing numbers of vaccines available or in development is impressive, the diversity of vaccines—including vaccines tailored to specific populations—has also contributed to public questioning of vaccine choices and the relevance of so many vaccines. Other concerns have arisen about the ability of low-income countries to afford the introduction of new vaccines, especially when access to even the least expensive vaccines is inadequate.[20]

Vaccine schedules

As new vaccines are introduced, vaccine schedules change. Schedules also vary across countries. These changes and differences in vaccine schedules further contribute to public questioning,[1,21] In the WHO listing of immunisation schedules by antigen and country,[22] for example, selection of a list of schedules for "tetanus and diphtheria toxoid childrens' dose" worldwide showed a listing of 72 countries with 29 different variations of diphtheria and tetanus schedules. Explanations for these programme differences include variations in the epidemiological aspects of the diseases and in the health-care financing and delivery systems between the countries. However, a substantial part of the variation cannot be justified on the basis of best public health practice, and some public questioning is understandable.

New research

Public concerns can also emerge after publication of new research, such as the 1994 publication by Talwar and colleagues[12] about an antipregnancy vaccine, in which the mention of tetanus toxoid used as a carrier protein was misinterpreted. A pro-life Catholic group, Human Life International, consequently suggested that tetanus vaccines could cause sterilisation, resulting in vaccine scares in Mexico, the Philippines, Tanzania, and Nicaragua. Concerns were also raised by the 1998 publication by Andrew Wakefield that proposed links between the MMR vaccine, autism, and bowel disease. Although the research was later retracted, Wakefield's misuse of that work—including statements in the press conference that were not included in the published report[23]—catalysed widespread fears, some of which persist today.

Government policies

Policy choices or recommendations are also a key public concern. Such choices that have prompted public debate and affected public trust include: legislation requiring vaccination for school entry; the US Centers for Disease Control and Prevention (CDC) and American Academy of Pediatrics (AAP) recommendation in July, 1999, that thiomersal be removed from childhood vaccines; and the decision in France in 1998 to withdraw the hepatitis-B-vaccination programme from schools.[24]

Public trust is challenged particularly when public authorities disagree, such as was the case in 1998 when the French Government suspended the use of the hepatitis B vaccine, which went against the recommendation of WHO and the viral hepatitis prevention board (an expert committee convened by WHO).[25] The result of this decision was that 10 years after the temporary vaccine suspension, three-dose vaccine coverage with hepatitis B vaccine was still only 30%.[26]

Another example of such disagreement was the Japanese Government's decision to suspend the pneumococcal conjugate vaccine Prevnar (Pfizer, New York, NY, USA) and the *Haemophilus influenzae* type b vaccine ActHIB (Sanofi-Aventis, Bridgewater, NJ, USA), while investigating suspected links of these vaccines with the death of four children, which prompted widespread media coverage. A Google search for "Japan" and "Prevnar" and "2011" on April 7, 2011, 1 month after the vaccines were suspended, showed more than 85 000 reports globally. Of the first 100 results listed, only three were about the decision to resume use of the vaccines on March 30, 2011; these three reports were 45th, 91st, and 93rd in the list. When the same search was done on WHO and CDC websites, no information was available on either the suspension or resumption of the two vaccines.

New media and horizontal communication

Democratisation movements and the advent of the internet have changed the environment around vaccines from top-down, expert-to-consumer (vertical) communication towards non-hierarchical, dialogue-based (horizontal) communication, through which the public increasingly questions recommendations of experts and public institutions on the basis of their own, often web-based, research. Such public questioning is not unique to vaccines, but part of a broader environment of increasing public questioning and the emergence of dissent groups, particularly in areas that include risks such as climate change.

The internet, social media—which allows interactive exchange between many users—and mobile phone networks have shifted the methods and speed of communication substantially, allowing information about vaccines and immunisation to be gathered, analysed, and used—especially through blogs—very differently compared with even a decade ago. The amount of information available has increased greatly, including scientifically valid data and evidence-based recommendations alongside poor quality data, personal opinions, and misinformation.

Media attempts to balance coverage by provision of equal opportunity to all viewpoints exacerbates the challenges to public confidence in vaccines by allowing outlier views and small extremist opinions the same media space as views validated through a rigorous process of peer review by the scientific community. This disproportionate share of outlier views has been further amplified by celebrities—such as Jim Carrey or Jenny McCarthy—who encourage parents to question vaccines, often telling highly emotional stories of children who were perceived to have been harmed by vaccines.[27]

The emergence of social media tools, such as Facebook with more than 500 million users globally,[28] has helped create new methods of self-organisation and empowerment of newly founded virtual communities both locally and across wide geographical areas, building constituencies that argue against or for vaccines.[29–31] Although some of these networks have a national focus, they are also quick to pick up and amplify events occurring in other countries that support their cause.

The new mix of highly varied and often conflicting information contributes to the scepticism of some vaccine consumers. These views need to be far better understood as they are developing, rather than when vaccination rates start to decline because of distrust.

Determinants of public trust in vaccines

Public trust in vaccines is a complex issue that often has many converging determinants. Research into environmental-risk communication has identified three factors that affect the extent to which an individual or institution is trusted: perceptions of knowledge and expertise, openness and honesty, and concern and care.[32] The credibility of vaccine information, for example, is influenced by the perceived trustworthiness of the messenger—whether a government authority, the vaccine industry, a health provider, a friend or colleague, or the media. To address persisting concerns about oral polio vaccines causing sterilisation, especially in poorer, marginalised Muslim populations in northern Nigeria and Uttar Pradesh, India, WHO and the Global Polio Eradication Initiative partners convened meetings with the Organisation of Islamic States, as trusted intermediaries or brokers with the public, to successfully rebuild trust in the polio vaccine in their Muslim constituencies. Similarly, when fears spread through Catholic pro-life groups that the tetanus vaccine had sterilising elements, WHO officials requested that the Vatican choose the laboratory in which the vaccine was tested, because it was a trusted institution for these groups (Ciro de Quadros; Albert B. Sabin Vaccine Institute, Washington, DC; personal communication).

Whether the public perceives new information about vaccines as honest and not hiding information about risks also affects public trust in vaccines. Similarly, openness and transparency in decision making about new vaccine policies or research processes can influence the trust of the public or interest groups in the population. The suspension of the human papillomavirus vaccine demonstration project in India, in April, 2010, is an example of the potential effect of distrust, because of inadequate open dialogue with groups who question the vaccine.[14]

Individual and group experiences also affect public willingness to trust vaccines.[13] Public trust of the internationally driven polio vaccination campaign in northern Nigeria, for example, was undermined by Pfizer's trial of the Trovan vaccine in northern Nigeria, because child deaths were suspected to be linked to the trials.

The personal nature of a particular vaccine concern is another determinant of trust, and can mean that individuals or groups are overly trusting because of an eagerness for an answer to their concern. In their search for answers to questions such as "why does my child have autism?", individuals and groups might be willing to trust information that is not scientifically proven if it addresses their concerns.

To improve understanding and address determinants of public trust in vaccines, and the potential effect of these determinants, research is needed not only into individual determinants of trust, but on understanding what mix of factors is most likely to sustain, or damage, public trust. Risk events, such as an adverse events after immunisation, or even perceptions of risk, such as fears of vaccines causing sterilisation or autism, can be amplified or attenuated, depending on how the event or perception of the event is communicated to, and interpreted by, individuals, institutions, or the media.[33]

Case studies

The following case studies describe examples of how vaccine risk concerns were prompted and sustained by individuals—from religious leaders to scientists and health experts, governmental and non-governmental institutions, religious and other interest groups, and the media. The tipping point, whereby vaccines were refused or programmes were disrupted because of fears, was due to a convergence of events, creating a "social amplification of risk".[33]

Thiomersal and autism

Thiomersal, a compound containing ethylmercury, has been used to prevent bacterial contamination in biologics since the 1930s. In 1997, the FDA noted that, in view of the increasing number of vaccines given in early infancy, the total amount of ethylmercury (as thiomersal) might exceed the level set for methylmercury by US Environmental Protection Agency guidelines. In a period of increasing concern about poisoning from mercury in the environment, the AAP and CDC issued a joint statement in 1999 asking vaccine makers to remove thiomersal from childhood vaccines as soon as practical.[34] This statement, issued to show caution and assure the safety of vaccines, paradoxically supported

 Published online June 9, 2011 DOI:10.1016/S0140-6736(11)60678-8

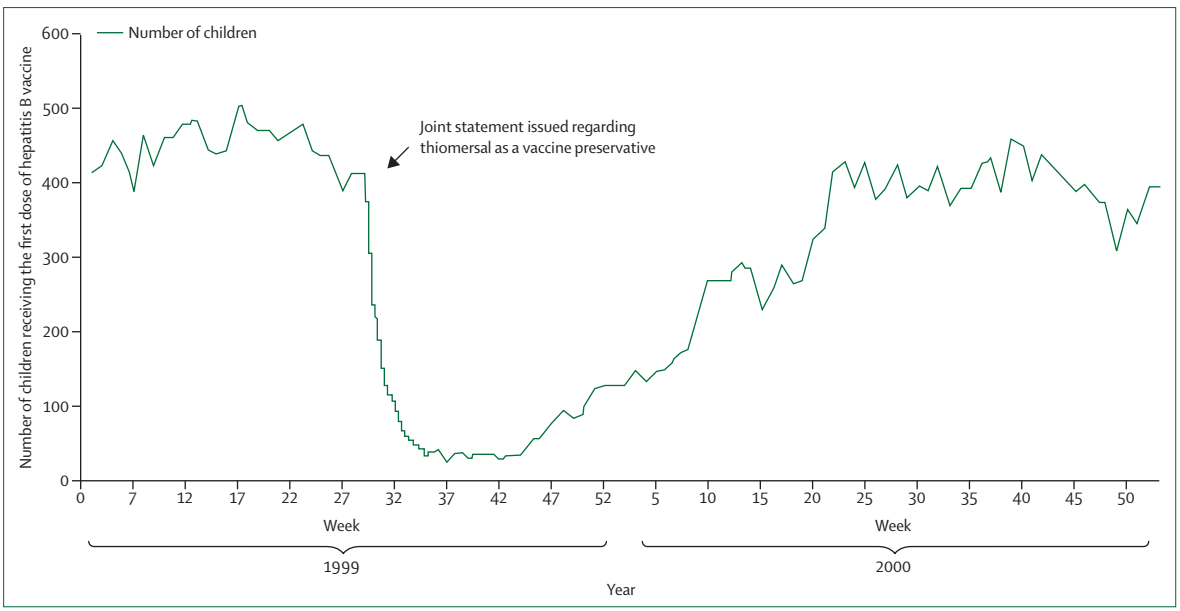

***Figure 1*: Number of children who received the first dose of hepatitis B vaccine less than 5 days after birth (USA, 1999–2000)**
Data from the US Centres of Disease Control and Prevention's morbidity and mortality weekly report.[38]

the argument of those suggesting that vaccines were contributing to what was called an epidemic of autism. Public concern was fuelled by organised groups of parents convinced that their children's autism was caused by mercury-containing vaccines, who prepared to seek compensation through the US National Vaccine Injury Compensation Program; a series of hearings by the chair of an oversight committee in the US House of Representatives who believed his own grandchildren had been harmed by vaccines; and studies and testimonials in public forums, by scientists and celebrities who are now discredited.

Since 1999, many studies have failed to support any causal relationship between thiomersal and autism.[35,36] The absence of this compound from childhood vaccines in the USA for almost a decade has not altered the frequency of autism. After exhaustive review, no evidence has been identified by the vaccine court, a component of the US Vaccine Injury Compensation Program, or the US Institute of Medicine to justify compensation of claimants on the basis of thiomersal in vaccines.[10]

This case is an example of the perverse consequences of application of the precautionary principle, which is applied when there is scientific uncertainty and when an intervention is deemed necessary before harm occurs.[37] The AAP and CDC joint statement showed the transparency of vaccine policy, but it did not necessarily earn trust from those convinced that vaccines are harmful, and in fact prompted more questioning of the safety of vaccines. Removal of thiomersal from childhood vaccines in the USA also created tension between the USA and global vaccine programmes, especially in developing countries where direct vaccine and logistical costs would be prohibitive if thiomersal were removed and single-dose vaccines were instead mandated. Additionally, removal of this compound caused an unexpected temporary decline in rates of hepatitis B vaccination in infants in the USA (figure 1). However, the precautionary measure was based on scientific evidence available at a given point in time and a value system based on the best interests of the public. Had a causal link between thiomersal and autism been discovered, the recommended early removal of thiomersal would have been lauded by the public.

Haemophilus influenzae type b vaccine in India

Similar tensions between experts occurred in India in relation to introduction of the *H influenzae* type b pentavalent vaccine combined with diphtheria, poliovirus, and tetanus, and hepatitis B virus. Introduction of this vaccine was challenged by Puliyel and colleagues,[39,40] who asserted that the disease burden in India did not justify addition of the expensive vaccine.

Puliyel and colleagues also claimed that the disease burden data were misrepresented by the GAVI Alliance and WHO.[41,42] Indian pediatricians contested their assertions with evidence on the disease burden of *H influenzae* type b in India, which they felt made a compelling case for introduction of the vaccine against this disease.[43] Others accused Puliyel of leading an antivaccination lobby.[44]

Puliyel and academic and government colleagues who share his view reject the antivaccination label. In a statement published in 2010, they wrote that "we are a group of pediatricians, healthcare activists, teachers in public health, and bureaucrats who have championed

universal immunisation in India throughout our working lives". They went on to note that they were "taken aback" by the fact that their questioning of the appropriateness of introducing the *H influenzae* type b vaccine in India was misconstrued as a broad anti-vaccination movement.[31]

Although introduction of the vaccine was endorsed by WHO and the Indian National Immunization Technical Advisory Group (INITAG), opposition from Puliyel and colleagues led the Indian Health Ministry to stall introduction of the vaccine. The Health Ministry convened an independent expert group to re-examine WHO and INITAG's recommendations. This group has since concluded that the government should move forward and accept the GAVI Alliance's financial support to the Government of India to allow it to proceed with the introduction of the vaccine. Nonetheless, the Indian press picked up the debate and widely publicised Puliyel's concerns, which will probably not be forgotten.

MMR vaccine and autism

The public's eagerness for answers to their felt needs is another determinant of trust. Wakefield's claims in 1998 that the MMR vaccine could cause autism was embraced by parents who were eager to find a reason for their child's autism. His suggestion that a single-antigen measles vaccine should be considered as a safer alternative to the MMR vaccine also gave the parents a solution. When the then Prime Minister Tony Blair refused to reveal whether his young son had been given the MMR vaccine, Wakefield's findings seemed validated. Although many subsequent studies failed to reproduce Wakefield's findings,[9] and his research paper was formally retracted,[45] the distrust generated around the MMR vaccine contributed to declines in MMR vaccine coverage and consequent measles outbreaks.[46] Research done in the UK by the Department of Health showed that overall trust in the MMR vaccine has recovered at least in Britain, where the controversy began.[47] Wakefield continues public speaking engagements internationally to perpetuate his views by appealing to vaccine-sceptical parents—even after being scientifically discredited. The groups that still champion Wakefield's views, especially in the USA, are a stark example of the vulnerability of public confidence in vaccines.[27,48,49]

Tetanus vaccine and sterilisation

In the case of fears related to sterilisation caused by tetanus vaccines in the early 1990s, a Catholic organisation with membership in more than 60 countries, popular media, religious and political leaders, and legislative authorities converged to amplify perceived risks of sterilisation associated with vaccination, which led to reduced uptake of the tetanus vaccine and vaccine programme disruptions.

In 1994, a research article on a birth control vaccine[12] made reference to the use of tetanus toxoid as a carrier protein. Although the birth control vaccine had no relation with tetanus immunisation, it created a perceived connection between tetanus vaccination and contraception that travelled widely thoughout the internet; Human Life International communicated this perceived connection to their members in more than 60 countries. In the Philippines, the tetanus vaccination campaign was interrupted by a court injunction. The subsequent panic led to a 45% drop in tetanus vaccination coverage between 1994 and 1995.[50] In Nicaragua, Catholic Cardinal Obando, a member of Pro-vida, played a substantial part in stopping the tetanus immunisation campaign in that region.[47] In Mexico, the Comite Pro-vida accused the government of genocide, claiming that the tetanus vaccine caused abortion. Although the damage caused by these antivaccination campaigns has been largely mitigated by proactive measures by the Pan American Health Organization—through engagement with the media and the Vatican—the notion that vaccines contain sterilising substances periodically resurfaces, most recently in the polio campaigns in Nigeria and India.[51]

Oral polio vaccine and sterilisation

In northern Nigeria, religious and political leaders, led by the chairman of the Supreme Council for Sharia in Nigeria, Datti Ahmed, boycotted the polio vaccine in 2003, claiming that the oral polio vaccine was contaminated with HIV and could also cause sterilisation in those vaccinated, fuelling widespread public distrust. Political and cultural disparities between northern and southern Nigeria also influenced the willingness of the people in the north to sign-up to a mandate thought to be imposed by the head of state, and international health bodies.[15] Memories of the Trovan trial in 1996, during which children died, were still vivid in the minds of many, undermining their trust. Although subsequent investigation did not attribute the children's deaths to the drug being tested, the trial was deemed illegal because of unethical conduct.[52] The legal proceedings of the trial, which were undertaken in the northern state of Kano, took place in the background of the polio vaccination boycott.

The boycott of oral polio vaccination in Kano State lasted 11 months and poliomyelitis cases in Nigeria rose from a nadir of 56 in 2001 to 1143 in 2006. Spread of the poliovirus in Nigeria led to outbreaks in 15 other sub-Saharan nations,[53] and spread as far as Indonesia where 303 cases were all traced to Nigeria.[54]

This boycott was a wake-up call to the Global Polio Eradication Initiative on the need for better engagement with both local leaders and affected communities. At the 60th World Health Assembly, a report on poliomyelitis[55] called on member states to improve engagement with local and national leaders and with affected communities. Although calls for public engagement are not new, the polio experience has prompted detailed, research-driven communication and public engagement strategies.

 Published online June 9, 2011 DOI:10.1016/S0140-6736(11)60678-8

The Global Polio Eradication Initiative has done extensive, block-by-block research in some settings to understand who are locally trusted sources of vaccine information and who are the trusted providers of vaccines, and to understand the reasons behind vaccine refusals.[56] In Pakistan, research showed that some of the public resistance was actually among health workers, who felt underpaid and perceived the initiative as being imposed from outside Pakistan, and was not locally owned.[57] Understanding how to build and restore trust can only be addressed with research.[58] In the case of the Global Polio Eradication Initiative, the need for improved understanding of specific public concerns and reasons for distrust came only in the face of a crisis of confidence. The lesson learned was that not only is research within the local communities needed, but that it is needed early on in the planning of vaccination programmes, well before a crisis occurs.

Effects of public distrust

Evidence about the effects of misinformation, rumours, and antivaccine groups on vaccine coverage and consequent disease outbreaks in many countries is well documented. In addition to the polio, tetanus, and MMR vaccine examples, increases in pertussis outbreaks have occurred in Russia,[59] Japan, the USA, Sweden, and England and Wales after antivaccine activity.[60] In France, the political decision to suspend hepatitis B vaccines in schools exacerbated public concerns associating hepatitis B vaccines with autism, multiple sclerosis, and leukaemia and led to low levels of hepatitis B vaccination.[61] In the Ukraine, scares and negative public reaction to a measles and rubella vaccination campaign led to quarantining of the vaccine and suspension of the campaign, which was targeting 7·5 million people, but only reached 116 000.[62]

In all of these situations, management of the effects of declines in vaccine uptake, consequent disease outbreaks, and loss of public trust in the vaccines has taken a toll on human and financial resources in addition to long-term reputational costs to individual vaccines and immunisation programmes.

New methods of communication, dialogue, and engagement are urgently needed across all vaccine stakeholders—vaccine experts, scientists, industry, national and international health organisations, policy makers, politicians, health professionals, the media, and the public. No single player can reverse the vaccine confidence gap.

The way forward: who needs to do what?

The foregoing examples show that the process of building, rebuilding, and sustaining public trust in vaccines is highly variable and depends on a thorough understanding of the community and its socioeconomic status, previous experience, views of those they trust (and distrust) including religious or political leaders, and understanding of the risks and benefits of vaccines versus the diseases they prevent.

Traditional principles and practices of vaccine communication remain valid,[63] especially those that ensure timely and accurate communication of information about where, when, and why vaccines are given, and those that ensure mutual respect in health provider–patient interaction. However, additional emphasis should be placed on listening to the concerns and understanding the perceptions of the public to inform risk communication, and to incorporate public perspectives in planning vaccine policies and programmes.

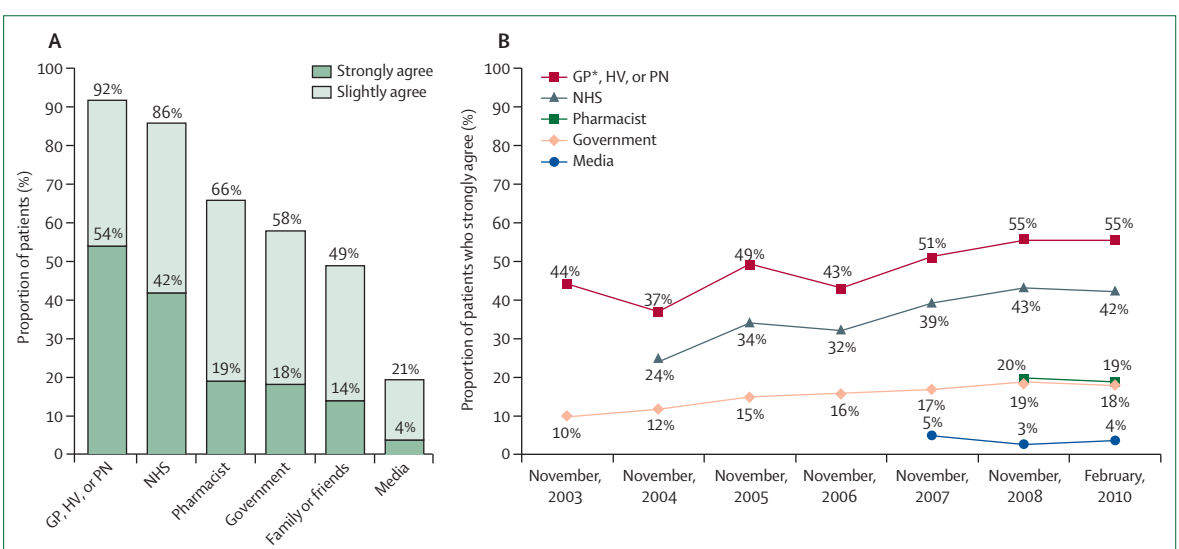

***Figure 2*: Research into who parents trust**

Data were provided by David Salisbury (Department of Immunisation, Department of Health, UK). (A) Who parents trust to give advice about immunisation (2010); data are for parents of children aged 0–4 years (n=1730). (B) Who parents trust to give advice about immunisation (2007–10); data are for parents of children aged 0–2 years (n=1142). GP=general practitioner. HV=health visitor. PN=practice nurse. NHS=national health service. *GP data gathered before 2007.

***Panel 2:* Actions needed**

- In view of the heterogeneity of populations, and the local specificity of vaccine concerns and trust relations, strategies to build public trust need to be locally tailored and not prescriptive in recommendations of what specifically needs to be done by various stakeholders to build confidence in vaccines.
- Evidence-based approaches used in risk communication[76] should be adopted as core principles by all health providers, experts, health authorities, policy makers, and politicians when communicating information about vaccines. These approaches include engagement with and listening to stakeholders, and being transparent about decision making, and honest and open about uncertainty and risks.
- A systematic approach is needed to listen to public concerns. As with infectious diseases, where surveillance is essential for disease control, systematic monitoring of dynamic and evolving vaccine rumours, concerns, and refusals is crucial to guide prompt responses to build and sustain public confidence. Such a surveillance system is being trialled at the London School of Hygiene and Tropical Medicine.[77]
- Decision and policy makers cannot assume what the public wants without undertaking social science and decision science research. The vaccine community demands rigorous evidence for vaccine efficacy and safety and the technical and operational feasibility of initiating a new vaccine initiative or introducing a new vaccine, but have been negligent in demanding evidence on the social and political feasibility of introducing new vaccines and the factors that determine the local acceptability of vaccines.
- Models of multidisciplinary research for vaccine introduction are emerging[78,79] and need to be expanded. These models include not only technical and operational assessments, but also research into social and political factors that need to be considered in planning the introduction of vaccines. The Global Polio Eradication Initiative has shown that monitoring of public concerns needs to be continuous and responsive, and hand in hand with the monitoring of technical strategies.[54]

To build public confidence, it is key to understand what drives public trust in each community,[64–66] and what are the local perceptions of vaccines and their risks.[1,67–72] According to a US National Research Council report, risk communication "emphasizes the process of exchanging information and opinion with the public".[73] Building public trust is not about telling them what they need to understand better, and it is not merely about being clearer or teaching parents about risk–benefit decision making. Trust is built through dialogue and exchange of information and opinion. Valuable models can be drawn from environmental-risk research, which emphasise the importance of listening to public concerns and can protect against simplistic solutions to complex problems.[74]

Research is needed to understand who the public trusts. The UK Department of Health, for example, continues to monitor not only public perceptions of different vaccines, but also who the public trusts (figure 2). Similar studies are in progress in academic institutions[75] and in the CDC.[1] Such efforts should be encouraged and funded.

The immunisation enterprise is a complex matrix involving academia, government, industry, private clinicians and other health providers, and public-health systems. Every one of these entities is vulnerable to public mistrust. Improved communication, dialogue, and trust-building across these entities is essential. The private sector is very conscious of consumer confidence levels as a metric of success and acceptance of their products. The public health community needs similar attentiveness to ensure consumer confidence if we are to achieve the potential benefits of new and existing vaccines (panel 2).

Conclusion

Vaccination is a complex social act that effects both direct, perceived self-interest, the interest of one's children, and the broader community. The decision leading to immunisation remains a personal summation of each individual's perception of the complexity of information they receive and their trust in the institutions that produce, legislate, and deliver vaccines. For vaccines to realise their full potential in protection of health, public and private health practices need to take into account the range of social and political factors that affect the public's willingness to accept vaccines.

The immunisation community, including scientists, policy makers, and health providers, needs to come to terms with the reality that individuals and groups will continue to question and refuse vaccines. Extremist antivaccination groups whose minds will not change will exist. Many people—the majority—who accept vaccines could change their mind. The focus should be on building and sustaining trust with those who accept and support vaccines, while working to understand and address the growing confidence gap.

Contributors

HJL, LZC, SLK, and JE outlined the report. HJL prepared the first and subsequent drafts with input from LZC, SLK, JE, SR. All authors read and approved the final draft.

Conflicts of interest

JE received funding from Novartis for a pneumococcal advisory meeting and as a data and safety monitoring board member for meningococcal and typhoid vaccines. SR edits the *Journal of Health Communication*, with faculty appointments at Tufts School of Medicine and George Washington School of Public Health and Health Services. SR contributed independently of his principal employer, Johnson & Johnson. Some technical work, travel (LZC and SLK), and meetings relevant to this work were funded by the Bill & Melinda Gates Foundation. The funding organisation had no role in the drafting or direction of this report. HJL declares that she has no conflicts of interest.

Acknowledgments

HJL is funded by the Bill & Melinda Gates Foundation as principal investigator for research on public confidence in immunisation. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of their employers. We thank David Salisbury for providing data for figure 2 and for useful discussion on the paper; Anne Louise-Kinmonth for reviewing subsquent drafts; and Pauline Brocard, Lee Barker, Caitlin Jarret, Isaac Ghinai, Jay Dowle, Larry Madoff, Melissa Cumming, and Louise Paushter for researching case studies.

References

1 Black S, Rappuoli R. A crisis of public confidence in vaccines. *Science* 2010; **61:** 61mr1.
2 Shetty P. Experts concerned about vaccination backlash. *Lancet* 2010; **375:** 970–71.
3 Spier RE. Perception of risk of vaccine adverse events: a historical perspective. *Vaccine* 2001; **20:** S78–84.
4 Poland GA, Jacobson RM. The age-old struggle against the antivaccinationists. *NEJM* 2011; **364:** 97–99.
5 Bean SJ. Emerging and continuing trends in vaccine opposition website content. *Vaccine 2011*; **29:** 1874–80.
6 Cooper LZ, Larson HJ, Katz SL. Protecting public trust in immunization. *Pediatrics* 2008; **122**: 149–53.
7 Campbell P. Understanding the receivers and the reception of science's uncertain messages. *Phil Trans Roy Soc A* (in press).
8 Clements CJ, Ratzan S. Misled and confused? Telling the public about MMR vaccine safety. *J Med Ethics* 2003; **29**: 22–26.
9 Institute of Medicine. Immunization safety review: vaccines and autism. Washington, DC: National Academies Press, 2004.
10 Honda H, Shimizu Y, Rutter M. No effect of MMR withdrawal on the incidence of autism. *J Child Psychol Psychiatry* 2005; **46**: 572–79.
11 Tollefson J. An erosion of trust. *Nature* 2010; **466:** 24–26.
12 Talwar GP, Singh O, Pal R, et al. A vaccine that prevents pregnancy in women. *Proc Natl Acad Sci USA* 1994; **91:** 8532–36.
13 Larson HJ, Heymann DL. Public health response to influenza A (H1N1) as an opportunity to build public trust. *JAMA* 2010; **303:** 271–72.
14 Larson H, Brocard P, Garnett G. The India HPV-vaccine suspension. *Lancet* 2010; **376:** 572–73.
15 Yahya M. Polio vaccines—difficult to swallow. The story of a controversy in northern nigeria. Working paper 261. Institute of Development Studies 2006. http://www.eldis.org/vfile/upload/1/document/0708/DOC21227.pdf (accessed Jan 6, 2011).
16 Poland GA. Vaccidents and adversomics. *Vaccine* 2010; **28:** 6549–50.
17 Davis MM, Butchart AT, Coleman MS, et al. The expanding vaccine development pipeline, 1995–2008. *Vaccine* 2010; **28:** 1353–56.
18 WHO. WHO prequalified vaccines. http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/index.html (accessed Oct 15, 2010).
19 US Food and Drug Administration. Complete list of vaccines licensed for immunisation and distribution in the US. http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833 (accessed Oct 15, 2011).
20 WHO, UNICEF, World Bank. State of the world's vaccines and immunization, 3rd edn. Geneva: World Health Organization, 2009.
21 Lopalco PL, de Carvalho HG, Kreidl P, Leitmeyer K, Giesecke J. Childhood vaccination schedules in Europe vary widely: is this a problem? *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2009; **52:** 1095–98.
22 WHO. WHO vaccine preventable diseases monitoring system. http://apps.who.int/immunization_monitoring/en/globalsummary/scheduleselect.cfm (accessed March 30, 2011).
23 Mnookin S. The panic virus. New York, NY: Simon & Schuster; 2011.
24 Akehurst C. France suspends hepatitis B immunisation for adolescents in schools. *Euro Surveill* 1998; **2:** pii=1143.
25 Viral hepatitis prevention board. Multiple sclerosis and hepatitis B vaccine? Meeting report. *Vaccine* 1999; **17:** 2473–75.
26 Global Advisory Committee on Vaccine Safety (GAVCS), WHO Secretariat. Global safety of vaccines: strengthening systems for monitoring, management and the role of GACVS. *Expert Rev Vaccine* 2009; **8:** 705–16.
27 Jenny Mccarthy joins the defense of Andrew Wakefield. http://www.liquida.com/article/15670682/andrew-wakefield-autism-jenny-mccarthy (accessed March 30, 2011).
28 Facebook. Press room. http://www.facebook.com/press/info.php?statistics (accessed March 28, 2011).
29 Kirby D. Evidence of harm mercury in vaccines and the autism epidemic: a medical controversy. New York: St Martin's Press, 2005.
30 Offit PA. Deadly choices: how the anti-vaccine movement threatens us all. New York, NY: Basic Books, 2011.
31 Mudur G. Anti-vaccine lobby resists introduction of Hib vaccine in India. *BMJ* 2010; **340:** c3508.
32 Peters RG, Covello VT, McCallum DB. The determinants of trust and credibility in environmental risk communication: an empirical study. *Risk Anal* 1997; **17:** 43–54.
33 Pidgeon N, Kasperson R, Slovic P, eds. The social amplification of risk. Cambridge: Cambridge University Press, 2003.
34 Centers for Disease Control and Prevention. Thimerosal in vaccines: a joint statement of the American Academy of Pediatrics and the public health service. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4826a3.htm (accessed March 10, 2011).
35 Schechter R, Grether JK. Continuing increases in autism reported to califronia development services system: mercury in retrograde. *Arch Gen Psychiatry* 2008; **65:** 19–24.
36 Fombonne E. Thimerosol disappears but autism remains. *Arch Gen Psychiatry* 2008; **65:** 15–16.
37 United Nations Educational, Scientific and Cultural Organization. The precautionary principle. World Commission on the ethics of scientific knowledge and technology (COMEST). Paris: COMEST, 2005.
38 Centers for Disease Control and Prevention. Impact of of the 1999 AAP/USPHS joint statement on http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4826a3.htm (accessed on March 10, 2011).
39 Lone Z, Puliyel JM. Introducing pentavalent vaccine in the EPI in India: a counsel for caution. *Indian J Med Res* 2010; **132:** 1–3.
40 Puliyel J. India cannot afford to use vaccines that are not cost-effective. *The Guardian* (London) Oct 27, 2010.
41 Puliyel J, Mathew JL, Priya R. Incomplete reporting of research in press release: Et tu, WHO? *Indian J Med Res* 2010; **131:** 588–89.
42 Puliyel JM. GAVI and WHO: demanding accountability. *BMJ* 2010; **341:** 266.
43 John J, Bose A, Balraj V. Misrepresenting data: deception or dogma? *Indian J Med Res* 2010; **132:** 463–65.
44 Saxena KB, Banerji D, Qadeer I, et al. "Antivaccine lobby" replies to the BMJ. *BMJ* 2010; **341:** c4001.
45 Murch SH, Anthony A, Casson DH, et al. Retraction of an interpretation. *Lancet* 2004; **363:** 750.
46 Wright JA, Polack C. Understanding variation in measles-mumps-rubella immunization coverage—a population-based study. *Eur J Public Health* 2006; **16:** 137–42.
47 UK National Health Service. Increase in MMR vaccination coverage in England, report shows, but child immunisation levels are still lower than the rest of the UK. http://www.ic.nhs.uk/news-and-events/news/increase-in-mmr-vaccination-coverage-in-england-report-shows-but-child-immunisation-levels-are-still-lower-than-the-rest-of-the-uk (accessed May 15, 2011).
48 Vaccine liberation army. http://vaccineliberationarmy.com/our-hero-dr-andrew-wakefield-on-the-today-show-2 (accessed May 15, 2011).
49 Vitamin lawyer health freedom blog. http://vitaminlawyer healthfreedom.blogspot.com/2010/04/dr-andrew-wakefield-medical-hero.html (accessed May 15, 2011).
50 Milstein J, Griffin PD, Lee J-W. Damage to immunisation programmes from misinformation on contraceptive vaccines. *Reprod Health Matters* 1995; **3:** 24–28.
51 UNICEF. Combatting antivaccination rumours: lessons learned from case studies in east africa. Nairobi: Eastern and Southern Africa UNICEF Regional Office. http://www.path.org/vaccineresources/files/Combatting_Antivac_Rumors_UNICEF.pdf (accessed March 27, 2011).
52 Stephens J. Pfizer to pay $75 million to settle trovan-testing suit. *Washington Post* (Washington, DC), July 31, 2009.
53 CDC wild poliovirus type 1 and type 3 importations—15 countries in Africa, 2008–2009. *MMWR* **581:** 357–62.

54 WHO. Polio virus respects no borders. http://www.searo.who.int/LinkFiles/Advocacy_Efforts_Polio_virus_respects_no_borders_Aug07.pdf (accessed Dec 15, 2010).

55 Global Polio Eradication Initiative. Report by the WHO Secretariat to the 60th World Health Assembly. Poliomyelitis: mechanism for management of potential risks to eradication. http://www.polioeradication.org/content/general/WHA61_Resolution_English.pdf (accessed Dec 15, 2011).

56 Taylor S, Shimp L. Using data to guide action in polio health communications: experience from the Polio Eradication Initiative (PEI). *J Health Commun* 2010; **15:** 48–65.

57 Closser S. Chasing polio in Pakistan: why the world's largest public health initiative may fail. Nashville: Vanderbilt University Press, 2010.

58 Chaturvedi S, Dasgupta R, Adhish V, et al. Deconstructing social resistance to pulse polio campaign in two north indian districts. *Indian Pediatrics 2009;* **46:** 963–74.

59 Galazka AM, Robertson SE, Oblapenko P. Resurgence of diphtheria. *Eur J Epidemiol* 1995; **11:** 95–105.

60 Gangarosa EJ, Galazka AM, Wolfe CR, et al. Impact of anti-vaccine movements on pertussis control: the untold story. *Lancet* 1998; **351:** 356–61.

61 Parry J. No vaccine for the scaremongers. *Bull World Health Organ* 2008; **86:** 425–26.

62 Martin R. Lessons learned from SIAs: magnification of the opportunities and risks to routine immunization programmes. 4th Annual Global Immunization Meeting; New York, NY, USA; Feb 19, 2009.

63 McAlister A, Puska P, Salonen J, et al. Theory and action for health promotion: illustrations from the North Karelia project. *Am J Public Health* 1982; **72:** 1.

64 Flynn J, Burns W, Mertz CK. Trust as a determinant of opposition to a high-level radioactive waste repository: analysis of a structural model. *Risk Anal* 1992; **12:** 417–29.

65 Alesina A. Who trusts others? *J Public Econ* 2002; **85:** 207.

66 Das J, Das S. Trust, learning, and vaccination: a case study of a north Indian village. *Soc Sci Med* 2003; **57:** 97–112.

67 Savage I. Demographic influences on risk perceptions. *Risk Anal* 1993; **13:** 413.

68 Fowler GL, Kennedy A, Leidel L, et al. Vaccine safety perceptions and experience with adverse events following immunization in Kazakhstan and Uzbekistan: a summary of key informant interviews and focus groups. *Vaccine* 2007; **25:** 3536–43.

69 Bedford H, Elliman D. Concerns about immunisation. *BMJ* 2000; **320:** 240.

70 Streefland PH. Public doubts about vaccination safety and resistance against vaccination. *Health Policy* 2001; **55:** 159–72.

71 Wroe AL, Bhan A, Salkovskis P, Bedford H. Feeling bad about immunising our children. *Vaccine* 2005; **23:** 1428–33.

72 Streefland P, Chowdhury AMR, Ramos-Jimenez P. Patterns of vaccination acceptance. *Soc Sci Med* 1999; **49:** 1705–16.

73 Stern PC, Feinberg HV, eds. Understanding risk: informing decisions in a democratic society. Washington, DC: National Research Council, National Academy Press, 1996.

74 Pidgeon N, Fischhoff B. The role of social and decision sciences in communication uncertain climate risks. *Nat Clim Chang* 2011; **1:** 35–41.

75 Freed GL, Clark SJ, Butchart AT, Singer DC, Davis MM. Parental vaccine safety concerns in 2009. *Pediatrics* 2010; **125:** 654–59.

76 Covello VT. Best practices in public health risk and crisis communication. *J Health Commun* 2003; **8** (suppl 1)**:** 5–8.

77 Project to support public confidence in immunization programs. http://www.lshtm.ac.uk/eph/ide/research/vaccinetrust (accessed April 19, 2011).

78 Andrus JK, Toscano CM, Lewis M, et al. A model for enhancing evidence-based capacity to make informed policy decisions on the introduction of new vaccines in the americas: PAHO's PRPVAC Initiative. *Public Health Rep* 2007; **122:** 811–16.

79 Bingham A, Janmohamed A, Bartolini R, et al. An approach to formative research in hpv vaccine introduction in low-resource settings. *Open Vaccine J* 2009; **2:** 1–6.