SYMPOSIUM ON CONSENT AND CONFIDENTIALITY

Misled and confused? Telling the public about MMR vaccine safety

C J Clements, S Ratzan

..... See end of article for authors' affiliations

Correspondence to: Dr C J Clements, Department of Vaccines and Biologicals, World Health Organization, Avenue Appia 20, 1211 Geneva 27, Switzerland; clementscj@who.ch

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The extraordinary events surrounding the measles, mumps, and rubella (MMR) vaccine in the United Kingdom have not only placed in jeopardy the use of this triple vaccine but have also spread concern to other parts of the world. Examination of the public's worry about MMR vaccine reveals they have been exposed to a range of conflicting views resulting in the feeling of having been misled about the safety of the vaccine. There are various groups and individuals who have legitimate roles in informing the public about such subjects. But is each one behaving in an ethically responsible way? And if confidence falters, vaccine coverage dips, and an outbreak of measles, mumps, or rubella ensues, who, if anyone, will stand and say "I misled them, I confused them, this is my responsibility"? We examine the ethical issues of each group with a voice in the debate about vaccine safety.

re the public in the United Kingdom being misled and, as a result, are they confused about the safety of the triple measles, mumps, and rubella vaccine (MMR)? If so, why, and by whom? There is extraordinary media interest regarding the safety of the MMR vaccine, raising, for those with a mind to reflect on it, several key ethical issues about vaccine safety,¹ namely:

- Are vaccines safe and are we right to continue giving them?
- Are there economic incentives for health care providers that mitigate against free choice in this area?
- Are caregivers (proxy decision makers for infants) given enough appropriate information to allow them to provide correctly informed consent for vaccination?

We have heard the first two issues raised recently, the first having been clearly discussed in public and in scientific circles for several years. Vaccines are very much safer than the diseases they protect against. The second issue is beyond the scope of this discussion. But the third, the one that we find most worrisome, namely whether the public have been provided with the right information to enable them to make the choice about whether their children should receive vaccines, has not been discussed adequately anywhere. While those in the United Kingdom may think the safety of the MMR vaccine is a peculiarly British debate, similar dynamics exist in most countries, given minor regional variations. By examining the debate through an ethical filter, we will attempt to provide clarity on a universal dilemma facing immunisation programmes.

THE PUBLIC FEELS MISLED

The British public have been fed by the media on a mixed diet of scientific evidence, theories, views, and other verbal roughage. Because of the huge amount of media coverage of the safety of MMR, the public, not unreasonably, have come to the conclusion that there is no smoke without fire; there must be some truth in all this alarmism. They are not convinced that vaccines are safe; they are not sure who to listen to and trust. They are reverting to the belief that it is safer to have the disease than have their children vaccinated. And even if children were to get the disease, they argue, it is not serious.

THE PUBLIC IS CONFUSED

If the safety of vaccines was the only subject the public felt misled about, it might be possible to restore the balance fairly

easily. But a host of other subjects come to mind where the public have considered themselves to have been either directly misled or offered incomplete information over a period of time. Foot and mouth disease, bovine spongiform encephalopathy (BSE), atomic power stations, overhead power cables, mobile phones, and many other examples underline that the public have learnt to distrust the information offered through a variety of channels.

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THE PUBLIC IS A TOUGH AUDIENCE

There are many reasons why the public do not willingly accept everything they are told. Issues tend to be simplified in public debates. Once the peoples' mind is made up, it may be very difficult to change it. Members of the general public are less likely to be able to detect flaws or inconsistencies of argument, analyse the risk benefit ratios, or identify omissions in evidence presented to them. The public may focus more on the presence or absence of risk rather than the relative risk of a situation. Because of these and other potential problems in communicating with the public, professionals somehow need to draw them into a participatory process in any risk communication efforts.

WHOSE RESPONSIBILITY TO INFORM?

If the public are expected to participate in a public health programme, they have a right to be informed of the advantages and disadvantages that accrue from participating, as well as the advantages and disadvantages of non-participation. Exactly who is responsible for informing them? Certainly governments (politicians) and their appropriate health agencies must take the vanguard in this task, and, of course, individual health care workers at the vaccination visit. But there are many other actors on the stage. Independent scientists may undertake research or possess specialist knowledge that the public may need to know about. The medical press is a valuable source of reference for informing both the professions and the public in this area. Independent authoritative bodies such as the World Health Organization (WHO) may contribute technical information and advice at a global level. For instance, WHO has access to the world's top experts in the area of public health and is able to distil their wisdom into useful, independent guidelines for member nations.

Finally there are independent individuals and organisations who make their voices heard about the safety of vaccines, especially when they differ from the official view on some aspect of safety. This heterogeneous group of individuals has become known as the antivaccine lobby and encompasses parent groups, individuals, and even congressmen. They operate through a number of methods, including an extensive number of internet sites. The antivaccine lobby is not, however, mandated with responsibility to inform. Instead they form an invaluable, if at times uncomfortable, voice of dissent, a capacity highly valued in Western civilisation.

INTERESTED PARTIES

If Shakespeare was right, and all the world's a stage, then there are certainly many actors on this stage. And they are often reading from different scripts. In truth they have rather different interests.

Liberal governments and their ministries of health are generally perceived by the public to make decisions about public health based on what is best for the nation's wellbeing. There may be times when this takes precedence over the interests of the individual, but the rights of the child are not considered to have been jeopardised if the vast majority benefits. Governments are not likely to pursue a policy that is shown to be scientifically unsound, unethical, or unsafe. Having chosen a public health policy, it is in the interest of the government to pursue and promote that policy as completely as possible. Failure to do so may be perceived by the voting public as weakness on the part of the government, doubting the correctness of its choice of policy, or experiencing concern arising from new scientific evidence related to the policy.

Health care workers generally operate out of a high level of altruism and service to their community. But other factors also exist. For instance, there may be a monitoring system that detects poor performance in the form of low immunisation coverage levels. There may be a financial reward for good achievements. In addition, the health care worker may wish to preserve a positive relationship with parents in the community in which he lives. Providing advice that conflicts with the pervading community values or the stated government policy (a government that may pay his salary) may be very hard to sustain.

An independent scientist may have a completely different agenda. He is not generally focused on supporting a government policy as such. But his professional success may depend on undertaking research and getting it published in a prestigious medical journal. Sadly, negative findings in studies are less attractive for publication, and prestige comes most readily from new discoveries. Thus there is huge pressure on the scientist to come up with new information.

The medical press also has its own agenda. Those journals that are largely funded by their parent organisation are freer to choose what articles to publish. Many journals, however, rely to a greater or lesser extent on high sales revenues to keep going. With the proliferation of medical journals in the market place, and largely free access web publication, competition is now intense. Even the prestigious journals must look for articles and research that will attract readership. It is common practice for journals to create press releases about high profile articles prior to publication dates, thus ensuring the lay press reviews the material ahead of medical readers.

Medical correspondents of the newspaper, radio, and television companies are part of the team of reporters who harvest news items for inclusion in a commercial product whose purpose is to make a profit by informing the public. Journalists have their own high standards of behaviour in the way they carry this out. They are expected to be impartial and report all sides of an event.

Because the antivaccine lobby is so heterogeneous, it is not easy to describe succinctly and in general terms what their involvement, they may unwittingly prefer to believe information that supports their point of view. On the down side, individual citizens' rights may be hindered by a "tyranny of the minority" that in effect results in policies that protect the rights of a few rather than the health of the wider public.

HOW THE PUBLIC HEARS ABOUT VACCINE SAFETY

Governments frequently create information packages about public health policies they wish to promote. These packages are generally culture specific. In the United Kingdom, immunisation is promoted through printed material, television slots, and other public service announcements. In this way the government controls the content, providing as much information for and against the policy as they consider appropriate to the situation.

The information reaching the public through the media takes a very different route. The reporter creating the story is looking for high interest, and wants to present at least two sides of the issue. In so doing, there is a real danger that two points of view on the same subject will be presented as if they are more or less equal in merit. In the best situation, two experts may discuss slightly differing points of view from an informed perspective. Sadly, too often the standard medical view (the fact that vaccines are safe and effective and save millions of lives) is presented along side the view of an individual that a particular event might be caused by a vaccine. To the audience, these polar views may appear more or less equal in merit. They may feel frustrated that they are now left to make an important decision about whether to immunise their child on this basis. In reality, these two options are wildly unequal, with hugely different levels of certainty (table 1).

The internet represents a new medium in which to present information with openness. It also, however, allows pressure groups and activists a global platform to tell the public "what the government does not want us to know". Some of these internet sites seem highly plausible to the outsider, but present very biased information.

PARTIAL DISCLOSURE

Are any of the participants involved in the vaccine safety debate practising partial disclosure? Partial disclosure is not unique to health. For a long time it has been characteristic of our public (and private) life, a sad fact lamented by St Augustine's writings over 1500 years ago.² Sissela Bok wrote a ground breaking book in 1978 on lying in public life, ³ spurred on by the Watergate affair. In so doing, she provided, perhaps unwittingly, useful insight into the dilemma of providing incomplete information on vaccine safety. How can we decide what is acceptable and adequate information for a particular audience in a particular situation? Are we absolved from accusation if we provide all available information?

One of the greatest fears of the public is the thought that they are being told only part of the truth, and that there is a conspiracy to withhold the whole truth. Thus any story in the media that suggests such activity is met with outrage.

What is less well understood is the partial disclosures sometimes perpetrated by those not in favour of immunisation. The antivaccine lobby understandably wants to rid the nation of the risk of damage by vaccination. The general strategy for this is to promote avoidance of vaccination. They propose to the public two options: vaccine damaged children or no

 Table 1
 Risk of complications from natural measles infection compared to known

 risks of vaccination with a live attenuated virus in immunocompetent individuals*

Complication	Risk after natural disease†	Risk after vaccination‡
Otitis media	7–9%	0
Pneumonia	1–6%	0
Diarrhoea	6%	0
Postinfectious ecephalomyelitis	0.5–1 per 1000	1 per 1 000 000
SSPE	1 per 100 000	0
Anaphylaxis	0	1 per 100 000-1 000 000
Death	0.1–1 per 1000 in industrialised countries up to 5–15% in developing countries	0
TRisks after natural measles are a tRisks after vaccination are calcu	up to 5–15% in developing countries calculated in terms of events per number of cas	ses.

SSPE = subacute sclerosing panencephalitis.

*Source: Duclos P, Ward BJ. Measles vaccines: a review of adverse events. Drug Safety 1998;6:435–54.

vaccine damaged children—to vaccinate or not to vaccinate. It sounds an easy choice, but the reality is different.

The provaccine lobby promotes high vaccine coverage that results in few deaths, few cases, and few disabilities from the vaccine preventable disease. The down side is a small number of children suffering mild adverse events following immunisation (AEFI) and an extremely small and well documented proportion suffering more serious AEFIs (less than one per million doses administered for most childhood vaccines (table 1).

The antivaccine lobby canvasses for no AEFIs. Do they make it clear that the price for an absence of AEFIs is a loss of confidence in the vaccine, low vaccine coverage, with many deaths, cases, and disability from the vaccine preventable disease, and a possible return of the vaccine preventable disease in epidemic proportions (as occurred with diphtheria in the 1990s in the former USSR when coverage dropped?⁴ When only a small number of parents follow the advice not to vaccinate, and coverage levels for a particular vaccine are high, the number of cases of the disease occurring is likely to be very low. For certain vaccines, if around 5% of infants do not get immunised due to parental neglect or choice, the unimmunised child will be protected by "herd immunity"-in other words the immunised protect the unimmunised. For parents "doing their duty" by getting their baby immunised, this may seem unjust. The situation changes, however, when vaccine coverage drops to lower levels, resulting in outbreaks of the disease when virtually every unimmunised child (in the case, for instance, of measles) will contract the disease.

WHAT IS THE RESPONSIBILITY OF THE POLITICIAN?

Should vaccination be considered so important in a nation's life that it is above party politics? Vaccination would then become a "superordinate objective" that is, an objective so important that it is placed in the same category as the right to freedom of speech, free movement, shelter, and enough to eat. Should the politician make a distinction between issues surrounding vaccination and those on which his electorate vote him into government? While politicians as a group are renowned the world over for expediency, half truths, and deception to obtain political ends, surely vaccination must be preserved from this. If decisions are needed regarding national immunisation policy, should it not be the role of a non-partisan advisory committee that has the confidence of all parties and the public?

Can there ever be a justification for providing incomplete disclosure to the public in relation to vaccines? History has repeatedly shown that politicians and other individuals who do this in the political arena, claiming to advance the public good, are potentially practising one of the most dangerous forms of deceit. Such actions are undertaken apparently, on the basis of the benefits they may confer and the actual harm they can avoid. To act paternalistically is to guide and even to coerce people in order to protect them and to serve their best interests (as judged by others). It is similar to a father's actions on behalf of his child, keeping him out of harm's way.

Is it, then, acceptable to present limited information to a naïve audience who is unable or incapable of judging what is right in such medical issues? Using this argument, can ministries of health justify calling a vaccine safe, knowing it could cause encephalitis among a small number of their citizens, while at the same time saving thousands of lives and millions of illnesses amongt the total population?

A strong case can be made for limiting information provided to the illiterate mother in tropical Africa who has seen children in her village die from the complications of measles and who is likely to need little convincing to accept the measles vaccine for her daughter. For this mother, the statement that the vaccine is safe may be ethically acceptable, satisfy her, and convince local sceptics more readily than in the industrialised countries. In areas where measles is rare, parents and clients may need much wider ranging discussions and information before accepting a vaccine that appears to have only "herd" benefits along with some level of risk.

WHAT IS THE RESPONSIBILITY OF HEALTH PROFESSIONALS?

The health care worker cannot operate ethically if he is not fully informed about both the scientific facts and the societal issues surrounding vaccine safety. Because he is part of the societal spectrum, he will also bring to the interaction with the parent his own perceptions and values. These may be ambivalent, with a level of uncertainty about the value of immunisation—something that is inevitably going to be conveyed at some level to parents needing assistance in decision making. He may not fully realise the enormous potential his profession has for influencing the parents in their decision making process.

In some instances, there will be a reluctance to guide the parent one way or another because of these uncertainties. There may be a fear of being found to have given wrong advice, or advice that ultimately resulted in a child thought to be vaccine damaged. The fear may be related to the ethics of advice giving or about the possibility of being sued for malpractice.

Honesty is one of the qualities most sought by patients in their relationship with health care professionals, yet teaching about honesty with patients is almost non-existent in nursing and medical training.⁵ If all the facts are not laid out to the parent at the time of vaccination, will health care workers be seen as providing incomplete information regarding vaccine safety? They have certainly been accused of this.^{6 7} Vaccines are now available that have been shown to be as safe as humanly possible, products that save millions of lives a year and have the potential for saving many more. There is no need to The health care worker about to administer a vaccine to a child could assure the mother that the vaccine is safe, knowing in his understanding that it is likely that the child (and society at large) will be very much better off if the vaccine is given. Or he could "truth dump"³ and inform the mother of initial side effects and the potential one in a million chance of encephalitis or other reactions. If the mother is alarmed by too much information and leaves without the vaccine being given, has the health professional served the best interests of the child, the parent, the public, or himself? Whichever alternative is chosen, shouldn't it also include the information that, despite the slight risk from the vaccine, there is overall a much greater risk from contracting the disease?

WHAT IS THE RESPONSIBILITY OF RESEARCHERS?

The first ethical principle of the researcher is to be honest in both the conduct of the research and its reporting. He must also understand and communicate the limitations of his study. The write up must be of a standard that will allow the experiment to be repeated exactly by another researcher seeking to validate the work. The results and conclusions must be limited to what has been shown by the study, and personal views should only be expressed if they are clearly identified as such, and not given the same weight in the report as the scientific observations.

But sometimes the truth may get lost somewhere. There may be occasions when a researcher presents his results in an honest way but his findings are later proved to be incorrect. When individuals convey false information they believe to be true, such action may still be considered ethical—there is no intention to deceive. The researcher who believes he has made an observation about a vaccine adverse event may feel ethically obliged to publish his results. But if it is later discovered that statements made by him are false, should the scientist be exonerated from having knowingly spread falsehood? Should the researcher be condemned if his research results in a loss of confidence in the vaccine in question? How certain should he be of his findings before exposing them to public scrutiny and risking a loss of confidence in the vaccine?

WHAT IS THE RESPONSIBILITY OF THE MEDICAL PRESS?

The journal receiving the raw manuscript relating to research into the safety of vaccines also faces a number of ethical dilemmas. Has the editor understood the limitations of the study? Should he go ahead and publish what may turn out to be false claims and shoddy evidence? To refuse to publish or ignore such data may infringe upon the journal's moral obligation to the readership and its freedom to publish. Even though the manuscript's claims challenge current conventional wisdom, its findings may turn out to be the seminal groundwork on the subject for the future. Should an article be rejected because of inadequate standards even if the resulting paper would be of high interest? What should the editor do if subsequent published research shows an article he accepted for publication is in error?

The common practice for most journals is to call on a panel of experts to undertake a peer review of an article before its acceptance. But flaws in the research may be hard to detect. Reviewers are unlikely to be in a position to repeat the observations for themselves—and may allow the paper's publication. Ultimately, who owns the ethical responsibility for such a course of action? Has anyone intentionally deceived? An infuriated public feels helpless when confronted by such shifting sands of responsibility. How did the truth become lost, and who has misled them?

WHAT IS THE RESPONSIBILITY OF THE MEDIA IN GENERAL?

Some of the key principles of the press include accuracy, impartiality, and freedom to publish. But how is this balanced with the possibility of providing the public with poor or incorrect information pertaining to such life decisions as whether to vaccinate? Is the newspaper or television channel with national readership or audience to blame if they simply report what a scientist said, and it later turns out that he was an unreliable witness who gave incorrect information? If this information causes a drop in vaccine uptake and eventually an outbreak with loss of life, whose responsibility is it? Is there a difference between the responsibility of the reporter, the sub editor (the person who writes the headline), and the editor in how the information is presented to the public?

When a story is shown to be inaccurate or wrong, should the paper, journal, television, or radio show provide a correction or retraction with the same level of prominence as the original feature? Hiding a retraction in small print or failing to provide any at all is surely not ethical practice.

COMMUNICATION CHALLENGE

The ability of individual professionals to communicate the virtues or otherwise of vaccines is highly variable, particularly their skill in getting across complicated concepts such as causality.⁸ If additional aspects of vaccine safety enter the public dialogue, such as the possibility that MMR vaccine might be causative in autism, medical science can investigate the complaint openly. But the information on its own may not be sufficient to change the public's mind. Unfortunately, even the United States Institute of Medicine's impartial committee report failed to convince all congressmen of the vaccine's important information in the debate will depend on both the communication skills, and the credibility, of the source.

Suspicion that professionals have not provided the whole story about vaccines does not, by itself, explain the loss of trust prevalent in our society today. Yet, certain activities aggravate the situation. Those who discover they have been given incomplete information are resentful, disappointed, and suspicious of the sources of such deceptive practices. Once misled, the public become suspicious-no longer able to accept information unquestioningly. The result is a credibility gap between audience and source. The public no longer has confidence that the tainted source will restrict himself to subjects of little consequence. Prior to an outbreak of vaccine associated events, the public in Jordan had suspected the government of contaminating drinking water. The mistrust generated by the idea "they are trying to poison us" spilt over into the next crisis.¹⁰ The danger here is that authority figures are no longer trusted. Well meaning official statements, intended to reassure the public about vaccine safety, are now met with cries of conspiracy,¹¹ scorn, derision, or, at best, suspicion.

CONCLUSIONS

Vaccines are as safe as humans can presently make them. Yet as in any health intervention, some level of uncertainty will always remain. It is not easy to present this concept accurately and ethically to the public without giving them the impression that vaccination should be avoided. The information providers include a range of different groups: the government, health care workers, scientists, the medical press, the media as a whole, and the antivaccine lobby. Each comes to the debate with a slightly different agenda, a fact not widely understood. But if each actor in the play performs his part ethically, there is a real chance that high quality communication will take place and the public's confidence will be maintained in the process of immunisation. Sadly, this is not always the case.

Ultimately the public must decide whether to follow the lead of the antivaccine lobby and the media that encourages rejection of government vaccination policy, or to follow the official voice that encourages vaccination. But if confidence falters, vaccine coverage dips, and an outbreak of measles, mumps, or rubella ensues, with cases and deaths from measles, or babies born with congenital rubella syndrome, who, if anyone, will stand and say: "I misled them, I confused them, this is my responsibility"?

DISCUSSION

John Harris suggested that, as long as enough of the population were vaccinated, some individuals could choose to be "free riders"—avoiding vaccination safe in the knowledge that they had a degree of protection from exposure to infection. It might therefore be difficult to convince individual parents of the benefits and rationality of vaccination when there may be little risk, providing that a large enough pool of the population had been immunised. Was this likely to change if the balance shifted as a smaller and smaller percentage of the total population was vaccinated? He also asked whether vaccination could be considered a child protection issue? Could we force parents to take up vaccination on behalf of the community?

In John Clements's view, there are no absolute answers. Epidemiologists have shown that vaccination offers the best protection for children but this may be in conflict with the choice of the parent to immunise or not immunise. A useful way to approach the problem might be to say that a child has the right to protection when there is a safe tool. Then the debate moves to what is a safe tool? Certainly, the WHO promotes the concept of immunisation as a right for every child. It may not be the right of the parents to deny their child immunisation.

Onora O'Neill took up Dr Clements's comment that the press sometimes appears to be "public enemy number one". She suggested that it is perhaps less the press itself, than the process by which the press works which gives huge incentives to create scandals, scares, and exposés. John Clements said he certainly wasn't suggesting that the press is public enemy number one; in fact, the WHO works very successfully with the press. The health professions as a whole should use the media in a creative way for health education and promotion.

Professor David Coggon from the MRC environmental epidemiology unit in Southampton suggested that perhaps it is ethical to promote immunisation only as long as the risk of harm from not being immunised is greater than the risk of complications arising from being immunised. John Clements sympathised with this sentiment, using polio as an example. As long as there is polio in a country, oral immunisation is the most effective way of protecting against polio paralysis. Once a country ceases to have polio, the only risk of paralysis is the one in four million chance of being affected by the vaccine itself; so the equation then tips the other way.

Peter Lachmann recalled that some coercion of individuals for the greater good was necessary in the campaign to eradicate smallpox. Would coercion also be required if the WHO undertook a programme to eradicate measles? Some countries don't allow coercion as such, but make it difficult and expensive to refuse immunisation. For example, in France and the USA, it is not possible to send your children to state primary school unless they have been immunised to the national requirements.

In reply, John Clements said there were no plans for a campaign to eradicate measles. The WHO believes it is up to individual states to decide policies towards vaccination. In some communities, enthusiasm for immunisation has led to a grassroots demand for it from parents. This is the ideal.

AUTHORS' NOTE

We have used gender specific examples in the text for simplicity, but this should not be taken as endorsing any gender stereotype.

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Authors' affiliations

C J Clements, Department of Vaccines and Biologicals, World Health Organization, Geneva, Switzerland S Ratzan, US Agency for International Development, Washington, USA

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