EDITORIAL

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A Risk Worth Taking?

I. Ralph Edwards

Uppsala Monitoring Centre, Uppsala, Sweden

Vaccine vigilance has a number of significant and well known challenges associated with it. One of the most obvious is that many safety issues are a matter of continuous public debate, which have damaging effects on vaccine programmes and do not seem to be laid to rest.[1] The measles, mumps and rubella (MMR) vaccine scare damaged the vaccination programme in the UK for about a decade with a resulting increase in the number of measles cases, and only now is the vaccination rate against measles returning to normal. The relationship between MMR vaccination and autism has been shown to be erroneous at best and may even have been the subject of scientific fraud.[1]

A recent feature in the *British Medical Journal* discusses the general concerns about vaccination and the role played by the 'anti-vaccination lobby'. It points to the multiplicity of such lobby groups, the different issues they espouse and their attitudes towards vaccination.[1] The article offers few suggestions as to how the situation might be changed, but has great value in giving a description of the challenges. Below are some selected points to consider.

- Many of the action groups are small and built around a single case, or few cases, of children who have developed serious illness after vaccination. Their parents are looking for reasons and proximate prior vaccination may seem compelling.
- Lobbyists make wide and active use of the media and internet.
- The story they tell of human tragedy is immediate and compelling. The messages are linked with the promotion of uncertainty (there is so much that is unknown in science) or non-disprovable hypotheses (generally linking 'environmental diseases' with increased vaccination in children).
- Many of the campaigners are anti-establishment, interested in alternative medicine, and generally concerned about government cover-up and industry profitability.

Because of the continuing media pressure, many of those responsible for vaccination programmes have apparently become, or tried to become, immune to the assault of the anti-vaccination lobbyists.[1] Most of the responses by experts reiterate the safety of vaccines, point out the necessity of herd immunity, and assert the need to consider only scientific evidence. These approaches are not likely to be effective on the hard core of anti-vaccination campaigners, and indeed the public, when the case for personal tragedy is so strongly presented and contrasted with impersonal science, and uncertainty; chance happenings are not easy for parents to accept when serious illness strikes a loved child who has been otherwise fit and happy.

Moreover, in the enthusiasm for advocating vaccination to gain the desired herd immunity, the pressure to vaccinate is clearly felt by the public.[1] The move to vaccinate large numbers has become an issue in the Netherlands for vaccination against human papillomavirus (HPV),[2] which concerns the 70% level of protection afforded set against the costs of the vaccine, with a background of falling cervical cancer rates, and the relatively low costs and success of screening for cervical cancer. Other questions come to mind. Will the situation become one where young women who think they are protected will be worse off because they neglect screening? If one

emphasises that the protection is incomplete, then why bother with vaccination? Such a debate can be seen as negative if one is concerned only about the promotion of vaccination, but it really is a debate that challenges all medical interventions to prove their economic worth, not just the humanitarian value out of context of other healthcare needs.

Paradoxically, vaccination programmes suffer from their own success. Many of the diseases that childhood vaccination is used for are not now known to many parents (although I have known those who have died from polio, tetanus and tuberculosis) so it is difficult for them to see individual benefit for their child. Because serious vaccine-induced injury is rare, there are significant challenges in getting good evidence on case causality, and the success of mass vaccination makes it difficult to do epidemiological studies with satisfactory controls. All of this heightens the uncertainty felt by experts as they face the public: this must have its impact on our own presentation to the public. A good example of this is the link between tetanus toxoid and Guillain-Barré syndrome, which is not found as an association in epidemiological studies but has been demonstrated to occur on two rechallenges in one patient. No-one can deny that the reaction can occur on the current information, but its rarity makes it invisible above the background in an active study of new cases of Guillain-Barré syndrome in over 23 million adults in the US.[3]

On top of all this, the minor adverse events related to immunization are a constant reinforcement to the public that vaccination might be harmful. In an atmosphere of distrust, even relatively minor reactions after vaccination are likely to cause more concerns to parents. Therefore, it is very important to be clear in our statements about these 'systems errors'.

Are there any possible productive ways forward? I am sure this question has been asked by many, but the answers lie in the difficult areas of public expectancy and trust of experts and politicians, and because of the scientific challenges of being at all certain about the causality of rare events.

It is natural for anyone to want minimum risk, or no risk, for one's children, but we all know that is impossible. What we might agree is that an acceptably low risk is a different matter. The risks of serious consequences caused by vaccination are very small indeed: smaller than the 10 773 hospital admissions caused by accidents with socks and tights that caught the headlines in 1999 in the UK.[4] This was regarded almost as a joke and shows that public perceptions of risk are fickle, particularly so when control is in the individual's hands and the risk area is familiar.

We should not be so eager to merely promote vaccination but to pose the challenge of disease eradication to the public: 'Do you want to help to remove serious diseases from our lives?' At the moment it is authorities that make the decisions; they decide for the public. That should be changed to include the public in decisions on vaccination, even more than now, as well as to have the public support vaccination campaigns.

We should not hide the instances of adverse reactions to vaccines, nor the adverse events following immunization that are not related to the vaccine itself. This information should be not only passively available but made into a suitably graphic, easily presented format that can be used by vaccinators in explaining risks to parents, and to help put into context any known adverse events with the number of vaccinations and the benefits of vaccination. The UK National Health Service website[5] very reasonably answers a broad question about vaccine safety by saying "No vaccine is totally without side effects". There is also a broad statement that the risk of the disease is very much greater than the risk of the vaccine. But the challenge for a parent is "in deciding whether to have your child immunised you need to weigh up the risks of the vaccine against those from the disease". This statement does not include the risk of getting the disease, nor does it give any indication of how to do such a balancing act. An important ethical question is involved here. If a parent is to make a decision for a medical procedure on behalf of their child, who is in the best of health, for the protection of the public as well as for individual prophylaxis, it is right that true *informed* consent is obtained on

the risk balance. In this context, it is interesting to note the difference between introducing a new vaccine, such as HPV, when the disease risk is more imminent, compared with the use of even the new, lower risk, inactivated poliomyelitis vaccination, let alone the live attenuated oral vaccine, where the disease risk in most countries is now vanishingly small.

There are many websites available that give all kinds of useful information; for example, one from the independent US Immunization Action Coalition (of several health professional groups),[6] which also gives very useful indications to other sources of sound information. In fact I was able to find so many excellent websites that I fell into a browsing reverie, but in spite of being able to find so very much good information, I was left with some negative impressions:

- The language and concept levels were relatively sophisticated.
- Information on the Internet is passive: there is no attractive, repeated active message.
- There was information overload and some contradictions even within documents (that inactivated polio vaccine is 'safe', but then giving information about what to do when something goes wrong after its use, as well as warnings on allergies to the vaccine and to some antibacterials) and a bewildering use of jargon related to different types of vaccines.
- In analyses of adverse effects, if there was doubt about causality, there was nearly always a nuance of expression that the vaccine was not to blame rather than an unbiased statement of doubt. I liked the statement on rare adverse reactions to diphtheria vaccination: ''… these are so rare it is hard to tell if they are caused by the vaccine''. This seems more honest and clear than ''there were no cases with a proven causal relationship''.
- Generally, there should always be advice about what parents should expect from vaccination, how to prepare for it and what to do if a child is ill after immunization (which was usually, but not always, present on websites) as well as information about how such a child will be investigated. This latter piece of information is also sometimes well done but it must cover the challenge of causality versus chance as well as the general diagnostic approach.
- Similarly, whilst it is a very good idea to offer financial relief and support for a child who has serious damage from vaccination, the general ways in which causality will be determined, including what to do in situations of doubt, must be very clear. Justice must be seen to be done.

In summary, there is an enormous amount of effort put into providing good information for the public on vaccines. The main problem is that such messages are often broad generalizations and largely promote the undoubted effectiveness of vaccines in public health and their safety.

If we are to convince the public and the media, perhaps we should pursue with them the idea that all vaccines have a risk and are not safe (in the sense of 100% safe); that the risk is very small for serious events, mostly to the level where there is scientific doubt about causality; and that the benefit is to remove the disease from society, with some smaller benefits for individuals (where the disease is not very prevalent). In addition, we should promote all the efforts we take to ensure the lowest risk for immunization, as well as how we investigate and support anyone who could be damaged by a vaccine. Only then will we have parents who can comfortably answer the question 'Is the risk worth taking?', when they need to decide to vaccinate their children.

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References

1. Coombes R. Vaccine disputes. BMJ 2009; 338: b2435
2. de Kok IM, van Ballegooijen M, Habbema JD. Cost-effectiveness analysis of human papillomavirus vaccination in the Netherlands. J Natl Cancer Inst. Epub 2009 Jul 10
3. Tuttle J, Chen RT, Rantala H, et al. The risk of Guillain-Barre syndrome after tetanus-toxoid-containing vaccines in adults and children in the United States. Am J Public Health 1997; 87 (12): 2045-8

4. Arthur C. Beware the loofah, beware the tea cosy. Most of all, watch out for perilous socks [online]. Available from URL: http://www.independent.co.uk/life-style/health-and-families/health-news/beware-the-loofah-beware-the-tea-cosy-most-of-all-watch-out-for-perilous-socks-673112.html [Accessed 2009 Jun 15]
5. Immunisation FAQs. What is the risk of side effects from a vaccine? [online]. Available from URL: http://www.immunisation.nhs.uk/FAQs/What_is_the_risk_of_side_effects_from_a_vaccine [Accessed 2009 Jun 15]
6. Immunization Action Coalition. Vaccines safety sites [online]. Available from URL: http://www.vaccineinformation.org/safety.asp [Accessed 2009 Jun 15]

Correspondence: Professor *I. Ralph Edwards*, Uppsala Monitoring Centre, Stora Torget 3, Uppsala S-75320, Sweden.
E-mail: ralph.edwards@who-umc.org