Primary care

Ethical debate

Vaccination against mumps, measles, and rubella: is there a case for deepening the debate?

Complex issues relating to ethics, values, and the nature of evidence lie behind the decision whether to give the MMR (mumps, measles, and rubella) vaccine. Tom Heller, a general practitioner, is uncomfortable with the evidence that the vaccine is safe. Together with Dick Heller, an epidemiologist, and Stephen Pattison, an ethicist, he explores some of the processes involved in doctors' decisions about whether to vaccinate.

How safe is MMR vaccine?

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BMJ 2001;323:838-40

My duties as a general practitioner include immunising babies and small children against a range of common diseases. Recently, I have been increasingly uncomfortable when giving the combined mumps, measles, and rubella (MMR) vaccine. I find myself wondering if I would submit my own children for this immunisation if they were currently at that age.

I find it difficult to be certain that the vaccine is as safe as the authorities say that it is. Somehow, the more strident the experts become, the less believable I seem to find them. The Department of Health website (http://193.32.28.83/mmrvac.htm) gives many references and internet links to the published studies that support its views, but it gives only one reference that raises the issue of a link between MMR vaccine and potential adverse reactions.

The partial use of evidence that is apparent within official pronouncements is echoed by other experts. For example, Elliman and Bedford focus on possible problems with the research methods of people concerned about possible adverse effects of the MMR vaccine.¹ They do not mention potential problems with the research that concludes that the vaccines are safe. In addition, what are we to make of these and other researchers² who declare funding from drug manufacturers involved in manufacturing vaccines?

Listening to people and parents

The NHS Plan emphasises the need to give people in receipt of treatment and services a greater part in the decisions that affect them and the NHS in general.³ However, for some reason, the choices seem restricted when it comes to discussing MMR vaccine. But parents remain anxious. Those with autistic children have become sensitised to the possibility that the condition may have been caused by an intervention such as vaccination.⁴

Other parents are convinced of the link between the MMR vaccine and their child's subsequent development of autism and have formed support groups and lobbying organisations. In the United Kingdom the main organisation is JABS (Justice, Awareness, and Basic Support, www.jabs.org.uk). When does a series of individual observations from families with affected children count as evidence if each one is dismissed as an isolated incident?

Professional issues

In the United Kingdom, general practitioners receive a fee for each child immunised and other payments are triggered for meeting targets. Missing these targets would have serious consequences for the financial



Whether to vaccinate children can be a difficult decision

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stability of the practice, and there is considerable pressure on members of the team to ensure that children are immunised with every recommended vaccine.

I am not alone in my concern, and possible confusion, about administering the MMR vaccine. A recent survey of health workers in north Wales sought to elicit the knowledge, attitudes, and practices relating to MMR vaccine, particularly the second dose.⁵ Only 45% of the professionals (54% of the general practitioners) agreed completely with the policy of giving the second dose of the MMR vaccine. These professional concerns do not seem to have greatly affected the numbers of children receiving the vaccine, and national MMR coverage has only fallen from 91% in 1994-5 to 88% in 1998-9, although in some districts the uptake is below 75%.⁶

It is not easy to question authority these days.⁷ Andrew Wakefield, the author of some of the studies

Validity of the evidence

Dick Heller

The basic question is, "what is the real evidence about the dangers of MMR vaccine?" The evidence for a link between MMR vaccine and the development of autism is based on a hypothesis derived from an observation that the parents of eight out of 12 children investigated for gastrointestinal symptoms and autism associated the onset of autism with the MMR vaccine.¹ There has been no evidence to support the hypothesis.

Several studies have been reported as negating the hypothesis, although there are doubts about each of these. Some of the studies are ecological in design; they examine trends in the development of autism with the trends in use of MMR vaccine. Recently reported studies^{2 3} show that the rise in reported autism over the past decade or so bears no relation to any changes in rates of MMR vaccination, and this is consistent with other data showing no epidemiological evidence for a causal association.^{4 5} Most people who have reviewed the evidence have rejected the notion that MMR might be associated with autism.⁶⁴ A recent review from the US Institute of Medicine concludes that "the evidence favours rejection of a causal relationship."⁹

Listening to people and parents

Unfortunately, patients are often not precise at identifying the cause of their illness, and personal anecdote can do no more than suggest a hypothesis that needs formal scientific testing: "Hypotheses can become 'facts' long before the critical data are in."¹⁰ The concern in the community comes from the difficulty in understanding and expressing evidence. All we have at the moment is a hypothesis based on anecdote, without supporting evidence. Any evidence that does exist, however weak it might be perceived to be, fails to support the hypothesis.

Comparing risk of autism with risk of vaccine preventable diseases

It is difficult to measure, express, and understand risk. The prevalence of autistic spectrum disorders is that have questioned the development and subsequent use of MMR vaccine, has been subjected to personal as well as professional abuse (www.autism-spectrum.com/ vaccine.htm). Perhaps keeping my head down and not even talking about these issues would be the easiest option.

Competing interests: None declared.

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91/100 000 children.¹¹ If as many as 15% of these children had autism as a result of the MMR vaccine, 7326 children would have to be vaccinated to "produce" one child with autism. How many cases of mumps, measles, or rubella would the lack of vaccination of this number of children produce? What would their complication rates be? Unfortunately, we have not established good intelligence systems to explore the public health effects of changes in immunisation.¹² We do know that for measles alone, death rates are 1-2 per 1000 infected people in the United States and that 1 in 1000 will get encephalitis (and some of these will have permanent brain damage).13 If most children who were not vaccinated developed measles, the complication rates suggest that discontinuing vaccination would do considerable harm and that this harm would far outweigh any possible benefit from possibly reducing the incidence of autism.

These common communicable diseases cannot be eliminated if the levels of immunisation in the community fall below a critical value. It is a legitimate concern of those with responsibility for public health to seek to maintain high vaccination rates.

In summary, I feel that there is no evidence that MMR vaccine causes autism and considerable evidence to say that it does not. I believe that the dangers of reducing vaccination on the basis of an unsubstantiated hypothesis are considerable.

Competing interests: None declared.

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BMJ: first published as 10.1136/bmj.323.7317.838 on 13 October 2001. Downloaded from http://www.bmj.com/ on 27 April 2024 by guest. Protected by copyright

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Dealing with uncertainty

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Pattisons@ cardiff.ac.uk Some moral theorists would say that Tom Heller is just having an emotional reaction, but I would say that this kind of discomfort is part of moral judgment.¹ He applies one of the best known tests for assaying the rightness or wrongness of acts called the golden rule,² expressing this as, "would I submit my own children for this immunisation if they were currently at that age?" He also discusses the voice of authority that says it is safe to administer MMR vaccine and how his doubts are amplified in inverse proportion to the experts' certainty. The question is, then, how might his colleagues and members of the public be helped to live with reality and limits of knowledge without necessarily abandoning useful public health practices that may be in their long term interests?

Although the scientists may be deemed to be working on one paradigm of rationality and correlative enlightenment, ordinary people, including doctors, have a more complex view of reality. This kind of composite knowledge is often seen, from a rational point of view, as superstition and irrationality which needs to be dispelled and destroyed.

You cannot discount another's knowledge even if you may doubt its scientific value. Making a decision to have a child immunised is a moral dilemma for parents and this must be respected. Not acknowledging others' moral dilemmas does not make them go away. There is a crisis of expert authority and trust in scientific judgment surrounding MMR vaccine and a crisis of

11 Roberts R. MMR vaccination and autism. BMJ 1998;316:1824.

- 12 Heller RC, Page J. A population perspective to evidence based medicine—"evidence for population health." *J Epidemiol Community Health* (in press).
- 13 Watson JC, Hadler SC, Dykewicz CA, Reef S, Phillips L Measles, mumps, and rubella–vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkh Rep 1998;47(RR-8):1-57.

mutual respect. A decision needs to be made about what kind of evidence counts and how this is weighed and related to lay views of reality. In doing so, scientists must take care not to treat fear and reservation as ignorance and then try to destroy it with a blunt "rational" instrument.

I wonder if people know that general practitioners are given financial incentives to deliver a certain proportion of vaccinations. This again raises the issue of whether doctors are acting in the best interests of the individuals or whether they are dancing to a financial tune. We need to ask whose interests do and should clinicians serve—do they focus on individuals, or is their job to deliver centrally determined, scientifically informed, health policy?

Risk and power are unequally distributed in this situation. The government determines the risk management strategy to deal with the diseases mumps, measles, and rubella. However, it is individual clinicians and parents who have to implement this strategy and may have to live with its consequences. The MMR vaccine issue focuses many of our concerns about ethical and responsive public health in the clinical context in a helpful way. We are trying to work out what individually respectful and sensitive, publicly accountable, evidence based clinical practice might look like.

Competing interests: None declared.

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GP's response

Tom Heller

Groups that have endorsed safety record of MMR vaccine¹

Committee on Safety of Medicines Committee on Safety of Medicines and Medicines Control Agency Joint Committee on Vaccination and Immunisation Working group of the Medical Research Council Public Health Laboratory Service Communicable Disease Surveillance Centre Royal College of Paediatrics and Child Health World Health Organization

I feel as though I have been through a process which is rather similar to the explorations that many parents go through at the time of taking important vaccine related decisions on behalf of their children. My search for understanding will have to continue. Of course, I respect that the full weight of the most powerful authority figures in modern medicine have concluded that MMR vaccine is safe (box), but lingering doubts remain for me and for many others.

My final thoughts are summed up in the following quotation: "Informed refusal must remain an acceptable choice in a free democracy, and the culture of informed consent, with both religious and philosophical exemption, must be maintained. The difficult balancing act will be in determining the right of the state to control an infectious disease and the right of the individual to chose."²

¹ Committee on Safety of Medicines. MMR vaccine: the facts. Current Problems in Pharmacovigilance 2001;27:3.

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