

VACCINATION AND ETHICAL ISSUES

Sharon Kling, MB ChB, DCH(SA) FC Paed(SA), MMed(Paed), MPhil

Department of Paediatrics and Child Health, Tygerberg Children's Hospital and Stellenbosch University, Parow, South Africa

ABSTRACT

Compulsory vaccination was originally introduced for smallpox, and mandatory immunisation is still in force in some countries. Vaccination is no longer compulsory in South Africa, but carries significant benefits both for individuals and for the community. An ethical dilemma is posed by the fact that the vaccine is administered to a healthy child, with the intention of protecting both the individual child and the community, but the risk has to be borne by the child alone. The antivaccination lobby claims that there is an association between measles-mumps-rubella (MMR) vaccine and autism, but there are no data to support this. Parents generally have the best interests of the child at heart, and parental autonomy to refuse vaccination should be respected unless the child is considered to be at significant risk from that refusal. Equity of access to vaccinations is ensured by the public health system in South Africa. The introduction of pneumococcal conjugate vaccine and rotavirus vaccine into the immunisation programme is in the interests of the public, but carries significant cost implications.

THE CASE

Mrs I consults Dr K because she has been told she has to have her baby immunised at the clinic. She understands that there are side-effects associated with vaccination and has decided not to subject her baby to this intervention, as she believes the risks of him contracting one of the infectious diseases is very low. Dr K says that she has to have the baby immunised as this is in his best interests and the risks are negligible. Is Dr K correct?

THE HISTORY OF VACCINATION AND ETHICS

The first vaccination, used to prevent smallpox, involved the transfer of virulent material between subjects, and was called variolation.¹ This method of vaccination was associated with a high risk of contracting smallpox, and many parents refused to have their children vaccinated. One of these parents was Benjamin Franklin, who lost his son to smallpox, to his eternal regret.

What is interesting about the development of the early vaccines is that they were tested on six prisoners who were promised pardons if they survived. After this test was successful and the prisoners were released, the smallpox vaccine was trialled on five children in an

orphanage. When they survived the test, children belonging to the royal family were immunised.¹

Jenner substituted cowpox for smallpox, and showed that he was able to boost the immunity of humans against smallpox. Jenner's initial vaccine tests were done on James Phipps, the son of a labourer. It is uncertain whether James or his parents gave informed consent for this test!¹ In France the Jenner vaccine was tested on orphans. This was thought to be morally acceptable because orphaned children were considered to be less important than children who had parents. Pasteur improved upon Jenner's method by attenuating the virulence of the infectious organism and using this in vaccination.¹

According to Bazin¹ vaccination was viewed in a positive light by the majority of the civil administration for two reasons: (i) people were protected from the smallpox; and (ii) the number of people who could be taxed and serve in the military was increased! Mothers were paid to bring their children for vaccination, thus attracting poor people. Certificates of vaccination were issued, together with financial incentives to poor people, to increase the number of vaccinees.

COMPULSORY VACCINATION

Compulsory vaccination for smallpox was introduced into Europe and some states in the USA in the 1800s.² These compulsory programmes are credited with contributing to the success of immunisation and subsequent eradication of diseases such as smallpox. In the UK the smallpox legislation was repealed in 1971 because of the virtual disappearance of the disease. However, other childhood vaccinations remained compulsory until 2004, when the British Medical Association determined that such a policy was inappropriate.² In Australia smallpox vaccination was not legislated, but childhood vaccination before school entry became a legal requirement in 1991, albeit with the possibility of exemptions being obtained. A subsequent financial incentive was introduced in 1997 to improve vaccine coverage and was legislated in 1999.^{2,3}

In the USA the Centers for Disease Control and Prevention (CDC) proposed that an immunisation policy before school entry be legislated, and this was adopted by all the states.² Exemptions are permitted for medical reasons in all states, with limited exemptions allowed for religious and philosophical reasons in 20 states.⁴

In South Africa BCG and polio vaccinations used to be compulsory, but these laws were repealed in 1987 (personal communication, Dr Neil Cameron). According to these regulations (No. R2438, section 13), in an emergency the Director-General of Health was empowered to identify an area and appoint people to carry out a campaign and isolate anyone that was not vaccinated. Travellers from a high-risk area entering South Africa are compelled to have been vaccinated against yellow fever. According to Dr Cameron, 'Besides yellow fever vaccine the only legal requirement for immunisation in SA at present, that I know of, is notice 2432 of 1998 (*Gov Gazette* 19377) ADMIS-SION POLICY FOR ORDINARY SCHOOLS in terms of the National Health Policy Act, 1996 (No 27 of 1996)

Correspondence: Dr Sharon Kling, Department of Paediatrics and Child Health, Faculty of Health Sciences, Stellenbosch University, P O Box 19063, Tygerberg 7505. Tel +27-21-938-9506, fax +27-21-938-9138, e-mail sk@sun.ac.za

Section 16: On application for admission, a parent must show proof that the learner has been immunised against the following communicable diseases: polio, measles, tuberculosis, diphtheria, tetanus and hepatitis B. If the parent is unable to show proof of immunisation, the principal must advise the parent on having the learner immunised as part of the free primary health care programme.'

RISKS AND BENEFITS OF IMMUNISATION

There are real risks associated with vaccination programmes. In the past live attenuated vaccines against respiratory syncytial virus resulted in more severe disease and increased mortality in infants. In 1976 the vaccination programme against swine influenza in the USA was stopped because it was thought to be associated with a concomitant increase in Guillain-Barré syndrome.⁵ This association could not be confirmed after seasonal influenza vaccination.⁵ The whole cell pertussis vaccine was previously thought to be associated with an increased risk of postvaccination encephalopathy, but this has been shown to be untrue.⁶ A recent study from the USA revealed that an increase in immunisation exemptions was associated with an increased incidence in pertussis.⁷ Reduced vaccination rates in the UK in the 1970s resulted in many paediatric admissions for pertussis and about 28 children died from the disease.⁸

Previously the antivaccination lobby was vociferous in its objection to smallpox vaccination.⁹ The major objection to routine immunisation by the current antivaccination lobby is their belief in the association of measles-mumps-rubella (MMR) vaccine and autism. The adverse effects are attributed to the combination of the MMR vaccine and thimerosal (thiomersal) in the vaccines.¹⁰ There are no data to support any association between MMR vaccine and autism. There are in excess of 5 300 claims for autism against the Secretary of Health and Human Services pending in the USA. The first 3 test cases were adjudicated in February 2009 and the National Vaccine Injury Compensation Program (VICP) found that 'the petitioners in this litigation have been the victims of bad science.'¹¹ The bad press and resultant decrease in MMR vaccination has resulted in increased measles incidence in certain communities.

ETHICAL CONSIDERATIONS

The 'prevention problem'

One of the main ethical objections to vaccination has been called the 'prevention problem,' 'a concern about the supposedly inequitable distribution of benefits and risks of harm resulting from preventive medicine's focus on population-based interventions.'¹² Dawson¹² explicates it as follows: 'The key elements of the "prevention problem" are that:

- a) Preventive public health measures are performed upon asymptomatic individuals;
- b) Every such public health intervention will carry some risk of harm;
- c) The benefits of such interventions lie at the level of populations, whilst any risks of harm are borne by the individual participants in the programme.

'Conclusion: such preventive programmes are unethical (given the distribution of risk and benefits).'

Dawson¹² argues that the main successes of vaccination programmes lie in their ability to create herd immunity, and that herd immunity confers 'public good' on *all* individuals in the pertinent community. In addition, the vaccinated individual is also protected from the disease against which s/he has been vaccinated. Herd immuni-

ty also confers protection on unvaccinated individuals, as they will probably not be exposed to infection in that population. Dawson restates (c) above as follows: 'Risks are carried by individuals but both individuals and populations benefit where herd protection exists in the relevant population.'¹²

Respect for parental autonomy

In westernised medicine the biomedical ethical principle of respect for autonomy tends to weigh more heavily than the other three, viz. beneficence, non-maleficence and justice. This implies that the decision of an autonomous patient must be respected by the doctor, even if the doctor believes that the patient's decision is wrong.

Young children are not autonomous and their parents are the decision-makers in health care. Parents should have the 'best interests' of their children at heart and are thus tasked with making the correct decisions for their children regarding their health and welfare. In order to be able to do this, they must have the correct information. Inaccurate publicity regarding the safety of vaccines has impacted negatively on immunisation rates, especially in developed countries.

Where health care workers believe that the parents' decision is not in the best interests of the child, they can override parental decision-making. Generally this applies to clearly beneficial or life-saving treatment, and vaccination would not fall into one of these categories. An exception to this would occur in the case of rabies, where vaccination could be life-saving.¹³

Beneficence and non-maleficence

I would like to consider these two principles together. Beneficence refers to doing good, and could encompass the utilitarian outcome of the greater good for the majority. In the case of vaccination this refers to the 'common good' or 'public good.' Non-maleficence implies to 'do no harm.' Where vaccines carry risks, e.g. pertussis vaccine with the risk of encephalopathy in children with underlying neurological disorders, it may be justified to withhold vaccination from an individual child.

Justice

The South African Constitution guarantees children 'the right to ... basic health care services,' which would include immunisation.¹⁴ Distributive justice requires fair allocation of resources, and in South Africa the public health immunisation programme is available to all. The new Expanded Programme on Immunisation includes pneumococcal conjugate vaccine and rotavirus vaccine, at a potential additional cost in excess of R800 million per year (personal communication, Dr Neil Cameron). It is beyond the capacity of this article to debate whether the money could potentially be better utilised elsewhere, but other claims on the money have to be taken into consideration. Isaacs *et al.*¹⁰ state, 'Decision-making by governments clearly faces ethical challenges as costs of new vaccines rise and the pharmaceutical industry uses disease support groups to lobby on their behalf. For developing countries, cost is often the paramount issue. All resource-poor countries use oral polio vaccine (OPV), because they cannot afford inactivated polio vaccine (IPV).' OPV may be associated with paralysis, with an incidence of 1 in 2.4 million vaccine doses.

Global justice should ensure that all those who can benefit from vaccination have access to it. This should include access to safer vaccines, even if they are more expensive. According to Jenifer Ehreth¹⁵ immunisation

programmes 'represent a low risk investment in human capital development with a proven impact. They are highly cost effective, have significant economies of scale, and can be financially sustained by developing countries.'¹⁵ She points out that a child in the developing world can be immunised against polio, diphtheria, pertussis, measles and tetanus for less than US\$20.

The concept of 'justice' includes human rights. What rights do children and their parents have in respect of compulsory immunisation, and how does this impact on the rights of the community to be protected from infectious diseases?¹³ In terms of the SA Constitution parental rights are limited by the best interests of their children. Regarding immunisation, parents' rights to refuse to have their children vaccinated should be respected where the risk to the child is very small. Bradley¹³ argues that the community cannot insist on compulsory vaccination for all because the risk that an unimmunised child poses to an immunised child is very small. The solution therefore is to ensure that they themselves are immunised rather than demanding compulsory vaccination for all.¹³ It is interesting that objections against vaccination tend to occur in more developed and richer communities, where vaccine-preventable diseases are less of a problem.

The human papillomavirus (HPV) vaccine poses new dilemmas for vaccine ethics. Some countries have proposed compulsory vaccination for schoolgirls aged 10-12 years because of the risk posed by cervical cancer. However, others have argued that this infringes on the rights of those girls.¹⁰ Does a young girl have the right to request HPV vaccine but demand that her parents not be informed?¹⁶

And finally, how does the principle of justice apply to pandemic situations? Who should have access to influenza vaccine during a pandemic, when the amount of vaccine may be limited? Should it be reserved for health care workers at the coal face? And if a health care worker has been vaccinated against influenza, does that mean that there is an obligation on him/her to provide care to infected patients?

THE CASE

In the case above Dr K should listen carefully to Mrs I and try to ascertain what is worrying her. She should take the time to discuss the evidence for the vaccine's efficacy and share the studies of the risks with Mrs I. She should explain that the majority of adverse effects of vaccination are minor (local reactions at the injection site or fever) and that severe side-effects are very rare. She should also explain the benefits of routine immunisation for the individual child and for the community. She should thus encourage Mrs I to have her baby immunised, but should respect Mrs I's decision if she continues to refuse vaccination.

CONCLUSION

In considering the ethical issues in relation to vaccination, the freedom of the individual to choose has to be weighed against the public benefit derived from herd immunity. Generally, the majority of parents believe that vaccination is beneficial and they do have their children immunised. Persistent parental refusal despite counselling should be respected unless the child is considered to be at risk, in which case the parental decision could be overridden by the authorities.¹⁷

Declaration of conflict of interest

The author declares no conflict of interest in respect of the content of this article.

REFERENCES

1. Bazin H. The ethics of vaccine usage in society: lessons from the past. *Curr Opin Immunol* 2001; **13**: 505-510.
2. Salmon DA, Teret SP, MacIntyre CR, *et al*. Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future. *Lancet* 2006; **367**: 436-442.
3. Australian Department of Health and Ageing. The Seven Point Plan. www.health.gov.au. Accessed 10 September 2009.
4. Childcare and school immunization requirements. National Center for Immunization and Respiratory Diseases. <http://www2a.cdc.gov/nip/schoolsurv/immunizationRqmts.htm>. Accessed 10 September 2009.
5. Stowe J, Andrews N, Wise L, *et al*. Investigation of the temporal association of Guillain-Barré syndrome with influenza vaccine and influenzalike illness using the United Kingdom General Practice Research Database. *Am J Epidemiol* 2009; **169**: 382-388.
6. Ray P, Hayward J, Michelson D, *et al*. Encephalopathy after whole-cell pertussis or measles vaccination: lack of evidence for a causal association in a retrospective case-control study. *Pediatr Infect Dis J* 2006; **25**: 768-773.
7. Omer SB, Pan WKY, Halsey NA, *et al*. Nonmedical exemptions to school immunization requirements. Secular trends and association of state policies with pertussis incidence. *JAMA* 2006; **296**: 1757-1763.
8. Peltola H. What would happen if we stopped vaccination? *Lancet* 2000; **356**: 522.
9. Williamson S. Anti-vaccination leagues. *Arch Dis Child* 1984; **59**: 1195-1196.
10. Isaacs D, Kilham H, Leask J, *et al*. Ethical issues in immunisation. *Vaccine* 2009; **27**: 615-618.
11. Stewart AM. When vaccine injury claims go to court. *N Engl J Med* 2009; **360**: 2498-2500.
12. Dawson A. Vaccination and the prevention problem. *Bioethics* 2004; **18**: 515-530.
13. Bradley P. Should childhood immunisation be compulsory? *J Med Ethics* 1999; **25**: 330-334.
14. Constitution of the Republic of South Africa, Act No 108 of 1996. Chapter 2 Bill of Rights. <http://www.polity.org.za/html/govdocs/constitution/saconst02.html>. Accessed 21 February 2006.
15. Ehreth J. The global value of vaccination. *Vaccine* 2003; **21**: 596-600.
16. Brabin L, Roberts SA, Kitchener HC. A semi-qualitative study of attitudes to vaccinating adolescents against human papillomavirus without parental consent. *BMC Public Health* 2007; **7**: 20.
17. Omer SB, Salmon DA, Orenstein WA, *et al*. Vaccine refusal, mandatory immunization, and the risks of vaccine-preventable diseases. *N Engl J Med* 2009; **360**: 1981-1988.