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Chapter 10: Vaccination

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10.1 Introduction

Public health measures vary greatly in their impact upon individuals. Some measures such as sanitation and water filtration are imposed upon whole populations without adverse effect. Medical interventions such as breast cancer screening are transiently uncomfortable but not invasive. Cervical smear tests are invasive but have no known lasting effects. Other public health measures such as water fluoridation may affect individual recipients, and the dilemma for those responsible for determination of public policy is the extent to which public health benefits justify individual risks. Vaccination is invasive, and involves the administration of pharmaceuticals to people who are well. The benefits of vaccines are prospective and to some extent speculative, and there is concern that they may occasionally have serious permanent adverse effects upon those who receive them.

It is important to define 'vaccination'. When a person is vaccinated, an infectious agent – antigen – is introduced into her body. The aim is that her immune system will respond to the antigen by producing antibodies which will protect against the disease from which the antigen was derived. This response is immunisation. Vaccination is thus the process whose desired outcome, usually achieved in at least 90% of cases, is immunisation. The term 'immunisation' is often used to denote vaccination by politicians and others who wish to stress the intended benefits of the process. The percentage of cases in which vaccination leads to immunisation is termed the vaccine efficacy. This is usually measured as the percentage reduction in the incidence of the disease in a vaccinated population compared with that in an unvaccinated population. For example, if there were 100 cases per 10,000 people in the unvaccinated population, and 10 cases per 10,000 in the vaccinated population, the efficacy would be 90%.

Vaccines fall into two broad groups. Special vaccines are administered to people who are unusually vulnerable to particular disease – travellers, for example, or persons susceptible to

chest infections. Mass vaccines are those administered to as many people as possible, usually young children, in programmes recommended by the public health authority.

Vaccination has two purposes. All vaccines aim to protect vaccinees against disease. Mass vaccines are additionally aimed at eliminating infectious disease from the population. When this occurs, even unvaccinated individuals are protected via the process of herd immunity. The respective sizes of these two benefits depend upon the incidence and severity of each disease in the relevant population, and the vulnerability of the individual. Special vaccines invariably afford greater protection to the individual than to society. There are currently no realistic prospects of eliminating influenza from the United Kingdom, or yellow fever from sub-Saharan Africa, so the benefit to each person protected from those diseases is high. Most mass vaccines, if administered to sufficiently large percentages of target populations, serve both purposes.

The dual purpose of mass vaccines raises questions about whether vaccines are therapeutic. In recent years judges in common law jurisdictions have debated, in the context of authorising medical treatment for incompetent patients, whether it is appropriate to classify treatments as therapeutic or non-therapeutic¹. A sensible approach is to require courts to have as their primary concern the protection of patients' human rights, but this should subsume express consideration of whether the treatment was therapeutic. The physical necessity for, and outcome of, invasive treatment should form a key element of determining whether such treatment is truly best for the patient. This approach was adopted by Brennan J in Department of Health and Community Services (NT) v JWB and SMB (1992)².

There are various definitions of 'therapeutic'. A narrow definition is 'of or pertaining to the healing of disease', defining 'heal' as 'to make whole or sound in bodily condition; to free from disease or ailments, restore to health or soundness; to cure (of a disease or wound)'³. Because vaccinees are required to be well at the time vaccines are given, this definition does not encompass vaccination. A textbook definition is that a therapeutic treatment is one 'intended to benefit the particular individual'⁴. This does not apply to all vaccines: tetanus is unique amongst mass vaccines in protecting only the individual, and a 21st century child in the developed world derives little benefit from a vaccine such as polio – which the World Health Organisation (WHO) has declared to be eradicated from the Western Hemisphere⁵ – or diphtheria. A judicial view is that a treatment is therapeutic 'when it is administered

for the chief purpose of preventing, removing or ameliorating a cosmetic deformity, a pathological condition or a psychiatric disorder, provided the treatment is appropriate for and proportionate to the purpose for which it is administered'⁶. Most vaccines would probably fall within the first part of this definition, but rubella for boys would not, since the primary reason for rubella vaccination is the protection of unborn children. The second part of the judicial definition, requiring proportionality, is harder to determine because the risks of vaccines are unknown. If the benefits to the vaccinee are small, it may not be justifiable to take an unquantified risk, which would position the vaccine outside the judicial definition. There is thus an arguable case that not all mass vaccines are therapeutic.

The WHO's 1978 Alma-Ata Conference identified immunisation against the major infectious diseases as one of its primary health care aims⁷. The WHO's current vision of Health for All in the 21st Century includes health outcomes such as substantial reduction in the incidence of tuberculosis and the global eradication of polio and measles by 2005 and 2020 respectively⁸. The WHO has consistently recommended vaccination as an important element of international public health policy, and its global vaccination programmes have been responsible for successes such as the worldwide eradication of smallpox by May 1980⁹.

This chapter will focus on mass vaccination in Britain, drawing comparisons with the position in other north American and European jurisdictions.

10.8 The role of ethics and law in mass vaccination

An ethical dilemma posed by mass vaccination is the conflict between community benefit and respect for individual autonomy. The latter, recognising the right to control over one's own body and the right to determine one's own medical treatment, is a value central to the ethics of medical practice¹⁰. Medical paternalism, allowing health professionals to decide which treatment is best, is – at least in theory – no longer acceptable. There are, however, limits to autonomy. Where the autonomous decisions of one individual conflict with the autonomy or interests of others, qualifications must be placed on the right to free choice. The overriding moral obligation to respect autonomy has been challenged by those who argue that, by focusing on the rights of individuals, we neglect the needs and interests of the community as a whole. One philosophical approach underlying such challenges is communitarianism, which advocates collective welfare, collective responsibility and a shared

willingness to act with those values in mind¹¹. Communitarianism recognises that the interest of the community is a value to be taken into account in medical decision-making. This conflict between community values and respect for autonomy is relevant to the importance given to herd immunity in vaccination policy. It is exaggerated because the vaccinees are children who are as yet unable to exercise their autonomy.

This ethical dilemma is reflected in the law regulating medical treatment. In English law, as in most Western legal systems, a competent adult patient can only be treated with her own consent¹². On the grounds of public policy and potential harm to others the law places some limits on what treatment a competent adult can consent to¹³, but it is reluctant to impose treatment on an unwilling competent patient. In Secretary of State for the Home Department v Robb¹⁴, in which a prisoner was on a hunger strike, Thorpe J commented, 'It seems to me that within this jurisdiction there is perhaps stronger emphasis on the right of an individual's self-determination when balance comes to be struck between that right and any countervailing interests of the state'. English law thus purports to prioritise respect for autonomy, while some other jurisdictions have taken a more communitarian line and have recognised state interests when determining whether medical treatment should be given¹⁵.

The right of self-determination in English law is not, however, supported by a doctrine of informed consent. Whereas many jurisdictions recognise that a patient has the right to any information which a reasonable prudent patient might think material to decision making¹⁶, in English law the adequacy of information for informed consent is determined in accordance with what the reasonable doctor would think appropriate to tell the patient¹⁷. In relation to a competent adult patient therefore, although vaccination can be given only with the consent of the patient, the information given to the patient on vaccination risks may be abridged according to medical common practice. If public health objectives form part of that practice, the information may understate the risks so as to maximise uptake of vaccination. It is generally agreed, nonetheless, that the requirements for legally valid consent to medical treatment are that the consent should be freely given by a person of capacity who is appropriately informed¹⁸.

It is arguable that in cases of non-therapeutic medical treatment, such as when the patient is taking part in a clinical trial, respect for autonomy requires that the decision to participate should be dependent on knowing all the risks and benefits of treatment¹⁹. Since it is arguable

that at least some mass vaccines are not therapeutic²⁰, there is a case for imposing a higher burden of information disclosure for participation in mass vaccination programmes than for consent to special vaccines. This is supported by parental opinion: one survey indicated that 75.9% of parents (264 out of 368) would like to receive more information about vaccines than is routinely given to them²¹.

Where the vaccinee is a child, medical practice assumes that consent may be given on behalf of the child by a proxy – the child’s parent or guardian – or the state²². There are limits to the treatment that can be consented to by proxy: the usual requirement is that the treatment should be in the child’s ‘best interests’. The courts have been wary of allowing parents to consent to non-therapeutic treatments such as sterilisation, cosmetic surgery, bone marrow donation and blood tests to determine paternity, unless it can be established that the treatment fulfils this requirement in some way²³. The interests of the community would therefore be unlikely to justify any potentially harmful invasive treatment on the child’s body. If, however, it were shown that it was in the child’s wider best interests to live in a community which was disease-free, and if the risks posed to the child by vaccination were small, then valid proxy consent could be given. Any such consent should, however, be fully informed. This view, too, finds support among parents: a study showed that 68% of parents (249 out of 346) desired more information before they accepted vaccines for their children than if the vaccines had been for themselves²⁴.

The balance between community interests and respect for individual autonomy is a matter for national legislatures. Although their vaccine schedules differ, Britain, Canada and the USA share the WHO’s aim of eliminating or reducing the incidence of infectious diseases via herd immunity. This approach can be contrasted with the approach to vaccination in Japan, which prioritises the protection of individual children over benefits to society²⁵. Japanese children do not receive pertussis vaccine, for example, until they are over two years old, and the eradication of the disease in this age group prevents infection in infants²⁶.

Some states which favour herd immunity have laws reflecting the priority given to societal interests over individuals’ rights of self-determination. In the USA, for example, many states have laws requiring proof of immunity to the primary and secondary schedule diseases²⁷ as a condition of school entry. The laws vary, some applying only to admission to kindergarten and some to admission to every grade. Rubella vaccination is required by 50 states at school

entry, but only 41 states for students in all grades²⁸. Certain vaccinations are thereby effectively compulsory, and their administration can be enforced via the usual public health measures of administrative orders, penalties or injunctions²⁹. Vaccination against the wishes of the individual has been upheld by the Supreme Court, even where the vaccination is not for the benefit of the individual or is refused on religious grounds³⁰. France also has laws requiring children to be vaccinated against smallpox, diphtheria, tetanus, polio and tuberculosis³¹.

Vaccination is not currently compulsory in Britain. Smallpox vaccination was made compulsory in 1853 following a series of Acts 'designed to extend the practice of vaccination'³². Vaccination remained compulsory until the middle of the 20th century, when statute provided that each local authority should arrange for medical practitioners to vaccinate against smallpox and diphtheria³³. In 1977 this was amended to require only that all medical practitioners should be able to participate in vaccination³⁴.

The withdrawal of legal involvement in vaccination in Britain between the mid 19th century and the late 20th century probably reflects reduced public interest in, and concern about, infectious disease. During this period sanitary, medical and socio-economic advances have hugely reduced disease-associated mortality and morbidity, and most childhood diseases are no longer considered dangerous. The same cannot be said of the developing world, where the greater urgency of disease eradication might justify more intrusive vaccination laws.

In the developed world, however, there has been considerable recent concern about the possible adverse effects of vaccines. This concern is at least partly a result of the virtual elimination of many of the diseases which posed a threat to earlier generations, such that today's parents are less keenly aware of the benefits of vaccination and very conscious of possible vaccine risks. In one study of pertussis vaccine uptake the main threat to children's health was perceived to come from the vaccine rather than from the disease itself³⁵.

In Britain, therefore, vaccination policy is now determined by practice rather than law. The only statutory involvement in vaccination is in the provision of a system of financial recompense for those who claim to have been injured by the administration of vaccines³⁶. Given that mass vaccines are by their nature administered to as many children in any age cohort as possible, the lack of related law merits brief consideration. Statute law includes

substantial protection for adults in the workplace, for consumers and for personal data. It is possible to argue that these issues are of importance to law-makers, who are usually healthy, financially solvent, competent adults. If this argument is accepted, a contrast can be drawn with the dearth of law protecting those who are ill. Aside from the Mental Health Acts, most medical law is case-law, and most cases arise when patients need to challenge unregulated medical decisions. A body of common law has thus developed in respect of such relatively rare events as the non-consensual sterilisation of incompetent patients. The recipients of mass vaccines are amongst the most vulnerable people in society, yet they are unprotected in Britain by either statute or common law. Vaccination policy is determined by population-scale health concerns, and high levels of vaccine coverage are regularly quoted in Parliament as positive indicators of public health. There is certainly scope, in such a situation, for political expediency to have a greater effect on policy than does concern for the rights of individuals.

10.9 The administrative framework of vaccination in Britain

One consequence of parents' reduced fear of infectious disease has been that, although more childhood vaccinations have been available from the late 1950s, uptake of vaccination has been variable. Overt political intervention came in the 1987 White Paper Promoting Better Health³⁷, which first mooted the idea of financial incentives for GPs who achieved high levels of vaccination coverage amongst children on their patient lists. General practitioners rejected this proposal 3:1 but that did not prevent it from being given effect in the new GP contract introduced in 1990, and the maximum target payment now stands at £2,685. The success of this initiative was such that by 1992 child vaccination was no longer regarded as a key area of public health improvement because it was considered to be sufficiently established. It was, however, stated that 'the emphasis must be on sustaining and building on progress which has been made already – such as ... childhood immunisation (for which the Government has set a target of 95% uptake by 1995, the existing target of 90% for all such immunisations having been achieved in may 1992)'³⁸. The GP incentive system is a primary cause of pressure on parents to consent to their child's vaccination³⁹, and it is arguable that consent given under pressure is not legally valid⁴⁰.

Official publications and statements invariably refer to the desirability of achieving high levels of vaccination uptake. Health visitors discuss vaccination with potential parents ante-

nately. One study found that most health visitors view their role as promoting vaccination uptake, varying from 'mild encouragement, to pushing, and to chasing up defaulters'⁴¹. Another found that health professionals legitimised exerting pressure to vaccinate by their conviction that vaccination was beneficial⁴². Because many new parents are overwhelmed by their responsibilities and are very tired, they may feel unable to challenge or resist well-intended pressure of this kind.

Unsolicited appointments for each of the visits required by the primary and secondary vaccine schedules are sent to children's home addresses. The appointment slips are generated by health authorities' computerised child health records. Appointments are offered at the mother's chosen venue, which is ascertained by the health visitor during a home visit 14 days after the child's birth. If two appointments are missed without reason, the child's record is suspended and a report is sent to the health visitor. She will then contact the parents to discuss the matter⁴³. If she advises the health authority that a parent has refused a particular vaccine, no further appointments are sent. One result of the automated appointments procedure is that some parents believe that vaccines are compulsory, and others feel they have no real opportunity to decline vaccination⁴⁴.

It is agreed by most public health commentators that vaccination in Britain should remain optional⁴⁵. If this is so, all parents should be made expressly aware that they may decline vaccination for their children. They must also be confident that they will not suffer any detriment, such as being removed from a GP's patient list, if they do so. The danger of such an approach is that more parents might opt for their children to be 'free riders'. Such people benefit from herd immunity but run none of the possible risks associated with vaccination. Herd immunity would then cease to exist, and those who cannot be vaccinated for medical reasons would become vulnerable to preventable diseases, defeating one of the principal aims of mass vaccination. Another effect of reduced herd immunity would be that people would tend to contract diseases later in life, when the effects are more serious. The balance between the objective of eliminating infectious diseases and respecting patient autonomy is delicate. As King has remarked, '(t)he recurring challenge for public health authorities is to find the best way to communicate with the public, so that they truly are informed on the relative risks and benefits of a vaccination programme'⁴⁶.

10.4 The diseases against which mass vaccination is offered in the West

Diphtheria

Diphtheria is an acute respiratory infection which can lead to obstruction of the airways and death. An effective mass vaccine became available in the 1930s, and greatly reduced the incidence of the disease. The vaccine was introduced to developing countries by the WHO in the late 1970s, and global coverage is now 80%, including most countries outside Africa. This has been demonstrably successful: the number of cases reported to the WHO declined from over 70,000 in 1974 to 20,444 in 1992⁴⁷.

The present situation is that diphtheria has been virtually eliminated from most developed countries, and is reducing in developing countries. Mass vaccination in developed countries is deemed necessary maintain protection against infection via unimmunised immigrants. The continuing importance of mass vaccination is demonstrated in the former USSR, where there were very low levels of diphtheria from the early 1960s to the late 1980s, but 125,000 cases and 4,000 deaths between 1990 and 1995. The WHO has responded by ensuring that all the states had sufficient stocks of the vaccine, and by re-emphasising the benefits of the vaccine and the risks of the disease⁴⁸.

Tetanus

Tetanus is caused by bacilli found in soil, dust, faeces and on the skin. The toxin causes agonising muscular contractions which can lead to respiratory failure, pneumonia, malnutrition and death. The tetanus bacillus cannot be eradicated, but the disease can. A vaccine became available in the 1930s, and has been routinely used in mass infant vaccination in Britain since 1961. Five doses are believed sufficient to confer lifelong immunity to the disease.

The disease is now uncommon in developed countries: there were no more than 10 cases in Britain in any year between 1990 and 1995⁴⁹. In developing countries neonatal tetanus caused by contamination of the umbilical stump caused an estimated 490,000 deaths in 1994⁵⁰. The WHO aims to eliminate neonatal tetanus from the world⁵¹, which involves ensuring a high level of coverage of at least two doses of vaccine amongst women of

childbearing age, to enable transplacental transfer, and ensuring that babies are delivered hygienically.

Pertussis

Pertussis (whooping cough) is a highly infectious disease characterised by a paroxysmal cough accompanied by a whooping sound. Complications, which tend to be most serious in babies under six months old, can include brain damage, lung damage and death⁵². The killed whole-cell vaccine used in Britain has been available since the 1950s, and has significantly reduced the incidence of the disease: there were previously an average of 100,000 reported cases annually in Britain, and the maximum number of cases in any year since 1988 has been 5,000. The efficacy of the vaccine is at least 80% after three doses. There were epidemics of pertussis in Britain in 1977/79 and 1981/83 when vaccine coverage fell to 35% following public concern about the safety of the vaccine⁵³. The United States has addressed similar concerns by developing acellular pertussis vaccine, now routinely used in the trivalent diphtheria-tetanus-acellular pertussis vaccine (DTaP). Some studies have indicated that this vaccine is associated with a lower incidence of adverse reactions than its whole-cell counterpart⁵⁴.

Much of the decline in mortality from whooping cough in Britain had occurred before the vaccine was introduced, indicating the influence of other factors. The death rate in Britain is now around one per 100,000 cases overall, although the equivalent figure for infants under six months old is 500 in 100,000⁵⁵. The WHO estimates that global vaccine coverage is 80%, and that there are still 39 million cases of whooping cough, leading to 350,000 deaths, annually⁵⁶.

Haemophilus Influenzae B

Haemophilus influenzae B (Hib) is an organism which can cause bacterial meningitis and other invasive diseases such as pneumonia and epiglottitis in children, 95% of whom are under five years of age. Hib-related diseases have a death rate of 3–6% in developed countries, and 20–30% of cases lead to blindness, mental retardation, seizures or hearing loss⁵⁷. Before widespread vaccination, 0.16% of children in the Britain contracted a disease caused by Hib. The conjugate vaccine has an efficacy of 95% after three doses, and has

dramatically reduced the incidence of Hib diseases in Britain, from 1,259 cases in 1989 to 39 in 1995⁵⁸.

Poliomyelitis

Poliomyelitis (polio) is an acute viral infection of the intestines which can attack the central nervous system leading to permanent paralysis or death. The parenteral (injected) vaccine, developed in the 1950s by Salk, contains killed whole viruses and is therefore known as inactivated polio vaccine (IPV). It was largely superseded by the Sabin oral polio vaccine (OPV) which contains live attenuated (weakened) strains of the three types of polio virus. Polio has now been eradicated from most of the developed world, and the vast majority of cases which occur in the United States and Britain are due to the infection of non-immune individuals by live vaccine in the stools of newly-vaccinated infants⁵⁹. America's routine vaccine schedule is therefore now based primarily on IPV, with OPV being used only in circumstances of unusually high risk⁶⁰. OPV is still routinely used in Britain.

The global eradication of polio is being sought by routinely administering three doses of OPV to high percentages of infants, and additionally vaccinating young children on National Immunisation Days. In some countries – such as India, which accounted for 70% of the world's reported polio cases in January 2000 – three doses do not offer sufficient protection against the high levels of wild polio virus, and additional intensive vaccination campaigns are sometimes conducted.

Meningococcal C

Meningococcal C is the bacterium which causes one form of meningitis, an inflammation of the lining of the brain and spinal cord. The initial presentation is often very mild, but within hours sufferers can become dangerously ill. If meningitis is accompanied by septicaemia, it can lead rapidly to coma and death⁶¹. From July 1998 to July 1999 there were 1530 cases of meningitis C infection in Britain, with 150 deaths. The vaccine was introduced into Britain in autumn 1999, and is discussed below⁶².

Measles

Measles is an acute viral illness whose symptoms include spots, rash, fever, conjunctivitis and bronchitis. It can have severe complications including brain damage and death, although deaths from measles in the developed world had declined to virtually zero before the introduction of a vaccine⁶³. Before vaccination, virtually all children contracted measles. It is highly contagious, and one sufferer can transmit the disease to 12–18 others. A live attenuated single measles vaccine was introduced in Britain in 1968, and was eventually administered to about 50% of children. This increased to 80% in 1988 when the trivalent measles-mumps-rubella (MMR) vaccine, whose measles component has an efficacy of 90 – 95%, was introduced. The vaccine is now given to approximately 88% of children. This is lower than the 95% coverage estimated to be required to eliminate the disease, and occasional outbreaks occur⁶⁴.

In the developing world, where there are still one million measles-related deaths per year, the vaccine is given at nine months of age, because it is too risky to wait until children are one year old⁶⁵.

Mumps

Mumps is characterised by parotid swelling. It is not usually serious but its side-effects can include deafness and epididymo-orchitis⁶⁶, and in rare cases it can cause encephalitis or meningitis leading to death⁶⁷. Single mumps vaccine was introduced into the United States in 1977. The vaccine within MMR, whose efficacy is 90 – 95%, has been in widespread use in Britain since 1988. There were 2,021 reported cases of mumps in Britain in 1995⁶⁸.

There is no WHO target for global elimination because the disease has an insufficient impact on health in developing countries⁶⁹.

Rubella

Rubella (German measles) is usually a very mild disease which often has no symptoms. It has few serious complications⁷⁰, but the disease became the subject of medical interest in 1940 when it was realised that its contraction during pregnancy could cause congenital rubella syndrome (CRS), which involves numerous birth defects. In Britain women and teenage girls were able to receive a 97 – 98% effective single vaccine from 1970, and 97–

98% of this population had been vaccinated by 1987. In order to eliminate CRS the vaccine was included in the mass-administered MMR from 1988⁷¹. There are now usually fewer than ten annual cases of CRS in Britain, mainly amongst mothers born elsewhere.

10.5 The primary and secondary schedules in the west

The primary and secondary schedules consist of the vaccines which are routinely administered to children who have not yet entered full-time education.

At present, the primary and secondary schedules in Britain are as shown in Table 1:

Age	Vaccines
2 months	Diphtheria-tetanus-pertussis-Hib (DTP-Hib) Polio Meningococcal C
3 months	DTP-Hib Polio Meningococcal C
4 months	DTP-Hib Polio Meningococcal C
13 months	Measles-mumps-rubella (MMR)
4 –5 years	Diphtheria-tetanus (DT) MMR

Table 1: UK Primary and Secondary Schedule Vaccines

This schedule was designed to be practical, and in some cases immunological perfection has been sacrificed in order to maintain simplicity and a relatively low number of visits to vaccination clinics⁷². In general there is a sufficiently high uptake of these vaccines for herd immunity to be maintained. This is the principal aim of vaccination in Britain; in the words of a public health epidemiologist, ‘the aim of mass immunisation is to improve the health of the public, the population, by preventing preventable disease’⁷³.

The primary and secondary schedules recommended by the Canadian National Advisory Committee on Immunisation⁷⁴ are more complex, as shown in Table 2:

Age	Vaccine
2 months	Hepatitis B DTP Polio Hib
4 months	Hepatitis B DTP Polio Hib
6 months	Hepatitis B DTP Polio (only if IPV used; not required for OPV) Hib
12 months	MMR
18 months	DTP Polio Hib MMR
4–6 years	DTP Polio

Table 2: Canadian Primary and Secondary Schedule Vaccines

Territories and provinces within Canada produce their own vaccination schedules which vary from that in Table 2, but the differences are few and minor. The most significant is in the timing of MMR vaccines – Prince Edward offers the first dose at 15, rather than 12 months, and in four cases the second dose is given at age 4–6 years, rather than 18 months. The recommended schedule involves six vaccination visits, compared with five in Britain. The programme is designed to achieve the elimination or reduction of each infectious disease by a

specified date. These goals are to be achieved by attaining specified target levels of vaccination coverage of children in particular age groups. The goals and targets were set in 1996 and reviewed in 1997⁷⁵. Progress towards all the goals was being made by 19 June 1998 – the date when the 1997 review was last updated on the Internet – but no target for 1997 had been met nationally.

The primary and secondary schedules in the United States⁷⁶ are even more complex, and are shown in Table 3:

Age	Vaccine
0–2 months	Hepatitis B
1–4 months	Hepatitis B
2 months	Diphtheria-tetanus-acellular pertussis (DTaP) Hib Polio (inactivated vaccine)
4 months	DTaP Hib Polio (inactivated vaccine)
6 months	DTaP Hib
6–18 months	Hepatitis B Polio (inactivated vaccine)
12 –15 months	Hib MMR
12–18 months	Varicella (chicken pox)*
15–18 months	DTaP
4–6 years	DTaP Polio (inactivated vaccine) MMR

* Varicella is recommended only for children deemed by a health care provider to be ‘susceptible’, that is, those who have not been vaccinated and who lack a reliable history of chicken pox.

Table 3: USA Primary and Secondary Schedule Vaccines

The aim of the American schedules has been described by a British consultant epidemiologist as ‘immunological perfection ... where vaccines are given at very prescribed intervals which are done so as to generate the best immune response’⁷⁷. The United States’ Vaccines for Children (VFC) programme provides for vaccines to be purchased federally and made available to children who are Medicaid-enrolled, not covered by health insurance, covered by health insurance which does not include vaccination or who are American Indian or Alaskan Native. The aim of VFC is to ‘combine the efforts of public and private providers to help accomplish and sustain vaccine coverage goals’⁷⁸. The public funding available to VFC indicates the priority given to vaccination in a jurisdiction where much health care is required to be privately funded.

10.6 One-off vaccination campaigns

Two one-off mass vaccination campaigns took place in Britain between 1994 and 2000. The campaigns are of interest because they illustrate a number of legal and ethical issues.

In October 1994 all children aged five to 16 years were offered the opportunity to be vaccinated with a divalent measles-rubella (MR) vaccine. The primary schedule had since 1988 included a dose of MMR vaccine, administered at around 15 months of age. It was known that not all children had received this, and that the measles component of the vaccine had an efficacy of about 90%. The belief that 14% of schoolchildren in England and Wales were therefore not immune to the disease, coupled with an epidemic of 5,000 cases in Scotland in 1993–4, led to official fears of a measles epidemic. The decision to offer to vaccinate all schoolchildren against the disease was made public via an advertising campaign which aimed to make parents fear the potentially serious side-effects of measles – ‘blindness, brain damage, and even death’⁷⁹ – even though these were then extremely uncommon in the developed world.

Vaccines were administered at schools to all children whose parents had not expressly withheld consent – non-response to the notification of the campaign was taken to indicate consent. The leaflet sent to parents stated that the potential epidemic ‘will happen next year

unless we immunise children now'. It stated that side-effects from the vaccine were likely to be 'uncommon, ...very mild [and] likely to disappear quickly', although the leaflet sent to health professionals indicated that up to 25% of adolescent girls could develop joint pains. Parents who withheld consent have reported being subject to considerable pressure to accept the vaccine, and one child recalls being the only one in her class who did not receive it⁸⁰. The vaccines were administered by school nurses. It was reported that one vaccine was administered every 30 seconds, reducing the cost per child to 62 pence⁸¹.

This campaign was strongly criticised in the Bulletin of Medical Ethics. A series of articles disputes the reality of the predicted epidemic and questions why rubella vaccine was included. The accuracy of the information given to parents is criticised. The author – apparently Dr Richard Nicholson, the journal's editor – questions the propriety of the tendering method applied in the awarding of the contracts for vaccine supply⁸². He also asserts that the campaign constituted research because the divalent vaccine had not been used anywhere else in the world. Two doses of the trivalent MMR vaccine were already in routine use in other jurisdictions, but the omission of the mumps component was unprecedented.

One of the British Government's advisers has publicly agreed that the leaflet sent to parents before the campaign was less than ideal: '[c]ertainly leaflets can be improved. I myself think there was a problem with the 1994 leaflet. It should have had more information about other sources of information ...'⁸³. It breaches medical ethics to understate vaccine risks and to overstate disease risks in order to maximise uptake of a vaccine whose value is unproven. The official report into adverse events attributable to the campaign identified 530 serious reactions from over seven million vaccinees⁸⁴. The statement that no child died as a result of the campaign is inconsistent with the payment by the Vaccine Damage Payments Unit of two statutory awards in respect of deceased children⁸⁵.

In autumn 1999 a campaign began to vaccinate everyone under 19 years of age with meningococcal C vaccine. This bacterium is responsible for one strain of meningitis, the disease which probably holds the greatest fear for 21st century parents in the developed world. The first groups to receive the vaccine were those at highest risk: babies, toddlers and young people aged 15 to 17 years. During 2000 the vaccine was offered, at school, to all children⁸⁶. Consent forms were required to be returned before a child was vaccinated. This requirement for active, rather than passive, consent was ethically appropriate for a non-

essential medical intervention. In the case of at least one school, however, parents were unaware of the campaign until their 10- and 11-year-old children told them they had been vaccinated⁸⁷. Such vaccines were administered unlawfully because there was no valid consent.

The success of the vaccine in preventing 75–85% of predicted cases of meningitis C is marred by reports of relatively large numbers of adverse reactions to the vaccine. In 1999–2000 there were 16,527 reported adverse events apparently associated with about 15 million doses of vaccine – an adverse event reporting rate of one per 1,000 doses⁸⁸. This is much higher than the equivalent figure for any other vaccine. The Department of Health has pointed out that many of the reactions were minor, and has detailed the causes of the 11 deaths apparently associated with the vaccine.

This vaccine was, as is usual, tested on a relatively small number of people whose possible adverse reactions were monitored for a period of four weeks before being licensed for use in the general population⁸⁹. The novelty of the vaccine was heralded by the Secretary of State for Health – ‘the NHS will be the first health care system in the world to have the use of this new vaccine’⁹⁰ – yet the publicity leaflet for the vaccine included the statement that ‘the vaccine has been thoroughly tested on children of all ages and provides good protection with very few side effects...The new vaccine has been tested carefully and has proved to be safe’⁹¹. Within a year of its launch, the new vaccine had been given to a large percentage of schoolchildren in Britain. These children comprised the first population-wide cohort to receive it, but their parents had not been told that they were to be research subjects.

The MR and meningococcal C vaccination campaigns raise serious ethical questions because the targeted diseases were not currently causing epidemics. The MR campaign was in response to an epidemic predicted by a disputed mathematical model, and the meningococcal C campaign dealt with a disease which was rare but greatly feared.

If there is a present or imminent risk of a large-scale epidemic of a very serious disease, known vaccine risks to individuals may be justified by the potential benefit to the health of a community. At such times public perceptions of the risk/benefit ratio alter. There was an epidemic of smallpox in New York in 1947. Five million people were vaccinated against the disease in six weeks, resulting in 45 known cases of encephalitis and four deaths due to the

vaccine. This was felt to be an acceptable casualty level because the vaccine campaign averted thousands of deaths⁹². This situation contrasts with the 19th century riots against compulsory smallpox vaccine which occurred in Leicester because there was a low incidence of smallpox in the city.

It is generally accepted that normal ethical constraints may be waived when there is an immediate and serious risk to the health of large numbers of a population – such derogations exist in, for example, the European Convention on Human Rights⁹³. Normally, however, medical ethics require that the autonomy of patients should be respected by obtaining fully informed consent to any medical procedure. Without respect for autonomy it is inevitable that individual rights will be sacrificed in favour of the accumulation of the happiness of the majority. Neither law nor medical ethics sanctions such an approach even for the achievement of worthy public health goals. Since the children receiving primary and secondary schedule vaccines are unable to give their own legally valid consent, this respect for autonomy should be transferred to their proxies who, in the great majority of cases, are the parents. For parental consent to be legally valid⁹⁴, parents should be neutrally presented with as much information as possible before deciding whether to accept vaccines for their infant children.

10.7 The Costs and Benefits of Vaccines

The vision of a world free of preventable infectious diseases has to be considered in the context of the expense of vaccination. In January 2000 a further \$300 million was believed to be required to achieve certified global eradication of polio by 2005⁹⁵, and the sum had risen to \$450 million by September 2000⁹⁶. Although individual vaccines are cheap, politicians and public health authorities who decide vaccination policy must continually assess costs and benefits. Many have argued that it is inappropriate to place a value upon human life and health, but hard choices must be made in the pragmatic context of limited resources⁹⁷. The costs of vaccines must be demonstrably justified, and this is most likely to occur if they are seen to result in herd immunity.

The main financial benefit of vaccines is derived from the reduced costs of treating people affected by disease. The average cost of treating a hospitalised person with meningitis C, for example, is £3,200. The vaccine is believed to have cut cases by about 75% of the previous

figure of 1530 in its first year of use, representing an estimated saving of £3.6 million⁹⁸. The total cost of the campaign was not disclosed, but £9 million was made available to health authorities administering the campaign, and the vaccine was centrally purchased and supplied free of charge to the authorities⁹⁹. The net expenditure was thus £5.4 million, plus the cost of the vaccine itself. This sum prevented an estimated 112 deaths and 337 cases of permanent brain damage – a cost per potential victim of over £12,000. The 1998–9 figures suggest that one case of meningitis C was avoided by roughly every 1,000 vaccines given in 1999–2000, coincidentally, the same ratio as that for reported adverse reactions to the vaccine¹⁰⁰.

Another example of a mass vaccine with a high dose-to-avoidance ratio in Britain is *Bacillus Calmette-Guérin* (BCG), which has an efficacy of 70–80% in protecting against tuberculosis (TB). The vaccine was introduced in Britain in 1953, and has played a major role in significantly reducing the disease. It was calculated in 1984 that 2,200 doses of BCG vaccine were required to prevent a single case of TB. The Department of Health still recommends routine administration of BCG vaccine to all children aged 10–14 years who give a negative result to a skin test¹⁰¹. This policy is not, however, complied with in all areas, and there have recently been supply problems which have meant that the vaccine has only been available to the groups at highest risk of TB¹⁰². There have been small annual increases in notified cases of the disease since 1985, notably among recent immigrants from countries where the disease is still common, and in inner city areas¹⁰³.

Vaccines sometimes have unexpected beneficial effects in addition to reducing the incidence of infectious disease. A meta-analysis of two case-control and 10 cohort studies of measles vaccine in the developing world showed that the vaccine was associated with a greater number of avoided deaths than would be expected from acute measles infection¹⁰⁴.

Vaccines can also have unexpected negative effects. As mentioned above¹⁰⁵ three doses of polio vaccine leave children in India susceptible to the disease, and polio paralysis has been triggered in the limbs of children injected with DTP vaccine. The introduction of the WHO's recommended three-dose programme of DTP has therefore caused polio paralysis in hundreds of thousands of children¹⁰⁶.

There are other, currently unverified, studies which have linked certain vaccines with some kinds of long-term injury. The most notable of these, published in Britain in February 1998,

postulated a link between MMR vaccine, inflammatory bowel disorders and autistic spectrum disorders. This was a small-scale study of 12 cases, and was published as an ‘early report’. The paper itself notes the study’s methodological limitations, and states: ‘[w]e did not prove an association between measles, mumps, and rubella vaccine and the syndrome described’ before concluding ‘[f]urther investigations are needed to examine this syndrome and its possible relation to this vaccine’¹⁰⁷. This paper came to the attention of the media, some of which misreported it, and public confidence in the safety of MMR vaccine fell. The Government’s response was to convene a meeting of 37 experts who decided, a month after the study’s publication, that parents should continue to accept the vaccine for their children.

Two major studies, published in June 1999, were used by the Chief Medical Officer to reassure parents about the safety of MMR. One of these collated parental accounts of the ages at which their children had first exhibited signs of autistic spectrum disorders, and compared these with the ages, if any, at which they had received MMR vaccine. There was a statistically significant clustering of cases with a five-month interval, but this was dismissed as an artifact. Without these cases, the study showed no evidence for a causal association between MMR and autism¹⁰⁸. The study was strongly criticised for omitting these cases from analysis, but its authors defended their decision. The second study collated information about apparent adverse effects following MMR or MR vaccine. 531 reports were received, and all but 12 were disregarded on various specified grounds before final analysis. This study found that the information available did not support the suggested causal associations between the vaccines and bowel or autistic disorders, and noted its own methodological limitations¹⁰⁹. Numerous other papers and letters have been published on this subject, and there is as yet no agreement on whether the postulated causal link exists.

It is certain, however, that there are in the Western Hemisphere today diseases which manifest themselves in childhood and are much more common than ever before. No link has been established between any of these and vaccines, but there is much speculation about what has caused so many children to suffer from autistic spectrum disorders, learning difficulties and asthma. It is probable that the increases are due at least in part to improved diagnostic techniques, but a greatly increased number of vaccines in early childhood is one of many factors which may be contributing towards changes in patterns of children’s health. Much more research is needed into the possible causes of these disorders, ideally via prospective double-blind cohort studies in which one group of children would be exposed to various

possible risk factors while another, similar, group would not be so exposed. The health outcomes of both groups would be monitored, and any significant differences could then reasonably be attributed to the risk factor in question.

One problem with such studies is that it is very difficult to isolate each risk factor – some environmental allergens, for example, are virtually omnipresent. Investigating vaccines in this way also poses ethical difficulties. Given the generally-held belief that vaccines are, on balance, a beneficial influence on children's health, it is unreasonable to expect 50% of a given population to agree that their children should receive placebos instead. It has been suggested that some parents would probably be willing to defer their children's vaccinations, but this would not be useful if the possibly linked diseases do not manifest themselves for many months, as is often the case with bowel and psychological disorders. The best study design realistically available is therefore the case control method. This involves starting with people who have the health problem under investigation. The difficulties with this are that detailed access to health records is required, subjects are frequently self-selecting, and no suitable comparison group is available¹¹⁰. The importance of vaccines, however, makes it necessary to surmount these difficulties. If parents are not convinced of vaccine safety then fewer children will be vaccinated, with potentially serious consequences for public health. Governments need to identify common features in parents' anecdotal reports, and fund appropriate large-scale investigations into these possible links.

In societal terms the number of children apparently damaged by vaccines is greatly outweighed by the number protected from childhood diseases, so the cost-benefit ratio is considered acceptable. The official attitude to risks and benefits is exemplified in the history of the link between bovine spongiform encephalopathy (BSE) and variant Creutzfeldt-Jakob Disease (v-CJD). When the possibility of the association was first mooted in Britain, the Government responded that beef was completely safe to eat. It is not difficult to see the potential political problems following any official acknowledgment of a possible risk that was likely to do irreparable harm to the farming industry. Pharmaceuticals, including vaccines, were also realised to be possible sources of v-CJD infection, but this was not admitted publicly because of the official belief that it was imperative to maintain high levels of vaccine coverage. Kenneth Clarke MP, then Secretary of State for Health, told the BSE Inquiry of 'the needless death of infants' when 'mothers had been induced not to vaccinate their children'. It had been necessary to avert a similar situation:

‘The difficulty is if you said, as we all believed, that the risk from vaccine was remote, that unless you say there is absolutely no risk or 110 per cent certain that there is never any risk, it is terribly easy for somebody to go haring off starting another vaccine scare’¹¹¹.

This is an admission from a former Cabinet member that a deliberate decision was taken to overstate the true level of official confidence in vaccine safety. Guidelines against the use of British bovine serum in vaccines were issued in 1989, yet four vaccines which did not comply with the guidelines were not withdrawn. It was believed at the time that the stocks would last until late 1990–91. In the event the affected MMR vaccine was never licensed, so the problem applied to one measles vaccine, one Tuberculin and one line of DTP¹¹².

Volume 1 of BSE Inquiry (2000) concludes with ‘Lessons to be learned’. Two of these seem particularly applicable to current doubts about vaccine safety: ‘[a]n advisory committee should not water down its formulated assessment of risk out of anxiety not to cause public alarm’ and ‘[a]lthough likelihood of a risk to human life may appear remote, where there is uncertainty all reasonably practicable precautions should be taken’¹¹³. Norman Baker MP has described the Government’s attitude to possible vaccine risks as ‘a terrible averting of eyes’, and its response to the BSE risk as ‘sweep[ing] it under the carpet’¹¹⁴. Doubts about vaccine safety must be identified and investigated if the beneficial effects of vaccines are to be maximised.

10.8 Legal redress for the adverse effects of vaccines

In Britain there are two possible routes to financial recompense for a child who may have been injured by the administration of a mass vaccine: the common law and the statutory Vaccine Damage Payments Scheme (VDPS).

There has been no successful common law claim for vaccine damage in England or Wales. The leading case is Loveday v Renton¹¹⁵ which was heard to determine whether in principle the pertussis vaccine could cause brain damage in young children. Stuart-Smith J concluded that the claimant had failed to prove on the balance of probabilities that this general causative link existed. No case has since reached the English courts. The Irish case of Best v Wellcome Foundation¹¹⁶, in which the claimant was awarded £2.75 million for damage

caused by a faulty batch of vaccine, was based on exceptional facts and is unlikely to provide a useful precedent.

A group of children whose parents believe they have been damaged by the MMR vaccine are claimants in an impending multi-party action against vaccine manufacturers¹¹⁷ framed under the strict liability provisions of the Consumer Protection Act 1987. The claimants will argue that a 'defective' vaccine for the purposes of the Act was one that is capable of causing, however rarely, the injuries from which they are suffering. By November 2000 several case management hearings had been held, but no date had been set for a full hearing. The claimants' research into issues of causation is being funded by over 700 individual legal aid certificates and one generic certificate.

It has long been recognised that the slow adversarial processes of the civil courts are unsatisfactory as a means to compensation for vaccine damage. Because of this, and in recognition of the social desirability of universal vaccination, the VDPS was established under the Vaccine Damage Payments Act 1979. Initially claimants received a one-off payment of £10,000 if they could show that they had been at least 80% disabled by one of the vaccines recommended by the state for mass administration. The time limit for instituting the claim was six years from the later of the claimant's second birthday and the date of vaccination. The VDPS remained almost unchanged, except for increases in the statutory sum, for over 20 years. In June 2000 major changes to the scheme were announced in Parliament¹¹⁸. The statutory sum has now been increased to £100,000¹¹⁹. Legislation scheduled for 2001 will provide for top-up payments for those who have received lower awards, and will lower the disability threshold from 80% to 60%. Claims will be able to be instituted at any time until the victim's 21st birthday.

These changes, although substantial, will not solve the significant problems underlying the present scheme, which has granted awards to very few claimants in recent years¹²⁰.

Politicians are unanimous that the statutory payment does not constitute compensation, and it is clear that a payment under the scheme does not preclude a future common law action for damages. This contrasts with the equivalent scheme in the United States, the Vaccine Injury Compensation Programme. This no-fault scheme was introduced in October 1988, and one of its objectives is the avoidance of litigation, so recipients of awards are debarred from

bringing an action in negligence. Claims under the American scheme are twice as likely to succeed as claims under the British scheme¹²¹.

In Britain, parents who believe their children to have been damaged by vaccination are unlikely to receive any financial recompense to cover the medical and social costs of raising a damaged child. Their main difficulty is the paucity of evidence of a causal link between vaccines and the alleged adverse effects of vaccination. Government-funded research is therefore the key not only to safer vaccines but also to fairer treatment of those who bear the risks of vaccines for the benefit of the community. Moral considerations suggest that the burden should lie with the benefit, and therefore that society should be prepared to pay when necessary for the disease immunity and protection which results from mass vaccination.

10.9 Conclusion

Vaccines are constantly being developed and improved. Investigations are currently under way into the possibility of DNA-based vaccines, and into vaccines against diseases including cancer and human immune deficiency virus (HIV). The WHO has initiated an Immunisation Safety Priority Project whose 'ultimate goal is to enable national immunisation programmes to prevent, early detect and quickly respond to adverse events in order to minimise their negative impact on health and on national immunisation programmes'¹²². The project includes ensuring that vaccine delivery systems are safe and that all national regulatory authorities will have access to adverse event monitoring systems by the end of 2002.

Although commendable, this initiative does not deal with the problem that passive surveillance systems, such as the USA's Vaccine Adverse Events Reporting System and Britain's Yellow Card system, are thought to capture only very low percentages of suspected adverse reactions. The WHO has not advocated improving such systems, although adequate and accurate recording is a prerequisite of any project to improve vaccine safety.

Globalisation has affected patterns of disease. If populations were less mobile, it is likely that diphtheria and polio vaccines could safely be discontinued in the Western Hemisphere. CRS, too, could probably be eradicated from developed countries if there were no cases being imported from elsewhere. National strategies for disease eradication must therefore be devised in the context of global initiatives. There are instances, however, as India's experience with polio caused by DTP vaccine illustrates, when global policies can be fully

effective only if they are modified to take account of local conditions. There is no room for complacency: TB, which is largely preventable, is increasing in Britain and elsewhere, and diphtheria has increased in the former states of the USSR¹²³. The European Committee of Ministers considers it unnecessary to devise a pan-European vaccination policy because the Member States already co-operate within the WHO's programme¹²⁴. Such reliance makes it imperative that the WHO's strategies are effective in the eradication of infectious disease.

Equally importantly, the WHO must ensure – via the instigation and careful monitoring of appropriate long-term studies – that vaccines are not inadvertently causing some public health problems while solving others. Parents need to be justifiably confident that vaccines are not going to injure their children in any way. If this can be achieved, the maximum possible benefit will be derived from immunisation, which has been described as 'the single most cost-effective form of prevention and a positive health benefit to children'¹²⁵.

¹ See, for example, Re Eve [1986] 2 SCR 388 (Canada: distinction accepted); In Re B (A Minor) [1988] 1 AC 199 (England: distinction rejected); Department of Health and Community Services (NT) v JWB and SMB (1992) 175 CLR 218 (Australia: distinction accepted as necessary)

² (1992) 175 CLR 218

³ Oxford English Dictionary., Second Edition, 2000, Oxford: Oxford University Press. Obtained from: <http://dictionary.oed.com> 17 October 2000

⁴ Grubb, A, Kennedy & Grubb Medical Law, Third Edition, 2000, London: Butterworths, p 778

⁵ Schlafly, R, 'Official Vaccine Policy Flawed', 1999 4(3) Medical Sentinel 106–8. Obtained from <http://www.hacidendapub.com/vaccine.html> 24 November 2000, p 2. However seven new cases of polio were confirmed on the island of Hispaniola in January 2001, where many children had not received the recommended three doses of vaccine. If an epidemic ensues, plans to eradicate polio from the world by 2005 may be jeopardised (Radford, T, 'Polio returns to threaten world plan for eradication', The Guardian, 19 January 2001)

⁶ Brennan J in Department of Health and Community Services (NT) v JWB and SMB (1992) 175 CLR 218

⁷ World Health Organisation, Health for all in the twenty-first century, undated, Geneva: World Health Organisation. Obtained from <http://ww.who.int/wha-1998/pdf98/ea5.pdf> 11 September 2000, p 5

⁸ Ibid pp 24–5; Brundtland, G H, untitled, text of speech to Global Polio Partners Summit, New York, 27 September 2000. Obtained from <http://www.polioeradication.org/news.html> 27 November 2000, p 1

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- ¹⁰ Mason, J and McCall Smith, R, Law and Medical Ethics, 1999, London: Butterworths
- ¹¹ Harris, J, Legal Philosophies, 1997, London: Butterworths
- ¹² Re C (adult : refusal of treatment) [1994] 1 All ER 819
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- ¹⁴ (1994) 22 BMLR 43
- ¹⁵ See Flamm, A and Forster, H, ‘Legal Limits: When Does Autonomy in Health Care Prevail?’, in Freeman, M and Lewis, A, Law and Medicine, 2000, Current Legal Issues Volume 3, Oxford: OUP
- ¹⁶ For example Reibl v Hughes [1980] 114 DLR (3d) 1 (Canada); Rogers v Whittaker [1993] 175 CLR 479 (Australia)
- ¹⁷ Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] 1 All ER 643
- ¹⁸ Stauch, M, Wheat, K & Tingle, J, Sourcebook on Medical Law, 1998, London: Cavendish Publishing Ltd, p 115. Grubb, A, Kennedy & Grubb Medical Law. Third Edition, 2000, London: Butterworths, p 592
- ¹⁹ Halushka v University of Saskatchewan (1965) 53 DLR (2d) 436. See Mason, J and McCall Smith, R, Law and Medical Ethics, 1999, London: Butterworths
- ²⁰ See 10.1
- ²¹ Pywell, S, ‘Vaccination and other altruistic medical treatments: should autonomy or communitarianism prevail?’, 2000, Medical Law International, 4 223–43, p 237
- ²² Re W [1992] 3 WLR 758
- ²³ See for example Re H (A Minor) (Blood Tests: Parental Rights) [1996] 4 All ER 28; Re Y (Transplant: Bone Marrow) (1996) 35 BMLR 111
- ²⁴ Pywell, S M, Compensation for Vaccine Damage, 2001, unpublished PhD thesis, University of Hertfordshire, pages not finalised at time of writing
- ²⁵ Ueda, K et al, ‘Aseptic meningitis caused by measles-mumps-rubella vaccine in Japan’, Lancet, 1995, 346: 701–2, p 702
- ²⁶ Loveday v Renton, [1982], The Times, 31 March; page 4 of LEXIS transcript
- ²⁷ These are the diseases against which vaccines are routinely offered in infancy and early childhood respectively. They are detailed in section 10.5
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- ²⁹ Richards, E P and Rathburn, K C, ‘Public Health Law’, in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 1147–54, pp 1148–9
- ³⁰ Ibid pp 1151–2
- ³¹ Code de la Sante Publique, Chapitre II, Arts L5–10
- ³² The Vaccination Act 1853 – ‘An Act further to extend and make compulsory the practice of vaccination’ – 16 and 17 Vict c 100
- ³³ National Health Service Act 1946 Section 76 and schedule 10 Part II, which came into force in 1948
- ³⁴ National Health Service Act 1977 Section 53
- ³⁵ Gill, E and Sutton, S, ‘Immunisation uptake: the role of parental attitudes.’, in Hey, V (ed), Immunisation research: a summary volume, 1998, London: Health Education Authority, p 13
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³⁸ Department of Health, The Health of the Nation : A Strategy for Health in England 1992 Cmd 1986 London, HMSO

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⁴² Alderson, P *et al*, 'Childhood immunisation: support to health professionals', 1998, in Hey, V, Immunisation research: a summary volume, 1998, London: Health Education Authority, pp 19–37, p 24

⁴³ Personal conversation with the east Hertfordshire Health Authority Child Health Department, 20 December 2000

⁴⁴ Oral and written comments made by parents interviewed during research for PhD thesis, 1999

⁴⁵ For example Dr David Salisbury, Principal Medical Officer, Communicable Disease branch, Department of Health, speaking at the Healthcare Forum Vaccines and Health, University of Hertfordshire, 10 December 1999. See also Bartlett, P, 'Doctors as Fiduciaries: equitable regulation of the doctor-patient relationship', Med L Rev, 1997, 5: 193–224, p 216; and Bradley, P, 'Should childhood immunisation be compulsory?', Journal of Medical Ethics, 1999, 25: 330–4, pp 105–6

⁴⁶ King, S, 'Vaccination policies: individual rights *v* community health', BMJ, 1999, 319, 1448–9, p 1148

⁴⁷ Vitek, C, 'Diphtheria' in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 105–7, p 106

⁴⁸ Ibid

⁴⁹ Great Britain: Department of Health, Welsh Office, Scottish Office Department of Health and DHSS Northern Ireland, Salisbury, D M and Begg, N T (eds), 1996 Immunisation Against Infectious Disease, 1996, London: HMSO, p 206

⁵⁰ Prevots, D R and Sutter, R W, 'Tetanus', in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 102–5, pp 102–3

⁵¹ World Health Organisation, Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Volume 3, 3rd Edition, 1993, Geneva: World Health Organisation, Resolution 42.32

⁵² Strebel, P M, Guris, D and Wassilak, S G F, 'Pertussis', in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 98–102, p 98; Great Britain: Department of Health, Welsh Office, Scottish Office Department of Health and DHSS Northern Ireland, Salisbury, D M and Begg, N T (eds), 1996 Immunisation Against Infectious Disease, 1996, London: HMSO, p 115; Howson, C, Howe, C and Fineberg, H, Adverse Effects of Pertussis and Rubella Vaccines, 1991, Washington DC: National Academy Press, pp 11–4

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⁵⁴ Strebel, P M, Guris, D and Wassilak, S G F, 'Pertussis', in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 98–102, p 100

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- ⁵⁵ Howson, C, Howe, C and Fineberg, H, Adverse Effects of Pertussis and Rubella Vaccines, 1991, Washington DC: National Academy Press, p14
- ⁵⁶ Strebel, P M, Guris, D and Wassilak, S G F, 'Pertussis', in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 98–102, p 99
- ⁵⁷ Great Britain: Department of Health, Welsh Office, Scottish Office Department of Health and DHSS Northern Ireland, Salisbury, D M and Begg, N T (eds), 1996 Immunisation Against Infectious Disease, 1996, London: HMSO, p 77; Wenger, J D, Fraser, D W and Broome, C V, 'Haemophilus influenzae Infections', in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 116–7, p 116
- ⁵⁸ Great Britain: Department of Health, Welsh Office, Scottish Office Department of Health and DHSS Northern Ireland, Salisbury, D M and Begg, N T (eds), 1996 Immunisation Against Infectious Disease, 1996, London: HMSO, p 77
- ⁵⁹ Ibid p 178; Sutter, R W and Cochi, S L, 'Poliomyelitis', in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 123–5, p 124
- ⁶⁰ Source: Undated and anonymous Recommended Childhood Immunization Schedule United States, January – December 2000, received with personal communication from Centers for Disease Control and Prevention, Department of Health and Human Services, Atlanta, 12 October 2000
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- ⁶⁶ Stratton, K, Howe, C and Johnston, R (eds), Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 1994, Washington DC: National Academy Press, p 121
- ⁶⁷ Wharton, M, 'Mumps', in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 93–5, p 93
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⁷² Source: personal interview with Dr Norman Begg, Consultant Epidemiologist at the Public Health Laboratory Service, Colindale, London on 13 July 1999

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⁷⁴ Source:

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⁷⁵ Canada: Health Protection Branch, 1997, Chapter 3, pp 1–4 and 1998, pp 4–6. No National Report on Immunisation for 1998–2000 was available via the Internet on 4 December 2000, despite the published intention (December 1999/January 2000) of Canada’s Population and Public Health Branch to produce the Reports annually

⁷⁶ Source: Undated and anonymous Recommended Childhood Immunization Schedule United States, January – December 2000, received with personal communication from Centers for Disease Control and Prevention, Department of Health and Human Services, Atlanta, 12 October 2000

⁷⁷ Source: personal interview with Dr Norman Begg, Consultant Epidemiologist at the Public Health Laboratory Service, Colindale, London on 13 July 1999

⁷⁸ USA: Centers for Disease Control, Vaccines For Children (VFC) Program Overview, undated. Obtained from <http://www.cdc.gov/nip/vfc/about.htm> on 24 November 2000, p 1

⁷⁹ Quotation from television advertisement shown in Britain in 1994

⁸⁰ Personal oral accounts from individuals whose anonymity is respected

⁸¹ Anonymous, ‘News’, Bulletin of Medical Ethics, 1994, 102, 3–5; Roberts, J, ‘A horrendous gap in research in this country’, The Independent, 7 October 1995

⁸² Anonymous, ‘News’, Bulletin of Medical Ethics, 1994, 102, 3–5; 1 Anonymous, ‘UK measles campaign’, Bulletin of Medical Ethics, 1995, 104, 3–4; Anonymous, ‘Measles and deception’, Bulletin of Medical Ethics, 1995, 110, 3–9; Anonymous, ‘Measles and rubella again’, Bulletin of Medical Ethics, 1996, 114, 13–23

⁸³ Dr Robert Aston, a member of the Joint Committee on Vaccination and Immunisation, speaking on BBC Radio Four, File on Four, 9 December 1997

⁸⁴ Bedford, H and Elliman, D, Childhood immunisation: a review, 1998, London: Health Education Authority, p 35

⁸⁵ BBC Radio Four, File on Four, 9 December 1997

⁸⁶ Health Education Authority, Meningitis C Reduce the risk, 1999, London: Department of Health, p 2

⁸⁷ Personal oral account from individual whose anonymity is respected

⁸⁸ Kelso, P, ‘Meningitis vaccine cuts cases by up to 85%’, The Guardian, 4 September 2000

⁸⁹ For a detailed critique of vaccine pre-licensing trials, see Wakefield, A J and Montgomery, S C, ‘Measles, mumps, rubella vaccine: Through a glass darkly’, Adverse Drug React Toxicol Rev, 2000, 19(4), 265–83. This article was unusual in that its referees’ comments were also published. The Department of Health’s response, Combined measles, mumps and rubella vaccines: Response of the Medicines Control Agency and Department of Health to issues raised in papers published in “Adverse Drug Reactions and Toxicological Reviews, volume 19 no 4, 2000”, 2001, was obtained from

<http://www.doh.gov.uk/pdfs/mmrresponse.pdf> on 1 February 2001. Both these are critically reviewed in Pywell, S, Compensation for Vaccine Damage, 2001, unpublished PhD thesis, University of Hertfordshire

⁹⁰ Hansard, House of Commons Debates, 20 July 1999, Col 983

⁹¹ Health Education Authority, Meningitis C Reduce the risk, 1999, London: Department of Health, p 5

⁹² Last, J M, 'Ethics and Public Health Policy', in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 35–43, p 37

⁹³ For example Article 5, The right to liberty and security, which provides (para 1(e)) that persons may lawfully be detained 'for the prevention of the spreading of infectious diseases...', and Article 8, The right to respect for private and family life, which provides (para 2) for interference with the exercise of the right 'for the protection of health or morals...'

⁹⁴ See section 10.2

⁹⁵ Brundtland, G H, Final Push for Polio Eradication in Year 2000 – Every Child Counts, text of speech given in New Delhi, 6 January 2000. Obtained from <http://www.polioeradication.org/news.html> 27 November 2000, pp 2–3

⁹⁶ Brundtland, G H, untitled, text of speech to Global Polio Partners Summit, New York, 27 September 2000. Obtained from <http://www.polioeradication.org/news.html> 27 November 2000, p 2

⁹⁷ See, eg, R v Cambridge Health Authority, ex parte B (a minor) [1995] 2 All ER 129 (CA) at 137 where Sir Thomas Bingham MR said: '[d]ifficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients'

⁹⁸ Hansard, House of Commons Written Answers, 19 June 2000, Col 53W

⁹⁹ Hansard, House of Commons Written Answers, 11 January 2000, Col 143W

¹⁰⁰ See section 10.6

¹⁰¹ Bedford, H and Elliman, D, Childhood immunisation: a review, 1998, London: Health Education Authority, p 57

¹⁰² Hansard, House of Commons Written Answers, 11 January 2000, Cols 143–4W

¹⁰³ Great Britain: Department of Health, Welsh Office, Scottish Office Department of Health and DHSS Northern Ireland, Salisbury, D M and Begg, N T (eds), 1996 Immunisation Against Infectious Disease, 1996, London: HMSO, pp 219 et seq

¹⁰⁴ Aaby, P et al, 'Non-specific beneficial effect of measles immunisation: analysis of mortality studies from developing countries', BMJ, 1995, 311, 481–5, p 481

¹⁰⁵ Section 10.4

¹⁰⁶ Mudur, G, 'Flawed immunisation policies in India led to polio paralysis', 1998, BMJ 316 1261, p 1261

¹⁰⁷ Wakefield, A J et al, 'Ileal-lymphoid nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children', Lancet, 1998, 351, 637–41, p 64

¹⁰⁸ Taylor, B et al, 'Autism and measles, mumps, and rubella vaccine: no epidemiological evidence for a causal association', Lancet, 1999, 353, 2026–9

¹⁰⁹ Committee on Safety of Medicines, 'The safety of MMR vaccine', Current Problems in Pharmacovigilance, 25 June 1999, pp 1–3. Report of the Working Party on MMR Vaccine obtained from www.open.gov.uk 21 June 1999 p2

¹¹⁰ Taylor, C W and Last, J M, 'Epidemiology', in Wallace, R B (ed), Maxcy-Roxenau-Last Public Health and Preventive Medicine, 1998, Stanford, Connecticut: Appleton and Lange, pp 2–33, p 19

¹¹¹ Transcript of Day 87 of the BSE Enquiry, page 111, lines 2–18. Obtained from: <http://www.bse.org.uk/transcripts/tr981127.txt>, 13 May 1999

¹¹² BSE Inquiry, BSE Inquiry, The Report, 2000, obtained from <http://www.bseinquiry.gov.uk/report> 15 November 2000, Volume 7, paragraph 6.227

¹¹³ Ibid Volume 1, paragraphs 1275 and 1283

¹¹⁴ Meikle, J and Clark A, 'BSE risk in polio vaccine revealed', 2000, The Guardian, 21 October

¹¹⁵ [1990] 1 Med LR 117

¹¹⁶ [1994] 5 Med LR 81

¹¹⁷ Sayers and others v Smithkline Beecham plc and others [199] MLC 0117

¹¹⁸ Hansard, Parliamentary Debates (House of Commons), 27 June 2000, Cols 719–27

¹¹⁹ SI 2000/1983

¹²⁰ Pywell, S, 'A Critical Review of the Recent and Impending Changes to the Law of Statutory Compensation for Vaccine Damage', 2000, Journal of Personal Injury Law, 4/00: 246–56

¹²¹ UK data obtained from personal communication with Vaccine Damage Payments Unit, 7 December 1999. US data provided by letter from the Department of Health and Human Sciences, Rockville, Maryland

¹²² World Health Organisation, Health for all in the twenty-first century, undated, Geneva: World Health Organisation. Obtained from <http://www.who.int/wha-1998/pdf98/ea5.pdf> 11 September 2000, p 1

¹²³ See section 10.4

¹²⁴ Council of Europe, Committee of Ministers, 1997, Item 6.2, paragraph 4

¹²⁵ Mayon-White, R and Moreton, J, Immunizing Children: A Practical Guide, Second Edition, 1998, Abingdon, Oxfordshire: Radcliffe Medical Press Ltd, p 1