

Chapter 4

Case study –
Infectious disease



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Introduction

4.1 In this chapter we outline some of the main ethical and policy issues raised by public health measures relating to infectious disease. The chapter is divided into three sections, focusing on: prevention through vaccination (paragraphs 4.7–4.35); surveillance (paragraphs 4.36–4.55); and control strategies (paragraphs 4.56–4.72). Regarding vaccination schemes, we examine the tension between individual choice over receiving or not receiving vaccination, and the potential benefits or risks to the community. We also discuss the policy options of voluntary, quasi-mandatory and incentivised vaccination programmes. We next consider surveillance for identifying infectious disease trends, for researching the nature and epidemiology of a disease and for detecting cases of disease for which control interventions may be needed. The ethical issues raised here include the acceptability of surveillance measures for which people do not give individual consent. In the final section we consider whether approaches for the control of infectious diseases that infringe personal liberty, such as quarantine and isolation, can be justified. As in other chapters, our main focus is on the situation in the UK and in the context of the developed world,¹ but in the sections on surveillance and control we also consider the global context of infectious disease, especially with regard to preparedness for a pandemic (paragraphs 4.47–4.55, 4.66–4.68).

Background

Effects and 'costs' of infectious diseases

- 4.2 Infectious diseases are a leading cause of illness and death worldwide. Globally, infections cause over a fifth of all deaths and a quarter of all illnesses, disproportionately affecting poorer communities and resource-poor countries.² It is estimated that worldwide each year around 5.5 million people die from malaria, tuberculosis (TB) and human immunodeficiency virus (HIV)-related infections, 1.8 million die from diarrhoeal disease and more than a million children die from other diseases that are preventable through vaccines.³ The vast majority of these deaths are in the developing world, and similarly it has been suggested that in the case of an influenza pandemic up to 96% of deaths could occur in developing countries (see paragraphs 4.65–4.66).⁴
- 4.3 In Europe and other Western countries, death rates from infectious diseases have reduced over the past century. This trend results from factors such as improvements in living conditions, antimicrobial treatments and the introduction of vaccination programmes. However, in the UK infectious diseases still account for over 10% of deaths and around one

¹ We note that in 2007 the Department of Health for England held a consultation relating to a review of parts of the Public Health (Control of Disease) Act 1984, which included proposals relating to several of the topics discussed in this chapter, including disease notification, detention of individuals with serious infections, and vaccination, and more generally to principles that should be applied in considering issues relating to infectious disease control. Department of Health (2007) *Review of Parts 2, 5 and 6 of the Public Health (Control of Disease) Act 1984: A consultation*, available at: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_073452.

² Foresight (2006) *Infectious Diseases: Preparing for the future. Executive summary* (London: Office of Science and Innovation).

³ Estimates for 2002 by the World Health Organization, see World Health Organization (2004) *World Health Report 2004* (Geneva, Switzerland: WHO), Statistical Annex; available at: <http://www.who.int/whr/2004/en/>.

⁴ Murray CJ, Lopez AD, Chin B, Feehan D and Hill KH (2006) Estimation of potential global pandemic influenza mortality on the basis of vital registry data from the 1918-20 pandemic: a quantitative analysis *Lancet* **368**: 2211–8; Uscher-Pines L, Duggan PS, Garoon JP, Karron RA and Faden R (2007) Planning for an influenza pandemic – Social justice and disadvantaged groups *Hastings Cent Rep* **37**: 32–9.

in three consultations in primary care.⁵ There are also marked inequalities in morbidity due to common infectious diseases. For example, within the UK, hospitalisation rates for respiratory infections in children under five are twice as high in the economically most deprived fifth of the population as they are in the least deprived fifth of the population.⁶

- 4.4 While prevention and control of many infectious diseases has improved in recent decades, they continue to pose major challenges to public health, both in the UK and internationally. These stem from, for example, the emergence of new infections in humans such as HIV and SARS (severe acute respiratory syndrome),⁷ the emergence of old disease problems with new complexities⁸ and the continued periodic occurrence of worldwide epidemics of influenza resulting from new strains of the virus.⁹ Since AIDS (acquired immune deficiency syndrome) was first described in 1981, and the causative virus HIV was subsequently identified, over 25 million people have died of HIV/AIDS, and in 2006 it was estimated that around 40 million were infected with the virus.¹⁰ Although the outbreak of SARS in 2002/3 was controlled, it caused 774 documented deaths and was estimated to have cost over \$12 billion in the affected Asian countries alone (see also Box 4.6).¹¹ Other potential costs of infectious diseases include reductions in the capacity of the health service to deal with other conditions and restrictions or changes affecting the lives of individuals and their businesses where an outbreak occurs. Higher levels of international travel and trade increase the risk of infectious agents spreading rapidly around the world, causing epidemics and pandemics (worldwide epidemics); meanwhile, changing behavioural, environmental, economic and migration patterns create new ecological niches for the multiplication and spread of infectious agents.¹²

Causes of infectious diseases

- 4.5 Infectious diseases in humans are caused by a wide range of disease agents including viruses, bacteria, fungi and protozoa (single-celled organisms including amoebae). They vary widely in their ability to be transmitted in human populations, and different infections are transmitted by different means. The means of spread include:

- airborne and aerosol, e.g. measles, influenza, TB;
- food/water, e.g. typhoid, cholera, hepatitis A;
- close contact, e.g. scabies, impetigo, MRSA (methicillin-resistant *Staphylococcus aureus*);
- sexual intercourse, e.g. gonorrhoea, syphilis, chlamydia, HIV;
- blood, e.g. hepatitis B and C, HIV;
- insect vectors, e.g. malaria, dengue, plague; and
- from animal to man (zoonoses), e.g. rabies, avian influenza.

⁵ Health Protection Agency (2005) *Health Protection in the 21st Century – Understanding the Burden of Disease; Preparing for the future, Part 4 Infectious diseases*, available at: http://www.hpa.org.uk/publications/2005/burden_disease/.

⁶ Health Protection Agency (2005) *Health Protection in the 21st Century – Understanding the Burden of Disease; Preparing for the future, Part 12 Health inequalities*, available at: http://www.hpa.org.uk/publications/2005/burden_disease/.

⁷ Indeed, new infectious diseases are emerging at the “historically unprecedented” rate of one per year. WHO (2007) *The World Health Report 2007: A safer future* (Geneva: Switzerland).

⁸ Such as TB associated with HIV infection, malaria resistant to previously curative drugs, bacteria resistant to antibiotics, and the resurgence of sexually transmitted infections due to changes in sexual behaviour.

⁹ Influenza pandemics typically recur two or three times per century. Department of Health (2007) *Pandemic Influenza: A national framework for responding to an influenza pandemic – Draft for comment* (London: Department of Health).

¹⁰ Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (2006) *2006 AIDS Epidemic Update*, available at: http://www.who.int/hiv/mediacentre/2006_EpiUpdate_en.pdf.

¹¹ World Health Organization (2003) *Severe Acute Respiratory Syndrome (SARS)*, available at: www.wpro.who.int/sars/docs/RC54-08.pdf.

¹² WHO (2007) *The World Health Report 2007: A safer future* (Geneva: Switzerland).

4.6 The range of prevention and control strategies that may be used is wide, depending in part on the nature of the infectious agent and its mode of spread. It includes, for example, advice about safer sex, regulations on food hygiene, advice about hand-washing, and precautions taken in hospitals to prevent infections spreading between individuals, as well as vaccines. We focus first on vaccinations, which raise several particular ethical issues.

Prevention of infectious diseases through vaccination

4.7 The World Health Organization (WHO) estimates that vaccination programmes averted over two million deaths worldwide in 2002.¹³ The incidences of diseases such as tetanus, measles, hepatitis B and polio have been greatly reduced by vaccination programmes in the UK and worldwide, and smallpox has been eradicated.¹⁴

4.8 In the UK, vaccination rates differ between socio-economic groups, with children from lower socio-economic groups being less likely to receive the full suite of recommended vaccinations. Of children born between September 2000 and January 2002 in the UK, 3.3% were only partly immunised by the age of nine months.¹⁵ This percentage was higher among those living in areas that were deprived, or that had a high proportion of inhabitants from ethnic minorities. However, the proportion of children who received no vaccinations at all (overall rate being 1.1%) was higher among those whose mothers were educated to degree level, were older or were of Black Caribbean ethnicity. The often-observed tendency is for affluent groups to be the quickest to take up practices that are protective of child health.¹⁶ However, if doubts are cast, such as when public confidence in the combined measles, mumps and rubella (MMR) vaccine declined (see paragraphs 4.33–4.35 and Box 4.3), they may also be the first to refuse vaccination.¹⁷

Why vaccinate?

4.9 Vaccinations involve treating a healthy person with a substance that is derived from (or similar to) a particular infectious disease agent. The purpose is to induce a response by the body that leads to enhanced immunity, and consequent protection, when exposed to the infectious agent in the future.

4.10 Vaccines can be used in controlling an outbreak of infectious disease, either in the case of a pandemic or in the case of a localised outbreak, and we consider their use in this context later in the chapter (see paragraphs 4.63–4.68). More often, however, vaccines are used as a routine public health measure to prevent infectious diseases. Routine vaccination strategies can be designed with three different (but not necessarily exclusive) aims:

- **Population-wide vaccination to protect individuals:** Such vaccines are usually given during childhood. In the UK, childhood vaccination programmes exist for a number of diseases, including: diphtheria, tetanus, whooping cough, polio, some types of meningitis (*Haemophilus influenzae* type b (HiB) and meningitis C), measles, mumps and rubella.

¹³ World Health Organization (2005) *Fact sheet No. 288: Immunization against diseases of public health importance*, available at: www.who.int/mediacentre/factsheets/fs288/en/index.html.

¹⁴ *Ibid.*

¹⁵ Samad L, Tate AR, Dezateux C, Peckham C, Butler N and Bedford H (2006) Differences in risk factors for partial and no immunisation in the first year of life: prospective cohort study *Br Med J* **332**: 1312–3.

¹⁶ Middleton E and Baker D (2003) Comparison of social distribution of immunisation with measles, mumps, and rubella vaccine, England, 1991–2001 *Br Med J* **326**: 854.

¹⁷ *Ibid.* The uptake of the MMR vaccination (introduced in 1988) was initially and consistently higher in more affluent areas. From 1997 to 2001 coverage declined in all areas but more so in more affluent areas, leading to an overall reduction in coverage but also a reduction in social inequality.

- *Selective vaccination to protect individuals who are vulnerable or at-risk*: Examples include: annual influenza vaccines for health professionals, elderly and disabled people; and vaccinations advised for people travelling to regions where specific infectious diseases are common.
- *Population-wide vaccination to achieve/maintain 'population immunity'*: Some of the vaccinations given to protect individuals, including measles, polio and mumps, contribute to what might be called 'population immunity', also commonly known as 'herd immunity'. For some diseases that are transmitted from person to person, a 'herd effect' occurs when a sufficiently high proportion of the population is vaccinated for there to be a high likelihood that if a case of disease is introduced, all the people that the infectious person comes into contact with are already immune, and thus there is no onward transmission. As a consequence, the small proportion who are unvaccinated¹⁸ are at a much reduced risk of disease, because the chance of outbreaks of disease is much reduced. The level of vaccination cover required for sufficient population immunity to virtually eliminate the risk of significant disease outbreaks varies from around 80% to over 90%, depending on how infectious the disease is, the effectiveness of the vaccine, and various other factors.¹⁹ For diseases in which population immunity can be achieved, very high vaccination levels around the world, combined with outbreak control, may eventually bring about the global eradication of the infection. Smallpox has been eradicated in this way, and there is currently a global eradication programme in progress for polio.

4.11 Vaccination can therefore have an important role in protecting individuals from infection, and in reducing the transmission of infections in the population through population immunity and eradication. Furthermore, vaccination can have an effect on reducing health inequalities. This may be achieved through the targeting of vaccinations at those who are particularly susceptible to ill health, as in the case of influenza vaccines, or through the protection offered by population immunity as it will clearly extend to the most vulnerable (paragraph 3.22).

4.12 Population immunity can confer a substantial collective benefit. At the same time, achieving it requires the organised efforts of society in establishing vaccination schemes, and the collective action and cooperation by the population in taking part to achieve high levels of vaccination coverage. We next consider what kinds of vaccination policy might be used to achieve the high population coverage required for population immunity, and what ethical issues might be raised.

Benefits and risks of vaccination

Risks

4.13 Several consultation respondents expressed concerns about the safety and potential harms of vaccination and argued that on this basis they should not be used at all (see Box 4.1). While it is not our role to review the evidence for the safety of vaccines, we note that extensive reviews of vaccination programmes and rigorous regulatory processes generally

¹⁸ In vaccination programmes directed at children there may be various reasons why some children have not been or cannot be vaccinated. This might be, for example, because they cannot receive the vaccine for medical reasons, because they have not yet reached the age at which vaccination would be recommended, because they lack access to health services or because their parents have refused the vaccine. It is important to note also that few vaccines give total protection to all those vaccinated, so some people who have been vaccinated may not be immune from the disease, and would therefore depend on population immunity for protection from the disease.

¹⁹ Malone KM and Hinman AR (2003) Vaccination mandates: The public health imperative and individual rights, in *Law in Public Health Practice*, Goodman RA, Rothstein MA, Hoffman RE *et al.* (Editors) (New York: Oxford University Press), pp.262–84.

ensure that vaccine safety is at a very high level.²⁰ No vaccine can be said to be without risk, and for each vaccine an assessment will always be needed of the associated risks and benefits. Such assessments will be characterised by some degree of uncertainty (see paragraphs 3.10–3.11), and there will also be individual variation in response to vaccines, including the possibility of some rare unpredictable reactions. In the view of the Working Party it would be wrong, however, to suggest that the risks and/or variability in response to vaccination were a basis for undermining categorically the case for their use. To do so would be an abuse of the precautionary approach, paying insufficient attention to the criterion of ‘proportionality’ (paragraphs 3.15–3.19). We also note that in recognition of the potential risks that individuals bear in contributing to population immunity, a Vaccine Damage Payment Scheme exists in the UK.²¹

Box 4.1: Concerns about vaccination expressed by respondents to the consultation

Although the vast weight of scientific evidence supports vaccination, and generally most children receive the interventions, there are some people that criticise them, as illustrated by the following views expressed by respondents to the consultation²²:

“I believe that vaccinations are harmful and dangerous. I believe that we are compromising our children’s health with numerous vaccinations they receive nowadays. There has not been enough research done to show us that vaccinations are safe, effective and do not cause any long-term health problems.” *Mrs Marijke Roberts*

“The chances are that the vaccinations cause more health problems than they solve, ... the disease the vaccination is trying to prevent is, in the huge majority of cases, treatable with no side effects.” *C Buckley and S Nolan*

“Many of the diseases for which people are vaccinated were already coming under control through improved sanitation, healthcare, and measures such as quarantine. [...] Apart from all the uncertainty surrounding the MMR vaccine there is also a suggested link between other vaccines and various degenerative illnesses. [...] Some vaccines are not producing the herd immunity they are supposed to.” *Mrs Esther Hollands*

Weighing up benefits and risks

- 4.14 Benefits and risks of vaccinations need to be considered from two different perspectives: first, in relation to oneself or, more often, one’s children, on behalf of whom one may make decisions; and secondly, in relation to other people.²³
- 4.15 From the first perspective, most people accept vaccines in situations in which the incidence of a vaccine-preventable disease is high, the disease is potentially serious and the risks from the vaccine are proportionately low. The situation is different where incidence is relatively low, as there may be both statistical and perceptual changes in the assessments of risks and benefits. Statistically, where there is fairly high vaccine coverage, the risks of disease for those who are unvaccinated may decrease (owing to population immunity) while the risks of vaccination remain. For example, in the USA, as a result of high levels of vaccination for

²⁰ Relevant bodies in the UK that are concerned with such assessments include the following. The Joint Committee on Vaccination and Immunisation (JCVI) is an independent advisory committee whose role is “To advise the Secretaries of State for Health, Scotland, Wales and Northern Ireland on matters relating to communicable diseases, preventable and potentially preventable through immunisation” (see: <http://www.advisorybodies.doh.gov.uk/jcvi/>). The Medicines and Healthcare products Regulatory Authority (MHRA) is the Government agency that is responsible for ensuring that medicines and medical devices work, and are acceptably safe, and it continually monitors both the safety and quality of the medicines, including vaccines, available on the UK market (see: <http://www.mhra.gov.uk>). To aid it in this role various expert advisory groups and relevant committees operate, some of which relate specifically to vaccines, including the Committee on Safety of Medicines and the Biologicals and Vaccines Expert Advisory Group of the Commission on Human Medicines (see: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=908).

²¹ Under this scheme, individuals who have been severely mentally or physically disabled as a result of vaccination, or their families, can claim a one-off payment, currently £100,000. This payment is not intended to be considered as compensation but a payment to ease the financial burdens on the disabled person and their family. For further information see: Department of Health (2006) *Immunisation Against Infectious Disease: The Green Book* (London: The Stationery Office), available at: http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254.

²² Please note that these views should not be taken to be representative of all respondents.

²³ Bauch CT, Galvani AP and Earn DJD (2003) Group interest versus self-interest in smallpox vaccination policy *Proc Natl Acad Sci USA* 100: 10564–7.

measles, the risk of exposure to the disease-causing virus is very low, while the vaccine used causes fever or rash in around 5% of cases and very occasionally causes more severe reactions.²⁴ Although healthcare professionals consider the risks of such trade-offs carefully, low incidence of a disease may also affect people's perceptions of it.²⁵ They may view the risks of contracting a vaccine-preventable disease not to be serious,²⁶ since they are less familiar with its symptoms or severity as a result of its low prevalence (owing to a high level of vaccination coverage), and may be more likely to refuse vaccination.²⁷

- 4.16 We noted above that population immunity has two main benefits: first that of protecting individuals within the population, including those who are vulnerable;²⁸ and secondly that of reducing health inequalities. Population immunity also, however, raises particular issues about the distribution of costs and benefits across individuals and society. Where population immunity exists, the additional benefit to the individual from being vaccinated is very small because if they were not to be vaccinated it is likely that they would be protected from the disease as a result of those around them who had been. The main benefit from their being vaccinated is at the community level through the maintenance of population immunity, which includes the protection of those who, for various reasons, have not been vaccinated themselves.²⁹
- 4.17 The population immunity scenario also raises the 'free-rider' issue. Free-riders are individuals who take more than their fair share of the benefits, or do not bear their fair share of the costs, of a resource or institution that is contributed to by many.³⁰ Where population immunity exists and provides protection for those who refuse vaccination, it could be suggested that individuals who are not vaccinated are free-riders, as they do not share their fair burden, while nevertheless benefiting from population immunity. However, we find this suggestion unhelpful for understanding the complexities raised by vaccines. Although it is true that people pursuing such self-serving strategies would receive a personal benefit, not all who object to vaccinations or refuse them are motivated in this way. There are a range of other reasons for their objections: for example, people may not be convinced of the need for the vaccine, or may be concerned about its effects on themselves or their children.
- 4.18 Finally on population immunity, we consider a scenario that arises in a few cases where an infection causes serious disease in only some sectors of the population: for example those that seriously affect females rather than males or vice versa. In such scenarios, if there was a vaccine strategy aiming to achieve population immunity, this could mean that some individuals may receive a vaccine that protected against a disease that would not cause them serious harm, for the sake of achieving population immunity to protect others who could be more seriously harmed by it. An interesting example is the triple vaccine MMR, which confers protection against mumps, measles and rubella (see also paragraphs 4.33–4.35). MMR is

²⁴ Severe reactions including aseptic meningitis, encephalitis, and encephalopathy occur in less than one case per million vaccinated. Centers for Disease Control and Prevention, *Prevention of specific diseases: Measles*, available at: <http://www2.ncid.cdc.gov/travel/yb/utills/ybGet.asp?section=dis&obj=measles.htm>.

²⁵ Bauch CT, Galvani AP and Earn DJD (2003) Group interest versus self-interest in smallpox vaccination policy *Proc Natl Acad Sci USA* **100**: 10564–7.

²⁶ Alternatively, it could be suggested that the risks from a threat that is 'natural' such as the infection itself, are perceived differently from the risks associated with a more 'unnatural' procedure such as vaccination.

²⁷ For example, very few people in developed countries now know of people who have experienced polio, whereas it used to be widespread, and the implications of this serious condition were well known.

²⁸ In addition, where global eradication of disease is achieved through population immunity, this has benefits for individuals outside the immediate population and for future generations.

²⁹ Bauch CT, Galvani AP and Earn DJD (2003) Group interest versus self-interest in smallpox vaccination policy *Proc Natl Acad Sci USA* **100**: 10564–7. See also footnote 18.

³⁰ Cornes R and Sandler T (1996) *The Theory of Externalities, Public Goods and Club Goods*, 2nd Edition (Cambridge: Cambridge University Press).

given to both boys and girls, even though mumps is generally most serious for males³¹ and rubella is serious only for women during pregnancy.³² The rubella vaccine was previously given selectively only to girls, but this strategy was changed as pregnant women continued to contract the infection. Similarly, there has been some debate about whether males should be expected to receive a vaccination for a virus that causes cervical cancer in women,³³ with some suggesting that they should, in order to reduce overall virus prevalence and transmission to women.³⁴

4.19 The paragraphs above illustrate that there is a wide range of different risks and benefits, affecting a variety of people, that need to be considered when deciding whether or not to introduce or change a particular vaccination programme. This may give rise to competing interpretations about whether or not a vaccination presents an acceptable balance of risks and benefits. So although a healthcare professional may be keen to enrol a person in a programme, taking the view that the risks are acceptable and that the benefits to the person concerned and/or others are substantial, the individual may be undecided, or not persuaded, for whatever reason. The fact that some healthcare professionals receive payments for meeting vaccination targets may further complicate such situations.³⁵ Also, the interests of companies involved in the (expensive and potentially risky) business of developing and producing vaccines may need to be considered. Some are critical of the extent to which these industries influence debate and policies on vaccines, and are sceptical as to whether these interventions are genuinely offered on the basis of medical need only.³⁶ One consultation respondent who took this viewpoint commented that:

“those who support vaccination most strongly are the drug companies, who stand to profit the most”. *Mrs Esther Hollands*

Alternative approaches to vaccination: voluntary, quasi-mandatory and incentivised schemes

4.20 Where vaccination programmes are introduced, there is a range of approaches for ensuring uptake. These vary from simply providing information and encouragement to take up the vaccine, to influencing or reducing choices more directly. In the UK, vaccinations are voluntary; however, other countries have different approaches, and we consider these next.³⁷ The main argument for policies that go beyond voluntary participation is based on the ethical considerations of stewardship, especially in relation to reducing health inequalities, and of reducing the risks of harm to others (see paragraphs 2.41–2.44). The latter is particularly relevant as there will always be people who have not been vaccinated because

³¹ Mumps can, however, sometimes cause swelling of the ovaries in women. Health Protection Agency, *Mumps – General Information*, available at: http://www.hpa.org.uk/infections/topics_az/mumps/gen_info.htm.

³² Health Protection Agency, *Rubella – General Information*, available at: http://www.hpa.org.uk/infections/topics_az/rubella/gen_info.htm.

³³ This virus does, however, cause infection in males and could also be linked with penile cancer, so there may be some benefits to the males themselves.

³⁴ The Lancet (2006) Should HPV vaccines be mandatory for all adolescents? *Lancet* **368**: 1212; Elbasha EH, Dasbach EJ and Insinga RP (2007) Model for assessing human papillomavirus vaccination strategies *Emerg Infect Dis* **13**: 28–41.

³⁵ In the UK, GPs are eligible for two bonus payments when over 70% and over 90% of children registered at their practice are immunised against certain diseases.

³⁶ For example, there is some controversy about initiatives by the pharmaceutical company Merck. The company was criticised in 2007 for its campaign in the USA to persuade state legislators to add its vaccine against the virus that can cause cervical cancer to their mandatory vaccine programmes. In February 2007, an announcement was made that Merck was ceasing its lobbying activities, after criticism that it was more interested in profits than health concerns and that this was fuelling objections to the vaccine, making the campaign “counterproductive”. Merck intended nevertheless to continue to provide education about the vaccine to health officials and legislators, and to lobby for more financing of vaccines in general. Pollack A and Saul S (2007) Merck to halt lobbying for vaccine for girls, *New York Times* 21 February, available at: <http://www.nytimes.com/2007/02/21/business/21merck.html?ex=1177473600&en=9ad641d15c1e7da1&ei=5070>.

³⁷ We do not deal separately with incentives for healthcare professionals who meet certain vaccination targets.

of their vulnerable status (see paragraph 4.30) or because they have not been reached for logistical or other reasons, and these people would suffer from the loss of population immunity. Furthermore, such strategies may have the advantage of ensuring that children are not missed out from a childhood vaccination programme, for example if they were immigrants or if their parents might not otherwise have known of or considered vaccination for their child. It could also be suggested that such strategies are more easily justified where the disease that would be prevented is severe or where the eradication of a serious disease is in reach.

4.21 While we are not aware of any countries that go as far as to force individuals to be vaccinated, there are several approaches that may be used to influence their behaviour. We consider three main types: quasi-mandatory programmes, in which individuals are required to be vaccinated unless they qualify for an exemption and where there are penalties for those who do not comply; incentivised programmes, in which vaccinations are optional but individuals who comply receive some reward, usually financial; and approaches focusing on voluntariness, in which vaccinations are optional and complying or not complying involves no penalties or incentives. In all cases, education and information campaigns are generally used to promote the benefits of vaccination and improve uptake. Incentivised and quasi-mandatory programmes can be viewed as more directive than purely voluntary policies, although they may vary in their directiveness according to, for example, the size of the incentive or penalty, or the ease of securing an exemption. In Box 4.2 and Appendix 3 we outline different vaccination policies used in different countries and indicate some of the vaccine coverage rates achieved in these countries.

Box 4.2: Vaccination policies

Under quasi-mandatory vaccination policies, parents are required to have their child vaccinated, unless they qualify for an exemption. The penalties for those who do not comply vary: in Belgium, Italy and Poland parents can be fined and/or sent to prison;³⁸ in France, Spain and the USA children cannot enrol for school unless they have received certain vaccinations.³⁹ Countries that operate quasi-mandatory vaccination policies often do so for only some vaccines, and have voluntary policies for others.

In Canada, vaccinations are not quasi-mandatory, but some states require proof of vaccination status for a child to enrol for school, such that the child must either have been vaccinated or have documentation to indicate that their parents have actively refused vaccination. Throughout Canada unvaccinated children can be excluded from school during outbreaks of vaccine-preventable disease.

Most countries provide vaccines free of charge, or the costs may be covered through health insurance schemes. In addition, some countries with voluntary schemes give parents incentives for vaccinating their children, or give health professionals incentives relating to their vaccine coverage rates. The incentives for parents are typically financial, and vary in size. In some cases there are 'lottery-style' incentives, whereby parents who comply with the vaccination schedule are eligible for a prize.⁴⁰

An overview of some of the policies applied in different countries and the vaccination uptake rates can be found in Appendix 3.

Comparing and assessing vaccination strategies

4.22 Assessing the effect of alternative strategies on vaccination coverage is not easy because of the interaction of many factors that affect the vaccination uptake rate, including cultural, historical, political and social factors that influence attitudes towards healthcare, as well as educational background and the accessibility of health services. Nevertheless, comparisons

³⁸ Moran NE, Shickle D, Munthe C *et al.* (2006) Are compulsory immunisations and incentives to immunise effective ways to achieve herd immunity in Europe? in *Ethics and Infectious Disease*, Selgelid MJ, Battin MP and Smith CB (Editors) (Malden, MA: Blackwell Publishing), pp.215–31.

³⁹ *Ibid.*; Wellborn AA (2005) *Mandatory Vaccinations: Precedent and current laws*, available at: www.fas.org/sgp/crs/RS21414.pdf.

⁴⁰ Moran NE, Shickle D, Munthe C *et al.* (2006) Are compulsory immunisations and incentives to immunise effective ways to achieve herd immunity in Europe? in *Ethics and Infectious Disease*, Selgelid MJ, Battin MP and Smith CB (Editors) (Malden, MA: Blackwell Publishing), pp.215–31; Achat H, McIntyre P and Burgess M (1999) Health care incentives in immunisation *Aust N Z J Public Health* 23: 285–8.

between countries or areas within countries, and evaluations of new policies can provide some insight into the implications of different strategies.

- 4.23 In France the coverage rates for quasi-mandatory vaccinations such as diphtheria, tetanus and polio (83–98%) are generally higher than for those that are voluntary, such as hepatitis B and measles (26–84%).⁴¹ Similar trends are observed for some other countries.⁴² However, this is not necessarily to suggest that quasi-mandatory vaccination schemes are the most effective.⁴³ Some of the highest levels of coverage in Europe, across all vaccines, are seen in Sweden, where vaccinations are voluntary.⁴⁴ Even where quasi-mandatory vaccination policies are effective in increasing vaccination rates, they can have some negative effects on vaccination uptake patterns. First, there may be lower uptake of any other vaccinations for which a quasi-mandatory approach is not adopted, as noted above for France. Secondly, where vaccination is required for school admission it has been suggested that parents might only get their children immunised just before starting school rather than at the recommended age for vaccination; this would mean that they may be susceptible at ages when their risk of contracting and spreading the disease is highest.⁴⁵ Further questions may be asked over whether quasi-mandatory policies are just, as the punishments for refusal to vaccinate, such as fines or refusal of access to education may disproportionately affect those on lower incomes.⁴⁶
- 4.24 Regarding providing incentives for parents, an international review and other studies of their use in immunisation have found that they have a positive influence on immunisation uptake, although cost-effectiveness varies.⁴⁷ Incentives of modest value can be effective, which is particularly relevant in ethical terms, as higher-value incentives may lead people to take risks they might not wish to take had no incentive been provided.
- 4.25 Those favouring an entirely voluntary approach will generally do so by focusing on the values of individual autonomy and consent, and they may emphasise the possible harms involved in vaccination. The case of vaccination illustrates important limitations of purely voluntary approaches in the context of public health, because the consequences of decisions about

⁴¹ Antona D, Bussière E, Guignon N, Badeyan G and Lévy-Bruhl D (2003) Vaccine coverage of pre-school age children in France in 2000 *Euro Surveill* 8: 139–44; available at: <http://www.eurosurveillance.org/em/v08n06/0806-224.asp>.

⁴² *Ibid.*

⁴³ The coverage rates can also be affected by how strictly the quasi-mandatory policies are applied; for example, not all countries actively enforce the penalties for non-compliance, particularly when the level for population immunity is already reached. Moran NE, Shickle D, Munthe C *et al.* (2006) Are compulsory immunisations and incentives to immunise effective ways to achieve herd immunity in Europe? in *Ethics and Infectious Disease*, Selgelid MJ, Battin MP and Smith CB (Editors) (Malden, MA: Blackwell Publishing), pp.215–31.

⁴⁴ According to WHO, 99% coverage was recorded in 2005 for diphtheria, tetanus, polio, pertussis and HiB, see WHO, *Sweden Reported Immunization Coverage*, available at: <http://www.who.int/vaccines/globalsummary/immunization/timeseries/tscveragebycountry.cfm?country=Sweden>; Swedish Institute for Infectious Disease Control, *The Swedish Vaccination Program*, available at: <http://www.smittskyddsinstitutet.se/in-english/activities/the-swedish-vaccination-program/>.

⁴⁵ Moran NE, Shickle D, Munthe C *et al.* (2006) Are compulsory immunisations and incentives to immunise effective ways to achieve herd immunity in Europe? in *Ethics and Infectious Disease*, Selgelid MJ, Battin MP and Smith CB (Editors) (Malden, MA: Blackwell Publishing), pp.215–31.

⁴⁶ *Ibid.*

⁴⁷ Achat H, McIntyre P and Burgess M (1999) Health care incentives in immunisation *Aust N Z J Public Health* 23: 285–8. In 1998 Australia implemented several broad vaccination incentives for parents, and two subsequent studies investigating the effect of these strategies found that vaccination coverage increased significantly in the populations studied. However, one incentive was the payment of child care benefit only where the child was up-to-date with vaccinations, and it was reported in one study in 2004 that only 31% of the parents who were receiving this benefit could have afforded child care without it. Bond L, Davie G, Carlin JB, Lester R and Nolan T (2002) Increases in vaccination coverage for children in child care, 1997 to 2000: an evaluation of the impact of government incentives and initiatives *Aust N Z J Public Health* 26: 58–64; Lawrence GL, MacIntyre CR, Hull BP and McIntyre PB (2004) Effectiveness of the linkage of child care and maternity payments to childhood immunization *Vaccine* 22: 2345–50.

vaccinations affect not only the people who are considering whether to receive a vaccination, but also others. Quasi-mandatory approaches tend therefore to shift the emphasis away from protecting the interests of the individual, and towards providing benefits to others.⁴⁸

- 4.26 **In general, public health policies should use the least intrusive means to achieve the required public health benefit. Directive vaccination approaches that go further than simply providing information and encouragement to take up the vaccine may, however, be justified on the basis of minimising risks of harm to others, or protecting the health of children and other vulnerable people. A case-by-case assessment will always be required. When assessing whether more directive policies are acceptable, the following factors should be taken into account: the risks associated with the vaccination and with the disease itself, and the seriousness of the threat of the disease to the population. In the case of incentivised policies, the size of the incentive involved should be appropriate so that it would not unduly compromise the voluntariness of consent.**
- 4.27 **We identified two circumstances in which quasi-mandatory vaccination measures are more likely to be justified. First, for highly contagious and serious diseases, for example with characteristics similar to smallpox. Secondly, for disease eradication if the disease is serious and if eradication is within reach.**
- 4.28 A more difficult case is raised by a few diseases for which vaccinations could be targeted at the whole population to achieve population immunity, but where the disease would not have been a significant threat to all those vaccinated (paragraph 4.18). In this situation there is no substantial personal benefit to some of the people who might be included in the vaccination programme. Vaccination of males against rubella and a virus that causes cervical cancer or of females against mumps would be examples (see paragraph 4.18). These disease prevention strategies may not be successful if all involved take purely self-interested approaches.
- 4.29 **On the basis of the value of community and stewardship considerations, it is in principle ethically justified to encourage individuals to take part in vaccination programmes when there is no, or only a small, personal benefit, but significant benefits for others. However, consent is essential, and there should be careful assessments of the benefits to be gained for the population and the possible harm that may result for the people who receive the vaccination.**

Children as special cases

- 4.30 Special consideration of the role of consent (paragraphs 2.22–2.26) is required in the case of children, who are usually, and legally, unable to consent for themselves. Children are one of the more vulnerable groups in society, and the decision about whether to vaccinate a child may have significant implications for their prospect of leading a healthy life. A small number of children are unable to receive vaccinations for medical reasons, but for most the parents will decide whether they should be vaccinated. To decide such matters, it is reasonable to expect that parents should focus on best interest considerations. Where they fail to do so,

⁴⁸ We note that there may be other cases where quasi-mandatory vaccinations may be acceptable, where the aim is not to achieve population immunity. For example, the harm principle and the value of the community, as well as pragmatic considerations, could be invoked to support vaccination of all healthcare workers against specific serious diseases as a condition of their employment, as there might be a risk that they could otherwise infect their patients. In addition it could be argued that their professional role in the case of an epidemic is of such central importance that they need to be protected in order to protect others.

the stewardship-guided state may intervene in exceptional cases to ensure that the welfare of children is protected (paragraph 2.44). We therefore agree with the following response to our consultation:

“Ordinarily, ... parents are deemed to be the best judges of their [children’s] interests and ... make decisions [on] vaccination [etc.]. [...] Where parents make choices that seem ... seriously at odds with the child’s interests, legally and ethically such choices can be overridden. The courts have shown themselves willing to intervene to consent or refuse treatment on behalf of a child, even in the face of concerted parental opposition. Such cases have usually involved potential serious harm, and in relation to vaccination in the face of parental refusal, a risk of serious harm would have to be demonstrated.” *British Medical Association*

- 4.31 The best-interests standard can be difficult to apply in some scenarios raised by vaccinations. In particular, in the case of vaccinating against a disease for which population immunity exists, the additional benefit to the child from being vaccinated is very small since they would otherwise be protected by population immunity. As such it could be considered that it is rational, or possibly in an individual’s best interests, not to receive the vaccine (see paragraphs 4.14–4.19).⁴⁹ Nonetheless, there is a benefit to the community in contributing to the maintenance of population immunity. We therefore take the view that best interests considerations should take into account not only the health needs of the individual, but also the wider context of the decision, and that it is appropriate to appeal to parents to vaccinate their children on the basis of the value of community (paragraph 2.34).⁵⁰
- 4.32 We concluded above (paragraph 4.26) that when assessing whether more directive vaccination policies are acceptable, the following factors should be taken into account: the risks associated with the vaccination and with the disease itself, and the seriousness of the threat of the disease to the population. In addition, there needs to be consideration of whether directive measures would be more effective than voluntary ones. The evidence on this for routine childhood vaccinations is complex and limited. Therefore, **at present, there is not sufficient justification in the UK for moving beyond the current voluntary system and implementing incentivised or quasi-mandatory policies for routine childhood vaccinations.**

Vaccinations in the media

- 4.33 As we noted above, achieving population immunity through vaccination depends to a significant degree on the cooperation of very many individuals. Any situation that brings about a lack of cooperation by some of these individuals to the extent that population immunity is jeopardised has the potential to have a highly damaging effect on population health. This is a potential consequence where evidence or risk relating to vaccination is portrayed poorly or inaccurately by media reporting (see paragraphs 3.3–3.14, 3.44). A salient example is that of the MMR vaccine, and we outline the background to the controversy in Box 4.3.

⁴⁹ Bauch CT, Galvani AP and Earn DJD (2003) Group interest versus self-interest in smallpox vaccination policy *Proc Natl Acad Sci USA* **100**: 10564–7.

⁵⁰ *Ibid.*

Box 4.3: MMR and the media

A childhood vaccination scheme for measles has been in operation in the UK since 1968, initially with the single measles vaccine, and since 1988 with the combined MMR vaccine.⁵¹ In the 1950s the number of cases of measles reported in England and Wales regularly reached 500,000, but by the 1990s this number had fallen considerably, with fewer than 200 cases each year between 1996 and 2000.⁵²

In 1998 a paper suggesting a link between the MMR vaccine, and autism and bowel disease was published in *The Lancet*.⁵³ The study was weak and considerable other evidence did not support its findings,⁵⁴ but it was widely reported in the media, causing misperceptions of the strength of the evidence.⁵⁵ The journal has since stated that the study was flawed, that the lead author had a serious conflict of interest, and that as such it should never have published the paper.⁵⁶ In addition, ten of the 13 authors of the paper issued a retraction relating to the paper in 2004.⁵⁷ Further poor media coverage casting doubts over the safety of the MMR vaccine has, however, continued.⁵⁸

Public confidence in the vaccine declined after the publication of the 1998 paper, and the vaccine coverage decreased below the minimum population immunity level of 90% across the UK.⁵⁹ A low of 80% vaccine coverage was reached in 2003–4 in England and Wales, although uptake has now begun to increase in all areas. A number of large measles outbreaks have occurred since the vaccination rate began to fall,⁶⁰ and during 2006 the number of cases in England and Wales reached its highest level for 20 years, and the first death caused by measles for 14 years was reported.⁶¹

4.34 The MMR example illustrates how media reports can influence public perceptions, potentially hindering public health measures and affecting population health. The Council noted the importance of accurately reporting evidence in one of its previous Reports, on the example of genetic research.⁶² In the context of public health we consider this to be particularly important given the potential for adverse consequences on population health. As in our previous Report, **we consider that researchers, journalists and others who report**

⁵¹ Asaria P and MacMahon E (2006) Measles in the United Kingdom: can we eradicate it by 2010? *Br Med J* **333**: 890–5.

⁵² Health Protection Agency, *Annual Measles Notifications and Vaccine Coverage 1950–2000*, available at: http://www.hpa.org.uk/infections/topics_az/measles/vaccine_coverage.htm; Health Protection Agency, *Confirmed cases of Measles, Mumps & Rubella 1996–2006*, available at: http://www.hpa.org.uk/infections/topics_az/measles/data_mmr_confirmed.htm.

⁵³ Wakefield AJ, Murch SH, Anthony A *et al.* (1998) Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children *Lancet* **351**: 637–41.

⁵⁴ Further studies, in particular a Cochrane systematic review published in 2005, have found insufficient evidence for the claimed link between the MMR vaccine and either autism or inflammatory bowel disease. Demicheli V, Jefferson T, Rivetti A and Price D (2005) Vaccines for measles, mumps and rubella in children *Cochrane Database of Systematic Reviews* Issue 4, Art. No.: CD004407, DOI: 10.1002/14651858.CD004407.pub2.

⁵⁵ Hargreaves I, Lewis J and Speers T (2003) *Towards a Better Map: Science, the public and the media* (London: Economic & Social Research Council). For further information about the safety of the MMR vaccine and its review, see Medicines and Healthcare products Regulatory Authority, *MMR Vaccine*, available at: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=237.

⁵⁶ Dunne R (2004) Inside the world of medical journals *BBC News Online* 23 February, available at: <http://news.bbc.co.uk/1/hi/health/3513791.stm>.

⁵⁷ Murch SH, Anthony A, Casson DH *et al.* (2004) Retraction of an interpretation *Lancet* **363**: 750.

⁵⁸ On 8 July 2007 *The Observer* ran a front-page story on the issue entitled “New health fears over big surge in autism”, with the subheading “Questions over triple jab for children”. This piece received considerable criticism elsewhere, see Goldacre B (2007) The MMR story that wasn’t *The Guardian* 18 July, available at: <http://www.guardian.co.uk/comment/story/0,,2128807,00.html>; Ahuja A (2007) Autism: The truth *The Times* 12 July, available at: http://www.timesonline.co.uk/tol/life_and_style/health/article2060575.ece; Bad Science Blog, available at: <http://www.badsience.net/?p=464>. We note also that in February 2007 the BBC OneLife website carried an article on autism suggesting that “many people are convinced [a link between MMR and autism] exists” (copy available from the Nuffield Council on Bioethics), although by August 2007 a search for similar articles on autism revealed none that reported such a link as favourably.

⁵⁹ The Information Centre, NHS (2006) *NHS Immunisation Statistics (England) 2005–6*, available at: http://www.ic.nhs.uk/webfiles/publications/immstats2005to2006/ImmunisationStatistics280906_PDF.pdf; Scottish Executive (2003) *Latest Immunisation Statistics*, available at: <http://www.scotland.gov.uk/News/Releases/2003/06/3625>; National Statistics (2005) *NHS Immunisation Statistics (Wales) 2004–5*, available at: http://newydd.cymru.gov.uk/legacy_en/keypubstatisticsforwales/content/publication/health/2005/sdr109-2005/sdr109-2005.pdf; Department of Health, Social Services and Public Safety (Northern Ireland) (2006) *Community Statistics: 1st April 2005 – 31st March 2006*, available at: http://www.dhsspsni.gov.uk/community_stats_06.pdf.

⁶⁰ Jansen VAA, Stollenwerk N, Jensen HJ, Ramsay ME, Edmunds WJ and Rhodes CJ (2003) Measles outbreaks in a population with declining vaccine uptake *Vaccine* **301**: 804.

⁶¹ Health Protection Agency (2006) *Health Protection Matters*, Issue 5, available at: http://www.hpa.org.uk/publications/HPM/summer_2006.pdf.

⁶² Nuffield Council on Bioethics (2002) *Genetics and Human Behaviour: The ethical context* (London: Nuffield Council on Bioethics), paragraphs 11.12–11.14.

research have a duty to communicate findings in a responsible manner. Those who report research should take account of the *Guidelines on Science and Health Communication* published by the Social Issues Research Centre, the Royal Society and the Royal Institution of Great Britain.⁶³ In particular we emphasise that the source and the status of scientific evidence alluded to should be identified (for example, whether it is preliminary findings or a conference presentation, and whether it has been peer reviewed).

- 4.35 We also encourage initiatives that provide independent information that is accessible to the public on the accuracy and reliability of medical stories reported in the media. An example of such an initiative is the National Library for Health's 'Hitting the Headlines' resource,⁶⁴ which provides summaries relating to media reports within two days of their publication.

Surveillance

- 4.36 We examine the ethical issues raised by two distinct types of infectious disease surveillance. First, we consider population surveillance methods to detect important risks and trends in infectious diseases, and to inform the planning of public health interventions or further investigations. Secondly, we discuss schemes aiming to detect individual cases of diseases that might require control measures to be implemented, in particular through notifiable disease strategies.

Broad surveillance for research and monitoring trends

- 4.37 Surveillance involving the systematic collection, analysis and interpretation of data about incidence and prevalence of infectious diseases, and factors that may contribute to them, forms an integral part of the protection of population health. Data used in this context are generally collected in anonymised form, although the degree of anonymisation can vary. Such data can provide important insights into basic epidemiological questions and trends, and identification of emerging strains and novel infectious agents. Surveillance information is also important in identifying groups who are at risk of certain infections, and for devising strategies for preventing and controlling outbreaks. For example the Health Protection Agency uses data on the incidence of influenza and the uptake of influenza vaccines to guide policies on protecting the UK population from this infection.⁶⁵

Collection and use of surveillance data and consent

- 4.38 There are various benefits to this type of infectious disease surveillance, but there are also objections to the collection and use of surveillance data, in particular regarding consent.⁶⁶ We have noted that obtaining consent is crucial in legitimising interventions that involve some risk to the patient or research participant. There is no question that this requirement is important where there are potentially serious health risks to the individual, for example, in the case of clinical medicine or research involving a new medicine. However, it is far less clear whether people should necessarily have the same authority and control over, for example, biological samples or medical data, particularly where these are anonymised, because it is more difficult to identify relevant harms.⁶⁷ Overall the Working Party is not persuaded that there are significant harms involved where the data are suitably anonymised.

⁶³ Social Issues Research Centre, the Royal Society and the Royal Institution of Great Britain (2001) *Guidelines on Science and Health Communication*, available at: http://www.sirc.org/publik/revised_guidelines.pdf.

⁶⁴ See: <http://www.library.nhs.uk/hth/> and <http://www.library.nhs.uk/rss/newsAndRssArchive.aspx?storyCategory=0>.

⁶⁵ Health Protection Agency *Seasonal influenza*, available at: http://www.hpa.org.uk/infections/topics_az/influenza/seasonal/default.htm.

⁶⁶ For further discussion of issues raised in this section see: Verity C and Nicoll A (2002) Consent, confidentiality, and the threat to public health surveillance *Br Med J* **324**: 1210–3.

⁶⁷ We note that indeed the Human Tissue Act (2004) excludes public health monitoring from the purposes for which consent to tissue storage and use is required.

- 4.39 The collection of anonymised surveillance data on trends in infectious disease ranks low on the intervention ladder. Without sufficient data, it may not be possible to assess and predict trends and risks in infectious diseases. **It is acceptable to collect and use anonymised data for assessing and predicting trends in infectious disease without consent, as long as any invasion of privacy is reduced as far as possible.**
- 4.40 In some circumstances it may be necessary to collect surveillance data in a non-anonymised way, but provided adequate systems are in place to ensure confidentiality of the collected data, it may be justifiable to collect such data without consent. We are aware of several examples of surveillance policies in which consent requirements have had, or could have had, serious negative consequences for the surveillance in question. Some of these are discussed in Box 4.4.⁶⁸

Box 4.4: Consent and population health surveillance

Here we describe two policies that illustrate how consent requirements for population health surveillance schemes can be overly onerous, with implications for the research and surveillance being conducted:

1) Research and surveillance using newborn blood spots

At present in the UK, four 'blood spots' are routinely taken from newborn babies on a blood spot card, which is used for screening for certain diseases, including phenylketonuria and sickle cell disorders. In addition, these blood spot cards can subsequently be stored and used, after being unlinked and anonymised, for research. Because these blood spot cards are collected from nearly all newborn children,⁶⁹ they are very useful for surveillance, for example on HIV prevalence,⁷⁰ and other research purposes. Parents are given the choice over whether or not their baby has blood spots taken and screened,⁷¹ but there has been debate over whether their consent should also be required for the storage of the blood spot cards and research using these. In 2003, the consent process was changed in Scotland to require a parental signature for each of several elements of the programme, including taking and screening blood spots, storing residual specimens, and research on these specimens.⁷² Following this change more parents were found to refuse blood spot screening altogether, which became a cause of concern.⁷³ In 2005, the UK Newborn Screening Programme Centre published new guidelines on this matter, stating that "Residual newborn blood spots may also be used for research where the samples have been anonymised and the research project has ethical approval, as outlined in the Human Tissue Act and in MRC Guidance, without individual informed consent."⁷⁴ It should be noted though, that the parental information leaflets on blood spot screening do state that the blood spots may be used for public health monitoring and research.⁷⁵

2) Research using human tissue, e.g. tonsils

The National Anonymous Tonsil Archive (NATA) began collecting and archiving tonsil tissue from individuals undergoing routine tonsillectomy in 2003, except where individuals opted out, and hopes to collect 100,000 tonsils.⁷⁶ The tonsils collected would otherwise have been destroyed routinely after removal. One use of the archive is to study the prevalence of the prion protein that is believed to cause variant Creutzfeldt-Jakob disease (vCJD). In 2004 an early version of the Human Tissue Bill was drafted that required the consent of patients for the storage and use of these leftover tissues, which would have severely affected the NATA and other similar projects.⁷⁷ A number of groups including the British Medical Association (BMA) and the Royal College of Pathologists lobbied for changes on this. They suggest that such requirements would be costly in terms of money and human resources for the administration and infrastructure needed, and hence jeopardise the future of this form of surveillance. The Bill was subsequently amended to allow such storage and use without consent, although with safeguards, including the requirements that the research is approved by a Research Ethics Committee, and that the samples are anonymised.⁷⁸

⁶⁸ For further examples of surveillance systems that could be jeopardised if it became necessary to either obtain explicit patient consent or totally anonymise data, see additional online materials from: Verity C and Nicoll A (2002) Consent, confidentiality, and the threat to public health surveillance *Br Med J* 324: 1210–3.

⁶⁹ It has been reported that over 99% of newborn babies are screened; UK Newborn Screening Programme Centre, *Why we need a newborn screening programme*, available at: <http://www.newbornscreening-bloodspot.org.uk/>.

⁷⁰ Health Protection Scotland, *Unlinked Anonymous HIV Testing of Dried Blood Samples from Newborn Infants (The Guthrie study)*, available at: <http://www.hps.scot.nhs.uk/bbvsti/ssdetail.aspx?id=52>.

⁷¹ UK Newborn Screening Programme Centre (2005) *Newborn Blood Spot Screening in the UK – Policies and standards*, available at: http://www.ich.ucl.ac.uk/newborn/download/policies_standards.pdf.

⁷² UK Newborn Screening Programme (2004) *Proposed Standards and Policies for Newborn Blood Spot Screening – An integrated consultation*, available at: http://www.ich.ucl.ac.uk/newborn/download/proposed_standards_consultation.pdf.

⁷³ *Ibid.*

⁷⁴ UK Newborn Screening Programme Centre (2005) *Newborn Blood Spot Screening in the UK – Policies and standards*, available at: http://www.ich.ucl.ac.uk/newborn/download/policies_standards.pdf.

⁷⁵ Available to download at: <http://www.ich.ucl.ac.uk/newborn/resources/delivery.htm#parents>.

⁷⁶ Health Protection Agency (17 January 2007) *The National Anonymous Tonsil Archive (NATA)*, available at: http://www.hpa.org.uk/infections/topics_az/cjd/tonsil_archive.htm.

⁷⁷ Dyer C (2004) Human Tissue Bill is modified because of research needs *Br Med J* 328: 1518.

⁷⁸ This ensures that there is no information that would allow the identification of the person from whom the tissue was taken.

Surveillance to detect cases of disease that require intervention

4.41 Medical practitioners have a statutory obligation to report cases of certain infectious diseases to local authorities (see Box 4.5). The list of diseases that are 'notifiable' in this way varies from country to country, illustrating, in part, the international diversity in the cultural, ethical and regulatory frameworks that governs the control of infectious diseases.

Box 4.5: Notifiable diseases in the UK and elsewhere

UK policy

In the UK the statutory requirement for notification of infectious diseases was first established in London in 1891, when cholera, diphtheria, smallpox and typhoid had to be reported by the head of the family or the landlord to the local authority. Nowadays, doctors in the UK have a statutory duty under public health legislation⁷⁹ to notify the relevant officer of the local authority of suspected cases of around 30 infectious diseases, including, for example, measles, mumps, rabies and smallpox.⁸⁰ In addition, childminders, day care centres and schools that cater for children under eight years old are required to notify Ofsted (Office for Standards in Education, Children's Services and Skills) of any cases of notifiable diseases and of food poisoning affecting two or more children.⁸¹ Two main purposes of the notifiable disease system are for the rapid detection of outbreaks and epidemics and for the implementation of measures to control such outbreaks by local public health officials. Some of the information relating to each notification is passed on, in an anonymised form, to the Health Protection Agency for England and Wales and the Information Services Division (ISD) in Scotland for evaluation at a national level.⁸²

Policy in other countries

Notifiable disease schemes exist in other countries and internationally. The diseases included in each country are usually revised periodically, but, for example, at present in New Zealand there are around 50 such diseases and in the USA around 60, with some variations between states.⁸³

WHO policy

Under the revised *International Health Regulations* of 2005, a few diseases considered to have a "serious public health impact" (smallpox, poliomyelitis caused by wild-type poliovirus, human influenza caused by a new subtype, and SARS) must additionally be reported to WHO. So too must any other cases of infectious diseases deemed to constitute, under WHO definitions, a "public health emergency of international concern".⁸⁴

4.42 After a notification, the relevant authorities may take action to investigate the outbreak and implement measures to prevent the spread of the disease. For example, under UK legislation, in some circumstances an individual with an infection could be detained at a treatment centre,⁸⁵ or, more commonly, excluded from the work place if the infection represents a threat to the community (for example if they work in food production).⁸⁶ Where medical professionals pass on details of cases of notifiable diseases for the purposes of control, it is not required that the individual agrees to them doing so and the data passed on necessarily include information that identifies the individual. Some might take the view that consent and privacy considerations make this unacceptable. However, we noted previously the different roots of the concept of

⁷⁹ In England and Wales: the Public Health (Control of Disease) Act 1984 and the Public Health (Infectious Diseases) Regulations 1988; in Scotland: the Public Health (Notification of Infectious Diseases) (Scotland) Regulations (1988).

⁸⁰ The list of notifiable diseases is different in Scotland (see Schedule 1 of the Public Health (Notification of Infectious Diseases) (Scotland) Regulations (1988), available at: http://www.opsi.gov.uk/SI/si1988/Uksi_19881550_en_2.htm) and England and Wales (see: http://www.hpa.org.uk/infections/topics_az/noids/noidlist.htm).

⁸¹ Health Protection Agency, *Day Care and Child Minding (National Standards)*, available at: http://www.hpa.org.uk/infections/topics_az/noids/day_care.htm.

⁸² The information collected nationally is the age and sex of the individual, the disease, the local authority and the year and week of notification. Health Protection Agency, *General Information – Notifications of Infectious Diseases (NOIDS)*, available at: http://www.hpa.org.uk/infections/topics_az/noids/gen_info.htm; ISD Scotland, *Infectious Diseases*, available at: <http://www.isdscotland.org/isd/1522.htm>.

⁸³ Centers for Disease Control (2006) Summary of notifiable diseases – United States, 2004 *Morb Mortal Wkly Rep* 53: 1–79, available at: <http://www.cdc.gov/MMWR/preview/mmwrhtml/mm5353a1.htm>; Ministry of Health (New Zealand) (2005) *Notifiable Diseases*, available at: http://www.moh.govt.nz/moh.nsf/wpg_index/About-notifiable+diseases.

⁸⁴ World Health Assembly (2005) *International Health Regulations (2005)*, available at: http://www.who.int/csr/ihr/IHRWHA58_3-en.pdf.

⁸⁵ For example an individual with multi-drug-resistant tuberculosis who refuses to take precautions to prevent transmission to others. Public Health Laboratory Service (2002) Hospital acquired multi drug resistant tuberculosis *Commun Dis Rep CDR Wkly* [serial online] 12 (42), available at: <http://www.hpa.org.uk/cdr/archives/2002/cdr4202.pdf>.

⁸⁶ For example, in the case of typhoid or another serious gastrointestinal infection. In such circumstances the person may receive compensation for their loss of earnings.

consent in the context of clinical medicine and public health (paragraphs 2.22–2.26), and the role of proportionality (paragraph 3.18). Both of these are relevant where a public health intervention has significant potential benefits for the population and no substantial risks to the individual.⁸⁷

- 4.43 Infectious disease monitoring strategies involving the collection of information including identifying data for the purpose of implementing control measures for individuals, as for some notifiable diseases, rank higher on the intervention ladder than surveillance based on anonymised data (see paragraphs 4.37–4.39). The aim of such measures is generally to prevent harm to others from the spread of disease, which means that they can be justified under the classical harm principle. **The avoidance of significant harm to others who are at risk from a serious communicable disease may outweigh the consideration of personal privacy or confidentiality, and on this basis it can be ethically justified to collect non-anonymised data about individuals for the purposes of implementing control measures. However, any overriding of privacy or confidentiality must be to the minimum extent possible to achieve the desired aim.**

HIV and AIDS as notifiable diseases

- 4.44 Particular controversy surrounds the question of whether HIV and/or AIDS should be included as notifiable diseases. In the UK they are not, although there is a voluntary national reporting system, as well as other surveillance systems, but elsewhere, including the USA and Australia, these are included as notifiable diseases.⁸⁸ In some places, including New York State, the HIV notification legislation requires that infected individuals name their sexual partners and these people are notified by health professionals of their risk of having the infection, although no details will be given about the individual who named them.⁸⁹ This ‘partner notification’ law is controversial, but has been proposed as a means of limiting the spread of communicable disease.⁹⁰
- 4.45 The question of whether to include HIV/AIDS as notifiable diseases in the UK⁹¹ has raised concerns about human rights, discrimination,⁹² stigma and penalties from insurance companies.⁹³ Another concern was that mandatory notification might ‘drive the disease underground’, as it was feared that potentially infected people might avoid contact with healthcare professionals. Whether these negative consequences would have occurred in practice has been the subject of debate, but we use this example to note that the case of HIV/AIDS illustrates the importance of taking into account the particular context of the disease in question.
- 4.46 First, a main argument for making HIV/AIDS notifiable diseases would be the classical harm principle, i.e. that this would enable others to be protected from the infection. However, this approach might be of limited utility, as information about people’s HIV status cannot easily

⁸⁷ Verity C and Nicoll A (2002) Consent, confidentiality, and the threat to public health surveillance *Br Med J* 324: 1210–3.

⁸⁸ CDC (USA) (2006) *Nationally Notifiable Infectious Diseases*, available at: <http://www.cdc.gov/epo/dphsi/phs/infdis2006.htm>; Australian Government Department of Health and Ageing, *Nationally Notifiable Diseases*, available at: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/cda_surveil-nndss-dislist.htm#dislist.

⁸⁹ New York State Department of Health, *HIV/AIDS Laws and Regulation: What you need to know about the law*, available at: <http://www.health.state.ny.us/diseases/aids/regulations/notification/hivpartner/qanda.htm>.

⁹⁰ We note that in 2006 the Department of Health for England held a consultation “Confidentiality and Disclosure of Patient Information: HIV and Sexually Transmitted Infection (STIs)”, which relates to some of the issues discussed here. See http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4137711.pdf.

⁹¹ Similar issues arise in the debate about proposals for the routine screening of immigrants for infectious diseases such as tuberculosis.

⁹² We note that the existence and enforcement of anti-discrimination laws and protection of privacy varies greatly among countries, and that this influences policy on HIV surveillance.

⁹³ Berridge V (1996) *AIDS in the UK: The making of a policy, 1981–1994* (Oxford: Oxford University Press).

be used to protect others.⁹⁴ Secondly, it may be that the surveillance objectives of notifiable disease programmes could be realised without the full regime entailed by such schemes. HIV is subject to several surveillance and reporting systems⁹⁵ that allow the collection of useful data, but these data are either fully or partly anonymised, protecting as far as possible the individual from personal identification.⁹⁶ Indeed, because HIV often remains undiagnosed for some time after initial infection, case notification or reporting of cases would not necessarily give a full picture of the prevalence of the disease, whereas one of the surveillance programmes in use in the UK assesses prevalence across the population by testing unlinked anonymised samples from a large number of patients.⁹⁷ The information gained is used to plan and evaluate health promotion programmes and services for those affected by HIV/AIDS, and is likely to be better suited to this purpose than a notifiable disease scheme would be. Hence the question of whether or not a disease should be notifiable requires ethical consideration of issues such as the classical harm principle and the role of consent, in combination with evaluation of the empirical context of the disease.

Surveillance in an international context

4.47 Outbreaks of infectious disease can have global implications. We note that in 2007 the Department of Health for England published a report on the international context of health, which included discussion of infectious disease.⁹⁸ It describes “the need for an international approach if we are to protect the health of the UK population, reduce global poverty and harness the opportunities of globalization”, and suggests a UK Government-wide strategy in this area. In addition in 2007 the Department for International Development published a new health strategy, based on the principle that “improving health is crucial in the fight against global poverty”.⁹⁹

4.48 In relation to surveillance, the very nature of infectious diseases and the context of global travel and trade, which may assist in spreading diseases very rapidly, underline the fact that effective surveillance programmes are not simply a national matter.¹⁰⁰ The sharing of surveillance data is increasing through international agencies such as WHO, the European Centre for Disease Prevention and Control, the Centers for Disease Prevention and Control (CDC) in the USA and regional disease surveillance networks and initiatives. It is through these systems that emerging outbreaks such as SARS (see also Box 4.6) and avian influenza may be identified, and the information gained can be used to inform interventions and raise professional and public awareness. The global *International Health Regulations*, revised in 2005, now require member states to notify WHO of any potential international public health emergency.¹⁰¹

⁹⁴ Although, we note that Cuba has a quarantine policy for individuals infected with HIV, see: Hansen H and Groce N (2003) Human immunodeficiency virus and quarantine in Cuba *J Am Med Assoc* **290**: 2875.

⁹⁵ These include the HIV and AIDS patient reporting system (HAP), the Survey of Prevalent HIV Infections Diagnosed (SOPHID), the Unlinked Anonymous HIV Surveillance Programme and the National Study of HIV in Pregnancy and Childhood; see Health Protection Agency, *Epidemiology – HIV and AIDS*, available at: http://www.hpa.org.uk/infections/topics_az/hiv_and_sti/hiv/epidemiology/introduction.htm.

⁹⁶ See Health Protection Agency, *The Unlinked Anonymous Prevalence Monitoring Programme*, available at: http://www.hpa.org.uk/infections/topics_az/hiv_and_sti/hiv/epidemiology/ua.htm.

⁹⁷ Health Protection Agency, *Epidemiology – HIV and AIDS*, available at: http://www.hpa.org.uk/infections/topics_az/hiv_and_sti/hiv/epidemiology/introduction.htm; Health Protection Agency, *The Unlinked Anonymous Prevalence Monitoring Programme*, available at: http://www.hpa.org.uk/infections/topics_az/hiv_and_sti/hiv/epidemiology/ua.htm.

⁹⁸ Department of Health (2007) *Health is Global*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_072697.

⁹⁹ Department for International Development (2007) *Working Together for Better Health*, available at: <http://www.dfid.gov.uk/Pubs/files/health-strategy07.pdf>.

¹⁰⁰ USA National Intelligence Council (2000) *The Global Infectious Disease Threat and its Implications for the United States – Factors affecting growth and spread: International trade and commerce*, available at: http://www.dni.gov/nic/PDF_GIF_otherprod/infectiousdisease/infectiousdiseases.pdf.

¹⁰¹ World Health Assembly (2005) *International Health Regulations (2005)*, available at: http://www.who.int/csr/ihr/IHRWHA58_3-en.pdf.

- 4.49 The stewardship model we introduced in Chapter 2 is usually applied at the national level in relation to obligations that states have towards those affected by their laws and policies. However, it is also reasonable to apply it at a much higher level. In the case of SARS in 2002/3, China was criticised for delays in reporting cases and an initial lack of cooperation with WHO.¹⁰²
- 4.50 If a country fails to inform other countries of an outbreak of a serious infectious disease, the disease may spread more rapidly across the world. **Based on an application of the stewardship model (paragraphs 2.41–2.44) at the global level, countries have an ethical obligation to reduce the risk of ill health that people might impose on each other across borders. Therefore countries should notify other relevant countries and bodies about outbreaks of serious diseases at the earliest stage, following the relevant procedures laid out by WHO.** However, early detection of outbreaks requires an efficient surveillance system, and different countries at present have different capacities for surveillance, monitoring and reporting of infectious diseases. We note that both WHO and a Foresight report have identified a need for greater investment in surveillance capacity in poorer countries.¹⁰³ Guided by an application of the stewardship model (paragraphs 2.41–2.44) to the global context, we endorse this conclusion and recommend that **countries such as the UK should seek to enhance the capacities of developing countries to conduct effective surveillance of infectious diseases. The UK health departments, in liaison with the Department for International Development, should work to take this forward with international partners such as WHO, the European Centre for Disease Prevention and Control (ECDC) and the Centers for Disease Prevention and Control (CDC) in the USA.**
- 4.51 Gathering and passing on data related to infectious diseases that have pandemic potential is one important part of pandemic preparedness strategies, nationally and globally. The interests of many different parties may be affected by such activities, including: populations and governments of different countries, medical professionals, researchers, pharmaceutical companies and WHO. These interests can, however, come into conflict, and a controversy in early 2007 highlighted the fragility of global pandemic preparedness, when the Indonesian Government decided to suspend the sharing of clinical specimens of human avian influenza viruses with the surveillance system managed by WHO.¹⁰⁴
- 4.52 Indonesia has had more cases of avian influenza in humans than any other country in recent years and is considered to be a country in which a pandemic of H5N1 influenza might emerge.¹⁰⁵ Indonesian officials ceased cooperation with the surveillance system managed by WHO over concerns that the country would not have reasonable access to the benefits resulting from its contribution to global pandemic surveillance.¹⁰⁶ In particular, it was suggested that any vaccines developed by pharmaceutical companies using the virus isolates processed and made available through the WHO system were unlikely to be available and affordable in developing countries.

¹⁰² Fleck F (2003) How SARS changed the world in less than six months *Bull World Health Org* 81(8): 625–6. Other examples are those of cholera, plague and yellow fever, which are supposed to be reported by all countries. However, WHO reports that countries are sometimes unwilling to notify it of cases because of the fear of economic and political consequences, such as the loss of tourism and trade, and the imposition of travel restrictions. WHO Department of Communicable Disease Surveillance and Response (2000) *WHO Report on Global Surveillance of Epidemic-prone Infectious Diseases*, available at: http://whqlibdoc.who.int/hq/2000/WHO_CDS_CSR_ISR_2000.1.pdf.

¹⁰³ Foresight (2006) *Infectious Diseases: Preparing for the future. Executive Summary* (London: Office of Science and Innovation); World Health Organization (2006) *Strengthening Pandemic-Influenza Preparedness and Response, including Application of the International Health Regulations (2005)*, available at: http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_5-en.pdf.

¹⁰⁴ See WHO, *Global Influenza Surveillance*, available at: <http://www.who.int/csr/disease/influenza/influenzane트워크/en/index.html>.

¹⁰⁵ European Centre for Disease Prevention and Control (July 2007) *Interim ECDC Scientific and Public Health Briefing: Sharing influenza virus samples – July 2007* (Stockholm: ECDC), briefings available at: http://www.ecdc.eu.int/Health_topics/Seasonal%20Influenza/Guidance.html; World Health Organization (2007) *Areas with confirmed human cases of H5N1 avian influenza since 2003*, available at: <http://gamapserv.who.int/mapLibrary/app/searchResults.aspx>. As of 25 July 2007, the numbers of cases and deaths from H5N1 avian influenza, were 102 and 81, respectively; Viet Nam was the only other country to have over 50 cases.

¹⁰⁶ The Director-General of WHO subsequently thanked the Indonesian government for having “brought the very important issue to the world’s attention, and that is access to pandemic influenza [vaccine] by resource-poor countries” CNN (2007) Interview with Dr Margaret Chan, available at: <http://www.cnn.com/2007/WORLD/asiapcf/04/13/talkasia.chan.script/index.html>.

Instead, Indonesian officials agreed a deal with a USA-based vaccine producer under which Indonesia would receive assistance with improving its capacity for vaccine production. It was reported in the media that the deal gave the company sole commercial rights for the use of virus isolates, and would therefore have prevented access to the isolates for sequencing, analysis and other purposes by WHO,¹⁰⁷ although the company involved has denied that this was the case.¹⁰⁸ There have also been suggestions that another company offered to purchase samples from Indonesia rather than obtaining the virus through the WHO system.¹⁰⁹ The lack of cooperation by Indonesia became a cause for serious concern because of the risk that it would severely hinder international surveillance and preparedness activities, and WHO made efforts to restore collaboration with this country. After several special meetings and a dedicated WHO Resolution¹¹⁰ passed at the World Health Assembly in May 2007, cooperation briefly resumed; however, this was short-lived and the situation as of July 2007 was that no Indonesian samples were being sent to WHO Collaborating Centres.¹¹¹ The nature and details of the deal between Indonesia and the pharmaceutical company remains to be better defined at the time of writing, and many questions remain over details in the developments that led to Indonesia's initial decision to cease collaboration with WHO.

4.53 This case raises issues of considerable complexity about, among other things, intellectual property, global solidarity, and appropriate mechanisms and criteria for the fair and equitable sharing of vaccines and other benefits. We return later in the chapter to consider the issue of vaccine sharing and allocation in a pandemic (paragraphs 4.66–4.68), but for now we make two general observations about the responsibilities of the pharmaceutical industry and WHO in relation to surveillance.

4.54 Further to our observations on corporate social responsibility (paragraphs 2.47–2.50), the effect of commercial interests and intellectual property rights on public health surveillance measures requires careful consideration. From a purely commercial perspective it might be attractive for pharmaceutical companies to seek exclusive access to virus isolates.¹¹² However, even where such access is combined with measures aimed at benefit sharing, such as capacity-building initiatives, ethical issues still remain. The primary responsibility of pharmaceutical companies, as of any other larger commercial enterprise, is to their shareholders. It is possible therefore that commercial interests will be put before considerations of producing affordable vaccines for the people in developing areas that are most likely to be affected (especially in the early stages of a pandemic). Furthermore, commercial exclusivity would usually mean that access to virus isolates would be limited. Without access to these isolates, the numerous and important processes in which they would normally be used, such as surveillance for numbers of cases, emerging viruses and patterns of spread, would not be possible. Such developments would be detrimental to the ongoing surveillance work that has global benefits,¹¹³ and

¹⁰⁷ *New Scientist* (16 February 2007) Poor countries hold out for vaccine, available at:

<http://www.newscientist.com/channel/health/mg19325914.600?DCMP=NLC-nletter&nsref=mg19325914.600>.

¹⁰⁸ Baxter (7 February 2007) *Press Release: Baxter Continues Collaborations With Global Health Authorities To Advance Pandemic Preparedness*, available at: http://www.baxter.com/about_baxter/news_room/news_releases/2007/02-07-07-indonesia.html.

¹⁰⁹ European Centre for Disease Prevention and Control (April 2007) *Interim ECDC Scientific and Public Health Briefing: Sharing influenza virus samples – April 2007* (Stockholm: ECDC); European Centre for Disease Prevention and Control (July 2007) *Interim ECDC Scientific and Public Health Briefing: Sharing influenza virus samples – July 2007* (Stockholm: ECDC), briefings available at: http://www.ecdc.eu.int/Health_topics/Seasonal%20Influenza/Guidance.html.

¹¹⁰ World Health Assembly (23 May 2007) *Resolution WHA60.28: Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits*, available at: http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R28-en.pdf.

¹¹¹ European Centre for Disease Prevention and Control (July 2007) *Interim ECDC Scientific and Public Health Briefing: Sharing influenza virus samples – July 2007* (Stockholm: ECDC), briefings available at: http://www.ecdc.eu.int/Health_topics/Seasonal%20Influenza/Guidance.html.

¹¹² While we note that it is unclear whether this occurred in the case of Indonesia (see paragraph 4.52), we address this scenario as one that could nevertheless be pursued in the future.

¹¹³ WHO (2007) *The World Health Report 2007: A safer future* (Geneva: Switzerland).

therefore **we urge pharmaceutical companies not to enter into agreements with countries in a way that would potentially undermine the work of the WHO Global Influenza Surveillance Network.**¹¹⁴ WHO is in a unique position to enable centralised and transparent determination that a novel virus has emerged, to evaluate pandemic-related evidence, and to develop response strategies, as acknowledged in the *International Health Regulations 2005*. This capacity must be sustained.

- 4.55 At the same time, it is important to recognise that cooperation between pharmaceutical companies and the WHO-administered surveillance system could also lead to inequalities in access to vaccines (see paragraphs 4.66–4.68). This would also be undesirable from a more technical public health perspective, as the early provision of vaccines to people in the outbreak area could play an important role in limiting or containing an emerging pandemic.¹¹⁵ **WHO should not merely facilitate access to virus isolates for commercial companies, leaving the question of availability of vaccines to market forces. It should use its authority to impress on pharmaceutical companies their social responsibilities.** Patents and other forms of intellectual property rights can be useful ways of rewarding research investment and stimulating innovation and progress, but they can also come into conflict with the interests of the wider public, as the Council has reported elsewhere.¹¹⁶ While we cannot address here all the complexities raised by the sharing of virus isolates for the purpose of monitoring and developing vaccines, virus isolates should not be treated like any ordinary commodity, as adequate access and use is of the greatest importance for public health, both on a national and global level. Therefore, **we urge WHO to explore, in liaison with governments and relevant industries, the notion of viewing virus isolates as a form of ‘public good’** (paragraphs 1.8–1.10), **and to take a flexible approach to patenting and intellectual property protection.**

Control of infectious diseases

- 4.56 The control of different infectious diseases involves an extensive range of interventions. These may depend on the nature of the disease, how easily it is transmitted, the mode of transmission, the infectious period, the incubation period (i.e. the time from infection to the appearance of clinical disease), the population at risk, and the severity of its clinical manifestations. Many infections are relatively mild and often self-limiting, and although they may cause significant minor morbidity and be a major burden to the health services, they are not a major threat to population health. In this section, we focus on methods for the management of epidemics or cases of infectious diseases that pose a serious risk to those infected and which may affect the health of others by onward transmission of the infectious agent.
- 4.57 Measures implemented to tackle the SARS epidemic of 2002/2003 included isolation, quarantine, surveillance, contact tracing and restrictions or advisory warnings about travel (see Box 4.6). WHO judged that rigorous control schemes were responsible for the interruption of transmission in July 2003. However, measures such as these raise ethical issues, particularly about the acceptability of interventions that limit personal liberty for the sake of reducing the risk of disease to others.¹¹⁷ Control measures such as isolation have also been used for individual cases of serious disease, such as smallpox and drug-resistant tuberculosis,

¹¹⁴ We note that the terms of reference of the WHO Collaborating Centres and National Influenza Centres (which constitute the WHO Influenza Surveillance Network) are, at the time of writing, being revised under the recent WHA Resolution; World Health Assembly (23 May 2007) *Resolution WHA60.28: Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits*, available at: http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R28-en.pdf.

¹¹⁵ A so-called rapid containment strategy, discussed further in paragraphs 4.65 and 4.68.

¹¹⁶ Nuffield Council on Bioethics (2002) *The Ethics of Patenting DNA: A discussion paper* (London: Nuffield Council on Bioethics), available at: <http://www.nuffieldbioethics.org/go/ourwork/patentingdna/introduction>.

¹¹⁷ For further discussion see: Gostin LO, Bayer R and Fairchild AL (2003) Ethical and legal challenges posed by severe acute respiratory syndrome *J Am Med Assoc* **290**: 3229–3237.

in order to minimise the risk of transmission to others.¹¹⁸ Here we discuss, in particular, quarantine and isolation measures, and their ethical justification.

Box 4.6: SARS

In 2002/2003 an epidemic occurred of a new infectious disease, severe acute respiratory syndrome (SARS). The first known cases of SARS occurred in China in November 2002, and in total 8,098 cases were recorded in 26 countries, resulting in 774 known deaths.¹¹⁹ China was criticised by WHO and countries internationally for delays in reporting cases and an initial lack of cooperation with WHO, which in March 2003 classified the disease as a global health threat.¹²⁰ This was one of the major precipitants to changes in the *International Health Regulations*, which were published in 2005.

The disease was highly contagious, there was initial uncertainty over the identity of the disease-causing agent and its epidemiology, such as the time and period of infectivity to others, and there was no definitive diagnostic test or effective vaccine or treatment.¹²¹ These and other factors posed particular challenges in establishing an appropriate public health response.

During the epidemic, some countries implemented policies that severely restricted individual freedoms, as part of quarantine and isolation measures.¹²² In Beijing around 30,000 people were quarantined,¹²³ mostly in their own homes, and two major hospitals were sealed, one of which held 2,000 employees and an unreported number of patients.¹²⁴ News reports suggested that in Toronto in Canada over 2,000 people who showed no symptoms of SARS were in quarantine at one point, and 141 health workers who showed no symptoms were in “working quarantine”, meaning they worked with infected patients and had to take many precautions including isolating themselves from others in their homes.¹²⁵

Additional measures were also put in place for people travelling between countries. For example, quarantine officers at ports of entry and exit in Canada were given the authority to ask a person suspected of having the disease to undergo a medical examination and to detain that person if necessary for up to 20 days (the maximum incubation period set out for SARS).¹²⁶ We note, however, that no such detentions were made for SARS, and the amendments to this regulation were made as a “precautionary measure”.

Other consequences for individuals included those resulting from reduced travel, either where restrictions were in place or where individuals had voluntarily opted not to travel, and the postponement of some non-emergency medical care. More broadly there were financial implications due to disruption of travel, tourism, trade and production; it was estimated that the outbreak cost \$12.3 billion in the Asian countries affected.¹²⁷ Healthcare workers also suffered particularly (most transmission was in hospitals); 73 (51%) of the 144 SARS patients included in one study in Canada were healthcare professionals.¹²⁸

WHO has now published guidance on surveillance and management of a future SARS outbreak.¹²⁹ Many of the uncertainties that existed during the first outbreak have been resolved, and experience has been gained from this outbreak in dealing with the infection and other outbreaks involving similar infectious agents.¹³⁰

¹¹⁸ Public Health Laboratory Service (2002) Hospital acquired multi drug resistant tuberculosis *Commun Dis Rep CDR Wkly* [serial online] **12** (42), available at: www.hpa.org.uk/cdr/archives/2002/cdr4202.pdf.

¹¹⁹ World Health Organization (2004) *WHO guidelines for the global surveillance of SARS, Updated recommendations, October 2004*, available at: http://www.who.int/csr/resources/publications/WHO_CDS_CSR_ARO_2004_1.pdf.

¹²⁰ *Ibid.*

¹²¹ Zhong N and Zeng G (2006) What we have learnt from SARS epidemics in China *Br Med J* **333**: 389–91; Gerberding JL (2003) Faster ... but fast enough? Responding to the epidemic of severe acute respiratory syndrome *N Engl J Med* **348**: 2030–1.

¹²² For further details about the quarantine schemes implemented in China and Taiwan, see: Centers for Disease Control and Prevention (2003) Efficiency of quarantine during an epidemic of severe acute respiratory syndrome – Beijing, China, 2003 *Morb Mortal Wkly Rep* **52**: 1037–40; Centers for Disease Control and Prevention (2003) Use of quarantine to prevent transmission of severe acute respiratory syndrome – Taiwan, 2003 *Morb Mortal Wkly Rep* **52**: 680–3.

¹²³ Centers for Disease Control and Prevention (2003) Efficiency of quarantine during an epidemic of severe acute respiratory syndrome – Beijing, China, 2003. *Morb Mortal Wkly Rep* **52**: 1037–40.

¹²⁴ *New York Times* (26 April 2003) The SARS epidemic: SARS; Beijing broadens SARS quarantine; more cases found, available at: <http://query.nytimes.com/gst/fullpage.html?res=9B02E5DF153DF935A15757C0A9659C8B63&sec=health&pagewanted=1>.

¹²⁵ CNN (27 May 2003) Toronto traces SARS cases to 96-year-old patient, available at: <http://www.cnn.com/2003/HEALTH/05/26/sars.wrap/index.html>.

¹²⁶ Public Health Agency of Canada (2003) *Fact Sheet: Quarantine Act and Regulations – SARS Amendment*, available at: http://www.phac-aspc.gc.ca/sars-sras-gen/fact_sheet.html.

¹²⁷ World Health Organization (2003) *Severe Acute Respiratory Syndrome (SARS)*, available at: <http://www.wpro.who.int/sars/docs/RC54-08.pdf>.

¹²⁸ Booth CM, Matukas LM, Tomlinson GA *et al.* (2003) Clinical features and short-term outcomes of 144 patients with SARS in the Greater Toronto area *J Am Med Assoc* **289**: 2801–9.

¹²⁹ World Health Organization (2004) *WHO guidelines for the global surveillance of SARS, Updated recommendations, October 2004*, available at: http://www.who.int/csr/resources/publications/WHO_CDS_CSR_ARO_2004_1.pdf.

¹³⁰ Zhong N and Zeng G (2006) What we have learnt from SARS epidemics in China *Br Med J* **333**: 389–91; Gerberding JL (2003) Faster ... but fast enough? Responding to the epidemic of severe acute respiratory syndrome *N Engl J Med* **348**: 2030–1.

Issues raised by quarantine and isolation

4.58 'Quarantine' refers to restrictions on the activities of a healthy person or group of people suspected of having been exposed to an infectious disease and who therefore might go on to develop it. 'Isolation' refers to restrictions on the activities of a person who is known to be infected, typically at a treatment centre where they can also receive appropriate medical care for the infection. In both cases the aim is to prevent or limit the transmission of disease. These two measures can operate either on a fairly large scale in the case of epidemics or pandemics, or on a smaller scale for individual cases of a serious disease, such as multi-drug-resistant tuberculosis.¹³¹ An alternative measure that may be used in controlling epidemics or pandemics is that of 'social distancing', which would involve, for example, the closure of schools and workplaces, and avoiding large gatherings such as conferences and public events.¹³² Although this measure may disrupt the lives of individuals within the population, it does not restrict liberty to the same extent as quarantine and isolation, and we focus here on these. Several respondents to the consultation expressed views on the acceptability of forcefully restricting the movement of people and when this might be acceptable (see Box 4.7).

Box 4.7: Consultation responses on proportionality and control measures

"Decision makers must balance individual freedom against the common good, fear for personal safety against the duty to treat the sick, and short term economic losses against the wider implications of the potential spread of serious diseases." *Health Protection Agency*

"To enforce someone into quarantine is imprisoning them and this can never be right, no matter what the circumstance. Governments could potentially quarantine people for reasons other than disease control, using disease as the reason, and this is a highly questionable practice." *Vaccination Awareness Network (VAN) UK*

"If an individual has a contagious infection and does not comply with treatment maybe then it would be appropriate to enforce quarantine. While it is an individual's choice to accept or not accept treatment, their choice has to have limits when it impinges on another person's right to health." *Fiona Reynolds*

"Quarantine or isolation is a reasonable and responsible action as long as it is in proportion to the seriousness of the disease." *JABS – Justice, Awareness and Basic Support*

4.59 It has been suggested that quarantine and isolation, and particularly the latter, can be an effective part of the control of a serious disease. (It has been suggested that quarantine may add little benefit where effective isolation strategies are in place, although this is likely to depend on many factors.¹³³) Compulsory admission and detention in hospital of individual patients who pose a serious risk to the health of others and have refused to take precautions to prevent spread voluntarily is permitted in the UK under public health legislation,¹³⁴ and a few such cases have occurred in recent years.¹³⁵ In relation to isolation and quarantine in the case of epidemics or pandemics, at the time of writing, draft pandemic-planning documents

¹³¹ Public Health Laboratory Service (2002) Hospital acquired multi drug resistant tuberculosis *Commun Dis Rep CDR Wkly* [serial online] 12 (42), available at: <http://www.hpa.org.uk/cdr/archives/2002/cdr4202.pdf>.

¹³² World Health Organization (2005) *WHO Outbreak Communication: Influenza Pandemic*, available at: http://www.who.int/csr/don/Handbook_influenza_pandemic_dec05.pdf.

¹³³ These factors include some relating to the disease, such as how infectious the disease is and whether it can be transmitted before symptoms occur, and others relating to the society, such as how well the quarantine programme is adhered to. For further discussion see: Day T, Park A, Madras N, Gumel A and Wu J (2006) When is quarantine a useful control strategy for emerging infectious diseases? *Am J Epidemiol* 163: 479–85. We note that, for example, an assessment of the efficiency of quarantine in controlling SARS suggests limiting its use to only where individuals had contact with actively ill patients (Centers for Disease Control and Prevention (2003) Efficiency of quarantine during an epidemic of severe acute respiratory syndrome- Beijing, China, 2003 *Morb Mortal Wkly Rep* 52: 1037–40); Wynia MK (2007) Ethics and public health emergencies: restrictions on liberty *Am J Bioethics* 7: 1–5.

¹³⁴ See Section 37 and 38 of the *Public Health (Control of Disease) Act 1984*, and Joint Tuberculosis Committee of the British Thoracic Society (2000) Control and prevention of tuberculosis in the United Kingdom: Code of Practice 2000 *Thorax* 55: 887–901.

¹³⁵ Public Health Laboratory Service (2002) Hospital acquired multi drug resistant tuberculosis *Commun Dis Rep CDR Wkly* [serial online] 12 (42), available at: <http://www.hpa.org.uk/cdr/archives/2002/cdr4202.pdf>.

from both the Department of Health for England and the Scottish Executive stated that such measures would be “unsustainable after the first hundred or so cases”.¹³⁶ Nevertheless, it is conceivable that they might be considered in the future.

- 4.60 Both quarantine and isolation have costs in terms of individual liberty. Quarantining is potentially the more costly of the two as it restricts the liberty of more individuals. In addition it risks placing some individuals who are not infected at a higher risk of becoming infected if groups of people are quarantined together and the disease is transmitted among them. In view of these issues, on the basis of proportionality considerations (see paragraph 3.18, also Box 4.7), quarantine would require a stronger justification than isolation. In addition we note that there is the potential that these types of measures could be implemented inappropriately or abused, or that people may be suspicious of potential abuses, for example, in countries with totalitarian regimes.
- 4.61 When isolation and quarantine measures are introduced, it may be that some individuals willingly accept their confinement. People who have been found to carry an infectious disease are likely to have a strong personal interest in receiving treatment, and may accept that this is provided in a context of isolation. However, other individuals may be less willing to be confined in this way, especially for diseases for which there are limited treatment options. They are effectively, in this circumstance, being held against their wishes.
- 4.62 **Liberty-infringing measures to control disease, such as compulsory quarantine and isolation, rank towards the top of the intervention ladder. The ethical justification for such measures involves weighing the classical harm principle on the one hand, and individual consent and the importance of avoiding intrusive interventions on the other (paragraphs 2.13–2.15, 2.22–2.26, 2.43). Where risk of harm to others can be significantly reduced, these considerations can be outweighed (paragraph 3.18).**

Use of vaccines in control of infectious diseases

- 4.63 Whereas the use and effectiveness of quarantine and isolation in an influenza pandemic may be limited, it has been suggested that vaccination has greater potential. In a pandemic context, vaccines have two principal roles: they may be used, first, in the local containment of the epidemic at an early stage (using existing stocks of pre-pandemic vaccine), in a so-called rapid containment strategy.¹³⁷ Secondly, they may be used more widely if the pandemic becomes established, initially by using existing stocks of pre-pandemic vaccine¹³⁸ and later using pandemic-specific vaccine, once this has been developed. The rapid containment strategy is most relevant in the countries where the epidemic is more likely to emerge, which are generally developing countries, while the use of pandemic-specific vaccines would be relevant worldwide. In 2007, Margaret Chan, Director-General of WHO, stated that “vaccines are the single most important medical intervention for reducing morbidity and mortality during an influenza pandemic”.¹³⁹ However, the availability of both types of vaccine is

¹³⁶ Department of Health (2007) *Pandemic Influenza: A national framework for responding to an influenza pandemic – Draft for comment* (London: Department of Health); Scottish Executive Health Department (2007) *A National Framework for Responding to an Influenza Pandemic – Draft*, available at: <http://www.scotland.gov.uk/Resource/Doc/170231/0047533.pdf>. Note that a final version of this framework is due to be published in autumn 2007.

¹³⁷ A pre-pandemic vaccine, of a known strain, would not necessarily completely match the strain that emerges as the pandemic strain, but might be cross-reactive and therefore provide at least partial protection. The ECDC considers that this strategy could be feasible if the strain was the same subtype (i.e. H5). European Centre for Disease Prevention and Control (2007) *Technical Report: Expert advisory groups on human H5N1 vaccines – Scientific Questions*, available at: <http://www.ecdc.eu.int/pdf/Sci%20Questions%20final.pdf>.

¹³⁸ This vaccine is likely to provide only partial protection against the pandemic strain; however, the ECDC group's view is that it would be of some value even with protectiveness of as low as 15%. European Centre for Disease Prevention and Control (2007) *Technical Report: Expert advisory groups on human H5N1 vaccines – Public Health and Operational Questions*, available at: <http://www.ecdc.eu.int/pdf/PH%20Questions%20final.pdf>.

¹³⁹ Chan M (13 June 2007) *Address to the Pacific Health Summit: Pandemics – working together for an effective and equitable response*, available at: http://www.who.int/dg/speeches/2007/20070613_seattle/en/.

expected to be limited, and therefore difficulties arise in establishing how the available vaccine should be distributed, both on a national and international level.

- 4.64 There are many different options for allocation strategies.¹⁴⁰ We do not explore them here, but note that various considerations and principles might be involved, for example: even distribution across different sectors of the population; a ‘fair innings’ approach, whereby the youngest are given preference; focusing on reducing harms, ‘fair chance’ or saving-most-lives approaches; or preferential treatment of those most at risk through their occupation (healthcare workers) or those who perform critical duties (key workers).¹⁴¹
- 4.65 In the UK there are some stocks of a vaccine that could be considered for use in the pre-pandemic phase, and it is intended that these should be given to healthcare workers.¹⁴² Once a pandemic emerges, it is anticipated that a further vaccine specific to the pandemic strain would be developed and manufactured,¹⁴³ but in the UK’s draft pandemic framework there is no specific indication as to how these vaccines would be allocated even though clinical prioritisation is described as “inevitable”.¹⁴⁴ We noted in paragraphs 2.27–2.32 the importance of public health programmes being sensitive towards health inequalities between different groups. It has been suggested that in the case of a pandemic some groups that are already disadvantaged are likely to experience a further and disproportionate burden as, for example, they may be assigned a low priority on allocation plans.¹⁴⁵ The implications of allocation strategies for disadvantaged groups therefore require careful consideration.
- 4.66 The international context of pandemics raises further issues relating to the availability of vaccines at a global level. First, rapid containment strategies, if employed, would require a large-scale vaccination programme in whichever country it was that the pandemic strain emerged. Secondly, the likely global scale of the disease would lead to demand for pandemic vaccines that is likely to far exceed their supply.¹⁴⁶ We noted above the concerns expressed by Indonesia that it would have little access to vaccines in the case of an influenza pandemic

¹⁴⁰ We note the work by WHO and others in seeking to establish criteria for allocating resources in situations of scarcity exacerbated by emergency. World Health Organization (2007) *Global Consultation on Addressing Ethical Issues in Pandemic Planning: Summary of Discussions*, available at: http://www.who.int/trade/Ethics_PI_consultation_report_WHO_2006.pdf; The Hastings Center (2006) *Bioethics Background: Flu Pandemic and the Fair Allocation of Scarce Life-Saving Resources: How can we make the hardest of choices?*, available at: http://www.thehastingscenter.org/pdf/avian_flu_background.pdf; University of Toronto Joint Center for Bioethics Pandemic Influenza Working Group (2005) *Stand on Guard for Thee. Ethical Considerations in Preparedness Planning for Pandemic Influenza*, available at: <http://www.utoronto.ca/jcb/home/documents/pandemic.pdf>.

¹⁴¹ See also: Brock D and Wikler D (2006) Ethical issues in resource allocation and new product development, in *Disease Control Priorities in Developing Countries*, 2nd edition, Jamison DT, Breman JG, Measham AR et al. (Editors) (New York: Oxford University Press), pp.259–70.

¹⁴² The UK stockpile includes 3.5 million doses. Department of Health (2007) *Pandemic influenza: A national framework for responding to an influenza pandemic – Draft for comment* (London: Department of Health).

¹⁴³ It is estimated that it would take four to six months for manufacturing of such a vaccine to begin, and that therefore they would not be ready in time for the first wave of the pandemic. Department of Health (2007) *Pandemic influenza: a national framework for responding to an influenza pandemic – Draft for comment* (London: Department of Health).

¹⁴⁴ The Department of Health’s draft ethical framework for pandemic influenza lists seven general principles to draw on in the case of a pandemic, although these are not specifically discussed in relation to allocation of vaccine or treatment; See Department of Health (2007) *The Ethical Framework for the Response to Pandemic Influenza – Draft for Comment*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073179; Department of Health (2007) *Pandemic influenza: A national framework for responding to an influenza pandemic – Draft for comment* (London: Department of Health); Scottish Executive Health Department (2007) *A National Framework for Responding to an Influenza Pandemic – Draft*, available at: <http://www.scotland.gov.uk/Resource/Doc/170231/0047533.pdf>. Note that a final version of this framework is due to be published in autumn 2007.

¹⁴⁵ For example, the “entrenched poor, institutionalized populations, and people with mental and physical disabilities.” Gostin L (2007) Why should we care about social justice? *Hastings Cent Rep* 37: 3. See also: Uscher-Pines L, Duggan PS, Garoon JP, Karron RA and Faden R (2007) Planning for an influenza pandemic – Social justice and disadvantaged groups *Hastings Cent Rep* 37: 32–9.

¹⁴⁶ The WHO estimates suggest that there are likely to be enough pandemic vaccines for perhaps a quarter of the World’s population and in addition these would not be available when they are first needed. Chan M (13 June 2007) *Address to the Pacific Health Summit: Pandemics – working together for an effective and equitable response*, available at: http://www.who.int/dg/speeches/2007/20070613_seattle/en/.

(see paragraphs 4.51–4.52), and similar concerns are reported to have been raised by other countries such as Thailand.¹⁴⁷ We also noted above that the burden of an influenza pandemic is expected to fall disproportionately on developing countries, and that therefore the international context of such an outbreak raises particular issues around equity, and these should clearly be considered in relation to vaccine distribution (see paragraph 4.2).

4.67 In response to the situation in Indonesia, in May 2007 the World Health Assembly (WHA) passed a Resolution¹⁴⁸ that intended, among other things, to promote the access of developing countries to pre-pandemic and specific pandemic influenza vaccines. The WHA Resolution calls on WHO's Director-General to:

“formulate mechanisms and guidelines in close consultation with Member States aimed at ensuring fair and equitable distribution of pandemic influenza vaccines at affordable prices in the event of a pandemic in order to ensure timely availability of such vaccines to Member States in need.”

While the aspiration behind this provision is commendable, we note several significant practical challenges to its implementation. First, there are problems over timeliness: manufacture of the pandemic vaccine will only begin a few months after the pandemic strain has been established, during which time the first wave of the infection may already have passed around the world. Secondly, there are problems over fairness and equity, given that the vaccine will become available progressively, not all at once, and that by WHO estimates there are likely to be enough pandemic vaccines for at most only a quarter of the world's population.¹⁴⁹ Thirdly, much of the present potential global pandemic vaccine capacity has already been committed for use in developed countries through contracts with the manufacturers.¹⁵⁰ One suggestion that has been made is that developed countries should make commitments to supply sufficient doses for healthcare and other key workers in developing countries, or alternatively that WHO receive additional resources to establish contracts for production of vaccine for developing countries. However, global solidarity might be seriously tested even in such a relatively straightforward case, given that the supply of vaccines to developing countries¹⁵¹ would result in less access for people in developed countries.

4.68 We also draw attention to two further WHO initiatives relating to this Resolution. First, there is the establishment of an international stockpile of pre-pandemic vaccines for use by countries in need during a pandemic. At the time of writing, at least one pharmaceutical company had publicly offered to donate vaccines for this stockpile,¹⁵² and we encourage continued cooperation and discussion between vaccine-producing companies, WHO and its member countries so that they are all partners in this endeavour.¹⁵³ This initiative is at a fairly

¹⁴⁷ *New Scientist* (16 February 2007) Poor countries hold out for vaccine, available at: <http://www.newscientist.com/channel/health/mg19325914.600?DCMP=NLC-nletter&nsref=mg19325914.600>.

¹⁴⁸ World Health Assembly (23 May 2007) *Resolution WHA60.28: Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits*, available at: http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R28-en.pdf.

¹⁴⁹ Chan M (13 June 2007) *Address to the Pacific Health Summit: Pandemics – working together for an effective and equitable response*, available at: http://www.who.int/dg/speeches/2007/20070613_seattle/en/.

¹⁵⁰ European Centre for Disease Prevention and Control (July 2007) *Interim ECDC Scientific and Public Health Briefing: Sharing influenza virus samples – July 2007* (Stockholm: ECDC), briefings available at: http://www.ecdc.eu.int/Health_topics/Seasonal%20Influenza/Guidance.html.

¹⁵¹ *Ibid.*

¹⁵² GlaxoSmithKline has offered to provide 50 million doses of vaccine. Chan M (13 June 2007) *Address to the Pacific Health Summit: Pandemics – working together for an effective and equitable response*, available at: http://www.who.int/dg/speeches/2007/20070613_seattle/en/.

¹⁵³ We note that there can be potential difficulties in assembling a stockpile from multiple sources, and these should be taken into consideration. European Centre for Disease Prevention and Control (July 2007) *Interim ECDC Scientific and Public Health Briefing: Sharing influenza virus samples – July 2007* (Stockholm: ECDC), briefings available at: http://www.ecdc.eu.int/Health_topics/Seasonal%20Influenza/Guidance.html.

early stage of development, and further issues to be considered will include policies on the allocation of these vaccines, management of the stockpile and practical arrangements for coordinating the stockpile and for the deployment of the vaccine. Secondly, the Resolution pledged to improve the manufacturing capacity for influenza vaccines in developing countries.¹⁵⁴ While we recognise that endeavours such as these are not without their challenges, we consider them to be important applications of the stewardship model (paragraphs 2.41–2.44, also paragraph 4.50) on a global scale, and encourage further work by WHO, the international community and pharmaceutical companies in this area.¹⁵⁵ Initiatives aimed at strengthening the systems for rapid administration and delivery of vaccines, whether from national production or stockpiles or made available through WHO, are also of crucial importance.

The importance of information in the case of an epidemic or pandemic

- 4.69 As we have discussed in other contexts, effective communication of risk is often central to the success of the public health response to disease (paragraphs 3.13–3.14). Once there is an outbreak of a harmful infectious disease on a scale that might justify restrictions of movement, the pressure on governments and health protection agencies to be seen to be ‘doing something’ is substantial. Downplaying the risk of the disease may lead to higher rates of infection. By contrast, a campaign that overstates the risks may lead to panic and lack of trust in healthcare professionals in the longer term.
- 4.70 The media has an important role to play in this.¹⁵⁶ We note and endorse one of the goals outlined in the UK’s 2007 draft influenza pandemic framework: “Active media engagement to ensure that timely and accurate information and technical explanations are available to support informed reporting”¹⁵⁷ (see also paragraphs 4.34–4.35).
- 4.71 Information is important not only during an outbreak but also in planning for such scenarios. It is appropriate therefore that preparations should be made, and that these should include consultation and engagement with the public and other stakeholders. We note that another of the elements of the draft UK influenza pandemic framework is to encourage “prior public debate to explore the ethical, professional and practical implications of an influenza pandemic, condition public expectations and ensure that decisions are made in an inclusive and transparent way”.¹⁵⁸ The Working Party endorses this approach.

¹⁵⁴ One aspect of this, which had already been in progress, is the use of grants for developing countries to improve capacity for producing vaccines, and grants to six countries have already been announced. WHO (2006) *Global Pandemic Influenza Action Plan to Increase Vaccine Supply*, available at: http://www.who.int/csr/resources/publications/influenza/CDS_EPR_GIP_2006_1.pdf; WHO facilitates influenza vaccine technology transfer to developing countries, available at: <http://www.who.int/mediacentre/news/notes/2007/np18/en/index.html>.

¹⁵⁵ We note that the Department of Health’s draft ethical framework for pandemic flu comments on the need to “help other countries to fight a pandemic if it starts abroad”; Department of Health (2007) *The Ethical Framework for the Response to Pandemic Influenza – Draft for Comment*, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073179. In addition the Department for International Development’s 2007 health strategy commits to “strengthen the capacity of partner countries to plan for and manage emerging health challenges that affect poor people”; Department for International Development (2007) *Working Together for Better Health*, available at: <http://www.dfid.gov.uk/Pubs/files/health-strategy07.pdf>.

¹⁵⁶ See also World Health Organization (2005) *WHO Handbook for Journalists: Influenza pandemic*, available at: http://www.who.int/csr/don/Handbook_influenza_pandemic_dec05.pdf.

¹⁵⁷ Department of Health (2007) *Pandemic influenza: A national framework for responding to an influenza pandemic – Draft for comment* (London: Department of Health); Scottish Executive Health Department (2007) *A National Framework for Responding to an Influenza Pandemic – Draft*, available at: <http://www.scotland.gov.uk/Resource/Doc/170231/0047533.pdf>.

¹⁵⁸ *Ibid.*

4.72 Where a potentially serious infectious disease outbreak or incident occurs, the relevant authorities should ensure that they neither downplay the risks, which may lead to higher rates of preventable infections, nor overstate the risks, as this may result in panic or a lack of public trust that could be long-lasting. The UK health departments and health protection agencies,¹⁵⁹ in particular, have a responsibility to ensure the timely provision of adequate and appropriate information about the nature of an infectious disease outbreak or incident, the type of interventions to be implemented and the rationale for their use.

Summary

4.73 The principal ethical issue raised in relation to the prevention, surveillance and control of infectious diseases is how to reconcile consent and civil liberty concerns with community benefit. In the cases of infectious disease surveillance and control measures, we concluded that where harm to the population could be prevented through implementing measures that restrict civil liberties (isolation and quarantining) and challenge the notion of individual consent, this may be justified, particularly when the risks to the individual are minimal and/or the potential harms to others are substantial. We noted that it would be inappropriate to deny use of anonymised samples for epidemiological research and monitoring of trends in infectious disease, because it is unclear that there are significant harms involved where the data are suitably anonymised and this is the most effective way of ensuring thorough assessment and prediction of the risks of infectious diseases.

4.74 Regarding vaccination policy, we focused on vaccines given across the population both to protect individuals and to achieve or maintain population immunity. Here we concluded that in general, voluntary vaccine programmes should be preferred, but more coercive policies might be acceptable in some circumstances, depending on the risks of the vaccination, the seriousness of the disease, the degree of coerciveness involved, and the benefit to the community of implementing such a policy.

4.75 The international context of infectious disease requires consideration, perhaps more than in other areas of public health considered in this Report, and especially in relation to surveillance and control measures. We commented on the need for well-functioning surveillance systems for infectious diseases, and the central role of WHO in, for example, managing systems for receiving and distributing information and biological material (such as virus isolates), and ensuring transparent criteria for the allocation of vaccines internationally in the case of a pandemic.

¹⁵⁹ By this we refer to the Health Protection Agency, Health Protection Scotland, the National Public Health Service for Wales and the Communicable Disease Surveillance Centre (Northern Ireland).