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Whooping-cough vaccination: historical, social and political controversies

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Summary

• New acellular whooping cough vaccines may have the effect of leading us to forget that infectious diseases such as whooping cough have declined in the context of particular historical, social conditions and persist in the context of particular types of social inequalities.

• The debates over the existence of damage from whole-cell whooping cough vaccine, and the respective risks of the vaccine and the disease are still unresolved owing to methodological limitations of studies on both sides of the argument.

• One-sided health 'education' campaigns on whooping cough vaccine have questionable ethics, and suppression of dissenting views is counterproductive.

• Health professionals and parents have a right to know the political context of the debate.

Keywords: health education, methodology, social conditions, whooping cough, vaccination.

Introduction

In the next few years the Department of Health in England and Wales is likely to introduce a new acellular vaccine for whooping cough in place of those used previously which had been based on whole bacterial cells if, as expected, clinical trials in Sweden due to report in 1995/6 show the acellular vaccine to be less reactogenic than those currently in use in Britain. Some may feel that this marks an end to the period of controversy surrounding this particular vaccination. However, there are arguably wider lessons to be learned from the recent history of whooping cough vaccine. At the height of the whooping cough controversies of the 1980s, the then Health Education Council of England and Wales (HEC) adopted a stance which accepted as an unproblematic truth the statement that 'Having your child immunized against whooping cough will help wipe out the disease in the population', and noted uncritically that, 'Playing on people's social conscience may also lead to an uptake of the pertussis immunization' (Linthwaite, 1985). The campaign clearly rested on the twin assumptions of the infallibility of science (and in particular of the scientific 'expert') and also the moral certainty (if not also the moral superiority) of the 'educators'. It is these assumptions that are challenged in this article, which seeks to argue that in view of controversies such as vaccine damage, this campaign of certainty was fundamentally unethical.

The historical background

McKeown & Record (1962–3) have charted the importance of social and environmental factors in the unprecedented fall in the death rate from infectious diseases between 1780

and 1918. They calculate about 2·3% of this fall as attributable to a decline in whooping cough. Of course it is those under 12 months old who were (Smith, 1979) and still are (Miller, 1974; Bedford, 1993) most vulnerable to whooping cough, and the infant mortality rate (IMR) did not markedly decline until 1902–8, 30 years after the decline in adult mortality rates. During this period deaths ascribed to whooping cough in England and Wales fell by one-third. Again, social and environmental factors have been identified as relevant. Of overriding importance was the control of fertility and the greater care and attention that could be given to the fewer children born. Mechanical forms of contraception became available in the late nineteenth century, and compulsory elementary schooling from the 1870s onwards reduced the economic value of children to parents, as schooling meant no economic value from child labour. 'More effective family limitation meant that mothers could care more effectively for the fewer children they had, that the family income went further, and that the earlier completion of the family meant fewer defective children born to older mothers' (Smith, 1979, p. 122). Other factors seem to have played some part in the general decline of infant mortality, of which the decline of deaths from whooping cough was a part. One is the increase in personal hygiene, said to be attributable to the establishment of health visiting and the nursery movement in the years when the IMR started to decline. This would have included the lending of cleaning materials to mothers, as well as instruction on washing and feeding of children. Another factor would have been a relative improvement in infant nutrition. At first this would have been due to decreased family size, permitting income to go further. The decline of the number of mothers weakened by tuberculosis and 'better able to bear stronger infants with a higher birth-weight and breast feed them', was perhaps less significant, at least until the advent of mothercraft centres, some of which supplied free meals for 6 months before and 1 year after a child's birth. Other more marginal factors in the decline specifically of whooping cough are the lessening of deaths and damage resulting from inappropriate, dangerous and speculative medical techniques (e.g. bleeding and massive dosing) as the medical profession slowly abandoned these procedures. Also, the decline of cholera may have reduced the impact of whooping cough slightly, because previously the number of whooping cough cases had increased in years of cholera epidemics (Smith, 1979).

Social factors

The case for the primacy of social and environmental factors in explaining changes in deaths from whooping cough is strong. Whooping-cough deaths for children under 15 were already at 1% of the 1891 level by 1951 *before* vaccination on any significant scale and certainly before mass vaccination of the 1960s (Stewart, 1984). The relevance of this perspective to contemporary debates should alert us to the way in which a highly germ-centred, reductionist, medical-model theory of disease underpinned the HEC campaign. Social factors (e.g. diet or number of children in a family), environmental factors (e.g. quality of housing and hygiene) as well as the changing nature of the disease itself (Lancet, 1977) had been excluded from the agenda of the campaign. The campaign itself was arguably responding, among other factors, to the continued concern that whooping cough vaccine might be responsible for brain damage or death in a small number of children. Vaccination rates had, by the mid 1980s, still not fully recovered from the alarms raised about whooping cough vaccine a decade earlier.

Whooping cough and vaccine damage

Much of the 1980s debate centred on whether the average risk of a child becoming ill or dying through whooping cough was out-weighed by risks of brain damage or death from the vaccine. The legal status of payments to children successfully claiming to have been brain damaged by the pertussis vaccine did not carry medical opinion in 1985 in the UK (Smith, 1985), although a case in the Irish courts in 1993 led to an out of court settlement of $2.75 million for a mother of a 24-year-old brain-damaged son (Dispatches, 1993). The range of possible adverse outcomes, from minor (fever and localized soreness; Dyer, 1985) to serious (lesser degrees of brain damage with epilepsy, altered behaviour and other derangements) and from transient (convulsions, screaming fits and white apnoea with collapse; Stewart, 1984), to permanent (complete paralysis of all but the most vital reflexes; Melville & Johnson, 1982) were given less prominence. However, before looking at a series of estimates of the relative risk of whooping cough and pertussis vaccine there are a number of arguments and counter-arguments which may have a significant bearing on establishing whether the risks were overestimated or underestimated.

Whooping-cough risks underestimated?

It has been claimed that the risks stated may increase if fewer children are vaccinated as 'herd' immunity is reduced (Church, 1979; Linthwaite, 1985; Health Education Council, 1985; Bedford, 1993). Actual cases of whooping cough may have been recorded as pneumonia (Miller *et al.*, 1982, cited in Stewart, 1984). However, this was said to be

unlikely because cases of both whooping cough and pneumonia had been falling according to the Office of Population, Censuses and Surveys (Stewart, 1984). Miller (1974) claimed that whooping cough, in common with other infectious diseases, was undernotified. However, mid-1980s outbreaks affected older children, which had previously not been recorded for a long time (Ross, 1985). Cherry (1992) continues to argue that mortality from pertussis in unvaccinated children in the United States is underestimated. This, however, ignores the methodological complexities of establishing a diagnosis of whooping cough. Mink *et al.* (1992) claim to have found pertussis to be endemic in part of an adult university student population. The implication is that laboratory evidence suggests whooping cough may be more widespread than identified by clinical diagnosis. For example, Heiniger *et al.* (1993) argue that requiring a cough of 21 days to establish a case in vaccine-efficacy trials is too restrictive. However, Coulter & Fisher (1991) suggest that studies relying on the fluorescent antibody test can give false positives in between 6 and 40% of cases. Furthermore they claim that in 10–50% of cases clinically diagnosed as whooping cough, no causative agent can be found. These two latter estimates would, of course, suggest that we tend to overestimate the levels of whooping cough.

Vaccine risks overestimated?

In 1978 a Vaccine Damage Panel was established which offered a £10,000 one-off 'no fault' payment to parents of vaccine-damaged children. Half the panel's cases involved children who were given injections, despite a clear contraindication such as a cold, a reaction to a previous shot, or a history of convulsions (Dyer, 1985). It might be argued that better attention to contraindications would reduce risk, although Nicoll (1985) claimed many mythical contraindications to pertussis immunization. Furthermore, 'In a group of vaccine-damaged children, 65% showed contraindications to vaccination before the first injection. A further 20% reacted adversely to their first exposure to the pertussis vaccine although they had shown no initial contraindications, and they were given a second dose despite their reaction to the first. Further, 95% of children who reacted adversely to one injection had similar to more severe reactions to subsequent exposures. Even so 25 out of 143 children received three injections, reacting adversely to each' (Melville & Johnson, 1982). There were also claims that because 'four to eight months is the peak time of presentation of the central nervous degenerative diseases in babies who have previously appeared to be normal' that it is a fallacy to attribute brain damage to the vaccine merely because of time association (Smith, 1985). This argument has been applied to irritability after immunization which it is claimed were really cases of 'meningococcal septicaemia, acute abdominal pain due to malrotation of the gut, tuberculous meningitis and viral brain infection' (Ross, 1985). However, claims that investigation of sudden death after immunization rarely found specific features have been rejected as evidence that this rules out the vaccine by Stewart, who argues that 'by the nature of the reaction the change had to be non-specific; it was an indirect effect of hypoxia and poor circulation' (cited in British Medical Journal Editorial, 1986). The case for not blaming the vaccine is particularly difficult to sustain in the face of other evidence in both Britain and the USA concerning 'hot lots' (Coulter & Fisher, 1991) and cases of twins. 'Suspected "hot lots" of whooping cough vaccine have been associated with two series of deaths in the U.S. In 1978–9 in Tennessee, 11 babies died within eight days of vaccination, five of them within 24 hours. Nine (including four of the five who died within 24 hours) had been injected with vaccine from the same lot. Following injections from a single lot of a different manufacturer's vaccine, four babies died in 1979–80 in different parts of the U.S. The deaths, like those of the Clark twins were reported as sudden infant death syndrome. In the twins' case says Dr Gordon Stewart, former Professor of Public Health at the University of Glasgow, "If they'd been identical twins, they might have had a hereditary immunological defect and succumbed to infection. But the chances of that happening at the same time in non-identical twins, as the Clark twins were, are very remote." ' (Dyer, 1985).

Vaccine risks underestimated?

Firstly, cases of vaccine damage leading to death may have been misrecorded as cot deaths, as was the case with the Clark twins from Fife or with cases from the United States (Dyer, 1985). The vaccine itself only gave partial protection—'an appreciable proportion of proven cases (of whooping cough) occurred in fully vaccinated children' (Stewart, 1984). Whilst it was claimed at the time that 'the children who *do* get the disease even after being immunized usually get only a mild attack' (Health Education Council, 1985), this partial protection arguably shifted the balance against the vaccine. Moreover, the frequency of minor side-effects may be hidden behind drowsiness and unresponsiveness associated with the vaccine (Stewart, 1984). Furthermore, it was claimed that GPs have very different reporting rates for children with possible whooping cough depending on whether the children have been vaccinated or not (Stewart, 1980). The methodological issues in the

social construction of statistics appears to have received little further attention in Britain. In the USA, Coulter & Fisher (1991) call into question the work of Cody *et al.* (1981) by proposing four ways in which, statistically, the number of adverse reactions for vaccinations were suppressed in that Food and Drug Administration-funded study. These were firstly, providing data for risks in terms of number of vaccinations (which in the USA can be up to five per child) not children; screening out 'high-risk' children from the trial; excluding high-pitched screaming as a reaction; and placing an arbitrary time limit of 48 h for a reaction to occur. The association of time and statistical trends is an empirically relevant methodological dilemma for analysis of whooping cough controversies in at least two ways. On the one hand advocates of vaccination are content to attribute causality to any fall in notifications of whooping cough that follows increased uptake in vaccinations (Bedford, 1993), but not to attribute causality to any post-vaccination increase in severity of febrile seizures, for which, by one prominent advocate's own admission, no other cause is known (Cherry, 1993).

A summary of relative risk

An indication of the extent of scientific uncertainty may be judged from Table 1 which shows the considerable variation in estimated risk of both the vaccine and whooping cough itself, based on the various sources quoted.

	Moderate reaction	Severe reaction	Death
Whooping cough	1 in 336–1 in 3060	0–1 in 38 000	0–1 in 236 000
Vaccination	1 in 750–1 in 2000	1 in 15 000–1 in 310 000	0–1 in 180 000

The fallacy of the expert

If the assumption of health-education campaigns of the ability of medical science to furnish it with objective and clear-cut data is misplaced, then the moral certainty that science is producing high-quality knowledge from various 'experts' was equally misguided. For example, the pro-immunization report of the Joint Committee on Vaccination and Immunization (DHSS, 1977) had been severely criticized as ignoring the situation in Hamburg (low immunization rates of 15%, rising birth rate, yet declining number of whooping cough cases). The report also recorded 'long-disproved opinions' (e.g. about the age a child is vaccinated and its relation to convulsions), contradicted itself (about whether pathology following vaccination is disproved or needs investigating), ignored evidence (about the neurological sequelae of vaccination and about the under-reporting and under-investigation of deaths following vaccination), and contained inaccurate and misleading reporting covering a range of European countries (e.g. a 1 in 100 000 rate quoted for West Germany which should have been 1 in 30 000) (Ehrengut, 1978). However, so-called 'expert' evidence in favour of the view that the whooping cough vaccination does carry risks at least equal to that of whooping cough itself is equally uncertain. Cross-examined in the first English court case to try the issue of whether whooping cough can cause brain damage the evidence of Professor Stewart seemed less than secure. Amongst other mistakes he had to admit to a misreading of the terms of the National Childhood Encephalopathy Study (although equally, the legal correspondent reporting is misleading to the extent that despite the misreading many of Stewart's criticisms of that study remain intact) (British Medical Journal Editorial, 1986). In the light of such uncertainty on both sides the moral censure implicit in the HEC campaign during the 1980s could not be justified by an appeal to scientific knowledge. In the USA a national committee recently found 'many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines' (Institute of Medicine, 1991). More recent still is evidence from a study funded by the Health Education Authority of England and Wales (HEA). This found that some parents think deeply about decisions not to vaccinate, and are appalled by moralistic and scare tactics used by health professionals, and by the emotive tone of much health-education literature (Rogers, 1993–4). Furthermore, the former HEC chose to ignore the clear role that social, economic and environmental conditions play in whooping cough. More controversially, this means that they also ignored the relative risk that children from different social backgrounds ran of being severely affected by whooping cough itself. Stewart compared the risks of the disease causing death or being serious enough to warrant a hospital admission for so-called high-risk areas of material deprivation, such as parts of Glasgow, and for so-called low-risk areas, such as parts of Surrey. In his review no infants under 1 year in the low-risk areas died of whooping cough, compared to a death rate of 1 in 1300 in high-risk areas. In high-risk areas 1 in 336 required hospital admission compared to the much lower rate of 1 in 3060 in low-risk areas (Stewart, 1984). Those who would reject the primary importance of social factors have yet to satisfactorily explain why rates of whooping cough in some countries continue to drop even when vaccination rates fall below 20% (Ehrengut, 1978).

Vaccines and politics

The 1990 reforms of how GPs in England and Wales are paid for the vaccinations their staff carry out, in which thresholds of up to 90% have to be reached to trigger payment, have given an impetus to campaigns to increase the uptake of vaccines. However, it seems likely that at the same time the high threshold may have led to inactivity born of despair at reaching the target to trigger payments. Presumably this has been in precisely those areas where children are most likely to be at risk from whooping cough because of the materially deprived conditions they live in. However, notwithstanding these problems, the further question remains of whether it is a politically neutral act for health professionals to advocate that parents have their child immunized against whooping cough, since in the UK one company monopolized supplies of vaccine for many years, and the efficacy of that product has been called into question in a number of ways, as several investigative journalists have documented. For example, Harriman (1988) points out that the current triple vaccines Trivax and Trivax-Ad are whole-cell vaccines (i.e. they are made from whole dead whooping cough bacterial cells). Until they sold their vaccines business in 1991, Wellcome had monopolized supplies of vaccine since two other companies, Lister and Glaxo, had withdrawn from the market. German, Swedish and Japanese governments stopped recommending 'whole-cell' immunization in the 1970s. The French, Swedish and Japanese governments now have 'acellular' vaccines in which the cell wall is broken and the vaccine made from the contents of the cell. Harriman argues that these vaccines cause almost no adverse reactions and are cheaper and more effective than 'whole-cell' vaccines. In the 1950s trials involving similar vaccines to modern acellular ones were discontinued by Wellcome because of the expense. During the 1960s, Glaxo, Wellcome's main competitor, marketed the 'adsorbed' vaccine, and Wellcome followed suit, allegedly because this represented a cheaper solution to side-effects of the vaccine which included swollen arms and crying. The 1970s scare, when the possible links between whooping cough vaccines and brain damage and death were given mass-media coverage, saw a fall in vaccination rates and a fall in profits for Wellcome. Harriman cites an internal Wellcome memo from that time in which their chief scientist stressed how badly Wellcome's vaccine performed in trials, and that the vaccine itself should be regarded as less than 50% effective. He recommended investment to develop a new vaccine, but his plea was apparently refused as uneconomic. Despite this Wellcome found over $2 million during the 1980s to pay for legal-medical defences against compensation claims (Harriman, 1988). Despite a reported profit from Trivax-Ad of $1.3 million in 1987, Wellcome sold on their vaccine business a few years later as 'unprofitable'. In 1993 a decision in the Irish High Court that found in favour of a mother of a child brain-damaged by the whooping cough vaccine has revived hopes of parents in Britain of successfully filing claims (Dispatches, 1993). In 1986, a legal decision in Britain had ruled that the vaccine did not cause brain damage (British Medical Journal Editorial, 1986). The strength of the case for restarting litigation rests on evidence that a particular batch of vaccine from the early 1970s (number 3741) that caused the damage in Ireland was part of a series of batches released by Wellcome despite failing the 'Mouse Weight-Gain Test' for toxicity by being over eight times too toxic. Wellcome point out that at the time this particular toxicity test was non-mandatory in the UK, although the vaccine would have been banned as potentially toxic in North America. The series of batches were among those given to children in the UK, and a number of children who were given vaccines from these batches have been traced and found to have died soon after the vaccine, or to have developed brain damage. The importance of the Irish legal decision is that the ruling asserted that the fact that a test was not a legal requirement was not a defence, and that the company had a responsibility to use the best scientific checks available. Wellcome argue that the 'Mouse Weight-Gain Test' had, at that time, not proved itself fully scientifically (Dispatches, 1993). However, we should also be wary of concluding that academic research and politics can be neatly segregated. Coulter & Fisher (1991) set the work of Professor James Cherry into political context. One of the strongest advocates of the under-reporting of pertussis, of the efficacy of vaccines, and of the myth of vaccine brain damage (Cherry, 1992, 1993) is alleged to have received grants and gifts from vaccine manufacturers for his department's research, alleged to have received personal payment for testifying on behalf of vaccine manufacturers in up to 150 legal cases, and alleged to have failed to disclose such associations on the Journal of the American Medical Association's financial disclosure form before wring an editorial in March 1990 (Coulter & Fisher, 1991). Since Cherry is also a reviewer for that prestigious journal, there exists at least the potential to act as a gatekeeper against dissident views. If the allegations have substance it is not the funding *per se*, but the failure to make a description of the financial basis of the research a central feature of reporting results (or indeed to make any disclosure at all) that contravenes the basic tenets of good science.

Conclusion

As Bedford (1993) has argued, it is important to have balanced information about diseases and vaccinations, including whooping cough. Indeed a questioning of the ethics of some whooping cough health 'education' campaigns should not be taken as an argument against having a child immunized since if provaccine arguments are correct then it may be regarded as unethical not to vaccinate. However, there are arguably several dimensions to the unethical nature of some health-education campaigns on whooping cough immunization. The first is that it is immoral to cajole individuals to change their behaviour (and on the basis of unsubstantiated or controversial evidence) when 'The greater risk, in Britain as in developing countries, is that the persistence of gross economic and environmental differentials in the quality of living conditions will favour the persistence and increase of many forms of communicable disease' (Stewart, 1984). Secondly, there is the implicit but unethical appeal to the 'expert' as infallible. The 'health professional knows best' approach is bound to be, and deserves to be, undermined by the course of events. Thirdly, there is an ethical issue concerning the way in which ideas reach the public domain. The suppression of dissident views within academic circles such as was apparently the case for Professor Stewart, who found difficulty in publishing his ideas (British Medical Journal Editorial, 1986) may themselves be held responsible for more sensationalist reporting of the issues in the media. Next, the political context of whooping cough vaccine should remind us that no health issue, however biologically grounded it may seem, is without a vital social and political dimension. Health professionals cannot therefore take refuge in a strategy of arguing that they are carrying out a technical health-education programme of increasing uptake. Such campaigns need rethinking as politically controversial, as one political view might be that such campaigns amount to defending pharmaceutical profits. Furthermore, the overwhelming emphasis on increasing immunization levels could be said to be aiding a controversial conception that the key to controlling infectious diseases is biological and technical. Because the history of the decline of infectious diseases implicates social conditions as the overriding cause of the decline, the focus on the technical fix is arguably political as it draws attention away from current inequalities in standards of living. Finally, it may be suggested that to be ethical, a health-education campaign on whooping cough vaccination should address the following issues. Firstly, the disagreements amongst the 'experts' should be acknowledged. Secondly, the relative risks of whooping cough and the vaccine based on these disagreements (including chances of side-effects; of damage which is transient or permanent, moderate or severe; and of death) should be explained. Thirdly, the social and environmental influences on infectious diseases, and the relative risks based on these conditions should be discussed. Next, the meaning of probability must be explained not assumed, as studies of the effects of genetic counselling suggest that the concept of probability is often not well understood (Dyson *et al.*, 1993). Finally, the contraindications to a child being given the vaccine need to be explained to parents as well as health professionals. The arrival of an acellular vaccine in Britain may or may not prove to be the end of damage from whooping cough vaccine. The enduring lesson for health is that such issues are always social and political issues. The enduring lesson for health professionals is that if dissenting views are suppressed, then the whole profession risks being undermined by outside investigation, and by parents who are sometimes more discerning than they are given credit for.

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