

Pertussis immunization: an update

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A segment of chiropractic has historically opposed the practice of immunization. This opposition has been based on historical and philosophical precedent, but with little support from the scientific literature.

Pertussis immunization has successfully controlled a disease with a prior history of high childhood morbidity. An evaluation of the literature fails to find supporting evidence that whole-cell pertussis vaccine causes SIDS, asthma, or encephalopathy. Countries who discontinued pertussis immunization experienced a return of the disease, and in every case pertussis immunization has been reinstated.

The recent successful clinical trials and subsequent approval of an acellular pertussis vaccine should reduce the local reactions and discomfort sometimes experienced with the whole-cell product.

In view of the considerable scientific evidence for the desirability and efficacy of pertussis immunization, chiropractic should encourage patient participation in this worthwhile public health service.

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Introduction

Chiropractic has long been divided on the issue of immunization. Because chiropractors may represent a child's first contact with a health care provider, it is essential that

Historiquement, une branche de la chiropratique s'est toujours opposée à la vaccination. Cette opposition se basait sur des précédents historiques et philosophiques, sans grand fondement scientifique.

L'immunisation anticoquelucheuse a contrôlé avec succès une maladie qui avait auparavant un taux élevé de morbidité infantile. Un examen de la documentation disponible ne montre aucune preuve supportant le fait que le vaccin anticoquelucheux de type « cellule entière » puisse être impliqué dans le syndrome de mort soudaine du nourrisson, l'asthme ou l'encéphalopathie. Les pays qui avaient cessé l'immunisation anticoquelucheuse ont connu une recrudescence de la maladie et dans tous les cas, l'immunisation a été rétablie.

Récemment, la réussite d'essais cliniques suivis de l'approbation d'un vaccin anticoquelucheux acellulaire devraient réduire les réactions locales et le malaise parfois associés au produit cellulaire entier.

Étant donné l'abondance d'évidence scientifique montrant le bien-fondé et l'efficacité de l'immunisation anticoquelucheuse, la chiropratique devrait encourager la participation des patients à ce service de santé publique.

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MOTS CLÉS : chiropratique, immunisation, coqueluche.

the advice we give patients represents the best and latest in scientific evidence.

Background

Pertussis was once a major cause of infant and childhood morbidity and mortality in the United States. In 1922 pertussis became a notifiable disease. In the following year, 1923, 9,260 pertussis deaths were reported. The

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year 1934 saw reports of 265,269 cases and 7,518 deaths.¹

Pertussis is a highly communicable disease and, especially among the very young, a potentially deadly one. In the United States during the 1980's, there were still over 1,000 pertussis cases and numerous deaths reported annually in children under one year of age.¹ Globally, more than 350,000 deaths still result from pertussis annually, mostly in unimmunized children in developing countries.²

Pertussis was first recognized in the middle ages, and was described as 'the kink,' meaning fit, or paroxysm. A major epidemic occurred in Paris in 1578. The principle organism, *Bordetella pertussis*, was isolated by Bordet in 1906.²

Vaccine development

A wide variety of whole cell vaccines were tested in the 1930's and 1940's with wide ranges of efficacies.² In the late 1940s a standardized whole cell vaccine was introduced that by 1970 had reduced the United States incidence of pertussis by 99%.^{3,4}

The introduction of DTP vaccines produced a dramatic drop in the incidence of pertussis. It also changed the age distribution of the disease. Prior to the introduction of DTP immunization pertussis was distributed throughout the childhood years with less than 20% of cases occurring in children under one year of age. By the 1980's, while the incidence of the disease had been reduced to less than 1% of prior years, the few cases that did occur were concentrated in children under one year of age who had not yet completed their DTP immunization series.^{1,4,5}

Controversies

The well-recognized tendency of whole cell pertussis vaccine to produce unpleasant reactions such as prolonged crying, fever, local redness and soreness, led to concerns whether more serious health problems may result from pertussis immunization. These concerns most commonly asked whether SIDS, asthma, seizures or encephalopathies might result from pertussis immunization. Following is an examination of the evidence whether a vaccine connection with any of these conditions exists.

SIDS

One of the earliest studies to examine for vaccine related SIDS was done by Walker in 1987. This study examined

SIDS mortality over a period of eleven years, from 1972 to 1983, in 26,500 infants born in the Puget Sound area. Several cases of SIDS were identified, but the Walker study was inconclusive, and found "... only a small proportion of SIDS cases ... could be associated with pertussis," but that these "... relatively small number of SIDS cases in the present study also admits the possibility of substantial random error". Walker further noted that "SIDS rates in the UK did not rise and fall with the mass abandonment of pertussis vaccination, nor with the ensuing epidemics of pertussis."⁶

Later, better studies, using much larger population samples and careful case-matching, cast additional doubt on any measurable association between pertussis and the occurrence of SIDS.

In France, Jonville-Bera conducted a retrospective case-control study on 118 cases of SIDS carefully case matched with 332 control children and found: "... the victims of SIDS were not significantly more often vaccinated than control children."⁷

Bouvier-Colle conducted an extensive epidemiological study of SIDS cases in France and concluded: "No significant differences were found in the immunization rates between SIDS and other causes of death, nor between SIDS and living controls."⁸

Griffin examined a cohort of 129,000 children in Tennessee over a ten year period from 1974 to 1984 and found: "We conclude that in this large population of children there was no increase in the risk of SIDS after immunization with the DTP vaccine."⁹

The experience of Sweden is also illustrative. Amid concerns that pertussis vaccine might be contributing to SIDS and other infant problems, pertussis immunization was stopped in 1979, and was not reinstated until 1996. A recent study has demonstrated that not only did the incidence of SIDS not decrease during the time-frame when pertussis immunization was discontinued, it actually increased. In fact, the incidence of SIDS in Sweden nearly doubled during the time-frame when no pertussis vaccine was being administered: "In order to link the reported increasing incidence of SIDS in Sweden to environmental or other risk factors, we compared birth records and circumstances of deaths in infants who died in 1975-1977 with those who died a decade later, 1985-1987 ... The reported postperinatal incidence of SIDS increased from 0.51 per 1000 in 1975-1977 to 0.93 per 1000 in 1985-1987."¹⁰

Asthma

In 1994 Odent distributed a questionnaire to a series of his patients exploring issues related to asthma, and detected what he thought was a possible association between asthma and pertussis immunization.¹¹ To investigate this possibility, a formal double-blind study by Nilsson compared three large groups consisting of acellular vaccine recipients, whole-cell vaccine recipients, and a placebo vaccine control group to examine for any evidence of a pertussis vaccine/asthma connection. The findings: "We found no significant differences between the DTP vaccination groups ..." and "These results suggest that there is no reason to withhold pertussis vaccination because of fear of subsequent asthma or allergy."¹²

Encephalopathy and seizures

The National Collaborative Perinatal Project involved 54,000 pregnant women wherein 616 children experienced a seizure by one year of age for causes unrelated to vaccination. Thus, purely by coincidence, 7 infants per 10,000 will have convulsions on a day that is within two days of a vaccination, but which are unrelated to the vaccination.

The study concluded "... there is little scientifically derived information that indicates unequivocally that pertussis vaccine causes seizures."¹³

The National Childhood Encephalopathy Study (NCES) was conducted in the British Isles over a three year period from 1976 to 1979. This was a case-control study which examined all children aged 2 to 35 months of age with serious acute neurological disorders. In this study an estimated attributable risk of a serious neurological disorder occurring within seven days after DTP immunization was one in 110,000 immunizations. The NCES researchers made the important point that the data could not be used to measure risk or causation, but was rather an indicator of problem magnitude. Controversy remained as to whether the initial NCES data indicated any causative risk of vaccine injury.¹³

A more recent prospective, referral-based surveillance in Los Angeles examined for severe DTP vaccine reactions. The conclusion: "These data, as well as recent epidemiologic studies, point toward DTP vaccine's role in convulsions as simply a cause of fever in seizure-prone children," and that these "Seizures were similar to febrile seizures unrelated to immunization." They also noted

"... it has been shown that DTP vaccine-related seizures or hypotonic-hyporesponsive episodes are not related to any serious neurologic damage."¹⁴

Griffin also examined for seizures and encephalopathy after DTP immunization among a cohort of 38,000 Tennessee children and found: "... there was no significant increase in febrile, afebrile, or acute symptomatic seizures in the early post-immunization period, compared with the control period of 30 or more days following immunization."¹⁵

In the largest study of its kind ever conducted in the United States, Gale conducted a prospective examination of 218,000 children aged 1 to 24 months living in Washington and Oregon. All cases of neurological illness were carefully case-matched with two population control children. "This study did not find any statistically significant increased risk of onset of serious acute neurological illness in the 7 days after DTP vaccine exposure for young children."¹⁶

In 1996, a 10-year follow-up of the NCES in Great Britain was conducted. Those children with serious neurologic disorders were shown to have increased risks later in life, this without regard to the initial cause of their disorder. As part of the follow-up a major reassessment of the whole-cell pertussis vaccine was included. The results of this NCES update "... do not establish a causal relationship between pertussis vaccination and chronic neurologic abnormalities. The Academy reaffirms its earlier conclusion that whole-cell pertussis vaccine has not been proven to be a cause of brain damage and continues to recommend pertussis vaccination in accordance with the guidelines ..."¹⁷

The experience of countries that discontinued pertussis immunization

In the 1970s several countries, notably Japan, England, and Sweden, amidst concerns that pertussis might be producing severe adverse events, decreased or curtailed pertussis immunization. The result:

In England immunization coverage dropped to 30% by 1978. Simultaneously an epidemic of 102,500 pertussis cases occurred, with a second major epidemic occurring in 1982. The epidemics directly coincided with the sharp drop in pertussis immunization.²

In Sweden, "Immunization against pertussis was introduced in Sweden in the 1950s and discontinued in 1979. This was followed by a low endemic level of pertussis for

3 years. Thereafter the incidence gradually increased with two pertussis outbreaks in 1983 and in 1985. In the period 1980 to 1985 pertussis was confirmed by culture or serology in 36,729 patients ... The annual incidence rate per 100,000 population ages 0 to 6 years increased from the 700 cases in 1981 to 3200 in 1985." In addition: "Neurologic complications were noted in 4% and pneumonia in 14% of the hospitalized patients."¹⁸

In Japan, pertussis immunization was discontinued in 1975. The incidence of pertussis started climbing immediately, going from only 206 cases in 1971 to 13,105 cases and 41 deaths by 1979.¹⁹ To bring the pertussis problem under control Japan reintroduced pertussis immunization in 1981 with an acellular preparation which it has used ever since.²⁰

Acellular vaccine development

Hodder, et al., noted: "Although epidemiological studies appear to have largely, if not completely, absolved pertussis vaccine of responsibility for inducing death or permanent neurologic disability, a less reactive vaccine is highly desirable, not only to promote acceptance of a full course of immunization for the world's children but also for simple humanitarian reasons."²¹

The Japanese experience suggested the acellular vaccine produced immunogenicity equal to or greater than the whole-cell counterpart. Perhaps more importantly, the acellular product consistently produced noticeably fewer reactogenic effects.²²

Other countries began evaluating the acellular product for possible usage. A Swedish trial concluded the: "... acellular pertussis vaccine we evaluated can be recommended for general use, since it has a favourable safety profile and confers sustained protection against pertussis."²³

Another Swedish placebo-controlled study of an acellular vaccine concluded it was "... easily standardized is safe and confers substantial protection against pertussis."²⁴

A recent multicenter, randomized, double-blind study undertaken to evaluate the safety and immunogenicity of 13 acellular and 2 whole cell pertussis vaccines found that: "All of the acellular vaccines produced significant increases in antibody for included antigens ... The vaccines were well-tolerated. All acellular vaccines were associated with significantly fewer adverse reactions than the control whole cell vaccine."²⁵

A just completed German study found similar results with an acellular vaccine efficacy calculated to be 89%.²⁶

A January 31, 1997 press release by SmithKline Beecham announced U.S. Food and Drug Administration licensing to manufacture INFANRIX(TM), an acellular DTP vaccine. This is the same vaccine tested in several large European control studies. INFANRIX(TM) has now been licensed in more than 10 countries, including Germany, Italy, Sweden, Switzerland, Belgium and Greece.

Conclusions

Pertussis immunization has long been a major focal point of opposition to immunization. There is now substantial evidence that the whole cell pertussis vaccine did not deserve the bad press it has received. Its reactogenic properties very rarely resulted in permanent injury. This data is summarized in a just released study which noted "... several large epidemiologic studies indicate that whole cell vaccines do not cause infant deaths or neurologic disease."²

This more rational assessment is reflected in the precipitous drop in claims alleging vaccine injury being filed with the National Vaccine Injury Commission. From an inflated high of 3,246 petitions filed in 1990 which included retrospective cases, only 84 claims alleging vaccine injury were filed in 1996. Presently, only about 6 petitions claiming vaccine injury are being filed nationwide per month.²⁷ The number of petitions alleging vaccine injury continues to drop each year, this despite a growing population and an expanding immunization program.

Chiropractic's anti-immunization attitude has been based, not on an objective evaluation of scientific evidence, but on a visceral rejection of anything associated with medicine. An individual chiropractor advising a patient against immunization may expose that doctor to potential liability. It is ironic that both immunization and the chiropractic adjustment have comparable excellent safety records. A segment of chiropractic, however, has persisted in a highly distorted perception of immunization.

Despite an ever-increasing amount of scientific data supportive of immunization, "... many conservative chiropractors are still oblivious to the public health significance of this information. Some continue to publish articles filled with selective and outdated statistics, ..." and "... there is still a significant number of chiropractors who do

not accept or are not aware of scientific evidence supporting the role of immunization."²⁸

The issue is not one of whether a prudent and cautious approach should be taken toward immunization, or any health care intervention, but whether chiropractic's attitude is based on a rational and measured review of the latest and best in current evidence. It's time for chiropractic's attitude on immunization to become evidence based.

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