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Review

Hepatitis B vaccination and French Society ten years after the suspension of the vaccination campaign: How should we raise infant immunization coverage rates?

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ABSTRACT

In 1998, official concerns were first voiced over a possible association between hepatitis B virus (HBV) vaccination and multiple sclerosis (MS). Despite a number of studies that have demonstrated no such association, ten years on the French population's confidence in the vaccine remains shaken and immunization rates of infants have stagnated beneath 30%. With a chronic carriage of the virus estimated at 0.68%, it seems unlikely that France will be able to control the circulation of the virus. This article analyses attitudes towards HBV vaccination based on recent surveys: not only the public but also the vast majority of "vaccinators" (88%) questions the safety of the vaccine. Physicians opposed to vaccinating infants cite the possibility of adverse events occurring later in life and their lack of trust in the health authorities and the pharmaceutical industry. Both the general public and physicians feel more inclined to vaccinate adolescents and adults, even though it was for these age groups (especially the latter) that neurological adverse events were notified. It appears that above all, the *usefulness* of the vaccine and its safety profile for young children should be explained in understandable language by all those involved in public health, including the media. However, when opting for public health policies on the basis of statistical estimations, the importance of individual cases (e.g. MS in the family) should not be overlooked both for biological and ethical reasons.

Contents

1. Introduction: the background of HBV vaccination in France

The first generation of hepatitis B virus (HBV) vaccines became available in France in the early 1980s. Experience in the United States indicated a decade or so later that vaccinating high risk groups only would not result in significantly decreasing HBV circulation (among other reasons because about a third of acute HBV cases have no known risk factors). On the basis of the World Health Organization's (WHO) recommendations, the French Ministry of Health thus decided to launch a campaign in 1994/1995 targeting primarily infants (i.e. "universal vaccination"), but including a school-based ten-year catch-up programme for pre-adolescents; in addition, efforts to reach high risk groups were reinforced. This campaign (and more precisely the school-based vaccination campaign) was officially suspended after four years (in 1998) owing to reports of individuals having suffered demyelinating events and especially multiple sclerosis (MS) subsequent to vaccination

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against HBV. Worries were also fuelled by the presence of thimersoral and aluminium hydroxides used as adjuvants in the vaccine. The four-year vaccination campaign had had very mixed results. To begin with, the primary target was only partially reached since less than 30% of infants were immunized. School vaccination on the other hand was largely successful, but since it was short lived, by 2002 fewer than 50% of all children and adolescents in France had received complete immunization (i.e. tree injections). But perhaps most noteworthy was the popular enthusiasm induced by the campaign leading to vast numbers of adults *epidemiologically speaking not at risk* (i.e. not belonging to the "risk" groups) being vaccinated. All in all approximately one third of the French population was vaccinated against HBV. The purpose of this article is not to analyse once more the many ups and downs of the introduction of HBV vaccination in France, which has been done elsewhere. However, a brief reminder of the consequences of this campaign and its aftermath appears appropriate for the understanding of what follows.[1–3]

First, it seems likely that relatively few infants were vaccinated simply because they were not seen as being at risk of infection by HBV. Second, the suspension – but as time has shown, the interruption – of the school-based vaccination campaign brought about significant loss of confidence in the vaccine on the part both of parents and health care practitioners. Finally, the fact that so many (primarily young and female)[1] adults were vaccinated made it impossible, at the statistical level, to rule out conclusively an association other than temporal between HBV vaccination and MS, even if none of the early epidemiological investigations confirmed a causal link. Since that time, to my knowledge no epidemiological study has found strong evidence suggesting an association between HBV vaccination and subsequent development of demyelinating conditions, with the noteworthy exception of Hernan's nested case–control study, published in 2004; others subsequently expressed hypotheses in favour of HBV vaccination triggering autoimmune responses and advocated the "precaution principle", i.e. not vaccinating.[4,5] Overall faith in the health authorities has in any case suffered several setbacks over the last decades (for example, the Chernobyl incident[2] or the HIV contaminated blood scandal) and despite the fact that most studies have found no link between HBV vaccination and the onset of MS, uncertainty over the safety of this vaccine has done nothing to boost public confidence. Finally, French judges began compensating HBV vaccinated individuals suffering from MS at the end of the 1990s and this continues to this day.[6] Although the sales of HBV vaccine have been stable for several years and the 1994–1998 campaign appears to have had an impact by decreasing the number of acute cases of the disease, the present vaccination coverage rates are not high enough to interrupt transmission of the virus.[2]

The question today is whether the largely negative attitude towards HBV vaccination is amendable to change.

2. The latest available data on immunization status and attitudes towards the HBV vaccine (2008)

2.1. Immunization status

Ten years on (2008), it is believed that still less than a third of French infants are immunized against HBV.[3] Since the interruption of the school-based campaign, pre-adolescents are no longer systematically vaccinated. How many high risk individuals[3] (other than health care professionals who undergo obligatory vaccination) are being reached by vaccination efforts and, once reached, accept to be vaccinated is not precisely documented. However, the vaccine to which both physicians (general practitioners and paediatricians) and the general public are the most strongly opposed is the HBV vaccine.[7,8] Recent evidence has likewise revealed that between 2000 and 2005, public opinion towards the vaccine worsened.[9]

2.2. Attitudes towards the vaccine

2.2.1. General practitioners and paediatricians

Whereas in 2003 general practitioners declared themselves to be more favourable to vaccinating infants against HBV than in 1998 (right after the suspension of the school-based campaign), those opposing such vaccination was still close to 40% (having decreased from 45.4% to 38.4% from 1998 to 2003).[10] Later in the year, a consensus conference supported the promotion of childhood immunization.[11] This does not seem to have greatly influenced health care practitioners, since some months later both generalists and paediatricians remained highly dubious regarding both the usefulness and the safety of vaccinating small children: nearly 88% were unsure as to the safety of the vaccine, and over 60% doubted its usefulness. In fact, of all vaccines included in the 2004 French childhood immunization schedule, the HBV vaccine received the worst score. Nearly 30% of general practitioners and paediatricians did not follow the official recommendation of immunizing infants. The main reasons cited for so doing were

- "*Adverse events can occur later in life*".
- "*The pharmaceutical industry falsifies the data*".
- "*I lack confidence in the health authorities*".

Among the remaining 70 or so percent of practitioners who *did* follow the official recommendation, 95% stated that parents were "reticent", leaving open the question as to how many children were vaccinated even by those practitioners who advocated immunization against HBV. Curiously, and generally speaking, both general practitioners and paediatricians felt more comfortable about vaccinating all age groups other than infants, despite the fact that notifications of severe adverse events subsequent to HBV vaccination had only concerned adults and (to a much lesser extent) adolescents.[8]

2.2.2. The general public

The general public's attitudes are clearly influenced by their family practitioners as well as by the large media coverage periodically given to the subject. Thus, in 2004, 55% of the French population would not have chosen to vaccinate their infant child, and would have preferred vaccinating an adolescent or an adult. Interestingly, women were more opposed to the vaccine than men (whereas in general they are more favourable to vaccination as such),[8] an observation corroborated by a more recent study.[9] But it should be noted that in a context of great wariness towards a vaccine such as HBV, 92% of the French population felt in 2004 that the government "should invest more money in developing vaccines against hepatitis C, AIDS, and cancer."[8]

[1] It is known that primarily young women are affected by multiple sclerosis.

[2] When the nuclear cloud caused by the Chernobyl accident passed over France, the population was not informed or warned to stay indoors, despite knowledge on the part of public officials.

[3] Men who have sex with men, haemodialysis patients or patients receiving blood products, close family members of individuals with chronic HBV infection, travellers to areas of high endemicity.