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## EXPERT OPINION

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### concerning a simplification of the French vaccination schedule

21<sup>st</sup> December 2012

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The French vaccination schedule contains a large number of injections, particularly compared with other European countries, coupled with a difficulty in applying the recommendations for boosters for the adult population. Therefore, in May 2008, the High Council for Public Health took the initiative to examine and recommend a simplified vaccination schedule, the aim of which would be:

- to administer only the minimum number of injections consistent with a good level of protection;
- to facilitate the life of patients and the medical profession in following the vaccination schedule;
- to improve the acceptability of vaccination and thus the overall immunisation coverage and at the same time ensuring adequate protection throughout a patient's lifetime.

This opinion is based on a report drafted by a specially convened working group.

This working group met twenty-four times between 2009 and 2012. Its work consisted of carrying out an extensive review of the available literature, obtaining data from other countries, auditioning experts from France and abroad, and running an acceptability survey for the proposed vaccination schedule among general practitioners and paediatricians.

#### The Technical Committee on Vaccination (TCV) took the following into consideration

##### 1 - The French vaccination schedule [1] (simplified table reproduced in Appendix I)

A child vaccinated up to the age of two according to the existing French vaccination schedule will have received 10 injections if the hexavalent vaccine were to be used, and 13 if the vaccine against hepatitis B was handled separately. Subsequently, the child would receive another three booster shot and girls would have yet another three to be vaccinated against human papillomavirus (HPV). In total, a French child will receive a minimum of 13 injections and a maximum of 19.

For adults, a Td/IPV booster is recommended every 10 years. A dose of the vaccine containing a whooping cough strain (dTaP-IPV) is recommended for adults likely to be in contact with babies less than 6 months old, particularly at the time of the ten-year booster at the age of 26-28.

##### 2 - Vaccination schedules in other European countries

Vaccination schedules are different from country to country with certain countries having programmes with fewer injections than exist in the French schedule (Appendix II):

- ✿ Four countries (Finland, Italy, Denmark and Sweden) have chosen a simplified schedule for babies, with three doses of DTaP/IPV/Hib (primary vaccination at 3 and 5 months, and a booster at 11-12 months).

- In the United Kingdom, after the first three doses for the primary vaccination at 2, 3 and 4 months there is no planned DTaP-IPV booster in the second year but rather 3-5 years after the primary vaccination; there is no pertussis booster after this, but a Td/IPV boost between 13 and 18 and once again for an adult (when the number of doses in childhood has been insufficient) [2].
- Certain countries do not schedule a booster during adolescence (Denmark, the Netherlands and Sweden).
- Although most countries recommend a dT booster every 10 years for adults, certain countries make no recommendations (the Netherlands, the United Kingdom and Sweden).
- In Switzerland, follow-up dT boosters for adults have recently been moved to every 20 years up until the age of 65, and every 10 years thereafter [3].

### 3 - Vaccination coverage in France

#### For babies and toddlers

The vaccination coverage has been calculated from the health certificates produced at 9 and 24 months [4].

- For diphtheria, tetanus, polio and pertussis, coverage is very high: in 2009, it was over 96 % for the three DTaP-IPV shots by the age of 9 months. At 24 months, the coverage is over 98 % for the three primary doses of these strains, and over 91 % for the three doses of these same valencies and the booster.
- For Hib, the estimated rates, using the same source documents, are 97.3 % for the primary vaccination and 88.9 % for the booster in the second year [5].
- Vaccination against pneumococcus is co-administrated with the above-mentioned vaccines for the first two doses. An analysis of the data from the Social Security's permanent sampling programme shows that children born in 2010 had a vaccination coverage of 96.1 % and 86.4 % respectively for the first and third doses by the age of 12 months [6].

#### For school-age children

Vaccination coverage for schoolchildren is measured using tri-annual surveys.

- At the age of 6 and for the year 2005-2006, coverage was 96.4 % for DT/IPV (4 doses) and 94.5 % for pertussis (4 doses) [6-7].
- At the age of 11 and for the year 2007-2008, coverage was 91.9 % for DT/IPV (5 doses) and 92.9 % for pertussis (4 doses) [6-8].
- At the age of 15 and for the year 2003-2004, coverage was only 80.5 % for DT/IPV (6 doses) and 57.4 % for pertussis (5 doses) [6-9].

#### For adults

Vaccination coverage is only known through a certain number of *ad hoc* surveys. The results of these surveys are summarised in the table in Appendix III.

In general, vaccination coverage is low, including vaccination against tetanus, and well below the objectives set in the law on public health (95 %). Coverage decreases with increasing age and is greater for tetanus than for diphtheria and polio.

### 4 - Adults' knowledge of the state of their vaccination situation

In the 2005 Health Barometer survey [10], 64.3 % of the French population stated with certainty that they were up to date with their vaccinations, and 19.8 % said they probably were. In the 2010 Barometer (unpublished data from INPES) the figures are respectively 56 % and 25 %. In the survey by Guthmann *et al.* [11], only 16 % of respondents claimed not to know their

vaccination situation. Socio-economic level correlates well with a person's knowledge of his vaccination situation (knowledge is better in the higher socio-economic levels), but has no influence on the vaccination coverage. Although with increasing age vaccination coverage decreases, knowledge of one's vaccination situation increases.

In the 2006 Nicolle survey [12], 77.6 % of respondents claimed to have a health booklet in which their vaccinations were recorded.

However, although, in the 2005 Health Barometer survey [10], 67.8 % of respondents said that they had received their latest vaccination within the previous five years, 26.3 % were unable to say against what they were vaccinated (27.4 % in the 2010 Barometer).

## 5 - Epidemiology of the diseases concerned by the modifications to the vaccination schedule [13]

### Diphtheria

Epidemics caused by *C. diphtheriae* were reported in the former USSR countries in the 1990s. The situation is under control, despite the persistent circulation of *C. diphtheriae*, particularly in Russia, the Ukraine and Latvia. The disease remains endemic in other regions such as South East Asia and, to a lesser extent, South America, the Middle East and Africa (particularly Madagascar).

The wholesale programme of vaccination in France, effective since 1945, has seen the number of cases and of fatalities from diphtheria caused by *C. diphtheriae* fall dramatically (less than five cases per year and no fatal occurrence since 1982). The last native case to be declared was in 1989. The 7 cases reported between 2002 and 2011 were imported cases in people who were either not vaccinated or were incompletely vaccinated.

On the other hand, 20 cases of diphtheria from *C. ulcerans* carrying the TOX gene were reported in France between 1999 and the end of 2011. The average age of the patients was 65 (ages between 28 and 89) and 65 % of those concerned were women. Among these 20 patients, 14 had had close exposure to a domestic pet and only 4 had had any form of vaccination against diphtheria, and this most often a long time in the past.

A seroprevalence survey carried out in 1989 on the French population showed that 30 % of people over 50 years of age had either a non-detectable level of antibodies or a level below the threshold of 0.01 IU/ml considered as protection by the standard seroneutralisation tests. On the other hand, people who had followed the vaccination recommendations had a high level of seroprotection.

### Tetanus

In France, tetanus is a notifiable disease. In 1945, there were around 1,000 deaths from tetanus declared; in 1975, 369 cases and 171 fatalities and, in 2005, 17 cases of which 7 were fatal (Sources: InVS, Inserm CépiDc). Despite almost universal vaccination, tetanus has not been completely eradicated in France. A few cases or a few tens of cases are reported every year (28 in 2001, 17 in 2005 and 9 in 2011). These cases occurred mainly with elderly people (average age 78), in particular among women, who are less well protected than their male contemporaries who mostly were re-vaccinated during their national service. Tetanus is fatal in around 30 % of cases.

Given that an almost totally innocuous and extremely effective vaccine has been used for more than fifty years, one should not expect to see tetanus appearing in France again.

### Pertussis

Vaccination against pertussis is very effective, and all countries that have implemented widespread vaccination programmes for new-born babies have seen the incidence of the disease drop by over 90 % among the targeted population.

However, because there is a fairly rapid decrease in protection offered by such vaccination and because there is less contact with the bacteria which are much less in circulation, adolescents and young adults can readily be infected. Whooping cough amongst that population is often atypical. Adolescents and young adults are the source of contamination of young non-vaccinated babies, usually their own child. It is far less common for other siblings

to be the source of such contamination. This new epidemiology, initially reported in the United States around 1976, has been observed in France since the 1990s. In countries where vaccination is non-existent or limited, pertussis affects mainly children between the ages of 4 and 7. On the other hand, in countries with a high level of vaccination cover, such as the United States or France, young children are hardly affected by the disease, which typically targets non-vaccinated new-born babies, and the adolescents and adults that contaminate them.

In addition, recent data from the United States and Australia would suggest that acellular pertussis vaccines provide a shorter protection period and, more importantly, that the duration of immunity afforded by booster shots could be less among those children fully vaccinated with acellular vaccines [15-21].

Vaccination in France was introduced in 1959 and extended in 1966 following its association with the vaccines against diphtheria, tetanus and poliomyelitis. The result has been a spectacular reduction in the number of reported cases, as well as a drop in the number of fatalities.

Since 1986, pertussis is no longer a notifiable disease. In 1994, a National Reference Centre was set up and, in 1996, a network of hospital paediatricians and bacteriologists was created (Renacoq) to oversee paediatric cases of pertussis in the hospital environment.

The chart in Appendix IV shows the trend in the number of cases among babies up to the age of 2 months reported by Renacoq since 1996.

In 2011, 234 confirmed paediatric cases were reported, of which 74 concerned babies less than 6 months old among whom 68% were under 3 months. And among these, one in five required a stay in intensive care to treat an acute form of the disease.

According to data from the CépiDC, more than 80% of fatal cases of pertussis concern those less than twelve months old. Each year, between 0 and 10 deaths are attributed to pertussis according to an analysis of death certificates of children aged less than one year. The vast majority of these fatal cases occur before the age of 3 months.

### **Poliomyelitis**

In 1988, the World Health Organisation (WHO) set an objective of eradicating polio, originally targeted for 2000, but successively postponed to 2005, then 2010 and then again to 2012.

In the WHO's European region, eradication was pronounced on 21<sup>st</sup> June 2002.

Between 2003 and 2011, wild polioviruses were exported from India and Nigeria to countries previously declared free of polio and provoked local epidemics. In addition to the four countries where polio is still endemic (Afghanistan, India, Nigeria and Pakistan), four other countries have now been classified as countries capable of transmitting the wild viruses (persistent circulation for more than a year): Angola, Chad, the Congo Democratic Republic and Sudan. And a further 22 countries have recently been the scene of serious outbreaks: 17 situated in West and Central Africa (including Congo Brazzaville with an epidemic involving 441 cases), and the Horn of Africa, Nepal, but also in WHO's European region. This has involved Tajikistan (with an epidemic of 460 cases), Turkmenistan, Kazakhstan, and, for the first time since 1997, the Russian Federation, with 14 reported imported cases linked to the epidemic in Tajikistan.

India has been declared free of polio since February 2012, with the last case, involving poliovirus 1, reported in January 2011. Thus the latest report from the WHO issued on 28<sup>th</sup> November 2012, names three countries as still endemic (Afghanistan, Nigeria and Pakistan) and one country, Chad, as capable of transmitting the disease as a result of imported cases.

In France, poliomyelitis has been a notifiable disease since 1936. Since the introduction of polio vaccination into the French vaccination schedule (1958 for the inactive Salk or Lépine vaccine and 1962 for the oral Sabin vaccine) and making it mandatory since July 1964, the number of cases has dropped considerably. Between 1977 and 1989, 109 cases of poliomyelitis were recorded, 11 of which were associated with the oral vaccine. In 1990, for

the first time, not a single case of polio caused by a local wild virus was reported in France, and it has been the same every year since. One imported case was reported in 1995.

### **Infections due to type b *Haemophilus influenzae* (Hib)**

These infections were frequent and serious for children under the age of 5: the principal ones are bacterial meningitis, epiglottitis, bacteremia, cellulitis, septic arthritis, pneumonia and ethmoiditis.

The incidence of these infections was variable by country before the introduction of vaccination. This was between 20 and 60 per 100,000 children aged under five in the United States, 52 per 100,000 in Scandinavia and, in France, 18 per 100,000 giving around 700 cases per year. In France, bacterial meningitis was the most frequent pathology and was found in 80% of the cases in those aged between 3 and 18 months.

Since the introduction of the Hib vaccine in France in 1992, with very high vaccination coverage, the rate of invasive infection by *H. influenzae* has dropped from 18 per 100,000 to 0.8/100 000 inhabitants in the three years following the introduction of the vaccination programme. The rate of meningitis infection has dropped from 0.9 per 100,000 to 0.09/100,000, with a spectacular decrease (-96%) in the population of under fives including babies less than 3 months old, a situation that means that France has virtually eradicated such pathologies in young children. The situation with other age groups for invasive Hib infection is: reduction in those under 15, stability for those between 15 and 64, and a slight increase for those over 64. There has been neither evidence of any recrudescence of the disease nor emergence of encapsulated bacteria for serotypes other than serotype b.

## **6 - Duration of immunity with adult vaccination**

### **Immunity duration against tetanus**

It is generally accepted that protection is achieved with a titer of antibodies at 0.01 IU/ml using the neutralisation technique.

The primary vaccination affords sustained protection. Several Danish studies have shown that this goes well beyond 10 years. The effect of the booster is particularly noticeable and it maintains the antibody titer at a high level over the long-term. Thus, for the Danish population vaccinated by the adsorbed vaccine, Simonsen [22] has suggested a booster for school-aged children and then regular boosters every 20 years.

Elsewhere, Gardner [23] has estimated that, for a person well vaccinated from an early age, the persistence of the immune system's memory for several decades suggests that there is no need to apply any booster shot before the age of 50.

Similar results suggesting protection up to the age of 20 have been found in studies from Portugal [24] and France [14].

In a recent study of the immunogenicity of vaccinations, Amanna [25] assessed the decrease over time of the antibodies generated by tetanus vaccines in 35 patients for whom the seric antibody concentration was initially at a high level (>1 IU/ml). This study shows that the half-life of tetanus antibodies was 11 years and that the level remained above the protection threshold more than 40 years after vaccination.

Based on these arguments, the Swiss Federal Office for Public Health has recently recommended an interval of 20 years between adult boosters for diphtheria/tetanus up to the age of 65. This interval is to be reduced to 10 years after the age of 65 because of the ageing of the immune system [3].

In effect, for people over 60 - the population in which most cases of tetanus are found in developed countries - antibodies rise to a lower level after vaccination but the protection period is still greater than 10 years. It would seem that an injection of a toxoid is necessary every 10 years from the age of 60.

### **Immunity against poliomyelitis**

Polio has been eradicated in France thanks to the high level of herd immunity engendered by widespread and regular vaccination using the injectable polio vaccine. This primary vaccination ensures excellent immunity up to adulthood, indeed 100 % according to a study by Vidor [26]. Any subsequent dose is a booster that prolongs the immunity for as long again. The wide coverage of infant vaccination is a veritable “barrier” to any imported strains becoming established.

Several authors even go as far as to say that there is no need to give booster shots to adults [27]. All studies carried out on vaccines combining the three strains of polio show that they achieve the booster effect and a level of antibodies considered as offering protection in 95 to 100 % of those vaccinated.

Given the risk of exposure close to zero in France, it is reasonable to suggest that boosters be given every 20 years to those adults residing in France.

### **Immunity against diphtheria**

The mandatory and systematic vaccination of children in France - which produces a vaccination coverage of over 95 % in that population - has helped eradicate this disease from the country. The reduction in the circulation of toxic strains has also undoubtedly helped.

Given that boosters for maintaining immunity have not been systematic among the adult population, studies carried out before 2004 suggested that the majority of the population over 50 were no longer immunised against this disease. In the 1990s an epidemic caused by the circulation of a toxic strain of *Corynebacterium diphtheriae* broke out in the countries of Eastern Europe causing numerous cases of diphtheria amongst people either not vaccinated or poorly vaccinated. This affected primarily adults and led to the re-vaccination of the adult population with a vaccine containing the diphtheria valency (Td/IVP).

A recent study concerning the persistence of antibodies [28] and the effect of a new booster injection with dTap shows that the geometric mean concentrations of anti-diphtheria antibodies were at a high level in those who had been vaccinated ten years earlier, where between 75 % and 80 % of the subjects had a protective antibody titer. A booster shot produced a significantly greater increase in the level of antibodies in those already vaccinated.

In Portugal, Goncalvez [24] studied the anti-diphtheria immunity in 22 women aged between 30 and 49 who had all received their primary vaccination before the age of 8. All those participants who had received at least six doses (12 women) had a protection level of antibodies and they had received their last dose between 20 and 37 years earlier; all susceptible women had received their last dose at least 25 years before.

The survey by Amanna [25], carried out with 45 well immunised Americans, shows that the decrease in the anti-diphtheria antibodies is very slow; their half-life is estimated at 19 years.

All this information suggests that, if vaccination is completed during childhood, booster shots against diphtheria are no longer required every ten years for adults, and that this can be prolonged to every 20 years, in the same way as the recent Swiss recommendations.

## **7 - The arguments in favour of a simplified vaccination schedule for young babies**

- **The fact that four European countries have adopted a simplified schedule, with just 3 doses of the primary vaccination for the 'classic' infant vaccines (D, T, aP, IPV, Hib ± Hepatitis B), and the demonstration of its effectiveness, give the green light for removing one injection from the French vaccination schedule for infants, which currently contains 4.**
- **Adopting the 3, 5, 11-12 month sequence is considered unacceptable in France where more than 40% of vaccinations already take place after the age of 2 months, since such a recommendation would risk delaying even further the start of vaccinations. Experience in Sweden and Denmark [29] clearly shows that such a delay is responsible for an increase in pertussis cases among the very young where the disease is the most serious. The**

desire is therefore to maintain the age of 2 months for starting vaccination, and to improve the percentage of babies that are subjected to this.

- Whilst there have been studies that demonstrate that the protocol of primary vaccination with two doses (3 & 5 months) is no less effective than the scheme with three doses (2, 3 and 4 months or 2, 4 and 6 months), no study has been carried out to compare the immunogenicity of a scheme with doses at 3, 5 and 11-12 months to that of a 2, 4 and 11-12 months schedule. On the other hand, there are no arguments to suggest that the proposed scheme would be less immunogenic:
  - the primary vaccination's function is to activate the T helper cells and the germinal centre B cells enabling them to produce antibodies, then to ensure that antibody affinity matures in 3 to 6 months and, above all, to establish an immunological memory. The ability of the immune system to perform this function from the age of 2 months has been established. The use of three doses is simply historical, whereas the experience of the 'Nordic schedules' shows that two doses suffice as long as they are performed 2 months apart;
  - the Italian experience is worth looking at: Italy has chosen the 3, 5 and 11-12 month scheme. In practice therefore, this means that vaccination must be started before the babies are three months old, and it transpires that two thirds of Italian babies receive their first vaccine shot during the third month. Thus, their schedule is very close to the one proposed here. The Italian regulatory authorities have not seen any extra risk of infection with vaccine-preventable diseases compared with other European countries;
  - the 2, 4 and 11-12 month vaccination schedule is approved for the pneumococcal conjugate vaccine. This was initially used entirely empirically in the United States where there were vaccine shortages. It transpired that, in a context of a very high level of vaccination cover, children who had received one shot less had an identical level of protection to those who had received the classic number of doses. Since then, clinical immunogenicity trials have shown that, in primary vaccination, the immune response obtained by the simplified schedule is less than is obtained using the classic schedule concerning certain serotypes (6B, 23F), which were themselves slightly less responsive to the classic vaccination schedule [31]. Any difference in immunogenicity disappears after the booster. Those countries (Canada, France and the United Kingdom) which have adopted this schedule [32] have seen a regular decrease in the occurrence of invasive pneumococcal infections from the vaccine-treatable serotypes, without experiencing any significant increase in invasive pneumococcal infections from those other serotypes.
- The risk of an increase in the occurrence of vaccine-preventable infections by adopting the simplified schedule needs to be aired:
  - this does not concern tetanus (babies are not at risk), or diphtheria (babies not at risk thanks to a very high level of vaccination coverage, and herd immunity) or poliomyelitis (not present in Europe, and herd immunity), or hepatitis B, or pneumococcus (no change to the vaccination schedule);
  - particular attention, however, needs to be paid to the potential impact of any change in the schedule on the incidence of infections from type b *Haemophilus influenzae* (Hib) and whooping cough:
    - the very high vaccination coverage for Hib has generated a herd immunity situation, which protects any babies less than 2 months old not yet vaccinated. The effectiveness of the three-dose vaccination scheme has been demonstrated by field experience in Italy and the Nordic countries. The reappearance of cases among children in the United Kingdom, vaccinated without any booster [33], has shown that long-term protection relies on a booster shot at the age of 11 months. In theory, a more rapid

reduction in the level of antibodies created by primary vaccination could engender a short vulnerable period between the second and third doses, as was also imagined for the pneumococcal vaccine. In fact, data obtained from monitoring cases of invasive infection by Hib in France between 1999 and 2007 show that, out of 60 cases of infection in children targeted by vaccination, 23 of them were up to date with their vaccinations for their age: 21 had received the three primary vaccination doses but none had received a booster. And of these, 14, i.e. two thirds, were aged between 12 and 18 months. Bringing the booster forward to the age of 11 months is a positive step towards eliminating this type of case;

- particular attention needs to be paid to any possible consequences for pertussis epidemiology. It is worth recalling that the strategy in France is to avoid the really serious cases of pertussis which are largely confined to those less than 6 months old and especially those less than 3 months. This is relatively independent of the babies' level of vaccination and largely depends on the level of protection in those with whom they come into contact. Using the strategy of cocooning, something which takes times to get established but which seems to be better applied, associated with the single booster recommended for adults, one can realistically expect an improvement in the current situation. Giving the first dose at 2 months has shown itself to be effective and represents a strong argument for maintaining the start of vaccination at that age. The proposed new schedule should not, therefore, give rise to any increase in cases of pertussis in the very young. Those cases reported in countries which have adopted a simplified vaccination schedule concern mainly children too young to be vaccinated and not the failure of a full vaccination programme. As has been specified earlier, protection will be reinforced by a booster shot at the age of 6 years. This, coupled with the improved vaccination coverage for adults that the simplified schedule should produce and the strengthening of the cocooning strategy, should result in reduced circulation of the bacterium and thus an indirect protection of new-born babies;
  - the theoretical risk of a lesser degree of protection against pertussis and Hib a few months after primary vaccination, and before the booster, is a strong argument in favour of the booster at 11 months, and for widespread publicity to make this practice known.
- It should also be highlighted that pertussis and *Haemophilus* infections are the subject of specific epidemiological monitoring in France. Any unexpected increase in these affections would very soon be picked up by the French surveillance organisations.

#### 8 - Booster doses for school-age children and adolescents

Recent papers published in the United States and Australia [15-21], where there appears to be a recrudescence of pertussis, would indicate that the immunity period afforded by pertussis booster vaccinations is considerably reduced in children between the ages of 6 and 15 who received their primary vaccination with acellular pertussis vaccines, compared with those who received their primary vaccination with whole-cell vaccines. It seems that France is not concerned by this phenomenon at the moment, although it must be noted, first, that the French surveillance system is not able quickly to detect any increase in cases of pertussis among school-age children and, secondly, as whole-cell pertussis vaccines were abandoned in 2006, the children fully primary vaccinated with acellular vaccines were only aged 6 in 2012.

##### The booster for six year-olds

The current vaccination schedule contains a booster shot covering diphtheria, tetanus and poliomyelitis. The absence of a booster covering pertussis in the current schedule

was justified by epidemiological data which indicated very few cases occurring among children under 10 who had received their primary vaccination with whole-cell vaccines. However, these children had received one more injection during primary vaccination for pertussis than children will receive in the new schedule. **Therefore, it seems justified to recommend that the booster at age 6 includes a pertussis valency (DTaP-IPV).** The problem of a reduced immunity duration offered by the acellular vaccines is another argument in favour of this approach.

### **The booster for adolescents**

The current vaccination schedule includes a booster at age 11 to 13 and the addition of a pertussis valency was intended to cover adolescence and the beginning of the reproductive life of young adults. If this is really the case, then protection is likely to be relatively short if the reduction in the immunity period observed in the United States were to be confirmed. Whatever the reality here, it seems logical to keep the adolescent booster containing a Tdap-IPV vaccine at age 11 to 13 with a simultaneous shot for papillomavirus for young girls.

It is recommended to delete the booster against diphtheria, tetanus and polio for 16 to 18 year-olds in the absence of any immunological or epidemiological justification for such boosters for an adolescent. The first booster for adults is therefore proposed at age 25. The interval of more than ten years between the adolescent booster and the first one for adults brings with it the risk of losing the protection against pertussis. However:

- **the vaccination strategy in France for pertussis is not to eradicate the disease (this is probably illusory given the current vaccines) but to prevent the most serious cases, which affect babies under 6 months, by vaccinating those people most likely to be the source of contamination.** Adolescents are rarely the source of contamination of new-born babies (Renacoq). Young adults are contaminants only if they are the parents or professionally involved with babies.
- A strengthening of the cocooning strategy is thus necessary to reduce this risk. Previous recommendations were to give a pertussis booster shot to people of any age (particularly parents and siblings) who were in direct contact with babies less than 6 months old, if those people had not received a pertussis shot in the past ten years. As a result of the questions surrounding the immunity period afforded by the acellular pertussis vaccines, this interval is reduced **to 5 years.**
- Quite apart from the suggested changes to the vaccination schedule, later boosters are very likely to be required for the reasons outlined above. However, this is difficult to implement without a not combined pertussis vaccine, and it is appropriate here to underline the importance of developing this.

### **9 - Booster doses for adults**

The objective for the proposed changes to adult boosters is both to keep the number of shots necessary to an absolute minimum and to create a booster schedule that is easier to remember than the current ten-year one.

Given the information expounded above concerning immunity periods, it seems reasonable to propose Td/IPV boosters every 20 years for adults. However, from the age of 65 onwards with the onset of ageing of the immune system, the proposal is to keep the ten-year interval. As part of the prevention programme against pertussis in small babies, one of these boosters, in particular the one at age 25, would include a pertussis valency for those adults who have not had a pertussis vaccination **in the previous 5 years.**

### **10 - The impact on other vaccinations in the schedule**

**Vaccines with special recommendations are not affected by the proposed changes to the general vaccination schedule. In particular, the BCG vaccine is recommended at birth for babies at risk.**

The proposed schedule is designed to favour simultaneous vaccination as much as possible, whilst limiting the number of injections at any particular visit to 2 - simply to be more humanly acceptable.

Thus, bringing forward to 11 months the penta- or hexa-valent vaccine and the PCV13 boosters (as in the Nordic countries) has the additional advantage of enabling the first dose of the measles-mumps-rubella vaccine to be maintained at the age of 12 months.

#### **Vaccination against measles-mumps-rubella**

Bringing forward to 11 months the hexa-valent and the pneumococcal boosters enables the first dose of the MMR vaccine to be maintained at the age of 12 months. The idea of bringing forward the first dose of the MMR vaccine to age 9 months has been considered, particularly at the time of the recent measles epidemic during which babies less than one year old were the most affected. However, recent data has shown there to be less immunogenicity with the MMR vaccines given at age 9 months compared with vaccination given at age 12 months [34,35]. In addition, in a recent Canadian study [36] carried out during a measles epidemic in a school environment, those who had received two doses had a significantly greater chance of vaccination failure when their first dose had been received at the age of 12 months than when that first dose was received after the age 15 months. Thus, bringing forward the age at which the first dose of the measles vaccine is given carries the risk of less protection.

The option proposed is to maintain the first MMR dose at age 12 months. And at 12 months the MMR vaccine will be accompanied by the meningococcal group C conjugate vaccine.

There is no justification for starting MMR vaccination at 9 months for children entering childcare facilities outside possible periods of epidemics. Protecting babies not old enough to be vaccinated needs to be handled through a high vaccination coverage level among those aged more than 1 year and among professionals dealing directly with babies.

The second dose of the MMR vaccine is recommended for all at 16 to 18 months, which keeps the current vaccination point unchanged. This can always be given earlier, as long as an interval of one month is maintained between the 2 doses.

#### **Meningococcal group C conjugate vaccine**

This vaccine is recommended to be given at age 12 months (see above).

#### **Human papillomavirus vaccine (HPV)**

This vaccine was recommended to be given to girls at age 14 years.

Recent recommendations [37] allow widening the range to between 11 and 14 years. Catch-up can now be done before the age of 20. One of the doses for HPV can be given at the same time as the Tdap-IPV booster at age 11 to 13 years.

### **11 - The acceptability of the new schedule – The Percevac Survey**

A joint effort between the Technical Committee on Vaccination and Inserm (France's National Institute for Health and Medical Research) enabled making an up-front assessment of the acceptability of this modification for family doctors.

Using focus groups and certain semi-structured individual discussions, a qualitative analysis was carried out among family doctors and paediatricians. Four focus groups with doctors (general practitioners and paediatricians) were constituted and completed by four individual interviews.

This study enabled forming the opinion that the doctors consulted were in favour of the proposed schedule. The impressions gathered during this exercise showed that the likely changes to the DTaP/IPV/Hib vaccination schedule would be welcomed. A certain number of questions and concerns were however raised: the fear of a less rigorous programme for new-born babies resulting from removing one of the primary vaccination sessions, concerns for a less effective vaccination programme, suspicions concerning a possible financial motive for the changes and a

worry about correct insertion into the new schedule of those children already embarked on the current schedule. On the other hand, there were several suggestions made concerning the proposed changes: publish a solid scientific justification, make sure the public authorities give unreserved support, develop recommendations that are simple and stable, and make available some effective tools for monitoring and following-up on patients' vaccination status.

Overall, the opinions received give rise to the belief that doctors involved in the population's vaccination programmes welcome the potential changes in the DTaP/IPV/Hib vaccination strategy. The suggestions made by those doctors interviewed indicate that it would be possible and indeed advisable to involve doctors in developing the recommendations for the actions that they will be required to implement.

**As a consequence of all the above, the High Council for Public Health recommends the following vaccination schedule for the general population**

- **At 2 months**  
The hexavalent DTaP/IPV/Hib-Hepatitis B vaccine at the same time as the conjugate pneumococcal vaccine.
- **At 4 months**  
The hexavalent DTaP/IPV/Hib-Hepatitis B vaccine at the same time as the conjugate pneumococcal vaccine.
- **At 11 months**  
The DTaP/IPV/Hib-Hepatitis B booster at the same time as the conjugate pneumococcal vaccine.
- **At 12 months**  
The first dose of the MMR vaccine (including for those babies entering daycare facilities) at the same time as the meningococcal group C conjugate vaccine.
- **At 16 -18 months**  
The second MMR dose.
- **At 6 years**  
The DTaP-IPV booster.
- **Between 11 and 13 years**  
The Tdap-IPV booster.
- **Between 11 and 14 years**  
Vaccination against papillomavirus for young girls.  
One of the doses of this vaccine can be given at the same time as the Tdap-IPV booster.
- **At age 25**  
Tdap-IPV booster (or Td/IPV if the person has received the Tdap-IPV within the previous 5 years).
- **At age 45**  
Td/IPV booster.
- **At age 65**  
Td/IPV booster.  
This is possible at the same time as the flu vaccine which remains recommended to be carried out annually.
- **At age 75 and then every 10 years**

Td/IPV booster.

At the same time as the flu vaccine which remains recommended to be carried out annually.

▪ **Catch-up vaccinations concern:**

- **applying the cocooning strategy for preventing pertussis among very young babies by vaccinating young parents or expectant parents as well as other people likely to be in close contact with such babies (especially any siblings) who have not received any booster in the previous 5 years;**
- the measles-mumps-rubella vaccine for those born after 1980;
- the meningococcal group C conjugate vaccine for people from the age of 1 up to under 25;
- the papillomavirus vaccine recommended before reaching the age of 20;
- vaccination against hepatitis B for children and adolescents before the age of 16.

Recommendations for specific vaccinations for people exposed to particular risks remain unchanged: these concern the BCG and vaccinations against flu, hepatitis A, hepatitis B, meningococcus for serogroups C and groups A, C, Y and W135, pneumococcus and chickenpox.

Appendix V contains details for handling the transition phase.

The High Council for Public Health recommends putting in place a vigorous communication campaign for the new schedule to secure buy-in from the medical profession, acceptance by the public and thus implementation as quickly as possible to attain an extremely high level of coverage.

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*The TCV met on 16<sup>th</sup> November 2012: 15 out of 17 voting members were present with no conflicting interests. The text was approved as follows: For - 15, abstentions - 0, against - 0.*

*The TCV met on 21<sup>st</sup> December 2012: 10 out of 15 voting members were present with no conflicting interests. The text was approved as follows: For - 10, abstentions - 0, against - 0.*

Appendix I - Simplified vaccination schedule and a comparison with the existing schedule

	2 months	3 months	4 months	9 months	11 months	12 months	13/15 months	16/18 months	6 years	11 years	14 years	16 years	16/18 years	25 years	26/28 years	45 years	65 years
<b>Existing</b>	HEXA	PENTA	HEXA	MMR*		MMR	MMR	HEXA	Td/IPV	DTaP-IPV	HPV		Td/IPV		Tdap-IPV	Td/IPV every 10 years	
	PCV13		PCV13			PCV13	MENINGO C										
<b>Proposed</b>	HEXA		HEXA		HEXA	MMR		MMR	DTaP-IPV	Tdap-IPV (11-13 years)				Tdap-IPV		Td/IPV**	Td/IPV**
	PCV13		PCV13		PCV13	MENINGO C				HPV							Then every 10 years

\* For children in daycare structures

\*\* For cocooning, a Tdap-IPV shot is recommended for any adult who has not had a pertussis dose in the previous 5 years and is likely to have close contact with new-born babies (up to the age of 6 months). Adults should not receive more than one dose of a pertussis vaccine.

## Appendix II - Vaccination schedule in certain industrialised countries

Country	Vaccine valency	Children's schedule (0 to 18)	Adults' schedule (18 to 85)
Germany	DT	6 doses of which two d	1 booster every 10 years
	<i>Pertussis</i>	6 doses of which two ap	1 ap booster every 10 years
Belgium	DT	6 doses of which one d	1 booster every 10 years
	<i>Pertussis</i>	6 doses of which one ap	<i>People in contact with babies</i>
Finland	DT	5 doses of which one d	1 booster every 10 years
	<i>Pertussis</i>	5 doses of which one ap	—
France	DT	7 doses of which two d	1 booster every 10 years
	<i>Pertussis</i>	5 doses	1 dose ap + <i>People in contact with babies</i>
The Netherlands	DT	6 doses of which one d	No recommendation
	<i>Pertussis</i>	5 doses	—
Italy	DT	5 doses of which one d	1 booster every 10 years
	<i>Pertussis</i>	5 doses of which one ap	—
Spain	DT	6 doses of which one d	1 dose at 65
	<i>Pertussis</i>	5 doses	
United Kingdom	DT	5 doses of which one d	No recommendation
	<i>Pertussis</i>	4 doses	—
Sweden	DT	5 doses of which one d	No recommendation
	<i>Pertussis</i>	5 doses	—
Switzerland	DT	6 doses of which one d	1 booster every 20 years up to age 65, then every 10 years
	<i>Pertussis</i>	5 doses of which one ap	—

Australia	DT	5 doses of which one d	1 dose
	<i>Pertussis</i>	5 doses	1 dose
Canada	DT	6 doses of which one d	1 booster every 10 years
	<i>Pertussis</i>	6 doses of which one ap	1 dose
United States	DT	6 doses of which one d	1 booster every 10 years
	<i>Pertussis</i>	6 doses of which one ap	1 dose of ap

## Appendix III - Adult vaccination coverage in France

References	Number / population Site Survey year	Vaccination coverage Percentage of people up to date (10 years or less since latest vaccination)			
		Age ranges	Diphtheria	Tetanus	Poliomyelitis
Hommel C, <i>et al.</i> BEH 2009; 14: 129-32 [1]	721 pilgrims travelling to Mecca International vaccination centre - In 2006	All ages Aged 21-30 Aged 31-50 Aged 51-70 71 or over	22% 56% 22% 19% 7%	34% 63% 28% 34% 16%	25% 56% 24% 24% 11%
Gergely A, <i>et al.</i> BEH 2008; 9: 61-64 [2]	660 people aged over 60 - The Ile-de-France vaccination centre - In 2006	All ages Aged 60-69 Aged 70-79 79 or over	28% 44% 32% 17%	77% 77% 79% 74%	42% 58% 48% 28%
De la Rocque F, <i>et al.</i> Arch Ped 2007 (14): 1472-76 [3]	800 parents of young infants during the first consultation with a doctor following the birth - 33 paediatricians and 8 PMI Centres (Ile-de-France Region and Oise 'Département') - In 2006	All parents Mothers between 19 and 43 Fathers between 20 and 65	DT/IPV booster up to date: 62.6% DT/IPV booster up to date: 65.7% DT/IPV booster up to date: 59.2%		
Guthmann JP, <i>et al.</i> - SPS Survey 2002 -BEH2007; 51-52: 441-445 [4]	11,172 people aged over 16 in metropolitan France - declarative questionnaire - In 2002	People vaccinated less than 10 years ago People aged over 64	29.1% 10.5%	62.3% 60.5%	36.1% 13.3%
Beytout J, <i>et al.</i> Med Mal Inf 2004; 34 (10):460-468 [5]	6,269 patients from a representative sample of 2,122 general practitioners - France split into 8 regions - In 2001	Patients aged 44 +/- 15 years Geographic variation of coverage rate	58.4%	66.1%	63.4%

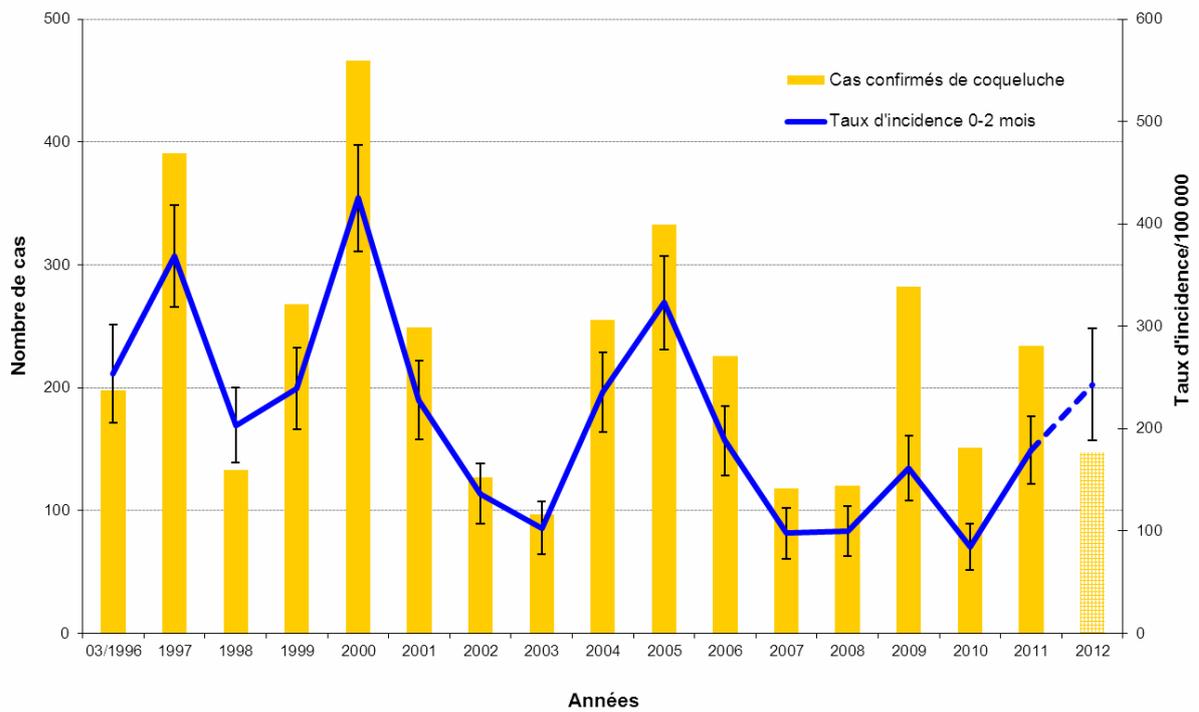
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Appendix IV – Incidence rate for pertussis in babies under 2 months old and the number of biologically confirmed cases notified by bacteriologists to the Renacoq surveillance network



## Appendix V - Managing the transition period

All new primary vaccinations should follow the new vaccination schedule.

It is appropriate to spell out the route to be taken by all people who have received at least one vaccination dose before the new vaccination schedule came into force.

- Babies who have received just the first dose for the primary vaccination should follow the new schedule.
- Babies who have received the first two doses for primary vaccination should finish the initial three dose programme under the former schedule and then follow the new schedule from the 11 month booster onwards. There must be a minimum interval of 6 months between the 3<sup>rd</sup> primary dose and the booster.
- Babies who have received the full three doses for primary vaccination (Hexavalent-Pentavalent or simple Pentavalent) should be given the 11 month booster and follow the new schedule thereafter. There must be a minimum interval of 6 months between the 3<sup>rd</sup> primary dose and the booster.
- Children who have received 4 doses of primary vaccination (the 3 doses of the initial series + the booster at age 16-18 months) should continue with the new schedule (DTaP-IPV at age 6 years).
- Children who have received a Td/IPV (or a Tdap-IPV) dose at age 6 will have a DTaP-IPV dose between the ages of 11 and 13 years.
- Children who have received a DTaP-IPV dose at age 6 will have a Tdap-IPV dose between the ages of 11 and 14 years.
- Children who have received a DTaP-IPV or a Tdap-IPV or a Td/IPV dose between the ages of 11 and 13 years will have a Tdap-IPV dose at age 25.
- Adolescents who have received a Td/IPV or Tdap-IPV dose at age 16/18 will follow the new schedule with a Tdap-IPV booster at the age of 25.

➤ **After the age of 25, the next Td/IPV booster will be given according to the following rules:**

1) The interval since the previous booster must be more than 5 years. If this is < 5 years, then the next booster will be given at the next vaccination appointment at a fixed age (n+1): i.e. a maximum interval of 25 years.

**AND**

2) The interval since the previous booster and the next vaccination appointment at a fixed age (n) must not exceed 25 years. If his interval is > 25 years an immediate booster should be given. The interval between this booster and the following vaccination appointment at a fixed age (n) must be at least 5 years. If this interval is less than 5 years, the adjustment will be deferred until the next but one vaccination appointment at a fixed age (n+1).

Examples:

A person aged 33, with previous booster at age 30 => next booster to be given at the next fixed age for vaccination, i.e. age 45 (n)

A person aged 43, with previous booster at age 40 => next booster to be given at the next but one fixed age for vaccination, i.e. age 65 (n+1) [and not at age 45 (n)]

A person aged 35, with previous booster at age 18 => booster immediately. Following booster at the fixed age of 45 (n)

A person aged 43, with previous booster at age 18 => booster immediately. Following booster at the fixed age of 65 (n+1) [and not at age 45 (n)]

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➤ **After the age of 65, the next Td/IPV booster will be given according to the following rules:**

1) The interval since the previous booster must be more than 5 years. If this is < 5 years, then the next booster will be given at the next vaccination appointment at a fixed age (n+1): i.e. a maximum interval of 15 years.

**AND**

2) The interval since the previous booster and the next vaccination appointment at a fixed age (n) must not exceed 15 years. If this interval is > 15 years an immediate booster should be given. The interval between this booster and the following vaccination appointment at a fixed age (n) must be at least 5 years. If this interval is less than 5 years, the adjustment will be deferred until the next but one vaccination appointment at a fixed age (n+1).

Examples:

A person aged 68, with previous booster at age 63 => next booster to be given at the next fixed age for vaccination, i.e. age 75 (n)

A person aged 73, with previous booster at age 70 => next booster to be given at the next but one fixed age for vaccination, i.e. age 85 (n+1) [*and not at age 75 (n)*]

A person aged 66, with previous booster at age 40 => immediate booster with the following booster to be given at the next fixed age for vaccination, i.e. age 75 (n)

A person aged 72, with previous booster at age 50 => immediate booster with the following booster to be given at the next but one fixed age for vaccination, i.e. age 85 (n+1) [*and not at age 75 (n)*]

**Special provisions**

- Against tetanus: think of a supplementary vaccination in the case of injury or an open wound depending on doctors' recommendations.
- Against whooping cough: strengthen all the elements of cocooning.

Expert opinion produced by the Expert Committee on Infectious Diseases at the request of the Technical Committee on Vaccination  
21st December 2012

**Haut Conseil de la santé publique**

14, Avenue Duquesne

75350 Paris 07 SP

[www.hcsp.fr](http://www.hcsp.fr)