



Vacunas

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Review article

25 years of systematic hepatitis B vaccination of pre-adolescents in Catalonia[☆]

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ARTICLE INFO

Article history:

Received 24 July 2017

Accepted 13 September 2017

Available online xxx

Keywords:

Hepatitis B vaccination

Preadolescents

Planning

Evaluation

Vaccination program

ABSTRACT

A description is presented on the planning and evaluation of the hepatitis B vaccination program for pre-adolescents in Catalonia, 25 years after it was started in 1991. For the incorporation of the vaccine into the systematic vaccinations calendar an analysis was made of the criteria (disease burden, safety, immunogenicity and protection efficacy of the vaccine, effectiveness, efficiency, and potential impact of the vaccination, compatibility with other vaccines and likely limited potential impact of selective vaccination). This was followed by choosing the most convenient strategy for the universal vaccination of the child population (elevated risk of infection and illness during adolescence and young adult age, and low risk in newborns, infants and small children, rapid impact on the incidence of cases, efficiency of the intervention, and likely increased vaccine coverage in schools). Lastly, the evaluation of the results of the targets set for the Program in the Catalonia Health Plan.

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Veinticinco años de vacunación sistemática frente a la hepatitis B de los preadolescentes en Cataluña

RESUMEN

Se describe la planificación y evaluación del programa de vacunación frente a la hepatitis B de los preadolescentes en Cataluña, 25 años después de su puesta en marcha, el año 1991. Para ello se analizan los criterios seguidos para la incorporación de la vacuna al calendario de vacunaciones sistemáticas (carga de la enfermedad, seguridad, inmunogenicidad y eficacia protectora de la vacuna, efectividad, eficiencia e impacto potencial de la vacunación,

Palabras clave:

Vacunación antihepatitis B

Preadolescentes

Planificación

Evaluación

Programa de vacunaciones

DOI of original article: <http://dx.doi.org/10.1016/j.vacun.2017.09.001>.

[☆] Please cite this article as: Salleras L. Veinticinco años de vacunación sistemática frente a la hepatitis B de los preadolescentes en Cataluña. Vacunas. 2017. <https://doi.org/10.1016/j.vacun.2017.09.001>

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<https://doi.org/10.1016/j.vacune.2017.11.005>

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compatibilidad con otras vacunas y presumible impacto potencial limitado de la vacunación selectiva) y los seguidos para la elección de la estrategia más conveniente para la vacunación universal de la población infantil (elevado riesgo de infección y de enfermedad durante la adolescencia y edad adulta joven y bajo riesgo en los recién nacidos, lactantes, y niños pequeños, impacto rápido en la incidencia de casos, eficiencia de la intervención y presumible elevada cobertura vacunal en las escuelas). Por último, se presentan los resultados de la evaluación de los resultados fijados para el programa en el Plan de Salud de Cataluña.

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Introduction

The hepatitis B vaccine prevents infection and acute clinical disease, and has the additional advantage of preventing chronic complications of infection (chronic hepatitis, cirrhosis, and hepatocellular carcinoma).^{1,2} In fact, this vaccine is the first marketed vaccine with the potential to prevent cancer.^{3,4}

The hepatitis B plasma vaccine marketed in the early 1980s was replaced in the middle of this decade in developed countries by the vaccine obtained through genetic recombination. In both vaccines the immunising antigen is HbsAg, obtained from human plasma in the first vaccine and expressed in yeast or mammalian cells in the recombinant.^{1,2}

Hepatitis B vaccination

The availability of vaccines of proven efficacy against the hepatitis B virus led to vaccination becoming the priority strategy for the prevention and control of this disease in both developed and developing countries.²

The first hepatitis B vaccine, the plasma vaccine, was marketed in the United States in 1981 and soon after arrived in our country. It contained purified HBs Ag obtained from human plasma from chronic carriers (HBs Ag+). Its production cycle was relatively long (about 65 weeks) and the cost of manufacturing was high. In addition, the supply was limited by the availability of plasma of chronic carriers of the HBs antigen and its safety was questioned (possibility of accidents due to inactivation of the antigen). For all these reasons, although it proved to be very effective, it lacked the qualities that a vaccine must possess in order to be systematically administered to the population. In our country, its use was very restricted, applying mainly to the high-risk groups of the adult population, especially hospital healthcare personnel, injecting drug users and newborn children of an HB Ag-positive mother.⁵

In 1986, the recombinant vaccine obtained through genetic recombination in yeast was marketed in the United States and Europe (the gene coding for the HBs antigen is incorporated into the genome of the yeasts and these, when proliferated in large fermenters, mass produce the immunising antigen). Unlike the previous vaccine, it was a high purity vaccine, very safe and with a very short production cycle. In addition, its production cost was very low, the consistency between batches was very high and the potential capacity for unlimited production. These

qualities opened the way to their inclusion in systematic vaccination programs for the protection of the entire population.⁵

In developing countries with high endemicity, in which the predominant transmission mechanism was the perinatal route in newborns carrying HBs Ag and the horizontal route during childhood, the strategy chosen was to vaccinate all newborns. This strategy, by incorporating the hepatitis B vaccine into the schedule of routine vaccinations, clearly facilitated compliance of the vaccination with three doses of vaccine.⁶

In developed countries with low endemicity, in which perinatal and horizontal transmission in childhood did not play any important role in the epidemiology of the infection and in which the majority of infections occurred in adolescence and young adulthood through sexual transmission, parenteral drug use or as a consequence of trips to developing countries with high endemicity, the possible strategies for universal vaccination were three: vaccination of infants, vaccination of pre-adolescents and vaccination of both population groups. The first strategy guaranteed high levels of vaccine coverage with three doses of vaccine, but had the drawback that the benefits of vaccination would not be expected until 15 or 20 years later. Vaccination of pre-adolescents would give benefits much sooner, but good levels of vaccine coverage could only be achieved by vaccinating in schools. Lastly, the third strategy guaranteed the attainment of short- and long-term benefits, but at a substantially higher cost. In fact, most of the developed countries initially ruled out universal vaccination, focusing efforts on the selective vaccination of the children of a carrier mother and of young people and adults belonging to high-risk groups.⁷

In developed countries with intermediate endemicity (Spain, Italy, France and in general all Mediterranean European countries, some areas of Canada and the United States) the strategy originally chosen was that of universal vaccination of pre-adolescents in order to obtain short-term results, although in most countries, universal vaccination of infants was also decided sooner or later.^{8,9} All this without forgetting the selective vaccination of newborns of HBs Ag+ mothers and the high-risk young and adult population.¹⁰ Catalonia in Spain and Puglia in Italy were the first regions of Europe to launch universal vaccination programs for pre-adolescents in schools.^{5,11}

In 1989, the General Directorate of Public Health decided to analyse the need and convenience of incorporating the recombinant hepatitis B vaccine into the routine vaccination schedule in Catalonia, and if so, to start the corresponding

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