



SPANISH ASSOCIATION OF PAEDIATRICS

## Consensus position document on the child with an allergic reaction after vaccination or an allergy to vaccine components<sup>☆</sup>



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**Abstract** Vaccinations are one of the main public health tools for the control of vaccine-preventable diseases. If a child is labelled to have had an allergic reaction to a vaccine, the next immunizations will probably be suspended in that child, with the risks involved in this decision. The rate of severe allergic reactions is very low, ranging between 0.5 and 1/100,000 doses. The causes of allergic reactions to vaccines, more than the vaccine itself, are often due to residual protein components in the manufacturing process, such as gelatin or egg, and rarely to yeast or latex. Most of vaccine reactions are mild, localised at the site of injection, but in some circumstances, severe anaphylactic reactions can occur. If an immediate-type allergic reaction is suspected when vaccinating, or a child allergic to some of the vaccine components has to be vaccinated, a correct diagnosis of the possible allergy has to be made. The usual components of each vaccine should be known, in order to determine if vaccination can be performed safely on the child.

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**PALABRAS CLAVE**

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Anafilaxia

## Documento de consenso sobre la actitud ante un niño con una reacción alérgica tras la vacunación o alergia a componentes vacunales

**Resumen** Las vacunaciones constituyen una de las principales herramientas de salud pública para el control de las enfermedades inmunoprevenibles. Si un niño es etiquetado de haber presentado una reacción alérgica a una vacuna es probable que se suspendan las siguientes inmunizaciones, con los riesgos que ello conlleva. La tasa de reacciones alérgicas graves es muy baja, oscilando entre 0,5 y 1/100.000 dosis. Las proteínas causantes de las reacciones alérgicas, más que los propios antígenos vacunales, son frecuentemente componentes residuales del proceso de fabricación, como son la gelatina y el huevo, y más raramente las levaduras o el látex. La mayoría de las reacciones son leves y localizadas en el lugar de la inyección, aunque en algunos casos pueden producirse reacciones anafilácticas graves. Si se sospecha que se ha producido una reacción alérgica inmediata a la vacuna, o si debemos vacunar a un niño con alergia a alguno de sus componentes, se deberá realizar un correcto diagnóstico de la posible alergia y conocer los componentes habituales de cada vacuna con el fin de determinar si la vacunación puede continuarse de forma segura.

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### Explanation and seriousness of the issue

The aim of vaccination programmes is to protect the vaccinated child and prevent the recipient from having the disease against which he or she was vaccinated. The goal is to vaccinate the greatest possible number of susceptible individuals to produce a collective protective environment for the entire population.

If a child is labelled as having had an allergic reaction to a vaccine (ARV), subsequent vaccinations will probably be suspended and that child will join the pool of individuals susceptible to the diseases against which he or she has stopped being vaccinated. Therefore, diagnosing the ARV accurately and confirming whether there is a direct relationship between the allergic reaction and the administration of the vaccine are of the essence.

The approach to a child with suspected ARV should start by determining whether the signs and symptoms presented by the child were directly related to the administration of the vaccine, managing the allergic reaction, and then assessing whether the adverse event was a reaction against the vaccine antigen itself or to any of the vaccine components, as this will determine the administration of future doses of the vaccine in question or similar vaccines.<sup>1</sup>

There is a wide variety of ARV. They are usually mild, local reactions, and exceptionally severe anaphylactic reactions that may even be fatal.<sup>2</sup>

### Vaccine composition: antigens, preservatives and adjuvants

Vaccines do not only contain the antigen responsible for stimulating the immune response in the vaccinated individual, but may also contain additional constituents (Table 1).

**Table 1** Vaccine composition.

- Immunising antigen
- Suspending fluid: may contain proteins or other components from cultures
- Antibiotics: to prevent contamination
- Preservatives: extend the shelf-life
- Stabilisers: the most common is gelatin
- Adjuvants: enhance the immunogenicity of antigens

### Epidemiological data. Incidence of allergic reactions after vaccination

Allergic reactions to vaccines are rare and usually have no causal relationship with immunisation. Estimates of true immediate hypersensitivity reactions to vaccines range from 1 in 50 000 doses for the DTP vaccine to 0.5–1 reaction per million doses for other vaccines.<sup>1</sup> The Brighton Anaphylaxis Working Group estimates that the number of true severe anaphylactic reactions to vaccines ranges between 0.5 and 1 in 100 000 doses.<sup>3</sup> The number of reported deaths due to anaphylaxis secondary to vaccination is approximately 1 in 50 million doses.<sup>4</sup>

There are few published data for Spain, with reported incidences ranging between 0.59% and 1.27% of reactions suspected to be associated with vaccination in the first visits to a paediatric allergy unit.<sup>2</sup>

Among the allergic reactions attributed to residual proteins, the most common are those related to egg in vaccines grown in both chicken embryo fibroblasts and fertilised chicken eggs.

It is convenient to complete a questionnaire before vaccination<sup>5</sup> asking the parents of the child that is to be vaccinated about the presence of certain circumstances that may lead to consider the vaccination to be contraindicated

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