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SPANISH ASSOCIATION OF PAEDIATRICS

Immunisation schedule of the Spanish Association of Paediatrics: 2023 Recommendations

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Abstract As it does every year, the CAV-AEP publishes the update of its recommendations for the use of vaccines in children, adolescents and pregnant women residing in Spain.

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♦ Appendix A lists the members of the Advisory Committee on Vaccines of the Asociación Española de Pediatría (CAV-AEP).

Infant;
Child;
Adolescent;
Pregnant;
Spanish immunisation schedule

The 2 + 1 schedule is maintained in infants (at 2, 4 and 11 months), including preterm infants, with the hexavalent vaccine (DTaP-IPV-Hib-HB) and the pneumococcal 13-valent conjugate vaccine.

A booster dose with DTaP-IPV is needed at 6 years for those who received the 2 + 1 series with hexavalent vaccine as infants, in addition to 1 dose of dTap in adolescence. Routine vaccination of pregnant women with a dose of dTap is recommended in each pregnancy, preferably between weeks 27 and 32 of gestation, although can be given from 20 weeks if there is risk of preterm delivery.

All infants should receive the rotavirus vaccine (2–3 doses) and the 4CMenB vaccine (2 + 1 series).

All children aged 6–59 months should be vaccinated against influenza each year.

The MenACWY vaccine should be given routinely at 12 months of age and in adolescence between ages 12 and 18 years.

The recommendations for the MMR vaccine (12 months and 3–4 years) and varicella vaccine (15 months and 3–4 years) also remain unchanged, using the MMRV vaccine for the second dose.

Recommendations for the use of SARS-CoV-2 vaccines in the paediatric age group will be updated periodically on the CAV-AEP website.

The HPV vaccine is indicated in all adolescents, regardless of sex, at age 12 years.

Novelties include the recommendation of routine administration of nirsevimab to neonates and infants aged less than 6 months for passive immunization against RSV, and the recommendations regarding the hexavalent vaccine are consolidated in a single section.

PALABRAS CLAVE
Vacunas infantiles;
Lactante;
Niño;
Adolescente;
Embarazada;
Calendario de inmunización español

Calendario de inmunizaciones de la asociación española de pediatría: recomendaciones 2023

Resumen Como cada año, el CAV-AEP actualiza sus recomendaciones de inmunización en niños, adolescentes y embarazadas residentes en España.

Se mantiene el esquema 2 + 1 en lactantes (2, 4 y 11 meses), incluyendo prematuros, para vacunas hexavalentes (DTPa-VPI-Hib-HB) y neumocócica conjugada 13-valente.

A los 6 años de edad, refuerzo con DTPa-VPI a los que recibieron la pauta 2 + 1 con hexavalentes siendo lactantes, y, en la adolescencia, Tdpa, una dosis. En gestantes, Tdpa en cada embarazo, preferentemente entre las semanas 27 y 32, aunque si hay riesgo de parto pretérmino se puede desde la semana 20 de gestación.

Todos los lactantes deben recibir vacunas contra rotavirus (2 o 3 dosis) y meningococo B (2 + 1).

Todos los niños de entre 6 y 59 meses deben ser vacunados anualmente contra la gripe.

MenACWY debe administrarse a los 12 meses de edad y a los adolescentes entre 12 y 18 años que no la hayan recibido.

Se mantienen las recomendaciones sobre SRP (12 meses y 3–4 años) y varicela (15 meses y 3–4 años), procurando en la segunda dosis el uso de tetravírica (SRPV).

Las recomendaciones para el uso de las vacunas contra la COVID-19 en la edad pediátrica se actualizarán periódicamente en la web del CAV-AEP.

Vacuna contra VPH indicada para todos los adolescentes, independientemente del género, a los 12 años.

Como novedades, se incluyen la recomendación de uso de nirsevimab sistemático en recién nacidos y lactantes menores de 6 meses como inmunización pasiva contra VRS, y se aglutinan las hexavalentes en un solo apartado.

Introduction

In adherence with its mission, the Advisory Committee on Vaccines of the Asociación Española de Pediatría (Spanish Association of Paediatrics, AEP) (CAV-AEP) publishes its annual recommendations for vaccination in infants, children, adolescents and pregnant women in Spain (Fig. 1), developed from the critical review of relevant scientific information from a variety of sources (Table 1) adapted to the domestic epidemiological trends. A detailed explanation of the grounds for these recommendations can be found in the website of the CAV-AEP and the online Vaccine Manual of the AEP.

The CAV-AEP insists on the need of a single, unified nationwide immunization schedule, exploring alternative funding sources for vaccines yet to be included in official immunization schedules, shifting away from the pharmacoeconomic criteria historically applied to establish vaccination policies and for the pharmaceutical industry to contribute to ensuring that children and adolescents in Spain receive the best possible protection against vaccine-preventable diseases.

In light of the crucial role played by vaccines against SARS-CoV-2 in controlling the coronavirus disease 2019 (COVID-19) pandemic, which evinced the degree of success that can be achieved by strategies developed through the collaboration of scientific societies and public health authorities, the CAV-AEP reafirms the importance of the active involvement of paediatricians, among other specialists, in the decision-making bodies responsible for vaccination in Spain.

There has been a marked decrease in vaccination coverage levels worldwide during the pandemic, and some previously controlled vaccine-preventable diseases have re-emerged, evincing the importance of the primary care (PC) system in the maintenance of adequate vaccination coverage rates. The only way to ensure that vaccination reaches the entire population is to reinforce paediatric primary care services and regional public health systems, actively addressing barriers to vaccination access and fighting conspiracy theories and disinformation.

Vaccination with hexavalent vaccines (DTaP-IPV-Hib-HB)

***2023 recommendation**: vaccination with hexavalent vaccines (DTaP-IPV-Hib-HB) with a 2 + 1 schedule (at 2, 4 and 11 months), DTaP-IPV, preferably, or Tdap-IPV at 6 years and Tdap at 12 to 14 years. In women, administration of Tdap is recommended in each pregnancy, preferably between 27 and 32 weeks of pregnancy, as early as possible and, if there is a high risk of preterm birth, starting from 20 weeks. Children and adolescents of any age who are not vaccinated against hepatitis B (HB) will be given 3 doses of monovalent vaccine (or combined with hepatitis A if indicated) on a 0-, 1- and 6-month schedule.*

In countries with adequate coverage, vaccination against diphtheria, tetanus, poliomyelitis, hepatitis B and *Haemophilus influenzae* type b is highly effective in controlling these diseases.[1] The 2 + 1 schedule with hexavalent vaccines with an interval of at least 2 months between doses in the primary series and 6 months between the primary series and the booster is safe and effective; this schedule was introduced in Spain in 2017 and requires administration of a fourth dose of inactivated poliovirus (IPV) vaccine at age 6 years. In 2022, children first vaccinated with this schedule should receive the DTaP-IPV vaccine, but if it is not available or the child is older than 7 years, the Tdap-IPV vaccine will be used instead.

In adolescence, the Tdap vaccine is administered to provide the fifth dose of vaccine against tetanus and diphtheria, thus completing the recommended series through age 60–65 years and boosting protection against pertussis in young adults.

Regarding to pertussis, since neither vaccination nor natural infection confer lasting immunity, individuals may be susceptible at any age, but morbidity and mortality are highest in infants aged less than 3 months.[2] Vaccination of pregnant women is an effective strategy to prevent severe disease in infants, with an effectiveness of up to 90.5% in preventing hospital admission in infants under 3 months.[3] The earlier it is administered, the greater the amount of maternal antibodies present in the infant at birth.[4] Maternal antibodies interfere to some extent with the infant's immune response to primary vaccination (*blunting*), but this does not requires delaying the dose, as there are studies that show that the decrease in post-vaccine antibody titres does not affect seroprotection.[5]

Hepatitis B is an universally distributed infection. In consequence, the World Health Organization (WHO) launched the Global Health Sector Strategy on Viral Hepatitis 2016–2021 with the aim of eradicating it by 2030. Spain is a low-endemic country, with 394 cases notified in 2021 and a very low incidence of vertical transmission and paediatric infection.[6]

The complete series achieves a seroprotective antibody response (HB antibody titre >10 mIU/mL) in more than 95% of infants, children and young adults that lasts 20 years and probably for life. However, seroconversion is not as likely to be achieved in patients treated with haemodialysis or who are immunocompromised, so these patients may require vaccination with a higher-antigen dose or more doses of vaccine.

Vaccination against pneumococcal disease

***2023 recommendation**: vaccination against pneumococcal disease is recommended for all children younger than 5 years and children of any age that belong to any risk group. A 2 + 1 series (at 2, 4 and 11 months) is recommended for routine vaccination of healthy infants, preferably with the 13-valent pneumococcal conjugate vaccine (PCV13)*

Pneumococcal conjugate vaccines (PCVs) protect against invasive pneumococcal disease (IPD) and non-invasive forms of disease (pneumonia and acute otitis media).[7,8] Routine childhood vaccination against pneumococcal disease has significantly reduced the global burden of IPD, with a corresponding decrease in antibiotic use and bacterial drug resistance.[9]

Following the introduction of PCVs, there has been evidence of an emergence of non-vaccine serotypes. This has

prompted the development of new vaccines covering additional serotypes (PCV15, PCV20, PCV24) for use in adults and children.[10] The PCV13 offers the best possible coverage against the serotypes currently circulating in the paediatric population in Spain.[10]

Vaccination against rotavirus

2023 recommendation: *Vaccination against rotavirus (RV) should be included in the routine immunization schedule for all infants.*

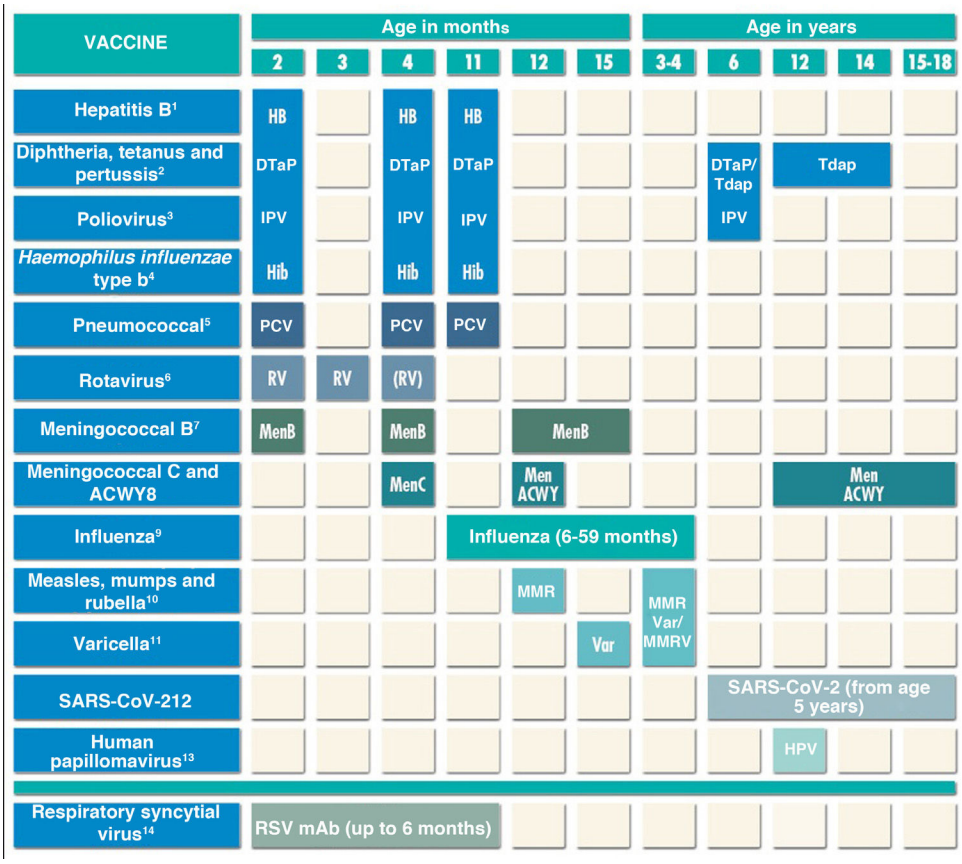

Figure 1 Routine immunization schedule of the Spanish Association of Pediatrics: 2023 recommendations.
(1) Hepatitis B vaccine (HB). Three doses of hexavalent vaccine at 2, 4 and 11 months. Children of HBsAg-positive mothers will be given 1 dose of vaccine and 1 dose of hepatitis B immune globulin (HBIG) (0.5 mL) within 12 h of birth. In the case of unknown maternal serologic status, children will receive the vaccine within 12 h of birth, followed by 0.5 mL of HBIG, preferably within 72 h of birth, if maternal HBsAg-positive status is confirmed. Infants vaccinated at birth will adhere to the routine schedule for the first year of life, and thus will receive 4 doses of HB vaccine. Unvaccinated children and adolescents should be given 3 doses of monovalent vaccine on a 0, 1 and 6-month schedule.
(2) Diphtheria, tetanus and acellular pertussis vaccine (DTaP/Tdap). Five doses: primary vaccination with 2 doses, at 2 and 4 months, of DTaP-IPV-Hib-HB (hexavalent) vaccine; booster doses at 11 months (third dose) with DTaP (hexavalent), at 6 years (fourth dose) with the standard load vaccine (DTaP-IPV preferable to the low diphtheria and pertussis antigen load vaccine (Tdap-IPV), and at 12–14 years (fifth dose) with Tdap. In children previously vaccinated with the 3 + 1 schedule (at 2, 4, 6 and 18 months), it is possible to use the Tdap for the booster at age 6 years, as they do not need additional doses of IPV.
(3) Inactivated poliovirus vaccine (IPV). Four doses: primary vaccination with 2 doses, at 2 and 4 months, and booster doses at 11 months (with hexavalent vaccine) and 6 years (with DTaP-IPV or Tdap-IPV). Children previously vaccinated with the 3 + 1 schedule (at 2, 4, 6 and 18 months), require no additional doses of IPV.
(4) *Haemophilus influenzae* type b conjugate vaccine (Hib). Three doses: primary vaccination at 2 and 4 months and booster dose at 11 months (with hexavalent vaccine).
(5) Pneumococcal conjugate vaccine (PCV). Three doses: the first two at 2 and 4 months, with a booster dose starting at 11 months of age. The vaccine recommended in Spain by the CAV-AEP continues to be the PCV13.
(6) Rotavirus vaccine (RV). Two or three doses of rotavirus vaccine: at 2 and 3–4 months with the monovalent vaccine or at 2, 3 and 4 months or 2, 3–4 and 5–6 months with the pentavalent vaccine. To minimise the already low risk of intussusception, vaccination must start between 6 and 12 weeks of life and be completed by 24 weeks for the monovalent vaccine and 33 weeks for the pentavalent vaccine. Doses must be given at least 4 weeks apart. Both vaccines may be given at the same time as any other vaccine (with the exception of the oral poliovirus vaccine, which is not currently distributed in Spain).

(7) Meningococcal B vaccine (MenB). 4CMenB. Three doses: start at age 2 months, with a primary series of 2 doses 2 months apart and a booster starting from age 12 months and at least 6 months after the last dose in the primary series. It can be administered at the same time as other vaccines in the schedule, although this could increase the likelihood of fever; so it can also be administered 1 or 2 weeks apart from other injectable inactivated vaccines in the primary series to minimise potential reactogenicity. The separation by 1–2 weeks is not necessary for the MenACWY, MMR, varicella and rotavirus vaccines. For all other age groups, the indication of vaccination with either vaccine (4CMenB or MenB-fHbp) is determined on a case-by-case basis, always adhering to the minimum age authorised for the vaccine.

Vaccination is also recommended in risk groups: anatomic or functional asplenia, complement deficiency, treatment with eculizumab or ravulizumab, haematopoietic stem cell transplant recipients, infection by HIV, prior episode of IMD caused by any serogroup, and contacts of an index case of IMD caused by serogroup B in the context of an outbreak.

(8) Meningococcal C conjugate vaccine (MenC) and meningococcal ACWY conjugate vaccine (MenACWY). One dose of conjugate MenC-TT at age 4 months. The CAV-AEP recommends 1 dose of the MenACWY conjugate vaccine at age 12 months and 11–13 years, and progressive catch-up vaccination to be completed by age 18 years. In ACs where the MenACWY vaccine is not included in the routine immunization schedule at 12 months, if parents choose not to administer it, the MenC-TT vaccine funded by the regional government must be administered instead. For all other age groups, the decision to vaccinate must be made on a case-by-case basis.

Administration of the MenACWY vaccine is still particularly recommended in children and adolescents that are to live in countries where the vaccine is administered at this age (Canada, United States, Argentina, Chile, Saudi Arabia, Australia, Andorra, Austria, Belgium, Cyprus, Greece, Ireland, Italy, Malta, Netherlands, United Kingdom, Czech Republic, San Marino and Switzerland) and for children with risk factors for IMD: anatomic or functional asplenia, complement deficiency, treatment with eculizumab or ravulizumab, hematopoietic stem cell transplant recipients, HIV infection, prior episode of IMD caused by any serogroup, and contacts of an index case of IMD caused by serogroup A, C, W or Y in the context of an outbreak. Individuals traveling to Mecca for religious reasons and to the African meningitis belt during the dry season should also receive the MenACWY vaccine.

(9) Influenza vaccine. Vaccination recommended in all children aged 6–59 months with administration of an inactivated vaccine via the intramuscular route (some can be administered via deep subcutaneous injection) or, from age 2 years, with the intranasal live attenuated vaccine. Children younger than 9 years who have not been vaccinated in previous campaigns should be given 2 doses 4 weeks apart, after which they only require a single dose in subsequent seasons. The dose is 0.5 mL delivered intramuscularly in the case of the inactivated vaccine and 0.1 mL in each nostril in the case of the attenuated vaccine. Vaccination is also recommended in all risk groups and their household contacts from age 6 months. Information on the risk groups for influenza is available in the online Vaccine Manual of the AEP.

(10) Measles, mumps and rubella vaccine (MMR). Two doses of MMR vaccine. The first at age 12 months and the second at age 3–4 years. The quadrivalent MMRV vaccine may be administered for the second dose. In susceptible patients outside the specified ages, vaccination with 2 doses of MMR at least 1 month apart is recommended.

(11) Varicella vaccine (Var). Two doses: the first one at 15 months (although it is possible to administer from age 12 months) and the second at age 3–4 years. The quadrivalent vaccine (MMRV) may be used for the second dose. Susceptible patients outside the specified ages will be vaccinated with 2 doses of monovalent Var vaccine at least 1 month apart, with a recommended 12-week interval between doses in children aged less than 13 years.

(12) SARS-CoV-2 vaccine. Two vaccines are currently authorised in Spain for use from age 12 years: Comirnaty-30 μg (Pfizer) and Spikevax-100 μg (Moderna). Another two are authorised for younger children: one for children aged 5–11 years, Comirnaty, with a lower antigen dose (Comirnaty-10 μg), and another for children aged 6–11 years, Spikevax-100 μg (Moderna), with administration of half the dose (0.25 mL). Children will be given 2 doses of vaccine. The Public Health Commission of Spain has decided that the 2 doses of Comirnaty 10 μg and Spikevax-100 μg (0.25 mL) in children aged less than 12 years should be given 8 weeks apart. If the second dose is administered in a shorter interval by mistake, it will be considered valid from 21 and 28 days, respectively. These vaccines may be administered the same day as other vaccines or with the desired separation. A booster dose is not currently recommended in children aged under 18 years, except from age 5 years in children and adolescents with risk conditions or taking immunosuppressive agents, who will be given a third, additional dose (at least 8 weeks after the last dose in the primary series) and a fourth, booster dose (at least 5 months after the third dose). Two other vaccines have been authorized by the EMA: for children from 6 months to 4 years, Comirnaty-3 mcg (Pfizer) in 3 doses and for children between 6 months and 5 years, Spikevax-25 mcg (Moderna) in 2 doses. The Public Health Commission has approved the vaccination of risk groups from 6 months of age with these vaccines.

(13) Human papillomavirus vaccine (HPV). Universal routine vaccination against HPV in children of any sex at age 10-12 years with 2 doses. The vaccines currently available are HPV2 and HPV9. Both are authorised for use in male individuals, although the evidence for the HPV2 vaccine in this group is scarce. Vaccination schedules: 2-dose series (at 0 and 6 months) between 9 and 14 years and 3-dose series (at 0, 1-2 [depending on vaccine] and 6 months) in individuals aged 15 years or older. It can be administered at the same time as the MenC, MenACWY, hepatitis A and B and Tdap vaccines. There are no data for administration with the varicella vaccine, although it should not cause any problems.

(14) Respiratory syncytial virus. Administration of 1 dose of nirsevimab (an anti-RSV antibody) is recommended in all newborns and infants aged less than 6 months, in addition to yearly administration of 1 dose in children aged less than 2 years with underlying disease that increases the risk of severe RSV infection.

Table 1 Bibliographic sources and literature search strategies used in the development of this document.

- [a]TripDatabase: Advanced search: (disease) (vaccine) (vaccination)
- Cochrane Library: Disease AND vaccine
- MEDLINE/Pubmed: (''disease/microorganism'' [MeSH Terms]) AND (''vaccine'' [MeSH Terms] OR ''vaccination'' [MeSH Terms]). Filters activated: Child birth-18 years, Human (Sort by: Best Match)
- EMBASE: ''disease''/exp AND ''vaccine''/exp
- Official websites of the Ministry of Health of Spain and the Instituto de Salud Carlos III
- Websites of medicines regulatory authorities: Agencia Española de Medicamentos y Productos Sanitarios and European Medicines Agency.
- CAV-AEP. Summaries of product characteristics
- Government agencies or international advisory bodies involved in vaccine policy:: ACIP (USA), JCVI (UK), STIKO (Germany), Public Health Agency of Canada, Australian Department of Health.
- Communications and presentations in national and international congresses
- Primary sources (textbooks, references of articles selected in the search)
- Data obtained directly from authors (unpublished)
- Publications not indexed in databases
- Information obtained from the pharmaceutical industry

[a] Faltan los hipervínculos que aparecen en el original en español.

Nearly all children experience gastroenteritis caused by RV in the first two years of life, with the severity of disease increasing with decreasing age, and it is possible to get reinfected by other RV genotypes. The severity is lower in low-income countries, but RV still generates high health care and social costs.[11] The most effective prevention strategy is vaccination. The WHO, the European Academy of Paediatrics and the European Society of Paediatric Infectious Diseases support this recommendation.

At present, 114 countries include the RV vaccine in their routine immunization schedules. The health benefits of this measure are incontrovertible. In Spain, 2 vaccines against RV are available.

Preterm infants, in whom vaccination is publicly funded on account of their risk-group status, should be vaccinated without delay, even if they are hospitalised, between 6 and 12 weeks post birth.[12]

A recent meta-analysis that assessed the effect of the vaccine in more than 100 000 children aged less than 5 years corroborated its effectiveness and safety and concluded that its benefits outweigh its costs.[13]

Vaccination against meningococcal disease

2023 recommendation: *Routine vaccination against meningococcus B is recommended in all infants starting at 2 months of age with a 2 + 1 schedule, against meningococcus C (at 4 months) and with the MenACWY vaccine (12 months, 12 years and catch-up in adolescents between ages 13–18 years). For all other paediatric age groups, the decision to vaccinate will be made on a case-by-case basis.*

Two vaccines are currently available for the prevention of invasive meningococcal disease (IMD) due to group B meningococcus (MenB): the 4CMenB vaccine (from age 2 months) and the MenB-fHbp vaccine (from age 10 years).

There is consistent evidence on the effectiveness of the 4CMenB vaccine. In the United Kingdom, its use was associated with a 75% decrease in the incidence of IMD due to MenB, with a vaccine effectiveness (VE) of 71.2% with a 2 + 1 schedule.[14] In Italy, vaccination of infants has proven highly effective in the regions of Tuscany (93.6%) and Veneto (91.0%), with a higher impact when early onset of the schedule.[15] Portugal found a VE of 79% with a series of at least 2 doses, with no documented deaths or sequelae.[16] A similar study conducted in Spain, pending publication, found a VE of 72% for the complete series (97% in infants < 1 year), corresponding to the prevention of 37 cases of IMD due to MenB, 25 admissions to the ICU, 3 cases with sequelae and 2 deaths.

The CAV-AEP continues to recommend routine vaccination of infants against MenB, the most frequent serogroup in Spain, with a 2 + 1 schedule starting at age 2 months. Andalusia, the Canary Islands, Castilla y Leon, Catalonia and Galicia have already included it in the official immunization schedules. The indication of vaccination in other age groups should be established on a case-by-case basis.[17]

The global increase in the incidence of IMD caused by groups W and Y[18] has motivated some countries to replace the MenC vaccine for the MenACWY vaccine in the dose administered in adolescence, while other countries have introduced the administration of the MenACWY vaccine to infants and children aged 2–24 months to looking for direct protection against these serogroups on account of their increased risk. The COVID-19 pandemic also resulted in a significant decline in these serogroups. However, given the unpredictable epidemiology of the disease, the CAV-AEP insists on the need to maintain close epidemiological surveillance and achieve a high vaccination coverage. Since the pandemic precluded catch-up vaccination between ages 13 and 18 years, making it difficult to achieve vaccination coverage levels that would provide indirect protection to infants, it is recommended that the MenACWY be introduced at 12 months and also used for vaccination at 12 years and catch-up vaccination in adolescence. For all other age groups, the indication of this vaccine is personalised. Andalusia, Castilla y Leon, the Balearic Islands, Galicia, Murcia and Melilla have already included it in their immunization schedules at age 12 months. In all other ACs where it is not administered routinely, if it is not

used for vaccination at 12 months, it is important to ensure administration of a dose of MenC.

Vaccination against influenza

2023 recommendation: *annual vaccination against influenza should be included in the routine immunization schedule for all children aged 6–59 months and for individuals in risk groups and their household contacts from age 6 months.*

The influenza vaccine is the most effective measure of prevention. Since 2012, the WHO[19] and other institutions consider children aged 6–59 months a priority group for vaccination against influenza. The reasons are that despite the common belief that influenza mainly affects children with underlying disease, numerous studies evince a high incidence of influenza in healthy children,[20] the role children play in the transmission of the infection in the community, especially to vulnerable groups, and the reduction in morbidity and mortality in older individuals achieved by vaccinating children.

Vaccines are available that are effective and safe in the paediatric age group. Childhood vaccination is one of the most effective measures for reducing the overall burden of disease, in children and in adults, especially elderly individuals, who have poorer responses to the vaccine.

Vaccination against measles, mumps and rubella (MMR vaccine)

2023 recommendation: *The first dose will be given at age 12 months with the MMR, and the second at age 3–4 years with the quadrivalent vaccine (MMR + varicella, MMRV).*

The WHO recommends a vaccination coverage greater than 95% for at least 1 dose of the vaccine, a target that has been achieved in the United States and many European countries, including Spain, which continues to have no cases of indigenous measles.

In 2021, there were 2 cases of measles, 4 of rubella (none of which was congenital) and 1095 of mumps reported in Spain.

We recommend administration of the first dose at age 12 months with the MMR and of the second dose at 3–4 years with the MMRV vaccine, although if the incidence of measles increased, the second dose could be administered earlier at age 2 years.[21]

When infants under 12 months need to be vaccinated for epidemiological reasons, the MMR can be administered to infants aged 6–11 months, but 2 additional doses will still have to be administered, at least 4 weeks apart, from age 12 months.

On the other hand, the CAV-AEP considers an initial dose of MMR administered by mistake or for other reasons between ages 11 and 12 months valid. Studies conducted in Spain[22] and neighbouring countries have evinced a lower concentration and faster waning of maternal antibodies in children of vaccinated women, which is associated with a reduced suppression of vaccine-induced immune responses in the children, thus corroborating the protective effect of the vaccine at 11 months.

We continue recommending separate administration of the MMR and varicella vaccines for the first dose of the series in children aged less than 2 years due to the increased risk of febrile seizures.

Vaccination against varicella

2023 recommendation: *routine vaccination with two doses at 15 months and at 3-4 years (MMRV vaccine may be used for the second dose). For unvaccinated children and adolescents that have not had the disease, we recommend catch-up vaccination with a 2-dose series.*

All varicella vaccines currently available have attenuated virus. There are two monovalent and one quadrivalent (MMRV) vaccine, all of which have exhibited a high effectiveness (92%–97%).[23]

Vaccination with 2 doses is necessary to control the disease.[24] Since 2016, all ACs offer routine vaccination against varicella (at 15 months and 3–4 years). The MMRV is given for the second dose in 10 ACs.

According to several studies, the incidence of herpes zoster in children vaccinated against varicella is lower compared to the incidence in unvaccinated children with a history of natural infection.[25]

Vaccination against SARS-CoV-2

2023 recommendation: *vaccination against SARS-CoV-2 with any of the mRNA vaccines authorised in Spain is recommended in children aged 5 to 11 years and 12 to 17 years.*

In children aged 12–17 years, adult vaccines Comirnaty and Spikevax, which contain 30 and 100 mcg of mRNA respectively are used. In children aged 5–11 years, vaccination with Comirnaty 10 μg and Spikevax 50 μg. Both manufacturers offer vaccines with lower amounts of mRNA for vaccination starting from age 6 months, which have been approved by the Food and Drug Administration in June 2022[26] and recommended by the Centers of Disease Control and Prevention.[27] The WHO also recommends vaccination in children once risk groups have received the primary vaccine series and the booster, if the latter is indicated.[28]

In children aged more than 12 years, the Spanish Ministry of Health[29] recommends an interval between primary series doses of 3 weeks for Comirnaty and 4 weeks for Spikevax. In children aged 5–11 years, the recommended interval is 8 weeks. Children undergoing immunosuppressive therapy or who are immunocompromised (group 7 of the Ministry of Health) should receive a 3-dose primary series, administering the last dose at least 28 days after the second. Two other vaccines have been authorized by the EMA: for children from 6 months to 4 years, Comirnaty-3 mcg (Pfizer) in 3 doses and for children between 6 months and 5 years, Spikevax-25 mcg (Moderna) in 2 doses. The Public Health Commission has approved the vaccination of risk groups from 6 months of age with these vaccines.

Although COVID-19 in children is generally benign and carries a low mortality, vaccination prevents hospitalization, admission to the paediatric intensive care unit and severe complications, including paediatric inflammatory multisystem syndrome.

The efficacy of these vaccines is lower when it comes to infections by Ómicron variants and subvariants (BA.1, BA.1.1, BA.2, BA.2.12.1, BA.4 and BA.5), as cumulative mutations in the S protein facilitate evasion of neutralising antibodies,[30–32] but they continue to confer substantial protection—probably mediated by cellular immunity—against hospitalization and severe disease.

Therefore, given the high population immunity in children resulting from vaccination or prior infection, the CAV-AEP is aware that

childhood immunization criteria may change in the future based on the trends of COVID-19 in the community.

The safety of mRNA vaccines in children has been confirmed. The most frequent adverse events are mild local reactions and systemic symptoms such as fever, headache, fatigue and myalgia. In the United States, after administration of 38 million doses in children aged 5–17 years, myocarditis was found to be a rare event, more frequent in boys and after the second dose. When both these conditions were given, the incidence per million inhabitants was of 4.3 cases in children aged 5–11 years, 45.7 cases in children aged 12–15 years and 70.2 in children aged 16 or 17 years. In most cases, the outcome was good, with spontaneous resolution within 2 or 3 days.[33]

Vaccination against human papillomavirus (HPV)

2023 recommendation: *universal routine vaccination, independently of sex, at age 10 to 12 years. The vaccines currently available are the HPV2 and HPV9.*

The recommended age for vaccination is 10–12 years, prior to sexual debut, with the aim of maximizing benefits and vaccination coverage. We also recommend catch-up vaccination and vaccination of individuals in risk groups.[34]

Most HPV infections are transient and resolve within 12–24 months in female patients and 6–12 months in male patients. However, in 3%–10% of cases, the infection persists and carries a risk of cervical cancer as well as other types that affect individuals of any sex, such as anal cancer or head and neck cancers.

The published evidence shows that vaccination protects against persistent infection, genital warts, premalignant cervical and anal lesions and, more recently, cervical cancer in women[35] and anogenital cancer in men.[36]

Multiple studiess[37] have evinced an excellent safety and tolerability of HPV vaccines in different age groups.

The CAV-AEP recommends routine vaccination against HPV in individuals of any sex.

Prevention of infection by respiratory syncytial virus (RSV)

2023 recommendation: *routine administration of 1 dose of nirsevimab to all newborns and infants aged less than 6 months and 1 annual dose in at-risk children aged less than 2 years.*

Respiratory syncytial virus is the most frequent etiologic agent of lower respiratory tract infection in infants. It is an important public health problem on account of the high volume of visits it generates in every level of care, the high rate of hospital admission and high mortality in infants and the elderly.

A study conducted in Spain that analysed the burden of disease over a 9-year period found that the annual frequency of hospital admissions due to bronchiolitis caused by RSV in infants aged less than 1 year ranged from 5997 to 8637. More than 98% of these infants had no risk factors (most were aged less than 3 months), while the presence of specific risk factors (preterm birth, chronic pulmonary disease, Down syndrome, congenital heart disease or neuromuscular disease) was associated with an in-hospital mortality of 90 deaths per 100 000 admissions.[38]

Emerging knowledge of the spatial configuration of the RSV F protein in vivo (in its prefusion and postfusion forms) and the sites bound by neutralising antibodies has allowed the development of promising preventive treatments: vaccines and monoclonal antibodies (mAbs).

The approach that can achieve the maximum possible reduction in the burden of disease due to RSV is a combined one, with administration of mAbs to infants under 6 months and at-risk individuals and vaccination of other populations (pregnant women, older infants, children and elderly individuals).

Nirsevimab is a human monoclonal antibody against the θ locus of the F protein and has a much longer half-life than palivizumab, on account of which a single dose of it confers protection for the entire RSV season. The MELODY phase 3 trial assessed its efficacy and safety in healthy infants and late preterm infants, and found an efficacy of 74.5% in preventing the need of medical care (95% CI, 49%.6–87.1%), 62.1% in preventing hospital admission due to lower respiratory tract infection by RSV (95% CI, −8.6% to 86.8%) and 59.0% in preventing admission due to any type of RSV infection.[39] Another trial conducted in preterm infants born between 29 and 34 weeks of gestation found an efficacy of 78.4% in the prevention of hospital admission (95% CI, 51.9%–90.3%).[40]

In light of this evidence and the recent recommendation of the European Medicines Agency (EMA) to authorise its commercialization, the CAV-AEP recommends administration of nirsevimab to all newborns and infants aged less than 6 months, in addition to yearly administration to children aged less than 2 years with underlying diseases that increase the risk of severe RSV infection.

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Conflicts of interest (last 5 years)

Francisco José Álvarez García has collaborated in educational activities funded by Alter, Astra, GlaxoSmithKline, MSD, Pfizer and Sanofi Pasteur and as a consultant in GlaxoSmithKline, MSD, Pfizer and Sanofi Pasteur advisory boards.

María José Cilleruelo Ortega has collaborated in educational activities funded by GlaxoSmithKline, Novartis, MSD, Pfizer and Sanofi, as a researcher in clinical trials for GlaxoSmithKline and Pfizer, and as a consultant in GlaxoSmithKline, Novartis, MSD, Pfizer and Sanofi Pasteur advisory boards.

Javier Álvarez Aldeán has collaborated in educational activities funded by AstraZeneca, GlaxoSmithKline, MSD, Pfizer, Sanofi Pasteur and Seqirus, as a researcher in clinical trials for GlaxoSmithKline and Sanofi Pasteur and as a consultant in AstraZeneca, GlaxoSmithKline, MSD, Pfizer, Sanofi Pasteur and Seqirus advisory boards.

María Garcés-Sánchez has collaborated in educational activities funded by Astra, GlaxoSmithKline, MSD, Pfizer and Sanofi Pasteur, as a researcher in clinical trials for GlaxoSmithKline, Janssen, MSD, Pfizer and Sanofi Pasteur and as a consultant in GlaxoSmithKline, Novartis and Pfizer advisory boards.

Elisa Garrote Llanos has received funding to attend domestic educational activities and has participated in educational activities funded by GlaxoSmithKline, MSD, Pfizer and Sanofi Pasteur, as a researcher in clinical trials for GlaxoSmithKline and MSD and as a consultant in a GlaxoSmithKline advisory board.

Antonio Iofrío de Arce has collaborated in educational activities funded by GlaxoSmithKline, MSD, and Pfizer and as a consultant in a GlaxoSmithKline advisory board. He has also received funding from GlaxoSmithKline, MSD and Pfizer to attend domestic educational activities.

Abián Montesdeoca Melián has collaborated as a researcher without remuneration in a study sponsored by MSD in 2019—20. In the past 5 years, he has not received fees or any form of direct funding from the pharmaceutical industry.

María Luisa Navarro Gómez has collaborated in educational activities funded by Gilead, GlaxoSmithKline, Janssen, MSD, Pfizer and ViiV, as a consultant for Abbott, AstraZeneca, Novartis and ViiV

advisory boards and as a researcher in clinical trials sponsored by GlaxoSmithKline, Pfizer, Roche and Sanofi Pasteur.

Valentín Pineda Solas has received funding from MSD, Pfizer and Sanofi Pasteur to attend educational activities in Spain and abroad, has collaborated in educational activities funded by AstraZeneca, GlaxoSmithKline, MSD, Pfizer and Sanofi Pasteur and as a consultant in GlaxoSmithKline, Pfizer and Sanofi Pasteur advisory boards.

Irene Rivero Calle has collaborated in educational activities funded by GlaxoSmithKline, MSD, Pfizer and Sanofi Pasteur, as a researcher in vaccine clinical trials for Abbot, Astrazeneca, Enanta, Gilead, GlaxoSmithKline, Janssen, Medimmune, Merck, Moderna, MSD, Novavax, Pfizer, Reviral, Roche, Sanofi Pasteur and Seqirus and as a consultant in GlaxoSmithKline, MSD, Pfizer and Sanofi Pasteur advisory boards.

Jesús Ruiz-Contreras has collaborated in educational activities funded by GlaxoSmithKline, MSD, Pfizer and Sanofi Pasteur and as a researcher in clinical trials for GlaxoSmithKline and Pfizer.

Pepe Serrano Marchuet has collaborated in educational activities funded by AstraZeneca, GlaxoSmithKline and MSD, as a researcher in clinical trials for Sanofi Pasteur and as a consultant in a GlaxoSmithKline advisory board. He has also received funding from GlaxoSmithKline, MSD and Pfizer to attend educational activities in Spain and abroad, and received grants sponsored by GlaxoSmithKline.

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