

SPECIAL COLLABORATION

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**COMMITTEE FOR IMMUNIZATION PROGRAMME AND REGISTRY
AND CHANGES IN THE NATIONAL IMMUNIZATION PROGRAMME IN SPAIN****Aurora Limia Sánchez (1), Carmen Olmedo Lucerón (1), Marta Soler Soneira (1), Elena Cantero Gudino (2)
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ABSTRACT

The Committee for Immunization Programme and Registry (*Ponencia de Programa y Registro de Vacunaciones*) was created in 1991 to advise the Interterritorial Council of the National Health System on the situation of vaccine preventable diseases and the establishment and evaluation of measures for their prevention and control. Among other functions, this Committee evaluates the immunization programmes taking into account the scientific evidence and the epidemiological situation. In this way the Committee advises decision makers on the Public Health Commission of the Interterritorial Council. Any change in the National Immunization Programme, since the first one published in 1996 by the Interterritorial Council to the current Immunization Programme throughout life, has been advised from the technical and scientific point of view by this Committee. Taking into account both the work developed and the methodology used for developing the technical advice, the Committee for Immunization Programme and Registry is considered the National Immunization Technical Advisory Group for Spain.

This paper reviews the functions and work developed by the Committee for Immunization Programme and Registry, the changes conducted in the National Immunization Programme under its advice and the current challenges.

Key words: Immunization, Immunization policy, National immunization programme, Committee for Immunization Programme and Registry, NITAG, Interterritorial Council of the National Health System, National Immunization Technical Advisory Group.

RESUMEN**Ponencia de Programa y Registro de Vacunaciones y evolución del calendario de vacunación en España.**

La Ponencia de Programa y Registro de Vacunaciones se creó en 1991 para asesorar al Consejo Interterritorial del Sistema Nacional de Salud en el conocimiento de las enfermedades inmunoprevenibles y el establecimiento y evaluación de medidas para su prevención y control. Entre otras funciones, la Ponencia evalúa los programas de vacunación teniendo en cuenta la evidencia científica y la situación epidemiológica. De esta manera, asesora en la toma de decisiones que se realiza en la Comisión de Salud Pública del Consejo Interterritorial. Desde su creación, la Ponencia ha realizado recomendaciones desde el punto de vista técnico y científico en las modificaciones que se han realizado en el calendario de vacunación, incluyendo la incorporación de vacunas y el cambio de pautas de vacunación, desde el primer calendario del Consejo Interterritorial de 1996 hasta el actual calendario común de vacunación a lo largo de toda la vida. La Ponencia es considerada el Comité Técnico Asesor de Vacunaciones de España, tanto por las funciones que desarrolla como por la metodología utilizada para la elaboración de propuestas.

En este artículo se revisan las funciones que desarrolla la Ponencia de Programa y Registro de Vacunaciones, las modificaciones que se han realizado en el calendario con su asesoramiento y los retos en el momento actual.

Palabras clave: Vacunación, Política de vacunación, Calendario de vacunación, Ponencia de vacunas, Ponencia de Programa y Registro de Vacunaciones, Consejo Interterritorial del Sistema Nacional de Salud, Comité Técnico Asesor de Vacunaciones.

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INTRODUCCIÓN

The first National Immunization Programme, official since 1975⁽¹⁾, was preceded by the smallpox vaccination, which began in 1800^(2,3), and the immunization campaigns, which began in 1963 with the administration of the oral polio vaccine (OPV)^(4,5,6). Since 1965, other vaccines were added to be administered to the target population during the campaigns. This first Immunization Programme (figure 1), which included vaccination against seven diseases, was updated in 1981⁽⁷⁾.

Since the public health matters were transferred from the State to the Autonomous Communities or regions between 1979 and 1985, they have been responsible for managing the immunization programme, from establishing their respective immunization programmes to the purchase, distribution and administration of vaccines⁽²⁾.

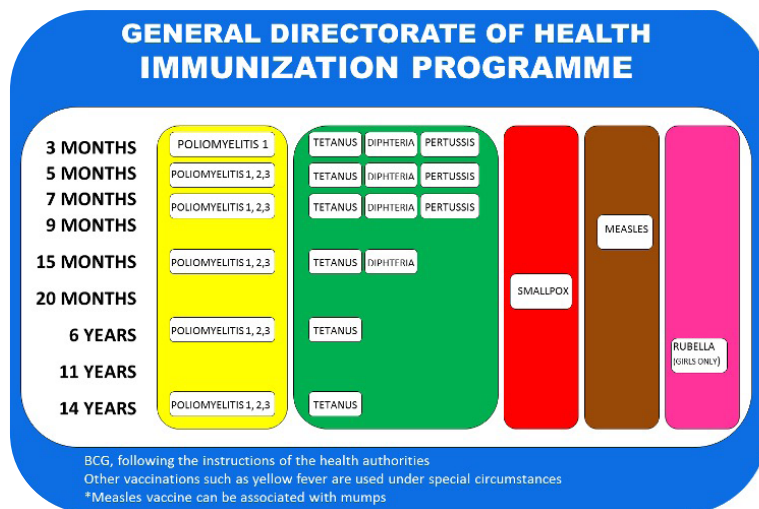
The General Health Law (1986) created the Interterritorial Council of the National Health System (ICNHS) as a permanent body for coordination, cooperation and communication between the State Administration and the regions⁽⁸⁾. The ICNHS agreed on a common immunization programme in 1996.

This article summarizes the operation of the Committee for Immunization Programme and Registry and its role in the evolution of the immunization programmes in Spain.

COMMITTEE FOR IMMUNIZATION PROGRAMME AND REGISTRY

The ICNHS has the mission of coordinating and harmonizing health strategies in order to maintain equity and cohesion in access to health services. The Minister of Health coordinates the Plenum of the ICNHS, which is also made up of the health councillors of the regions.

Figure 1
National Immunization Programme. Spain, 1975.



Source: Ministry of Health⁽¹⁾.

The ICNHS is organized in Commissions, with the Public Health Commission establishing agreements on basic common policies on Public Health matters. This Commission was created in 1992, is coordinated by the person in charge of the General Directorate of Public Health of the Ministry of Health and is made up of the General Directors responsible for Public Health of the regions.

Several Working Groups and Committees depend on the Public Health Commission, one of them being the Committee for Immunization Programme and Registry (hereinafter, Committee for Immunization). This Committee prepares technical documents based on scientific evidence and the epidemiology of preventable diseases, which support the Public Health Commission in decision-making on immunization programmes for the entire nation.

Table 1 shows the institutions involved in decision-making on the immunization programme in Spain and their purposes.

Structure and functions. The Committee for Immunization was created in December 1991 as the scientific-technical support body for the ICNHS, with the mission of studying “*the situation of diseases susceptible to vaccination and the formulation and monitoring of measures aimed at their prevention and control*”⁽⁹⁾.

Since the Plenum of the ICNHS started in 1987 until the creation of this Committee, matters of immunization programmes were dealt with in the Permanent Commission on the Monitoring of Health Programmes. For example, in 1990 it was recommended that the regions develop and implement nominal registration systems for the vaccines administered, including those recommended for specific population groups, such as hepatitis B or influenza vaccines⁽¹⁰⁾.

The Committee for Immunization is coordinated by the General Subdirectorate for Health Promotion and Public Health Surveillance (SHP) and is made up of an expert from each autonomous community and the cities of Ceuta and Melilla, appointed by the person in charge of the General Directorate of Public Health in each of them. In addition, experts from other institutions, such as the Spanish Agency for Medicines and Health Products, the National Institute of Health Management (INGESA), the Carlos III Health Institute, the Ministry of the Interior (Prison Institutions), the Ministry of Defence, as well as the Ministry of Health itself (the Coordination Centre of Healthcare Alerts and Emergencies, General Subdirectorate of Foreign Health and General Directorate of Basic Portfolio of Services of the NHS and Pharmacy, as well as the SHP) are participating. The Secretariat and the coordination of the Working Groups are carried out from the Vaccination Programmes Area (SHP of the Ministry of Health).

As previously indicated, the purpose of the Immunization Programme is to provide scientific and technical advice to the Public Health Commission on aspects related to vaccines and immunization programmes for decision-making purposes. Since its creation the Committee for Immunization has developed the following functions:

- Assessment of the modifications in the immunization programmes in force after the authorization of the new vaccines and other regulatory changes in the technical data sheets.
- Evaluation and proposal of modifications in immunization programmes.
- Evaluation of immunization coverage.
- Discussion and assessment of other aspects related to immunization programmes.

Table 1
Institutions involved in making decisions about
the Immunization Programme in Spain and their functions.

INSTITUTION		FUNCTIONS	
Ministry of Health (MoH).	General Directorate of Public Health, Quality and Innovation.	Coordination of the Immunization Programme in Spain.	
	Spanish Medicines Agency and Health Products	- Vaccine authorization. - Coordination of the Spanish Pharmacovigilance Network.	
	Inter-ministerial Price Commission (GD Basic Portfolio of Services of the NHS and Pharmacy).	Price allocation for vaccines.	
	Plenum of the Interterritorial Council.	Coordination: - Minister of Health (MoH) - Region Health Ministers	Assessment of the proposals submitted by the Public Health Commission and approval of the same if necessary.
	Public Health Commission.	Coordination: - General Director of Public Health, Quality and Innovation (MoH) - General Directors of Public Health of the regions	Assessment and approval of the proposals of the Immunization Programme. Transfer to the ICNHS, if such is deemed necessary.
	Interterritorial Council of the National Health System (ICNHS).	Coordination: - General Subdirector of Health Promotion and Public Health Surveillance (MoH) Representatives of: - Regions - Carlos III Health Institute - Ministry of the Interior - Ministry of Defence - INGESA (MoH) - Spanish Medicines Agency (MoH) - GD Basic Portfolio of Services of the NHS and Pharmacy (MoH) - Directorate of Public Health (MoH)	Preparation of proposals for recommendations on immunization for Spain. Recommendations must be approved by the Public Health Commission.
Autonomous Communities and Autonomous Cities (Regions)		- Establishment of the Immunization Programme - Management of the Immunization Programme	

Source: amended from “*Evaluation criteria to base modifications in the Immunization Programme in Spain*”⁽¹¹⁾.

The choice of the issues to work on from the Immunization Programme is made by the Public Health Commission, sometimes at the initiative of the Conference itself. In general, the proposals from the Conference include aspects related to the authorization of new vaccines or relevant modifications under evaluation at the European Medicines Agency (EMA) and immunization strategies following experiences in other countries.

Depending on the complexity of each particular issue, it can be resolved directly in the plenary session or an ad hoc Working Group can be formed. If a group is formed, it will draw up an initial proposal for assessment and discussion by the plenary session of the Conference and, once it has been approved, it will be submitted to the Public Health Commission for discussion and approval.

The Working Groups are formed with members of the Committee who voluntarily wish to participate. Depending on the complexity of the topic to be discussed and the time available for the preparation of the work, the collaboration of other experts may be requested, who are chosen at the proposal of the members of the Conference or from the Secretariat.

The Secretariat of the Committee is in charge of coordinating the Working Groups, preparing proposals, actively participating in the development of the work, supervising the work that is commissioned or contracted, as well as editing the texts and presenting the draft to the Committee.

The procedure used by the Working Groups to prepare proposals is described in the document “*Evaluation Criteria to Support Changes in the Immunization Programme in Spain*”. This technical document, agreed by the Public Health Commission in 2012, updated the one initially prepared in 2004⁽¹¹⁾. The procedure

shows that the evaluation will be carried out in three steps, in which five criteria are analysed in an orderly manner:

- i) Disease burden.
- ii) Effectiveness and safety of the vaccine.
- iii) Impact of the modification.
- iv) Ethical aspects.
- v) Economic evaluation.

The Committee also discusses and agrees on other issues related to the functioning of immunization programmes, such as joint acquisition of vaccines, actions to address problems in the supply of vaccines, records and information systems, etc.

The Committee meets at least twice a year. Additional meetings have been held in recent years via audio and video conferencing. These resources have been widely used in recent years to address specific aspects of immunization programmes. For example, the Committee met a total of fifteen times in 2015, thirteen of them by audioconference, and most of these meetings were to address problems related to the supply of pentavalent and Tdap vaccines, which significantly affected the good operation of immunization programmes for several years. In 2016, 2017 and 2018, the Committee met five times each year, holding at least one of those meetings being face-to-face, and in 2019 they held four meetings, three of which were face-to-face.

The participation of the members in the Committee and of other experts in the working groups is carried out in a disinterested manner and attendance at meetings or participation in the groups is not remunerated. Since 2016, all members of the Committee must annually sign

a confidentiality commitment and a declaration of interests. In the same way, these documents must be signed by each and every one of the participants in the working groups dependent on the Committee.

Al igual que en el resto de organismos dependientes del CISNS, las decisiones en la Ponencia se toman por consenso.

La Ponencia no tiene un presupuesto concreto establecido. En los últimos años, los trabajos solicitados desde la Ponencia o cualquier otro gasto derivado de las reuniones se han realizado con cargo al presupuesto de la Dirección General de Salud Pública, Calidad e Innovación del Ministerio de Sanidad.

EVOLUTION OF THE COMMITTEE FOR IMMUNIZATION PROGRAMME SINCE 1996 AND THE ROLE OF THE IMMUNIZATION PROGRAMME

Since its creation, the Committee for Immunization Programme has made recommendations on aspects of management and incorporation of vaccines in Immunization Programmes. For example, in 1992 the data that the regions had to supply at the central level to calculate vaccination coverage were agreed upon⁽¹²⁾, and have been regularly updated. **Table 2** shows the work carried out by the Committee for Immunization Programme regarding the National Immunization Programme from its creation to 1995.

Table 2
Work developed by the Committee for Immunization Programme and Registry.
Period 1991-1996.

Period 1991-1995	Agreement on surveillance of immunization coverage.
	Tetanus immunization in pregnant women.
	Immunization against influenza in risk groups. Annual campaigns.
	Immunization against hepatitis B: risk groups, adolescents, newborns.
First National Immunization Programme approved by the ICNHS in 1995 (Vaccines^(*) included and schemes)	OPV (3 doses at 2-3, 4-5, 6-7 months, y 2 booster doses at 15-18 months and 6-7 years of age).
	DTP (3 doses at 2-3, 4-5, 6-7 and booster doses at 15-18 months), DT (6-7 years) y Td (14 years).
	MMR (12-15 months y 11-13 years).
	HB (3 doses at 0, 1 and 6 months).
<p>(*) Vaccines: OPV, oral polio vaccine; DTP, diphtheria-tetanus-pertussis combination vaccine; MMR, Measles, rubella, and mumps vaccine; HB, hepatitis B vaccine. Source: modified from “<i>Evaluation criteria to Support changes in the National Immunization Programme in Spain</i>”⁽¹¹⁾.</p>	

In 1995, the Committee developed a Childhood Immunization Programme that was approved by the Public Health Commission and the ICNHS. This National Immunization Programme of the ICNHS, which came into effect throughout 1996, was flexible regarding the age of administration of the vaccine doses, establishing “range” or intervals for each of the doses to be administered. The purpose of these “ranges” was to facilitate immunization strategies in the different regions. The schedule incorporated the programmes that should be included in all the regions. An example is vaccination against hepatitis B which, although recommended since 1992, has not yet been incorporated in all the regions. In the 1996 schedule, all of them incorporated this vaccination during adolescence (table 3).

Since then, various modifications have been made to the schedule, including new additions, substitutions of some vaccines for others that

protect against the same disease, and changes in administration schemes. Tables 4 and 5 show schematically the modifications made to the systematic vaccination schedule from 1996 to 2019, by year and by immunization programme, respectively.

At the meeting held on March 18, 2010 by the Plenary of the ICNHS, it was agreed to adopt a series of actions and measures to promote quality, equity, cohesion and sustainability of the National Health System, including the approval of a single or common vaccination schedule for Spain⁽¹³⁾. The Committee for Immunization proposed a definition of a national vaccination schedule⁽¹¹⁾ and, as of 2012, the ages of administration of the vaccines included in the schedule began to be standardised, reaching in 2017 the greatest homogeneity since the decentralization of the Public Health System in favour of the autonomous communities.

Table 3
First National Immunization Programme of the International Council of the National Health System. Year 1996.

VACCINES	AGE											
	2-3 months	4-5 months	6-7 months	12 months	15 months	18 months	6 years	7 years	10 years	11 years	13 years	14 years
Poliomyelitis	OPV1	OPV2	OPV3		OPV4		OPV5					
Diphtheria-Tetanus-Pertussis	DTP1	DTP2	DTP3		DTP4		DTP5					Td ^(b)
Measles-Rubella-Parotitis				MMR1 ^(a)						MMR2		
Hepatitis B^(a)										HB3 ^(c)		

(a) In situation of particular risk, a dose at 9 months or earlier; (b) It is advisable to proceed with vaccination every 10 years; (c) Newborns will also be vaccinated when the Health Authorities deem it appropriate, as well as newborns from carriers mothers and groups at risk.

Fuente: Ministerio de Sanidad⁽¹⁾.

Table 4
Modifications in the National Immunization Programme
(recommendations for the general population) by year. Period 1996-2019.

Year	Modification	Vaccines ^(*)	No. doses	Scheme
1997	Inclusion	Hib	3+1	2-3, 4-5, 6-7m + 15-18m
2000	Inclusion	MenC	3	2, 4 6m
	Modification	OPV; DTP/Hib	3+1+1	2,4,6m + 15-18m + 4-6y
	Modification	P	3+1+1	2,4,6m + 15-18m + 4-6y
	Modification	MMR	1+1	12-15m + 3-6y
2004	Substitution	IPV (instead of OPV)	3+1	2,4,6m+15-18m
	Inclusion	HB (child)	3	0,1-2,6m or 2,4,6m
2005	Inclusion	VVZ in adolescents	1	10-14y
	Substitution	aP (instead of P)	3+1+1	2.4.6m + 15-18m + 4-6y
2006	Modification	MenC	2+1	2-6m + 15-18m
2007	Inclusion	HPV	3	11-14y
2012	Modification	HB	3	0,2,6m (or 2,4,6m)
	Modification	MMR	1+1	12m + 3-6y
	Modification	DTP/IPV/Hib	3+1+1	2,4,6m + 18m + 6y
	Modification	Tdap (instead of DTaP)	1	6y
	Modification	Td	1	14y
2013	Modification	MenC	1+1+1	4m + 12m +12y
	Modification	VVZ	2	12y
	Modification	HPV	3	14y
2014	Modification	HPV	2 or 3	14y
2015	Inclusion	PCV	2+1	2,4m + 12m
	Modification	HPV	2	12y
2016	Inclusion	VVZ child	2	12-15m + 3-4y
2017	Modification	DTaP/IPV/Hib/HB	2 + 1	2, 4m + 11m
	Substitution	DTP/IPV (instead of Tdap)	1	6y
Calendario a lo largo de toda la vida	Substitution	MenACWY (instead of MenC)	1	12y
	Inclusion	MenACWY	1	13-18y
	Inclusion	HPV (unvaccinated women)	2 or 3	13-18y (3d in a cohort between 11-14y, preferably 14y)
	Inclusion	HB (unvaccinated people)	2+1	In unvaccinated adolescents (according to year of inclusion)
	Inclusion	MMR	1+1	In susceptible adults and adolescents
	Inclusion	VVZ	1+1	In susceptible adults and adolescents
	Inclusion	Td	3+1+1	Complete immunization of adults and adolescents
	Inclusion	Td, PCV and annual influenza	1, 1, 1	Preferably from 65y onwards
	Inclusion	Tdap	1	Pregnant women (between weeks 27 and 36)**
	Inclusion	influenza	1	Pregnant women (in any trimester)

y: years of age; m: months of age; d: dose. (*) Vaccines: **Hib**, *Haemophilus influenzae* type b; **MenC**, conjugated vaccine against meningococcus serogroup C; **OPV**, oral polio vaccine; **IPV**, inactivated polio vaccine; **DTP**, diphtheria, tetanus and pertussis; **aP**, acellular pertussis; **MMR**, Measles, rubella, and mumps vaccine; **HB**, hepatitis B; **VVZ**, chickenpox; **HPV**, human papillomavirus; **Tdap**, diphtheria, tetanus and low-burden or adult pertussis; **Td**, low-burden or adult diphtheria and tetanus; **PCV**, pneumococcal conjugate vaccine.

(**) The recommendation to vaccinate pregnant women with Tdap has been recently updated: starting at week 27, preferably at weeks 27 or 28⁽²⁰⁾. Source: modified from "Review of the Immunization Programme"⁽¹⁵⁾.

Table 5
Modifications in the Immunization Programme (recommendations for the general population)
according to the Immunization Programme for each disease or group of diseases. Period 1996-2019.

Programme	Evolution
Poliomyelitis	1963: pilot immunization campaign with OPV in León and Lugo. Child population between 3m and 7y
	1964: systematic immunization campaign with OPV. Child population between 3m and 7y
	1975: first official immunization programme. OPV1 at 3m and OPV at 5 and 7m; boosters at 15m, 6y and 14y
	1981: first booster with OPV at 18m (instead of 15m). Booster at 18m, 6y and 14y
	1996: first immunization programme of the ICNHS. OPV at 2-3, 4-5 and 6-7m. Booster at 15-18m and 6-7y
	2001: OPV at 2, 4, and 6m. Booster at 15-18m and 4-6y
	2004: substitution of the OPV vaccine for IPV at 2, 4 and 6m. Booster at 15-18m
	2012: IPV booster at 18m
	2017: 2+1 scheme with IPV in children (2, 4 and 11m). Booster elimination at 18m. Second booster dose with IPV at 6y, for primary vaccinated with two doses at 2 and 4m (born in 2017, effective from 2023)
Diphtheria, tetanus and pertussis	1965: inclusion in systematic immunization campaigns (together with OPV) of children between 3m and 7y
	1975: first official immunization programme. DTP at 3, 5 and 7m; boosters with DT at 15m and with TT at 6 and 14y
	1981: first booster with DT at 18m (instead of at 15m)
	1996: first immunization programme of the ICNHS. DTP at 2-3, 4-5 and 6-7m. DTP booster at 15-18m, DT 6-7y and Td 14y and every 10y
	2001: DTP at 2, 4 and 6m. DTP booster at 15-18m, DTP or DT at 4-6y and Td 14-16y and every 10y
	2007: substitution of DTP for DTaP (in all doses administered)
	2009: no recollection required every 10y with TD if complete childhood immunization. In that case 1d Td booster at 65y
	2012: DTaP boosters at 18m, Tdap at 6y and Td at 14y
	2015: inclusion of Tdap in pregnant women (between weeks 27 and 36)**
	2017: 2+1 DTP scheme in children (2, 4 and 11m). Booster elimination at 18m. Second booster dose with DTaP at 6y for primary vaccinated with two doses at 2 and 4m (born in 2017, effective from 2023)
2019: Lifetime Programme. Vaccinate or complete vaccination with Td in adolescents or adults that do not have 5d. If vaccinated in childhood correctly, booster dose with Td at 65y	
Haemophilus influenzae type b (Hib)	1997: inclusion of the Hib vaccine at 2, 4, 6m and booster at 15-18m
	2012: booster at 18m
	2017: 2+1 Hib scheme in children (2, 4 and 11m). Booster elimination at 18m
Hepatitis B	1991: some regions began to vaccinate in childhood
	1996: first immunization programme of the ICNHS. 3 HB doses in adolescence at 10-14y (in all the regions in 2004). It is advisable to introduce systematic vaccination in newborns, as well as to vaccinate children of a carrier mother at birth and vaccination of risk groups)
	2004: HB at 0, 2 and 6m (other schemes 0, 1 and 6m or 2, 4 and 6m; as well as in adolescence at 10-14y)
	2017: 2+1 HB scheme in children (2, 4 and 11m)
	2019: uptake and vaccination of unvaccinated people up to 18y

Table 5 continuation)
Modifications in the Immunization Programme (recommendations for the general population)
according to the Immunization Programme for each disease or group of diseases. Period 1996-2019.

Programme	Evolution
Measles, rubella and parotitis	1978: Inclusion of monovalent measles vaccine at 9m
	1979: inclusion of monovalent vaccine against rubella in girls at 11y
	1981: inclusion of TV at 15m (to replace the monovalent measles vaccine at 9m)
	1996: first immunization programme of the ICNHS. TV at 12-15m and 11-13y (substitution of monovalent rubella vaccine in girls)
	2001: advance of 2nd dose of MMR to 3-6a
	2012: MMR at 12m and 3-4a
	2019: recruitment and vaccination of susceptible people
Invasive meningococcal disease (EMI)	2000: inclusion of MenC in November, given at 2, 4 and 6m
	2007: 2+1 MenC scheme of 2d at 2-6m and 1d in 15-18m
	2012: primary MenC vaccination at 2 and 4m and booster 12-18m
	2013: 1+1+1 scheme at 2m, 12m and 12y. (After reviewing the administration of 15d it is concentrated at 4m)
	2014: 15d from MenC at 4m
2019: Lifetime Programme. Immunization of unvaccinated adolescents from MenC to 18 years of age. In March, inclusion of MenACWY instead of MenC at 12y and 13-18y catch-up vaccination	
Smallpox	2005: Inclusion of PCV in children at 2, 4 and 12m. They may be effective in the regions until December 2016
	2013: booster at 11m (substitution of the dose that was administered at 12m)
	2015: Lifetime programme: pneumococcal vaccination starting at 65y
	2019: inclusion of VVZ in susceptible adolescents to 10-14y
Human papilloma-virus (HPV)	2007: inclusion of HPV (3d) in a cohort between 11-14y (preferably 11y)
	2013: HPV (3d) at 14y
	2014: 2 or 3d HPV depending on the vaccine used
	2015: HPV at 12y (2d, girls only)
2019: Lifetime Programme. Immunization of unvaccinated women with HPV up to 18y	
Influenza	2019: Lifetime Programme. Annual immunization of pregnant women and seniors (preferably from 65y)

y: years of age; m: months of age; d: dose. (*) Vaccines: **Hib**, *Haemophilus influenzae* type b; **MenC**, conjugated vaccine against meningococcus serogroup C; **OPV**, oral polio vaccine; **IPV**, inactivated polio vaccine; **DTP**, diphtheria, tetanus and pertussis; **aP**, acellular pertussis; **MMR**, Measles, rubella, and mumps vaccine; **HB**, hepatitis B; **VVZ**, chickenpox; **HPV**, human papillomavirus; **Tdap**, diphtheria, tetanus and low-burden or adult pertussis; **Td**, low-burden or adult diphtheria and tetanus; **PCV**, pneumococcal conjugate vaccine. (***) The recommendation to vaccinate pregnant women with Tdap has been recently updated: starting at week 27, preferably at weeks 27 or 28⁽²⁰⁾. Source: modified from “*Review of the Immunization Programme*”⁽¹⁵⁾.

Since 2012, the National Immunization Programme recommended by the ICNHS⁽¹⁴⁾ has been published annually on the Ministry of Health website.

In 2016, a thorough review of the child immunization schedule was conducted. The progressive incorporation of vaccines into the schedule had led to an increase in the number of punctures, mainly in younger children, which could influence the acceptance of vaccinations by parents. In addition, scientific knowledge had been expanded with respect to the immune response provided by vaccines and the effects on the control of immune-preventable diseases in the population. Following the review, it was agreed to reduce the number of punctures in children under 24 months, changing the primary vaccination against diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b and hepatitis B, which was performed with three doses at 2, 4 and 6 months, to be performed with two doses at 2 and 4 months of age and advancing the booster dose from 18 to 11 months of age^(15,16). This new child immunization programme, despite introducing several changes, was well received by health workers and the population.

In 2017 and 2018, the immunization recommendations for the adult population⁽¹⁷⁾ were reviewed and updated and, together with the child immunization recommendations agreed in 2016, the first common lifetime immunization programme for 2019 was agreed upon⁽¹⁸⁾. This new programme incorporated the recommended vaccines from the prenatal period, through the vaccination of pregnant women, to the elderly population, covering all ages of life. The incorporation into the schedule of recommended vaccines from the age of 15 for the adult and older population aims to raise awareness of the importance of vaccination beyond childhood and adolescence, as well as to facilitate the task of health personnel in identifying

the vaccines to be administered according to the age of the person.

In addition to evaluating the systematic immunization programmes aimed at the general population, the Committee for immunization has prepared recommendations for other population groups. In 2018, the vaccination recommendations for people in risk groups of all ages were updated, which also included the working environment, pregnancy and the post-partum period⁽¹⁹⁾. In 2019, recommendations were drawn up on the vaccination of unvaccinated people and immigrants⁽²⁰⁾, and also for premature infants⁽²¹⁾. The recommendations of the groups with the highest or most prevalent risk were also reflected in a schedule format, for infants, adolescents and adults^(22,23).

Additionally, each year vaccination recommendations against influenza are prepared⁽²⁴⁾. All recommendations and technical documents are published on the Ministry of Health website⁽²⁵⁾.

CURRENT CHALLENGES: PROBLEMS OF SUPPLY AND MAINTAINING OR INCREASING COVERAGE

Since the beginning of 2015, the Committee for Immunization has developed an important part of its activity in the joint management of vaccine supply problems, with the aim that they interfere as little as possible in the operation of immunization programmes and that it is maintained the protection of the population against preventable diseases. Several vaccines have been implicated in these supply problems: pentavalent (DTaP / IPV / Hib), diphtheria, tetanus and low-burden pertussis (Tdap), tetanus and adult diphtheria (Td), hepatitis A, hepatitis B, rabies and MMR. The causes of these supply problems have been diverse, but the increase in demand for vaccines worldwide without an

even development of production capacity may explain part of the problem⁽²⁶⁾.

A key aspect to maintain control over immune-preventable diseases is to maintain vaccination coverage in childhood and increase it in the so-called risk groups, as well as in the adolescent and adult population. To this effect, work must be done to maintain the confidence of the population and health personnel in immunization programmes, raising awareness of their importance at all ages. Encouraging the participation of all agents involved in vaccination in the development of adequate communication strategies, to disseminate truthful information, can help to unify messages about the benefits of immunization and on the safety of vaccines.

MOVING TOWARDS COLLABORATION BETWEEN TECHNICAL ADVISORY COMMITTEES IN THE EUROPEAN UNION

The World Health Organization (WHO) recommends that member states establish or strengthen a National Immunization Technical Advisory Group (known by the acronym NITAG). The objective of this Committee is to support leaders in making decisions about vaccination, providing information based on technical and scientific criteria. This momentum is embodied in the Global Vaccine Action Plan 2011-2020⁽²⁷⁾ and in the European Vaccine Action Plan 2015-2020 (Goal 5)⁽²⁸⁾.

The Committees of the countries of the European Union are heterogeneous in their structure and operation⁽²⁹⁾.

Taking into account the functions entrusted to the Committee for Immunization, as well as the work it has carried out since its creation, it is considered to be the NITAG for Spain. However, some aspects need to be reviewed

and strengthened to comply with the evaluation criteria of these Committees, such as the availability of a standardised working procedure, including the structure and operation⁽³⁰⁾.

Both the World Health Organization and the European Union are working to improve decision-making on immunization, recommending and advising on the strengthening of these NITAGs^(31,32).

The Council of the European Union has proposed the need to develop mechanisms for collaboration between NITAGs of the Member States^(33,34,35,36). Recently, a pilot project coordinated by the European Centre for Disease Prevention and Control (ECDC) has been launched, in which the Committee for Immunization is collaborating. This collaboration can help improve the procedures used to prepare technical documents in Spain, especially those that are difficult to implement because they consume a large amount of resources, such as conducting systematic reviews and developing mathematical models.

CONCLUSION

The Immunization Programme and Registry is the Technical Advisory Committee of the Public Health Commission and the Interterritorial Council on matters related to vaccines and immunization programmes. Since 1991 it has been making proposals based on scientific evidence and the epidemiological situation of immune-preventable diseases in Spain, providing support for decision-making.

The continuous evaluation of the immunization programmes carried out by this Committee has led to substantial changes in these programmes, with a lifetime immunization programme for the prevention of 14 diseases now available, as well as an immunization programme for risk groups and programmes for other specific situations.

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