

SPAIN

Spain have a decentralized administrative structure with 19 Autonomous Communities (17 Regions and 2 Cities). Spain's health system has become increasingly decentralization of health competencies to Autonomous Regions during 1980-85 and by year 2002 all Health competencies was transferred. Basic common health policies consensus are established by the Inter-Territorial Health Council formed by National and Regional Ministries of Health.

National Health System provide Universal public health care coverage for all residents.

There are also different special social support programmes- at central, regional and municipal levels - to extend social and healthcare service coverage to immigrant populations, specifically targeting illegal immigrant groups, with the collaboration of government supported NGOs

For the most part, the Spanish health system is financed through general taxation.

It is estimated that around 94% of Spanish citizens receive health care via the National Health Care Plan, while a minority of around 4%, comprised of civil servants, are covered under a special system that allows them to opt for coverage either under the National Plan or under a private insurance plan.

Responsibilities are divided according to the policy of devolution, with the central government assuming responsibility in central planning and basic health policy, while regional and local agencies have assumed responsibility for the of allocation of funds, implementation of national health policies, as well as general governance over regional health care facilities. The Ministry of Health is responsible for the general coordination of public health and health care services, in addition to drafting health policy and any basic enabling legislation required. The Ministry maintains direct control over other public health institutions National Institute of Health (INSALUD), the Institute of Health Carlos III (ISCIII) responsible for the epidemiological surveillance of vaccine preventable diseases, and technical advisor on the a priori evaluation of the epidemiological relevancy of the introduction of new vaccines into the schedule. and the Spanish Medicines Agency (AGEMED). The Ministry also regulates postgraduate training of medical professionals, pharmaceutical policy, and the standardization of medical and health products. The Spanish Parliament allocates some resources to the 19 Autonomous Communities.

The governments of the Autonomous Communities are responsible for health planning and programming, all financial matters, and maintaining direct control over health management. Local governments are in charge of environmental health control.

The Inter-Territorial Council, made up of representatives from each of the Autonomous Regions, meets regularly to debate and discusses issues related to the health and welfare of the population and to attempt to coordinate activity among the regions.

The Council has a Commission on Public Health that focuses on health care issues and priorities for the country and establish basic common health policies consensus. The

decisions of the Council are not binding by law but little can be accomplished if there is not consensus among the Council. The national government does not have the power to enforce public health and health care directives nor does it provide funding for the public health activities in the Autonomous Regions.

The Commission on Public Health, Chaired by the Director General of the Ministry of Health and Consumption (MOH), has several technical working groups that bring recommendations to the Council. One of the technical working groups focuses on vaccines and the immunization schedule :**Technical Working Group on Vaccines**, that is coordinated by the Immunization Program in the MOH, and participate representatives from Spanish Medicines Agency (SDA)(Agencia Española del Medicamento), National Centre for Epidemiology- National Institute Carlos III, as well as invited experts to provide information or opinions on specific matters. This Technical Working Group makes the immunization recommendations for the nation. Decisions are based on technical, issues and are made by consensus; Members base decisions regarding recommendations on the disease burden, and other epidemiological considerations, efficacy of the vaccine and the safety of the vaccine. There is no formal group of experts outside of the government which makes recommendations for the nation.

When decisions are made, as each Autonomous Community has participated in the decision, it is expected that all will follow the recommendations. Recommendations from the Working Group are then sent to the Commission on Public Health for approval before reaching the Inter-Territorial Council. Once vaccine recommendations are approved by the Council, they are incorporated into the National Immunization Schedule.

The National Immunization Program of the MOH works to coordinate the immunization activities of the Autonomous Communities. It also serves as the secretariat for the Working Group on Immunization and coordinates the experts and the information needed by that group. Also, it is the unit responsible for coordination with international organizations related to immunizations (e.g., European Union, WHO, EMEA).

Information Dissemination

When a new vaccine is recommended, the Autonomous Communities have the responsibility of communicating the information to the physicians and parents in their region. A variety of methods are used including letters, meetings, and conferences. The Immunization Program sends notices to the professional national associations including physician groups.

The Spanish Society of Primary Care Paediatrics maintains a section of its website dedicated to advice and questions related to childhood immunizations. It also publishes the current national vaccination schedule.

Vaccine Delivery

As with the majority of health care for children, most vaccines in the primary immunization series are given by paediatricians. Paediatricians provide care for children until they are 14 years old. In small towns there may be a central clinic that provides the vaccines as ordered by the paediatrician. This process differs by region.

The meningococcal vaccine is most often given in schools. A public health physician and/or nurse will go to the schools to provide the vaccine.

There are no school or day care requirements. All immunizations are voluntary.

Informed Consent

There are not national specifications for informed consent. Each of the Autonomous Regions is free to develop their own policy. However, informed consent is most often verbal, except in the case of vaccines given in school. For school immunization, a note is sent home with the child and the parents must sign it in order for their child to receive the vaccine.

Immunization Coverage

Collection of data on which to calculate immunization coverage is the responsibility of each Autonomous Community. Each region has their own method of collection but there are two types of methods most commonly in use: some regions have electronic registries in which immunizations for each child are entered into the system at the time of provision, other use some type of monthly chart manually completed by nurses in physician offices or vaccination clinics. The chart has the number of vaccines given to children within specific age groups by type of vaccine and number of doses.

The Autonomous Community then aggregates the data from all of their clinics to determine the numerator for their coverage calculation. The Autonomous Communities send their data to the Immunization Program where national coverage is calculated. Coverage is calculated at 1 year, 2 years of age and the booster doses.

According to the Spanish regulation, childhood vaccinations included in the national schedules are guaranteed free of charge for all Italian and foreign children residents in the Country. Therefore all vaccinations may be provided, irrespectively from the area of residence.

Spain have high vaccine coverage levels for those vaccines included in the national schedule in all Autonomous Regions:

[http://www.msc.es/profesionales/saludPublica/prevPromocion/vacunaciones/oberturas.htm](http://www.msc.es/profesionales/saludPublica/prevPromocion/vacunaciones/coberturas.htm)

Vaccine Financing

Each Autonomous Community is responsible for purchasing vaccine for use in their region. No national funds are provided to the Communities to purchase vaccines.

Funds to pay for the vaccine come from taxes raised by each of the Communities on their populations. Communities issue tenders each year with the manufacturers directly but do not work together to increase the volume of purchase and decrease prices. Prices paid for vaccines differ among the Communities.

Theoretically, as the Communities are responsible for purchasing vaccines, a Community would not agree to support a new vaccine recommendation in the Technical Working Group

on Vaccines or in the Committee on Public Health of the Inter-Territorial Council if it could not afford the vaccine.

The national immunization schedule is almost always followed by all of the Communities. However, a couple of Communities actually provide additional vaccines not on the recommended schedule (e.g., hepatitis A). Others may differ slightly on the recommended ages for a specific vaccine (e.g., viral influenza). It is very rare for a Community not to supply a recommended vaccine.

Families do not make any payment for any recommended vaccines. They are all paid for by their Autonomous Community government.

Administration Fees

Physicians and nurses are paid on salary. There are no additional fees paid to physicians or nurses by either the government or by parents for providing vaccines.

There are no patient or provider incentives for vaccines

Vaccine Distribution

Communities purchase the vaccine from the manufacturer and it is delivered by the manufacturer or a distributor to each region. There is variability among the Communities but the vaccine is usually sent to a distribution center from where it is then sent out to GP or paediatrician offices. In some Communities, there may be a public health center where children are sent from their physician to receive vaccines.

The National Immunization Program is not involved in the distribution of vaccine or maintenance of the cold chain. Each Autonomous Community produces its own documents regarding standards for immunization practice including cold chain and recommendations.

Vaccine Supply

There have been no significant shortages of any recommended vaccines in >5 years. Occasionally, one Autonomous Community may run out of vaccine but it can buy some from another Autonomous Community to alleviate potential shortages or disruptions in supply. No shortages have affected immunization rates.

Licensure Batch Approval

The batch approval process is governed by Spanish law. For all viral vaccines and all combined vaccines containing a virus, samples must be sent to the SDA. If tested in another EU country, the information is reviewed but no testing is performed. A formal batch release is then signed.

By Spanish law, for bacterial vaccines, the process as above takes place for DTP and typhoid fever vaccines. For other bacterial vaccines, no signed batch release or information review takes place (as long as the vaccine is approved in another EU nation).

Interactions with Other Nations

Under the new pharmacovigilance regulations of 2002, the SDA maintains interface with the European Agency for the Evaluation of Medicines (EMA). The SDA is responsible for

notifying the EMEA and the member states of the E.U. of suspected serious adverse reactions that have taken place in Spain within five days following the reporting. This communication takes place through the network of data processing established by the EMEA in collaboration with the States members and the European Commission.

Adverse Event Reporting

There is not a special reporting system for adverse events from vaccines. All adverse drug reports (ADRs) are handled in the same fashion. Only health care professionals and the pharmaceutical industry are allowed to make ADRs. There is a yellow card system where completed cards are sent to the health department in the Autonomous Community where the event took place. All reports are then entered within 10 days into a common database of the Spanish drugs surveillance System to which all regions have access. There is a Safety Committee of experts from the health system that meets 6 times per year to review all safety data. There is also a Technical committee on Drugs surveillance with representatives from all of the Autonomous Communities. All safety data are shared with EMEA.

Injury Compensation

There is no defined system for compensation for those who claim injury from vaccines. Some cases do go to court but it is uncommon and for very serious injury allegations only. Claims have been paid by the government for recommending a vaccine with which an adverse event occurred. Manufacturers have also been subject to litigation. Physicians do not have liability exposure when providing recommended vaccines.

Anti-Vaccination Groups

There is very little anti-vaccine activity in Spain. The public is very pro-vaccine and actually lobbies to have additional vaccines added to the immunization schedule. For example, the pneumococcal conjugate vaccine (Prevenar) is not currently recommended.

However, coverage is about 40% for the vaccine even though parents must pay for it out of pocket. The press does not write a lot of anti-vaccine stories. There is no special community or interest group that refuses vaccines.

CONSEJO INTERTERRITORIAL DEL SISTEMA NACIONAL DE SALUD
CALENDARIO DE VACUNACIONES RECOMENDADO (2006)
Aprobado por el Consejo Interterritorial el 29 de marzo de 2006

VACUNAS	EDAD													
	2 meses	4 meses	6 meses	12 meses	15 meses	18 meses	3 años	4 años	6 años	10 años	11 años	13 años	14 años	16 años
Poliomielitis	VPI1	VPI2	VPI3		VPI4									
Difteria-Tétanos-Pertussis	DTP ₁	DTP ₂	DTP ₃		DTP ₄			DTP ₅ o DT						Td
Haemophilus-influenzae b	Hib1	Hib2	Hib3		Hib4									
Sarampión Rubéola Parotiditis				TV1				TV2 ^(a)						
Hepatitis B	HB3 dosis 0; 1-2; 6 meses									HB3 dosis ^(b)				
Meningitis Meningocócica C	MenC1	MenC2 ^(c)			MenC3 ^(d)									
Varicela										VVZ ^(e)				

^(a) Niños no vacunados en este rango de edad, recibirán la segunda dosis entre los 11-13 años.

^(b) Niños que no han recibido la primovacuna en la infancia.

^(c) Se administrarán dos dosis de vacuna MenC entre los 2 y 6 meses de vida separadas entre sí al menos dos meses.

^(d) Se recomienda administrar una dosis de recuerdo a partir de los doce meses de vida.

^(e) Personas que refieran no haber pasado la enfermedad ni haber sido vacunadas con anterioridad, siguiendo indicaciones de la ficha técnica.

- children not vaccinated in this range of age, should received the second dose between 11-13 years old
- Children that was not received the primary vaccination in infancy
- 2 dose of MenC vaccine between 2-6 months of age, separated at least by 2 months
- A booster dose are recommended after 12 months of age
- Person that refers don't had pass the disease and don't had received before the vaccine

Vaccination schedule and coverage's, and official technical documents on vaccination can be found in:

Ministry of Health: Ministerio de Sanidad y Consumo. <http://www.msc.es>

National Vaccination Programme:

<http://www.msc.es/profesionales/saludPublica/prevPromocion/vacunaciones/vacunasProfesionales.htm>

National and Regional Vaccination Schedules:

<http://www.msc.es/ciudadanos/proteccionSalud/infancia/vacunaciones/p programa/vacunaciones.htm>

Adults Vaccination Recommendations:

<http://www.msc.es/ciudadanos/proteccionSalud/vacunaciones/docs/recoVacunasAdultos.pdf>

Modify Vaccination Programmes Criteria:

<http://www.msc.es/ciudadanos/proteccionSalud/vacunaciones/docs/criteriosVacunas.pdf>

New recommendations of vaccination:

<http://www.msc.es/profesionales/saludPublica/prevPromocion/vacunaciones/nuevaRecomenVacunas.htm>

Coverage of vaccination:

<http://www.msc.es/profesionales/saludPublica/prevPromocion/vacunaciones/coberturas.htm>

Spanish Medicines Agency: Agencia Española del Medicamento <http://www.agemed.es>

Instituto de Salud Carlos III: <http://www.isciii.es>