

# Quality Standards for Allergen Immunotherapy Clinics in Spain: Consensus Document

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## ■ Abstract

*Background:* Allergen immunotherapy clinics (AITCs) in Spain differ widely in terms of structure, organization, resources, and portfolio of services. Therefore, it is essential to unify treatment criteria and define quality standards for the most complex AITCs.

*Objective:* To establish a series of recommendations that make it possible to guarantee quality and safety in the administration of immunotherapy and define quality standards for the most complex AITCs.

*Methods:* This project began with an online survey of 65 allergy departments/units throughout Spain in 2013. Next, a 2-phase consensus process was carried out. In the first phase, 10 experts defined and agreed on the standards using the RAND/UCLA Appropriateness method; in the second, the agreements were validated by means of a 2-round Delphi consultation with 84 experts.

*Results:* Consensus was reached on minimum safety and quality criteria in the administration of allergen immunotherapy, and 2 levels of highly complex AITCs were defined: accredited AITCs and accredited AITCs with excellence. Consensus was also reached on quality standards and accreditation criteria for both levels.

*Conclusions:* This project is pioneering in terms of its purpose (the definition of quality standards for AITCs) and of the use of structured participation techniques (combination of the RAND/UCLA and Delphi methods). It enabled the design of minimum standards for quality and safety in administering AIT, as well as quality criteria for accreditation of AITCs supported by a broad panel of experts from the Spanish Society of Allergology and Clinical Immunology.

**Key words:** Allergens. Delphi. RAND/UCLA. Immunotherapy. Health care quality assurance.

## ■ Resumen

*Antecedentes:* Las unidades de inmunoterapia (UIT) en España son muy diferentes en cuanto a estructura, organización, recursos y cartera de servicios. Por ello, resulta esencial homogeneizar criterios de actuación y definir estándares de calidad para las UIT de mayor complejidad.

*Objetivo:* Establecer recomendaciones que permitan garantizar la calidad y seguridad en la administración de la inmunoterapia y definir estándares de calidad para las UIT de mayor complejidad.

*Métodos:* Proyecto iniciado (año 2013) con una encuesta on-line a 65 servicios o unidades de alergología de toda España. Posteriormente, se desarrolló un proceso de consenso en dos fases. En la primera, diez expertos definieron y consensuaron los estándares mediante el método RAND/UCLA; en la segunda, los acuerdos se validaron mediante una consulta Delphi a dos rondas con 84 expertos.

*Resultados:* Se consensuaron criterios mínimos de seguridad y calidad en la administración de inmunoterapia con alérgenos (ITA) y se definieron dos niveles de UIT de mayor complejidad: las UIT acreditadas (UITA) y las UIT acreditadas con excelencia (UITAE), consensuándose también los estándares de calidad y criterios de acreditación para ambos niveles.

*Conclusiones:* Proyecto pionero en su objetivo – definición de estándares de calidad de UIT– y en el empleo de técnicas de participación estructuradas –combinación de los métodos RAND/UCLA y Delphi–. El resultado es la definición de unos mínimos de calidad y seguridad para administrar ITA, y un conjunto de criterios de calidad para la acreditación de las UIT que cuenta con el respaldo de un amplio panel de expertos de la SEAIC.

**Palabras clave:** Alérgenos. Delphi. RAND/UCLA. Inmunoterapia. Calidad asistencial.

## Introduction

Allergen immunotherapy (AIT) is aimed at modifying the clinical-immunological response of individuals with IgE-mediated allergies. It is based on the controlled administration of pharmacological products in which the active ingredient is the allergen responsible for the disease. Thus, in order to ensure its safety and obtain maximum therapeutic efficacy, it is essential to monitor patients in allergen immunotherapy clinics (AITCs) that guarantee certain quality standards [1-4].

AITCs are staffed by professionals with expertise in the administration of allergen extracts. They are located within health care centers that have sufficient resources and access to an allergy specialist [3,5]. AITCs in Spain are numerous and very different, and their structure reflects the capacities of their organizers and the resources of each health care environment. Likewise, the portfolio of AITC services differs widely, as some clinics administer AIT for patient treatment purposes, others have research facilities, and others offer training. Accordingly, given the absence of a normative framework for authorizing the opening and/or operation of AITCs, it is essential to define a series of standards in order to guarantee the quality and safety of the treatment administered to patients in these units. Allergy specialists from the Spanish Society of Allergology and Clinical Immunology (SEAIC) and its AIT Committee agreed to implement a formal consensus process.

The objectives of this process were as follows: (a) to define minimum criteria and requirements to serve government agencies, clinic operators (public or private), and physicians and nursing staff who work in the allergy field and are involved in the administration of AIT, with the aim of guaranteeing safe conditions, quality, and patient rights in the AITCs; (b) to define minimum recommendations that allow operational criteria to be established and guarantee safety in the administration of the treatment; (c) to define a series of quality standards for high-complexity AITCs, with the final objective of establishing operational criteria at the treatment level, so that they can be accredited by the SEAIC in the future; and (d) to establish general recommendations relating to the organization, management, physical structure, and resources of AITCs.

## Methods

This study was carried out based on data from 153 allergy departments/units located throughout Spain. Data were obtained by means of an online survey conducted by the SEAIC AIT Committee in 2013. The purpose was to obtain

a map of the situation of the AITCs in the country at that time. The results of the analysis led us to design a 2-phase consensus process:

Phase 1. This involved application of the RAND/UCLA method, the results of which are based on available scientific evidence and expert opinion. The participants comprised 10 allergy specialists with specific expert profiles (quality, management, and care management), led by a group of 4 coordinators.

A 2-phase literature search was conducted. This involved an initial search for possible pre-existing criteria and sources concerned mainly with care quality and management, and a second, more specific search based on a nonexhaustive systematic review of the literature. This second review was conducted in Medline in Spanish and English and was limited to publications from the last 5 years: this was extended to 10 years if no relevant results were found. Likewise, clinical practice guidelines, reviews, consensus documents, care protocols, and recommendations were prioritized.

Based on the selected publications, a quality standards proposal was developed and evaluated by all the experts on an individual basis in an online validation round. Four response options were defined for each proposal, with 1 being “strongly disagree” and 4 being “strongly agree”. For the analysis, the results of 1 and 2 were grouped together as “disagree” and 3 and 4 as “agree”. The criteria for accepting or rejecting a standard were established based on the combined “agree” options (3 and 4) and defined as follows: unanimity (100% agreement), consensus ( $\geq 85\%$  agreement), variance (agreement between 66% and 84%), and rejection (agreement  $< 66\%$ ). The standards that were classified as variance or rejection were sent back to the experts for a second round of individual assessment. Lastly, a group validation session was held to discuss the proposals for which consensus had not been achieved in either of the 2 rounds.

Phase 2. For the purpose of extending the agreements to a larger group of experts, a consultation based on the Delphi method was conducted in 2 rounds. To do so, a group was formed comprising 5 advisors who had collaborated in the preparation and validation of the surveys, participated in the methodological decisions, and advised on the analysis and interpretation of the results. The panelists were selected based on their experience in the subject matter of the consultation. In the selection process, previous agreement by another expert from the same center to participate in the consultation was a potential exclusion criterion.

The survey used a Likert scale of 5 response options, where 1 was “strongly disagree” and 5 was “strongly agree”. For the analysis, 1 and 2 were grouped together as “disagree”

and 4 and 5 as “agree”. The criteria for accepting or rejecting a standard were established based on the combined “agree” options (3 and 4) and were defined as follows: consensus ( $\geq 90\%$  agreement), majority (agreement between 66% and 89%), and discrepancy (agreement  $< 66\%$ ).

Phases 1 and 2 were conducted between December 2014 and January 2017, with methodological support from the GOC *Networking* consultancy team.

## Results

### *Survey Prior to Consensus*

Of the 153 departments/units to which the survey was sent, a total of 65 (42.5%) responded. The data obtained provided a preliminary census and a map of the situation of the AITCs in terms of human resources, allergen extracts and guidelines followed, records used, teaching and research activity, type of patients treated, and communication with primary care. Nonetheless, identification of the considerable structural and functional variability of the AITCs surveyed justified the consensus process, the results of which are shown below.

### *Literature Search of the Consensus Process in Phase 1*

The nonexhaustive and systematic literature search yielded 1164 publications, of which 42 were prioritized based on topicality, theme, relevance, and quality of the scientific publication. Another 62 publications were added to these 42, based on a targeted search for topics related to care quality and management.

### *Experts Participating in Phase 2*

A total of 237 experts were invited to participate in phase 2 (2-round consultation): of these, 93 (39.2%) agreed to participate and responded in the first round, and 84 (90.3% of the first round respondents) responded in the second round.

### *Consensus Process (Phases 1 and 2)*

The criteria and indicators shown below are those proposed by the group of experts in the RAND/UCLA process (phase 2). Agreement by the panel of experts that participated in the Delphi consultation (phase 2) was  $\geq 90\%$ .

### *Minimum Safety and Quality Criteria*

The administration of medication (particularly allergen extracts) carries a risk of triggering adverse, mainly allergic reactions that can prove life-threatening if the necessary care is not provided. Accordingly, AITCs should be equipped and organized to guarantee patient safety, prevent risks, and properly treat adverse reactions. For this reason, it is essential that all AITCs administering AIT apply the minimum safety and quality criteria (Table).

### *Quality Criteria for Accreditation of AITCs*

The main purpose of the accreditation system for AITCs is to have a set of standards that define the minimum criteria required for units of similar complexity in order to guarantee

optimal quality of care, promote research in immunotherapy, and establish a continuous improvement model in all AITCs. Thus, the criteria shown below were prepared with a view to potentially accrediting AITCs with a seal of excellence. Nonetheless, any AITC that wishes to attain accreditation must meet the mandatory minimum safety/quality criteria for the administration of AIT; if the AITC opts for accreditation with the seal of excellence, it must also satisfy the criteria of the accredited AITCs (AITCAs). These criteria are human resources, specific physical spaces, specific technical resources, portfolio of services, standard operating procedures (SOPs), care activity, and training. The criteria that an AITCA must meet are outlined for each block (Table).

Lastly, the requirements that AITCs accredited with excellence (AITCAEs) must meet are defined. These must satisfy all of the previous specifications (the minimum and those required of an AITCA) and those indicated in the Table, which are grouped by type.

## Discussion

Our definition of a set of quality standards and the corresponding accreditation system for types of centers and treatment resources is not new. There are at least 2 significant forerunners in Spain: the Top 20 programme, promoted by IASIST [6], and the accreditation based on ISO 9001 standards obtained by the *Centro de Atención Primaria de la Vila Olímpica (Barcelona)* in 2002. Also noteworthy at international level is the model promoted by the Joint Commission in the United States since the early 1980s, which is based on a series of specific and differentiated indicators for each care center [7].

The review of the scientific literature conducted during the first phase of this consensus process enabled the identification of various clinical practise guidelines, both in Europe and in Spain. These guidelines proposed norms and standards for assuring quality and safety for certain diseases and for potential complications of some services provided by AITCs [8-11]. Nevertheless, none of the references found presented a global accreditation model for AITCs to administer the various types of AIT. Although the systematic literature review was not exhaustive and only 1 database was examined, our initiative can be considered pioneering. In addition, it is based on available scientific evidence and the opinion of a wide group of experts and established the most important criteria for patient safety and service quality in the AITC as regards human resources, physical spaces and technical resources, portfolio of services, SOPs, relationship between AITCs and primary care, continuous education, teaching, and research.

In order to gradually increase quality and safety in AITCs in Spain, the next step in this ambitious project is for the SEAIC to accredit Spanish AITCs until it completes, in the next 3-4 years, the full plan-do-check-act cycle of continuous improvement in quality of care. To do so, it is essential to define an accreditation standard with the corresponding certification process, expressed in the form of a document that the SEAIC will publish as soon as it has been drafted.

Table. Minimum, Advanced, and Specialized Safety and Quality Criteria to Be Met by Allergen Immunotherapy Clinics in the Administration of Allergen Immunotherapy

Minimum Criteria (MC)	Advanced Criteria (AC)	Specialized Criteria (SC)
Basic safety and quality criteria for an AITC.	Criteria that an AITCA must meet in addition to the MCs.	Criteria that an AITCAE must meet in addition to the MCs and ACs.
Human resources		
MC.1 One allergist or nurse with access to the allergist.	AC.1 One allergist with nonexclusive dedication to the AITC.	SC.1 At least 2 allergists with nonexclusive dedication.
MC.2 Allergist or nurse readily available (nearby and reachable) after administration to answer questions for approximately 10-20 minutes per patient and administered dose.	AC.2 Nurse trained in the administration of extracts.	
MC.3 Nurse readily available (nearby and reachable) to answer questions in the event that the allergist is unavailable.		
Physical spaces required		
MC.4 Specific medical office, or a specific nursing area, such as a consultation area for examination and assessment of patients (these spaces could also be shared for performing other activities).	AC.3 Nursing area for preparation of the AIT dose, with a storage area for consumables and refrigerators for medication.	SC.2 Extended observation area in the administration area or close to it, with capacity for observation of more than 4 h.
MC.5 Area that enables observation of the patient after treatment for at least 30 minutes.	AC.4 Area for administration of AIT, with the possibility of treating several patients simultaneously.	SC.3 Urgent care area with all the materials needed for treatment of adverse reactions, a direct telephone line to the ICU, proximity to the ICU or to emergency care by the ICU, and a resuscitation area to begin CPR procedures.
MC.6 Waiting area (chairs for patients and children or dependants).	AC.5 Urgent care area with all the materials needed for treatment of adverse reactions and a direct telephone line to the ICU.	
Specific technical resources		
MC.7 A treatment table, desk for the doctor, cabinet for storage of supplies, and refrigerator if extracts are stored.	AC.6 Computerized clinical database of patients that is accessible to all members of the unit.	SC.4 Availability of the following material for diagnosis and treatment of adverse reactions: <ul style="list-style-type: none"> <li>• Complete resuscitation trolley (with defibrillator and all supplies and drugs needed for responding to cardiorespiratory arrest).</li> <li>• Vital signs monitor.</li> </ul>
MC.8 Parenteral medication: adrenaline, antihistamines, corticosteroids, bronchodilators, and devices for their administration.		SC.5 Possibility of using data from the medical record of patients via a computer accessible to all members of the unit.
MC.9 Oral medication: antihistamines, corticosteroids.		
MC.10 Inhaled medication: fast-acting bronchodilators.		
MC.11 Oxygen and devices for administering it, bag valve mask.		
MC.12 Nebulizers and inhalation chambers.		
MC.13 1-mL syringes with subcutaneous needles, syringes for intramuscular injection, perfusion systems, fluids (crystalloids-NaCl 0.9%), cotton/gauze, antiseptics (chlorhexidine or alcohol), timers, tourniquets.		
MC.14 Instruments for monitoring vital signs (cardiac frequency, blood pressure, pulse oximetry), peak flow, spirometer, stethoscope, and cuff.		
MC.15 Telephone as a communication channel and for alerting the emergency room.		

(cont.)

Table. Minimum, Advanced, and Specialized Safety and Quality Criteria to Be Met by Allergen Immunotherapy Clinics in the Administration of Allergen Immunotherapy (cont.)

Minimum Criteria (MC)	Advanced Criteria (AC)	Specialized Criteria (SC)
Portfolio of services		
	AC.7 Capacity to perform subcutaneous AIT.	SC.6 Possibility of using experimental extracts (under research, not on the market).
	AC.8 Capacity to initiate treatment with any sublingual AIT product.	SC.7 Possibility of administering AIT to high-risk patients (eg, mastocytosis, prior systemic reactions).
	AC.9 Capacity to provide the patient with explanations and instructions regarding sublingual AIT (including the possibility of reactions at home).	
	AC.10 Capacity to administer the first dose of any product that is nonexperimental or that has a technical datasheet.	
	AC.11 Capacity to administer AIT for aeroallergens.	
	AC.12 Capacity to perform AIT with hymenoptera venom.	
	AC.13 Capacity to administer any extract or commercial aeroallergen, already tested, regardless of the associated risk.	
	AC.14 Capacity to administer native and modified depot extracts.	
	AC.15 Capacity to use aqueous extracts.	
	AC.16 Capacity to administer conventional and cluster build-up schedules and maintenance regimens in patients with prior incidents.	
SOP		
MC.16 An administration protocol for AIT.	AC.17 Systematically provide oral and written information on AIT (indications and contraindications, costs, objectives, risks and expected benefits) to all patients.	SC.8 Completion of the individualized instruction document at least 90% of the time.
MC.17 An action protocol for cases of adverse reactions.	AC.18 Availability of an individualized instruction document that contains all AIT-related information to be accessible when administering each dose.	SC.9 Availability of a checklist for AIT administration according to the level of patients that may be treated (high risk) with specific variables.
MC.18 Tolerability monitoring.	AC.19 Completion of the individualized instruction document at least 80% of the time.	SC.10 Completion of the checklist in at least 90% of cases.
MC.19 Coordination with PC if patients are referred from the AITC to PC.	AC.20 Availability of a specific AIT administration checklist that includes specific variables to be checked before administering each dose.	SC.11 Possibility of accessing data via a system for recording the administered doses.
MC.20 A patient record with the clinical report and a record of administration with incidents.	AC.21 Application of the checklist in at least 60% of cases.	SC.12 Monitoring of tolerance and efficacy using an objective parameter.
	AC.22 Monitoring of tolerability and efficacy.	SC.13 Application of measures to control extract storage (thermometer) and guarantee conservation at the correct temperature.
	AC.23 Supply of information to patients regarding storage of extracts when this will be performed by the patient.	SC.14 Availability of a safety plan that includes monitoring.

(cont.)

Table. Minimum, Advanced, and Specialized Safety and Quality Criteria to Be Met by Allergen Immunotherapy Clinics in the Administration of Allergen Immunotherapy (cont.)

Minimum Criteria (MC)	Advanced Criteria (AC)	Specialized Criteria (SC)
	<p>AC:24 Availability of a safety plan that guarantees patient safety and specifies how to respond to immediate and delayed reactions, with staff training and the resources necessary for such a response.</p> <p>AC:25 Availability of a register of immediate and delayed incidents<sup>a</sup> that is filled in for 100% of incidents.</p> <p>AC:26 Availability of a safety plan that includes adrenaline and fluids.</p> <p>AC:27 Availability of a record of the administration of immediate medication.</p> <p>AC:28 Application in the unit of a pre-existing anaphylaxis protocol.</p> <p>AC:29 Adaptation of the SOPs to children if the unit treats minors.</p>	<p>SC:15 Availability of a patient satisfaction questionnaire.</p>
Care Activity	<p>AC:30 Availability of a written document agreed upon with PC for AIT administration.</p> <p>AC:31 Collection and classification of all adverse reactions according to current guidelines.</p> <p>AC:32 Availability of a communication line during care service hours or continuously (according to capacity) for resolution of incidents<sup>a</sup>.</p> <p>AC:33 Recording of incidents<sup>a</sup> in the medical record following AIT administration completed in 60%-80% of cases.</p>	<p>SC:16 Care of high-risk patients (mastocytosis, prior systemic reactions, etc.).</p> <p>SC:17 Specific schedule for the AITC that has spaces for emergency consultations to attend to patients without an appointment.</p> <p>SC:18 Availability of a detailed document or record with all data related to AIT, which includes information about the extract, dose, tolerability, start date, and pre- and postdosing, PEF measurement.</p> <p>SC:19 Response to AIT-related incidents<sup>a</sup> within 48-72 h.</p> <p>SC:20 Recording of incidents<sup>a</sup> performed in over 80% of cases.</p>
Training and research	<p>AC:34 Completion of a basic CPR course by the medical staff of the AITC every 2 years and an advanced course every 5 years.</p> <p>AC:35 Completion of a basic CPR course by the nursing staff of the AITC every 2 years.</p> <p>AC:36 Organization of sessions on clinical/problem cases in the AITC.</p>	<p>SC:21 Accredited continuing medical education to all medical staff of the AITC.</p> <p>SC:22 Membership of a specific AIT network or participation in a specific AIT project in the last 5 years.</p>
Other		<p>SC:23 Internal auditing systems to evaluate the recording of adverse reactions.</p> <p>SC:24 Implementation of the PDCA cycle of continuous improvement.</p> <p>SC:25 Members linked to scientific societies.</p>

Abbreviations: AIT, allergen immunotherapy; AITC, allergen immunotherapy clinic; AITCAE, allergen immunotherapy unit accredited with excellence; CPR, cardiopulmonary resuscitation; ICU, intensive care unit; PC, primary care; PDCA, plan, do, check, act; SOP, standard operating procedure.

<sup>a</sup>Incidents: various adverse reaction incidents, such as extract unrefrigerated and delayed doses.

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- Juan María Beitia Mazuecos has participated in clinical assays from ALK-Abelló S.A. and Diater and has received fees as speaker from Stallergenes-Greer, Allergy Therapeutics, and LETI.

- Eduardo Fernández Ibáñez has collaborated in clinical trials from ALK-Abelló S.A., Allergy Therapeutics, Merck S.L, Roxall and Diater and has acted as a consultant for Stallergenes-Greer and ALK-Abelló S.A.
  - Jesus Garde Garde declares that he has no conflicts of interest.
  - Dolores Hernández Fernández de Rojas declares that she has no conflicts of interest.
  - Virginia De Luque Piñana has participated in clinical assays from ALK-Abelló S.A., Merck S.L, LETI, and Immunotek and has collaborated as a speaker with ALK-Abelló S.A., Allergy Therapeutics, and LETI.
  - Pedro Ojeda Fernández has participated in clinical trials or in scientific collaboration with ALK-Abelló S.A., Allergy Therapeutics, Roxall, Diater, Immunotek S.L., Probelte Pharma and Stallergenes-Greer.
  - Mar Reaño Martos declares that she has no conflicts of interest.
  - Fernando Rodríguez Fernández has participated in clinical assays from ALK-Abelló S.A., Allergy Therapeutics, and LETI.
  - Albert Roger Reig has participated in clinical trials from Stallergenes-Greer, ALK-Abelló S.A., LETI, Allergy Therapeutics, Merck S.L, Roxall and ALK-Abelló S.A. He has also received speaker fees from Allergy Therapeutics and has participated as consultant for Stallergenes-Greer, LETI, Allergy Therapeutics, Merck S.L., Roxall and Diater.
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  - Carmen Vidal has participated in clinical assays from Stallergenes-Greer, ALK-Abelló S.A., LETI, and HAL Allergy Group. She has also received speaker fees from ALK-Abelló S.A., Stallergenes-Greer, and Allergy Therapeutics and has participated as consultant for ALK-Abelló S.A.
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