



32 Requirements to be met to become an Anaphylaxis Center of Reference and Excellence (ANACARE)

Infrastructure and Facilities			
Nr.	Requirement	Explanation	Deliverable(s)
1.	Hospital setting	Center needs to be in a hospital or affiliated with a hospital with inpatient facilities to allow for extended diagnostic work up and on-site management of acute episodes and long-term management.	Evidence of hospital setting or affiliation with hospital and summary description of facilities, including proximity to emergency room
2.	Outpatient clinic with separate clinic hours for patients with anaphylaxis and food allergy headed by board certified expert(s)	Centre needs to have designated and expert leadership (experienced specialist physician) and to offer a minimum number of consultation hours per week exclusive for patients with anaphylaxis and food allergy	Led by experienced physician (board certified specialist) ≥20h / week of clinic including patients with anaphylaxis (physician contact time)
3.	Open to children and/or adult patients	Centers need to be able to provide care for pediatric and or adult anaphylactic patients, either by center staff and/or by affiliated specialists	Evidence that pediatric and/or adult anaphylaxis patients are provided with state-of-the-art care
4.	Patient demographics	Centers need to provide data on existing patient demographics, e.g., number of patients, age cohorts, ethnicity, sex, allergies, related diseases etc. as this data is especially important information for clinical trials	Provide number of patients treated annually by age cohort (eg, <18, 18-5-, >50 and by sex). Provide data to understand complexity of patients served (% with <25%, 25-50%, >50% comorbidities) i.e how many patients have multiple food allergies, severe food allergy with more than 3 episodes of food anaphylaxis a year and co-morbidities such as asthma and allergic rhinitis

5.	Team of dedicated staff, with specific training in managing anaphylaxis	Center staff needs to comprise more than one fulltime equivalent ("fte") physician and at least one fte nurse. All center staff needs to be specifically and regularly trained in managing anaphylaxis	<p>≥2 fte physicians and ≥1 fte nurse</p> <p>Record of ≥1 training on anaphylaxis per staff member per year as Internal training. Identify which published Guidelines are followed</p>
6.	Multidisciplinary approach	Center needs to be able to interact with other specialties for the management of comorbidities, the treatment of patients with differential diagnoses, and to perform extended diagnostics including the possibility to offer provocation tests as well as testing with native allergens for both food and drug allergies	<p>Evidence of interaction with other specialists and list of available specialties including dieticians, nutritionists, and psychologists</p> <p>Please provide number of provocation tests per year. Minimum of at least 100 provocation tests per year are required to qualify as Hub center.</p>
7.	Accessibility and visibility	Anaphylactic patients need to be able to find the center via information on the web; Centre needs to have referral network(s) of physicians; Centre needs to work with patient association(s), where applicable	<p>Center clinic hours are available to patients.</p> <p>Explanation of local referral network (eg, by pediatricians, other doctors) and if and how center works with local patient organization(s)</p>
8.	Communication skills	Centre staff needs to be able to communicate adequately with anaphylactic patients in national language and in English	Proof of adequate communication skills by interview with Centre staff. Number of English-speaking personnel at center
9.	Quality management	Centre needs to have Quality Management (QM) system in place, need to have written protocols and standard operating procedures (SOPs)	Explanation of QM system , Proof of presence and use of SOPs/ protocols
10.	Structured documentation, recording and archiving patient data	Centre needs to have in place and use a secure databank to record patient data. Databank needs to allow retrieval of information needed to address scientific questions. The Centre must be willing to share anonymized data for research purposes	<p>Status of secure patient databank</p> <p>Status of achieving a minimum of 100 patients with anaphylaxis in databank/year</p>
11.	Critical incidence reporting and error management	Centre needs to have and make use of an incidence report book documenting all critical incidents. Centers must analyze all reported incidents and take and document appropriate action	Evidence of presence and use of incidence report book and follow up and documentation of resolution of error reports by appropriate action taken

12.	Assessment of patient satisfaction and unmet needs	Centre needs to regularly assess how satisfied their patients are with the work of the Centre and take appropriate action based on the outcome	If not in place, willingness to request ≥100 patients about their satisfaction in last 12 months
13.	In team communication	Centre needs to have regular meetings of staff to discuss projects and concepts. Decisions should be protocolled and followed by action where applicable.	Evidence of regular team meetings, at least once per month, on Centre logistics, project updates and proposed concepts
14.	Active recruitment of research funding and support for educational activities and advocacy on anaphylaxis	Centre needs to actively recruit external funding to support research, educational activities and/or advocacy on anaphylaxis	Documentation of efforts to recruit funding (e.g., grant applications, donation program included in CV's of top center personnel). Evidence that educational and advocacy materials are available on center website
15.	Support of the ANACARE network	Training and activities in auditing and certifying GA ² LEN ANACAREs and interaction with other ANACAREs. Participation in ANACARE meetings and conferences	Status of submitting Letter of Intent to serve as a GA ² LEN ANACARE auditor and to contribute to other ANACARE network activities
Nr.	Requirement	Explanation	Deliverable(s)
16.	Knowledge of and adherence to the national and international anaphylaxis and food allergy guidelines. In case of discrepancy preference for local and most recent guideline.	All Center staff members require knowledge of the current version of the national and international guideline, when available. Centre approach to anaphylaxis needs to be based on guideline recommendations	At least one national or international anaphylaxis and food allergy guideline in the most recent version is present (paper or electronic version) and which guideline(s) is followed Centre staff can answer questions on the anaphylaxis and food allergy guideline recommendations Centre physicians can show, by use of an anonymized patient file, that management decisions are in accordance with guideline recommendations
17.	Knowledge and use of current definition of anaphylaxis and food allergy	Centre staff needs to know and use the current anaphylaxis and food allergy classification and nomenclature	Evidence that staff uses current anaphylaxis definition e.g., by interview and/or patient file review

18.	Knowledge and use of guided history taking	Structured history taking by center physicians is essential and a checklist will facilitate this	Checklist for history taking needs to be present and used as evidenced by interview and/or an anonymized anaphylactic patient file review
19.	Diagnostic Process	Explanation of different diagnostic tools used.	Evidenced by review of an anonymized patient
20.	Standardized assessments and monitoring of disease activity, impact and control of disease	Status of implementing standardized measurements and monitoring of patients can help to optimize anaphylaxis and food allergy management	Discussion with senior center staff on implementing the GA ² LEN Food Allergy Management Guidelines and EAACI Guidelines on Anaphylaxis need to be used
21.	Identification of comorbidities and underlying causes	Centre needs to have access to and use measures to identify comorbidities and causes of anaphylaxis including, for example, food and venom allergy, mastocytosis, asthma, drug allergy, latex allergy	Status of implementing the GA ² LEN Food Allergy Management Guidelines relative to diagnostic measures for anaphylaxis comorbidities and underlying causes are used, e.g., skin prick test, prick-prick test, serum specific IgE, tryptase standardized food challenge test, spirometry and patch testing for concomitant contact dermatitis
22.	Knowledge and use of preventive approaches	Center physicians need to know and educate patients and caregivers in the use of prevention strategies, e.g., avoidance and in certain patients' air and food allergen avoidance, early introduction of foods, <i>and in</i> recognizing psychological support needs	Evidence that Centre physicians are familiar with the use of preventive strategies and provide appropriate support services (eg, dietician, nutritionist, psychological)

23.	Knowledge and use of therapeutic algorithm	Centre physicians need to know and use therapeutic guideline algorithms including systemic therapy for pediatric and adult patients	Evidence that staff uses current therapeutic algorithms for the treatment of patients with anaphylaxis both for the acute episode and for long term management, e.g., by interview and/or patient file review Evidence which prophylactic measurements, e.g., OIT offered
24.	Counseling	Counseling of patients and their families, for example on skin care, triggers of exacerbation, stress, daily life issues can help to optimize anaphylaxis and food allergy management	Evidence that patients with anaphylaxis and food allergy receive counseling, e.g., by interview and/or patient file review and by reviewing materials that are made available to patients. Evidence of training on need to carry and use an epi autoinjector. Evidence that appropriate support services (eg, dietician, nutritionist, psychological) are available and provided

Research			
	Requirement	Explanation	Deliverable(s)
25.	Scientific orientation	Centre staff needs to be an acknowledged thought leader in establishing, disseminating, and implementing literature on anaphylaxis and food allergy by, for example, speaking at leading academic and industry conferences and publishing regularly in highly rated peer reviewed journals	List and bio briefs of personnel (and roles) with CV's and available indicating leadership roles (eg, on scientific committees, presenting at leading academic and or industry conferences and providing well established staff development including training and mentoring programs.

26.	Scientific activity	Research activities in basic science, clinical science, translational science, anaphylaxis and food allergy	Identification of areas of research focus (basic, clinical, translational science). List of personnel by areas of focus (including specialties and subspecialties). List of current projects underway by area of focus. List of planned research projects by area of focus. List of current and planned collaborations, highlighting collaborations with ANACARE members
27.	Scientific productivity	Centre needs to show that its research activities result in publications and other scientific output	List of peer reviewed publications (identifying top 5 most important publications over the past 3 years). Note participation in the development of published Guidelines in the field
28.	Clinical trials	Centre needs to participate in clinical trials (both pharma- and/or investigator-initiated) and diagnostic or therapeutic trials. Observational trial should be noted as well.	List of current clinical trials (by Phase) underway, sorted by pharma or investigator led and observational trials.
29.	Participation in registry and biorepositories / biobanks	Registries can help to better understand anaphylaxis Centre needs to participate in international, national, and/or regional registry activities. Biorepositories can similarly advance scientific discovery	Indication if center currently has, and/or contributes to and is willing to contribute to a food allergy and anaphylaxis registry and/or biorepository. Indication that Centre is willing to share anonymized data and/or specimens. Indication of Centre's capabilities to offer such resources

Education			
Nr.	Requirement	Explanation	Deliverable(s)
30.	Educational activities	Centre needs to contribute to the education of other specialists, e.g., allergists non-specialists such as emergency physicians, pediatricians, general practitioners and family physicians, psychologists, medical students, residents, patients, and the general public	Evidence of 1 educational activity on anaphylaxis per year for physicians /staff and 1 per year for patients and/or caregivers. Show evidence of partnering with local patient organizations on these efforts. Evidence/list of materials readily available on website and shared with patients on patient visits and of programs offered to patients

Advocacy			
Nr.	Requirement	Explanation	Deliverable(s)
31.	Increase awareness of anaphylaxis and food allergy	Centre needs to increase awareness and knowledge of anaphylaxis and food allergy	List of recent advocacy efforts. Evidence of 1 advocacy /awareness activity on anaphylaxis and food allergy (any triggers) per year. Evidence of partnering with local patient organizations on these efforts
32.	Interaction with and support of patient organization(s)	Patient organizations can help to improve the management of anaphylaxis and food allergy for patients suffering from severe allergic reactions	Evidence of interaction with patient organization (s) for anaphylaxis/ food allergy/allergic diseases

Categories (Cat.):

GA²LEN Food Allergy Management Guidelines 2022

EAACI Guidelines on Anaphylaxis Allergy 2021

WAO Anaphylaxis Guidelines 2020

AAAAI Practice Parameters on Anaphylaxis 2019

Abbreviations: EAACI (The European Academy of Allergy and Clinical Immunology (www.EAACI.org)); GA²LEN = Global Allergy and Asthma European Network; QM = Quality management, SOP = standard operating procedure; ANACARE = Anaphylaxis Centre of Reference and Excellence; AAAAI = American Academy of Allergy, Asthma and Immunology; WAO = World Allergy Organization.