

GA²LEN Urticaria Centers of Reference and Excellence (UCARE) Audit Report

Audit Date: _____

Head of the Center: *name and email* _____

Audited Center: _____

Auditor: _____

Deputy: *name and email* _____

Last audit: _____



Infrastructure / Set up					
	Requirement	Explanation	Deliverable(s)	Yes /No	Cat.
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 management of exacerbation	Evidence of hospital setting or affiliation with hospital	<input type="checkbox"/> <input type="checkbox"/> _____	B
2.	Outpatient clinic with separate clinic hours for urticaria patients headed by expert	Center needs to have designated and expert leadership (experienced specialist physician) and to offer a minimum number of consultation hours per week exclusive for urticaria patients	Lead by experienced physician (board certified specialist) ≥4h / week of dedicated urticaria clinic (physician contact time)	<input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____	A
3.	Open to children and adult patients	Centers need to be able to provide care for urticaria patients of any age, either by center staff or affiliated specialists	Evidence that urticaria patients of any age are provided with state of the art care	<input type="checkbox"/> <input type="checkbox"/> _____	A
4.	Team of dedicated staff, with specific urticaria training	Center staff needs to comprise more than one physician and at least one nurse. All center staff needs to be specifically and regularly trained in urticaria	≥2 physicians and ≥1 nurse Record of ≥1 urticaria training per staff member per year, e.g. GA ² LEN school on urticaria, urticaria CME activity, etc.	<input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____	A
5.	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	Evidence of interaction with other specialists	<input type="checkbox"/> <input type="checkbox"/> _____	B

6.	Accessibility and visibility	Urticaria patients need to be able to find the center via information on the web; center needs to have referral network(s) of physicians; center needs to work with patient association(s), where applicable	Center clinic hours are posted on website Evidence of local referral network Evidence that patient organization recommends the center	<input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____	B
7.	Communication skills	Center staff needs to be able to communicate adequately with urticaria patients in national language and in English	Proof of adequate communication skills by interview with center staff	<input type="checkbox"/> <input type="checkbox"/> _____	B
8.	Quality management	Center needs to have Quality Management (QM) system in place, need to have written protocols and standard operating procedures (SOPs)	Evidence of presence of QM system Proof of presence and use of SOPs/ protocols	<input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____	B
9.	Structured documentation, recording and archiving of patient data	Center needs to have in place and use a databank to record patient data. Databank needs to allow retrieval of information needed to address scientific questions	Patient databank ≥50 urticaria patients in databank/year	<input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____	B
10.	Critical incidence reporting and error management ¹⁵	Center 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 error reports by appropriate action	<input type="checkbox"/> <input type="checkbox"/> _____	B
11.	Assessment of patient satisfaction and unmet needs	Center needs to regularly assess how satisfied their patients are with the work of the center and take appropriate action based on the outcome	Proof that ≥40 patients were asked about their satisfaction in last 12 months (preferably by questionnaire)	<input type="checkbox"/> <input type="checkbox"/> _____	B
12.	In team communication	Center 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 center logistics, projects and concepts	<input type="checkbox"/> <input type="checkbox"/> _____	B
13.	Active recruitment of research funding and support for educational activities and advocacy on urticaria	Center needs to actively recruit extramural funding to support research, educational activities and/or advocacy on urticaria	Documentation of efforts to recruit funding (grant applications, donation programme)	<input type="checkbox"/> <input type="checkbox"/> _____	B
14.	Support of the UCARE network	Training and activities in auditing and certifying GA ² LEN UCAREs and interaction with other UCAREs	Letter of intent to serve as a GA ² LEN UCARE auditor and to contribute to other UCARE network activities	<input type="checkbox"/> <input type="checkbox"/> _____	A

15.	“Never give up” attitude	Staff needs to exhibit high motivation to help urticaria patients and show understanding that they may be the last resort of patients. Staff needs to convey to patients, that they are in good care and that the center will help them, however hard this may be.	Evidence of “never give up”-attitude by staff interview	<input type="checkbox"/> <input type="checkbox"/> _____	B
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Management					
	Requirement	Explanation	Deliverable(s)	Yes /No	Cat.
1.	Knowledge of and adherence to the EAACI/GA ² LEN /EDF/WAO urticaria guideline	All center staff members need to know the current version of the international EAACI / GA ² LEN / EDF / WAO guideline and their corresponding national guideline, if available. Center approach to urticaria needs to be based on guideline recommendations.	EAACI/GA ² LEN/EDF/WAO guideline is present (paper / electronic version ¹) Center staff can answer questions on the urticaria guideline recommendations Center physicians can show, by use of a patient file, that management decision are based on guideline recommendations	<input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____	A
2.	Knowledge and use of current nomenclature and classification of urticaria	Center staff needs to know and use the current urticaria classification and nomenclature	Evidence that staff uses current urticaria nomenclature and classification ¹ , e.g. by interview and/or patient file review	<input type="checkbox"/> <input type="checkbox"/> _____	A
3.	Knowledge and use of guided history taking/anamnesis	Structured history taking by center physicians is essential and a checklist can facilitate this	Checklist for history taking ¹ needs to be present and used as evidenced by interview or urticaria patient file review	<input type="checkbox"/> <input type="checkbox"/> _____	A
4.	Knowledge and use of differential diagnostic algorithm	Center physicians need to be aware of the differential diagnoses of chronic urticaria and know how not to miss them. The guideline algorithm can help with this.	Differential diagnostic algorithm ^{1,2} needs to be present and used as evidenced by interview or urticaria patient file review	<input type="checkbox"/> <input type="checkbox"/> _____	A
5.	Standardized assessments and monitoring of disease activity, impact and control of disease	The use of instruments for assessing disease activity, impact and control allows for standardized measurements and monitoring of patients can help to optimize urticaria management.	UAS7 ^{1,3} , AAS ^{4,5} , CU-Q ₂ oL ⁶ , AE-QoL ^{5,7} , UCT ^{5,8,9} need to be present and used At least one of them needs to be used in 80% of chronic urticaria patients	<input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____	A

6.	Identification of comorbidities and underlying causes	Center needs to have access to and use measures to identify comorbidities and causes of chronic spontaneous urticaria, for example autoreactivity/autoimmunity, infections, etc. including biopsies	Evidence that diagnostic measures for urticaria comorbidities and underlying causes are used, e.g. ASST, BAT, biopsy, etc.	<input type="checkbox"/> <input type="checkbox"/> _____	A
7.	Provocation and threshold testing in CINDUs	Provocation testing and threshold assessment are important in the diagnostic workup of CINDUs. SOPs are needed as is the use of appropriate instruments / protocols such as dermatographometers ^{5,10} TempTest ^{®11} , pulse controlled ergometry ¹²	Standardized documentation of provocation and threshold testing ¹³ Instrument / techniques are available and used as evidenced by patient file reviews	<input type="checkbox"/> <input type="checkbox"/> _____ <input type="checkbox"/> <input type="checkbox"/> _____	A
8.	Knowledge and use of therapeutic algorithm	Center physicians need to know and use therapeutic guideline algorithm, for example use of non-sedating antihistamines, up dosing of non-sedating antihistamines, restrictive use of glucocorticosteroids, use of step 3 therapies.	Evidence that staff uses current therapeutic algorithm ¹ for the treatment of chronic urticaria patients, e.g. by interview and/or patient file review	<input type="checkbox"/> <input type="checkbox"/> _____	A
9.	Counseling	Counseling of patients and their families, for example on triggers of exacerbation, stress, avoidance of non-steroidal anti-inflammatory drugs, daily life issues can help to optimize urticaria management	Evidence that urticaria patients receive counseling, e.g. by interview and/or patient file review	<input type="checkbox"/> <input type="checkbox"/> _____	A

Research					
	Requirement	Explanation	Deliverable(s)	Yes /No	Cat.
1.	Scientific orientation	Center staff needs to be up-to-date with the literature on urticaria, especially on pathogenesis, for example by participation in journal club, attending annual meetings of scientific societies, membership in research societies, for example EMBRN, ESDR, EAACI	Evidence of knowledge of the current urticaria literature, e.g. by interview	<input type="checkbox"/> <input type="checkbox"/> _____	A
2.	Scientific activity	Research activities in basic science, clinical science, translational science, epidemiology, and/or public health	Evidence of scientific activities and projects on urticaria	<input type="checkbox"/> <input type="checkbox"/> _____	A
3.	Scientific productivity	Center needs to show that its research activities result in publications and other scientific output	0.5 peer reviewed paper on urticaria per year per center physician	<input type="checkbox"/> <input type="checkbox"/> _____	A

4.	Clinical trials	Center needs to participation in clinical trials, pharma-and/or investigator-initiated; diagnostic and/or therapeutic trials	0.5 trials in urticaria per year per center physician	<input type="checkbox"/> <input type="checkbox"/> _____	A
5.	Participation in registry	Registries can help to better understand urticaria. Center needs to participate in international, national, and/or regional registry activities, e.g. CURE ¹⁴	Evidence that center contributes to a urticaria registry	<input type="checkbox"/> <input type="checkbox"/> _____	A

Education

	Requirement	Explanation	Deliverable(s)	Yes /No	Cat.
1.	Educational activities	Center needs to contribute to the education of other specialists, e.g. dermatologists, allergists, ER-physicians, non-specialists such as general practitioners and family physicians, medical students, residents, patients, and the general public	Evidence of 1 educational activity on urticaria per year for physicians and 1 per year for patients	<input type="checkbox"/> <input type="checkbox"/> _____	A

Advocacy

	Requirement	Explanation	Deliverable(s)	Yes /No	Cat.
1.	Increase awareness of urticaria	Center needs to increase awareness and knowledge of urticaria, for example by contributing to UrticariaDay ⁶ , support of the Urticaria Network ³ .	Evidence of 1 advocacy /awareness activity on urticaria per year	<input type="checkbox"/> <input type="checkbox"/> _____	A
2.	Interaction with and support of patient organization(s)	Patient organizations can help to improve the management of urticaria and urticaria patients	Evidence of interaction with urticaria patient organization	<input type="checkbox"/> <input type="checkbox"/> _____	A

Comments:

- Audit result:**
- All requirements fulfilled, center will receive certificate
 - Most requirements fulfilled, except for:
Center will receive certificate upon providing:
 - Re-audit in ____ months

Categories (Cat.): Requirements of the category A are specific for UCAREs, whereas requirements of the category B are part of the GA²LEN Centers of Excellence Quality Management and Certification programme. Category B requirements do, therefore, not need to be audited, if the urticaria center is part of an audited and certified GA²LEN Center of Excellence.

References: 1 = Zuberbier T et al. The EAACI/GA²LEN/EDF/WAO Guideline for the definition, classification, diagnosis and management of urticaria: The 2013 revision and update. Allergy 2014; 69: 868-87; 2 = Maurer, M., Magerl, M., Metz, M., Siebenhaar, F., Weller, K., and Krause, K.: Practical algorithm for diagnosing patients with recurrent wheals or angioedema. Allergy 2013a: 68; 816-819; 3 = www.urtikaria.net; 4 = Weller, K., Groffik, A., Magerl, M., Tohme, N., Martus, P., Krause, K., Metz, M., Staubach, P., and Maurer, M.: Development, validation and initial results of the angioedema activity score (AAS). Allergy 2013: 68; 1185-1192; 5 = www.moxie-gmbh.de; 6 = Baiardini I, Pasquali M, Braido F, Fumagalli F, Guerra L, Compalati E, Braga M, Lombardi C, Fassio O, Canonica GW. A new tool to evaluate the impact of chronic urticaria on quality of life: chronic urticaria quality of life questionnaire (CU-QoL). Allergy. 2005; 60: 1073-8; 7 = Weller, K., Groffik, A., Magerl, M., Tohme, N., Martus, P., Krause, K., Metz, M., Staubach, P., and Maurer, M.: Development and construct validation of the angioedema Quality of Life Questionnaire (AE-QoL). Allergy 2012: 67; 1289-1298; 8 = Weller, K., Groffik, A., Church, M. K., Hawro, T., Krause, K., Metz, M., Martus, P., Casale, T., Staubach, P., and Maurer, M.: Development and validation of the urticaria control test - a patient reported outcome instrument for assessing urticaria control. J. Allergy Clin. Immunol. 2014: 133; 1365-1372; 9 = www.urticariaday.org; 10 = www.htz.biz; 11 = www.courage-khazaka.de; 12 = Altrichter, S., Salow, J., Ardelean, E., Church, M. K., Werner, A., and Maurer, M.: Development of a standardized pulse-controlled ergometry test for diagnosing and investigating cholinergic urticaria. J. Dermatol. Sci. 2014: 75; 88-93; 13 = Magerl, M., Borzova, E., Giménez-Arnau, A., Grattan, C. E. H., Lawlor, F., Mathelier-Fusade, P., Metz, M., Młynek, A., and Maurer, M.: The definition and diagnostic testing of physical and cholinergic urticarias - EAACI/GA²LEN/EDF/UNEV consensus panel recommendations. Allergy 2009: 64; 1715-1721; 14 = www.urticaria-registry.com; 15 = Critical incidents are mistakes, for example in the diagnostic workup, the treatment, or the management of patients.

Abbreviations: AAS = Angioedema activity score; AE-QoL = Angioedema quality of live questionnaire; ASST = Autologous serum skin test; BAT = Basophil activation test; CAT = categories; CINDU = Chronic inducible urticaria; CME = Continued medical education; CURE = Chronic urticaria registry; CU-Q_oL = Chronic urticaria quality of life questionnaire; EAACI (The European Academy of Allergy and Clinical Immunology (www.EAACI.org); EMBRN = European mast cell and basophil research network (www.embrn.eu); ER = Emergency room; ESDR = European Society for Dermatological Research (www.esdr.org); GA²LEN = Global Allergy and asthma European Network; QM = Quality management, SOP = standard operating procedure; UAS7 = Urticaria activity score 7 (for seven consecutive days); UCARE = Urticaria Center of Reference and Excellence; UCT = Urticaria control test.