The GA²LEN UCARE Audit – Background information

How to do a UCARE audit

Urticaria centers that apply to become GA²LEN Urticaria Centers of Reference and Excellence (UCAREs) are audited. This audit is performed by one or more members of the GA²LEN UCARE audit group, which consists of the heads and deputies of certified UCAREs. If you are a GA²LEN UCARE auditor, then this background information may be helpful to prepare for an audit you are planning to perform. If you are a center that is to be audited for becoming a GA²LEN UCARE, then these notes will give you some background information on how to prepare for the audit and what the audit will be like.

In general, an audit visit and meeting make sure that an urticaria center complies with the rules of the GA²LEN UCARE program and fulfills the requirements of a GA²LEN UCARE. The audit visit is also meant to strengthen the interaction between UCAREs and to promote the discussion of urticaria management, the organization of urticaria centers and joint urticaria projects between UCARE centers in the future.

Ideally, an UCARE audit is performed on site and held in a place that allows for collegial discussions and meaningful scientific exchange. The center that is audited should provide enough space and time to properly do the audit. As the pandemic activity and time schedules do not always make it possible to conduct audits on site it is also possible to carry out the audit on remote via online conferencing. Please inform the UCARE office accordingly. A video conference platform should be used for the audit on remote and the UCARE office will be happy to help if auditors or applicant UCAREs do not have access to such a platform.

For both cases up to 2 hours should be scheduled for the audit meeting, and all the material (e.g. patient files, databank, standard operating procedures) that is needed to prove that the center meets all 32 UCARE criteria should be accessible at the time of the audit. For this reason, for the preparation of the auditor and for additional information to the audit report for the UCARE Steering Committee, the preparation of a written documentation is mandatory. This documentation should be sent to the UCARE office and the auditor 10 days before the audit takes place.

On site, the center should be ready to show to the auditor(s) the rooms and setup of the center. For both scenarios (on site or on remote) the team of the center should be present during the audit in addition to the head of the urticaria center.

The auditing of some of the requirements involves a review of patient files and standard operating procedures. These should be made available during the audit. Auditors and auditees should see the audit visit as an opportunity to learn from each other, to promote the harmonization of urticaria management and to discuss and plan interactions and UCARE network projects.

Auditors should see the audit visit as an opportunity to inform the audited center about GA²LEN and about current GA²LEN activities (www.ga2len.net). Auditors should update the center's staff on the GA²LEN UCARE network e.g. aims, number and location of UCAREs, ongoing UCARE network activities (ga2len-ucare.com) and global urticaria projects such as Urticaria Day (every year on October 1st, www.urticariaday.org), the global chronic urticaria registry, CURE (www.urticaria-registry.com), international urticaria meetings such as the international urticaria guideline consensus meeting held every four years in Berlin, Germany (www.urticariaguideline.org), and the activities of the urticaria foundation, the urticaria network e.V. (www.urtikaria.net).

As an auditor, you can arrive at three possible outcomes of an audit.

- The first outcome is that you find all the requirements to be fulfilled and in this case you can congratulate the center to becoming a UCARE right after the audit.
- A second possible outcome is that you find most of the requirements fulfilled and that the requirements that are not fulfilled will be fulfilled soon by measures already put in place or started soon by the center. For example, if the center did previously not have a critical incidence supporting system, e.g., a book where mistakes are documented and consequences of mistakes are provided (requirement number 10 in infrastructure/setup), but the center has now initiated that, and has this in place and will use it in the future, then this should be noted in the audit notes. It is at your discretion if you see the requirement as fulfilled and you tell the center at the end of the audit visit that it is now a UCARE, or if you want to discuss this with the UCARE coordinators first. The same applies if you are unsure of whether the center fulfills all requirements.
- A third outcome is that you find that one or more requirements are not fulfilled, and you see the need that the center changes its setup and performance before it can become a UCARE. In this case, you should inform the center about what needs to be done to meet the requirements and questions and then suggest a re-audit in 3, 6 or 12 months depending on how long you think it will take for the center to fix the problem.

If all requirements are fulfilled or if you as auditor anticipate that they will be with the measures now put in place, then a re-audit in 24 months for recertification will be scheduled. After the first re-audit, the certificate is valid for 3 years. From the second re-audit onwards, it will be 4 years and thus the maximum period of validity will have been reached.

After the audit, the auditor forward the audit notes (please use the UCARE audit report template) with a short summary to the GA²LEN UCARE office. The audit report should contain the name of the center you audited, as it will appear on the UCARE certificate. Therefore, please make sure that all information is given correctly.

The GA²LEN UCARE office will send the audit report and the short summary of the audit together with the documentation of the applicant center to the UCARE Steering Committee to receive their votes on it.

If their vote is positive, the UCARE office will send out a congratulation letter with the audit result and the UCARE certificate to the center. If the vote is negative, the GA²LEN UCARE office will explain the reasons and give the center advise which areas must improve before they can apply again for becoming an UCARE.

For any questions you have as an auditor or as a center that is audited, please be in touch with the GA²LEN UCARE office in Berlin.

How to audit the 32 UCARE requirements

Infrastructure/setup

1. *Hospital requirement*

   It is important for UCAREs to be at hospital departments or affiliated with such. Geographical differences in urticaria management are important here. In some countries, urticaria specialist centers are exclusively run by allergy departments or dermatology departments at hospitals. In other countries, urticaria specialist centers may be mostly outpatient centers. In this case, the center needs to show that it works with a hospital that has inpatient services to manage patients who cannot be managed as outpatients. This

refers, for example, to complex diagnostic workup measures that may be necessary in some patients as well as to the management of exacerbation of urticaria where patients need to be monitored overnight. If the UCARE is not at a hospital, then it needs to provide the name of the hospital and the contact person/team at the hospital they are working with for the management of their urticaria patients. This information should be included in the audit report.

2. *Outpatient clinic with separate clinic hours for urticaria patients headed by expert*

   There really are two requirements here. One is a sufficient number of clinic hours dedicated specifically to the treatment of urticaria patients. What this means is that urticaria patients are primarily or exclusively seen during defined times of the week. A minimum of 4 hours per week of dedicated urticaria clinic time is needed. This requirement is checked for by question and answer. The number of urticaria clinic hours per week is documented in the audit report. If there is written documentation on the number of urticaria clinic hours, for example from an organizational chart or from information on the website, then this is helpful and should be attached to the audit report.

   The second sub-requirement is that the center needs to be led by an experienced physician. Experienced, here, means that the head of a UCARE should have several years of training and experience in the treatment of urticaria patients. He or she must be a board-certified specialist (e.g. dermatologist, allergologist, internal medicine specialist, pediatrician) and this position must be clearly designated as such within the structure of the department or the center that the UCARE is part of. The lead physician and head of a UCARE needs a deputy and the name of the lead physician and the name of the deputy should be documented in the audit report. A UCARE may have more than one deputy head.

3. *Open to children and adult patients*

   The center should see children and adults with urticaria. There may be a focus on either children or adults. But in principle, it should be possible for patients of all age groups to receive treatment at the urticaria center. For UCAREs located at pediatric centers or children's' hospitals this may be a challenge, and flexible solutions should be accepted. To fulfill this requirement, a pediatric urticaria center could show, for example, that there is close interaction with adult physicians who are part of the urticaria center and do not need to be physically located at the center where children are seen. This requirement is checked for by question and answer.

4. *Team of dedicated staff, with specific urticaria training*

   There are two questions to be asked. The first one is regarding the number of physicians and nurses who work at and for the urticaria center. A minimum of two physicians (the head and the deputy) is required to constitute a UCARE. The number of physicians at the urticaria center should be documented in the audit report. This relates to the present number at the time of the audit. The same goes for nurses and other staff. Here, a minimum of one nurse should be working at and for the urticaria center. The number of nurses is documented in the audit report, and the same goes for the number of other staff (also provide information on the specialization/background of other staff). This sub-requirement is checked for by question and answer. The center needs to be made aware of the fact that, for later requirements, scientific activity and clinical trial activity needs to be shown per physician and that this should be kept in mind when providing physician numbers here.

   The second sub-requirement asks for at least one urticaria training of each staff member during the previous 12 months. Each staff member should be able to show for at least one

urticaria training per year. Urticaria training could come from GA²LEN allergy schools on urticaria, from participation in national or international congresses, from regional and local urticaria events and activities and others. This sub-requirement is also attested for by question and answer, with the answer options *yes* and *no*. Examples of urticaria training activities may be included in the audit report.

5. *Multidisciplinary research*

Here, the center needs to provide information on which other specialties it interacts with. If, for example, a urticaria center is located at a department of dermatology, possible interactions may be in place with gastroenterologists, psychiatrists, ENT specialists, dentists, psychologists, immunologists, or rheumatologists. The different specialties that the center interacts with are documented in the audit report.

6. *Accessibility and visibility*

The center should provide information on how it can be found on the web and how it interacts with physicians in the region as well as patient organizations. Ideally, the web presence of the center is documented by a screenshot added to the audit report. At the very least, the web address of the center should be documented in the audit report. The contact info for the urticaria center needs to be visible on the website, with specific contact information for patients and when the urticaria clinic holds their patient consultations. If this information is not clearly provided on the website, then this is to be changed by the center and confirmation that the center will do so should be documented.

Sub-requirements 2 and 3 (interaction with a local referral network and patient organization) are checked for by question and answer, for example, with the question "How are urticaria patients referred to you, by general practitioners or specialists and which ones?" or "How many referring doctors and doctors do you work with?". Centers are encouraged to work with or initiate local and regional referral networks for urticaria. Patient organizations may not exist in all countries and/or may not be active in all regions. If they are, then the name of the patient organization the center works with should be documented in the audit report.

7. *Communication skills*

This requirement is usually easy to check off at this point in time during the audit because the audit is likely to be held in English, and one can assume, in most cases, that the center staff is able to communicate in the national language. If the audit, up to this point, was held in the national language rather than in English, then it is advisable to do at least part of the remaining audit in English to assure that the center staff is able to communicate sufficiently in English. This is necessary for the interaction with other UCAREs and within the global UCARE network as well as for the management of non-native speaker patients.

8. *Quality management*

A quality management (QM) system needs to be in place, but there is global diversity on what QM systems are used and on the extent of QM procedures implemented. In general, QM systems aim at defining and describing responsibilities, pathways, and procedures within the center. They rely on a QM handbook that includes all the standard operating procedures (SOPs) of the center. If no formal QM system (e.g. ISO 9000) is in place than this requirement may still be met if the center can show that it has a QM system in place that assures that responsibilities are clearly defined, for example with an organigram, and that pathways and procedures are also clearly defined and described in detail. This relates to the collection of SOPs, which should be available either electronically or in hardcopy.

The audit should seek confirmation that these QM documents are used, revised on a regular basis, and accessible to all center members.

9. *Structured documentation, recording and archiving of patient data*

Urticaria centers need to be able to go back to their patient documentation to answer questions, compare their results to those of other centers, to promote research and to develop new hypotheses and research projects. For this, a patient data bank is crucial. This documentation/database may be as simple as an excel file that documents the patient characteristics (e.g. demographics, lab values, test results, score values) that are assessed during the clinic visit, or it may be a registry, where patient data are included. The center needs to provide evidence, ideally by presenting their databank or their registry-related activities, which confirms that this documentation of patient data is a continued process and that more than 50 urticaria patients during the last year are documented in this databank. Ideally, data from all urticaria patients seen by the center should be included in the data bank /registry.

10. *Critical incidence reporting and error management*

This requirement relates to mistakes that are made at the center and how the center deals with them. Each center should have a "mistake book" or some other form of documenting mistakes. Mistakes, here, means anything that goes wrong and should not go wrong again in the future. This may be, for example, a mix up in the administration of a drug, a mistake made during patient scheduling, or a problem with a diagnostic test. Mistakes should be documented in the "mistake book" and the action taken should also be documented. The idea is that this will help to avoid making the same mistakes again and that new members of the center can look at the mistakes that were made in the past. The center should present to the auditors the "mistake book" or whatever other system they have in place for critical incidence management.

11. *Assessment of patient satisfaction and unmet needs*

For urticaria centers to grow and improve, it is necessary that they assess how satisfied patients are with their performance. This should be done by surveys or other means that provide detailed information on where patients see the need for improvement or where patients are happy with the performance of the center. This could be an ongoing survey where all patients that come to visit the department are asked to fill in a patient satisfaction survey. This could be a patient satisfaction action that only runs for several weeks every year. This could also be a mailbox, where patients can drop notes on how satisfied they are or where they see problems. The requirement is usually assessed by question and answer and information on how patient satisfaction is assessed should be documented in the audit record.

12. *In team communication*

The team of urticaria center should have regular team meetings to discuss patients, protocols, projects, activities and strategy, as well as interactions with other centers. The center needs to provide information to the auditor(s) on who meets when and how, and ideally this is audited by a review of the minutes of team meetings or by questions to the team members on their team meetings. In the audit report, the frequency, duration and format of team meetings should be documented.

13. *Active recruitment of research funding and support for educational activities and advocacy on urticaria*

This requirement is assessed by question and answer and the center needs to provide information on its efforts to recruit funding. This could be by grant proposals sent to national grant givers, by requests for project funding from pharmaceutical industry, or by applications for funding to foundations or patient organization. The documentation in the audit report should include the name of the organizations that the center approached for research funding and for the support of education and advocacy activities.

14. *Support of the UCARE network*

This is an opportunity to inform the team (again) about the aims of the GA²LEN UCARE network and to obtain a commitment from the team and specifically the head and the deputy of the team to contribute to the activities of the GA²LEN UCARE network. The head and the deputy should be asked if they agree to serve as UCARE auditors of other centers, and their answers are documented in the audit report.

15. *"Never give up" attitude*

This important requirement is tested for by questions to the center staff. Here, the auditor usually asks questions to the team rather than the head of the center. It is a nice segway to the subsequent management requirements, where team members are also interviewed. To have a "Never give up attitude" means that no matter how frustrated patients or the team may be, centers will never give up finding solutions for patients. UCAREs frequently see patients who have been treated by multiple other physicians and who are not satisfied with their treatment. Patients need to be able to rely on "their" UCARE to find a satisfying solution, no matter how hard this may be. Audit questions to the staff may include "What would you recommend to a patient who has received all the guideline recommended treatment options and is still experiencing uncontrolled urticaria?" or "What would be your message when you communicate with patients who are referred to you by other physicians who told them that nothing can be done for them and that they just have to live with their urticaria?".

Management

1. *Knowledge of and adherence to the EAACI/GA²LEN/EDF/WAO urticaria guideline*

The 3 parts of this requirement are assessed by questions and answers/interview and by reviewing the presence and the implementation of the international urticaria guideline at the center. The center should show to the auditors that the guideline is available (electronically or on paper) at the center and accessible to all center members. Center members should be interviewed on the content of the guideline. For example: "What do the guidelines recommend for the diagnostic workup of chronic spontaneous urticaria patients?" or "What are the three steps in the symptomatic treatment of chronic urticaria patients?".

2. *Knowledge and use of current nomenclature and classification of urticaria*

This requirement is tested by interview. The staff should be able to answer questions like "What are the two types of chronic urticaria?" or "Name two subtypes of physical urticaria?". It is important that all UCAREs use the same nomenclature as provided by the international guidelines.

3. *Knowledge and use of guided history taking/anamnesis*

The auditor(s) should check by interview or by reviewing patient files that centers use a structured and systematic approach when taking patients' histories. A template is included in the guidelines and can be used, and auditors should encourage centers to development and use a written template for taking the history in all patients with chronic urticaria.

4. *Knowledge and use of differential diagnostic algorithm*

The guidelines provide a diagnostic algorithm that helps to identify the underlying disease in patients with wheals and/or angioedema. This algorithm should be available at the center and center staff is interviewed on the knowledge of this algorithm.

5. *Standardized assessments and monitoring of disease activity, impact and control of disease*

The use of patient-reported outcomes (PROs) and standard instruments by all UCAREs is important. It helps to improve patient management and allows for the comparison of data obtained at different UCAREs. Standard instruments such as the UAS7, AAS, CU-QoL, AE-QoL and UCT should be present and known at the center. Sub requirement 1 is assessed by interview and by reviewing the SOP collection of the center. Auditors are requested to advise centers to use these tools as often and in as many patients as possible. Use of at least one of these tools, preferably the UAS7 or the UCT, in at least 80 % of chronic urticaria patients is checked for by interview or by patient file review.

6. *Identification of comorbidities and underlying causes*

In patients with long-standing and/or severe disease, underlying causes of chronic spontaneous urticaria should be investigated. Centers need to show, by interview or patient file review, that they use extended diagnostic measures to investigate patients for underlying causes and comorbidities.

7. *Provocation and threshold testing in CINDUs*

Disease activity in patients with chronic inducible urticarias is assessed by provocation testing and by measuring trigger thresholds. In cold urticaria, for example, this should be done by subjecting patients to cold provocation tests. If the test is positive, the critical temperature threshold or the critical stimulation time threshold should be assessed. In cold urticaria, this is done using TempTest. Urticaria centers should show to the auditors that they have instruments and procedures for provocation test and threshold testing. Knowledge of how to do these tests should be verified by interview of center staff. Dermographometers (such as FricTest), graded UV provocation, and cholinergic urticaria testing by physical exercise tests are standard procedures that should be available at all UCAREs.

8. *Knowledge and use of therapeutic algorithm*

The international urticaria guideline-recommended treatment algorithm should be implemented at UCAREs. This is assessed by interview of center staff asking questions such as "What is your first line treatment of patients with chronic urticaria?" or "What treatment options do you recommend in patients who are resistant to up to fourfold dosed non-sedating antihistamines?". Patient file reviews can help to assess this requirement.

9. *Counseling*

Advise on triggers of exacerbation such as stress and counseling on urticaria-induced stress and other psychological issues is an important part of urticaria management in patients with chronic forms of the disease. UCAREs should provide counselling for patients

who need this or facilitate counselling by referring patients to psychologists or other specialized healthcare providers. This is assessed by questions to the center staff in an interview setting.

Research

1. *Scientific orientation*

   A UCARE's staff should be up to date with the scientific literature on urticaria. This may be achieved by regular journal clubs, by study of the literature, by participating in the annual meetings of scientific societies or by participation in other educational events. This requirement is also assessed by interview of center staff.

2. *Scientific activity*

   A UCARE needs to also be an urticaria research center. Research, here, includes scientific activities in the field of basic research, clinical research, translational research and epidemiological and public health research. This requirement is assessed by questions on the scientific activities of the center, for example on the ongoing projects, on recent results of research projects and on findings from center projects communicated by publications or at congresses.

3. *Scientific productivity*

   Here, the centers provide a list of publications or other form of evidence that each center physician has published at least one peer-reviewed paper within the last 24 months. This requirement may also be considered to be fulfilled if there is evidence that papers are in preparation and that physicians are actively working towards the publication of results. This applies especially to early-stage researchers.

4. *Clinical trials*

   The urticaria centers should inform auditors on the ongoing clinical trials and previously concluded trials. Participation in at least one clinical trial during the last 24 months is required for each center physician. This may be assessed by interview or by reviewing study protocols and reports.

5. *Participation in registry*

   All UCAREs should enter patient data in a registry. This may be a local, regional, national, or international registry. Centers should be encouraged to participate in CURE, the chronic urticaria registry. All information on how to become a CURE center is available on the CURE website and centers should be advised to obtain this information if they are not yet a CURE center. The requirement may be considered to be fulfilled if steps for participation in CURE or another registry have been taken.

Education

1. *Educational activities*

   This two-part requirement looks at the center's activities in the field of physician education and patient education. At least one educational event for physicians should have been held during the last 12 months and this should be a continued activity with one educational activity for physicians every year. The same goes for patient education.

Patient education formats include meetings with patients or patient organization meetings where physicians provide information on urticaria. This requirement is assessed by interview.

Advocacy

1. *Increase awareness of urticaria*

   The advocacy activities of urticaria centers are assessed by interview. This is done by asking center staff to report on their advocacy activities for example their contribution to Urticaria Day, press activities, joint projects with patient organizations to educate the general public on urticaria or other meetings. Centers are to provide evidence and information on at least one activity they did during the last year. Advocacy is an ongoing process and centers should show that they are planning for at least one advocacy/awareness event per year.

2. *Interaction with and support of patient organization(s)*

   Patient organizations are active in some but not all countries. If patient organizations are active in the country/region of a center then the center should seek interaction with this organization and provide information to the auditors on how this center interacts with the patient organization. This requirement may not apply if there is no organization of patients that is active in the region for the country of the center.