



LETTER TO THE EDITOR

Definition, aims, and implementation of GA²LEN/HAEi Angioedema Centers of Reference and Excellence

To the Editor,

GA²LEN, the Global Allergy and Asthma European Network, and HAE international (HAEi), the global umbrella organization for the world's hereditary angioedema (HAE) patient groups, have launched their joint ACARE (Angioedema Center of Reference and Excellence) program, within GA²LEN's center of reference and excellence (CORE) initiative. Angioedema is a common, heterogeneous, often debilitating and chronic condition and is frequently a challenge for physicians and affected patients, especially patients suffering from recurrent attacks. Additionally, it can be a challenge for some patients to understand the underlying etiology of their angioedema (Table 1). GA²LEN's CORE networks, such as UCARE for urticaria and ADCARE for atopic dermatitis, help to improve the management of difficult-to-treat conditions. Here, we describe the aims, requirements, provisions, application process, audit, and accreditation protocol for GA²LEN/HAEi ACAREs. ACAREs aim to provide excellence in angioedema management, increase the knowledge of angioedema through research and education, and promote advocacy activities that raise angioedema awareness. To become a certified ACARE, angioedema centers must fulfill 32 requirements, defined by specific provisions that will be assessed during an audit visit. The ACARE program will result in a strong network of angioedema specialists, promote angioedema research and awareness, and harmonize and improve angioedema management globally. ACAREs will

expand access to modern angioedema medicines in countries where they are available and help to bring them to countries where they are not.¹

This document summarizes the aims of GA²LEN/HAEi Angioedema Centers of Reference and Excellence (ACAREs) and elaborates the requirements that ACAREs must fulfill to become certified. It also provides (see Appendix S1) background information on GA²LEN and HAEi, including HAEi member organizations and regional patient advocates, on why we need an Angioedema Center of Reference and Excellence (ACARE) program and network, and on the accreditation and certification process, governance and funding, and on the interaction with other GA²LEN networks of centers of reference and excellence. The protocols, aims, requirements, and provisions related to becoming a certified ACARE are based on (a) the experience of the GA²LEN UCARE network and (b) input from angioedema patients, general practitioners, and angioedema specialists.

What are the aims of GA²LEN/HAEi ACAREs? The aims of ACAREs are to set the global standard for excellence in comprehensive angioedema care through research, education, advocacy, and interaction among ACAREs. By serving as referral centers for the diagnosis and management of patients with angioedema, ACAREs will complement the local healthcare system. ACAREs aim to increase knowledge and awareness of angioedema.

TABLE 1 Classification of angioedema

Bradykinin-mediated angioedema				Mast cell mediator-mediated angioedema		Unknown mediator
C1-INH deficiency/defect		C1-INH normal		IgE mediated	Non-IgE mediated	
Inherited	Acquired	Inherited	Acquired			
HAE-1	AAE-C1-INH	HAE nC1-INH (HAE-FXII, HAE-ANGPT1, HAE-PLG, HAE-KNG1, HAE-UNK)	AE due to medication that interferes with BK degradation, eg ACEi	Angioedema with or without wheals in patients with urticaria	Angioedema with or without wheals in patients with urticaria	Idiopathic AE
HAE-2				Anaphylaxis		

Abbreviations: AAE-C1-INH, acquired angioedema due to C1-inhibitor deficiency; ACEi-AE, angiotensin-converting enzyme inhibitor-induced angioedema; BK, bradykinin; HAE nC1-INH, hereditary angioedema with normal C1-inhibitor levels, either due to a mutation in factor XII (*F12*), angiotensin-converting enzyme 1 (*ANGPT1*), plasminogen (*PLG*), kininogen-1 (*KNG1*), or unknown (*UNK*) (HAE-FXII, HAE-ANGPT1, HAE-PLG, HAE-KNG1, HAE-UNK); HAE-1, hereditary angioedema due to C1-inhibitor deficiency; HAE-2, hereditary angioedema due to C1-inhibitor dysfunction.

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(A)

GALEN
Network of Excellence

HAEi

Audit Date: _____
 Audited Center: _____
 Auditor: _____
 Last audit: _____

Head of the Center: _____
 Deputy head(s): _____

Requirement	Description	Subdescription	Yes/No	Gr.
1. Professionalism or affiliation	Center needs to be a hospital or affiliated with a medical school or equivalent institution for the purpose of the accreditation process.	Center is a hospital or affiliated with a medical school or equivalent institution for the purpose of the accreditation process.	<input type="checkbox"/>	B
2. Accredited status with clear track record in accreditation processes	Center needs to have a track record in accreditation processes for the purpose of the accreditation process.	Center has a track record in accreditation processes for the purpose of the accreditation process.	<input type="checkbox"/>	A
3. Open to children and adult patients	Center needs to be able to provide care for children and adult patients.	Center provides care for children and adult patients.	<input type="checkbox"/>	B
4. Have multidisciplinary staff with specific angioedema training	Center staff needs to include multidisciplinary staff with specific angioedema training.	Center staff includes multidisciplinary staff with specific angioedema training.	<input type="checkbox"/>	A
5. Multidisciplinary approach	Center needs to have a multidisciplinary approach to the management of angioedema.	Center has a multidisciplinary approach to the management of angioedema.	<input type="checkbox"/>	B
6. Knowledge and skills	Angioedema specialists need to have a high level of knowledge and skills in the management of angioedema.	Angioedema specialists have a high level of knowledge and skills in the management of angioedema.	<input type="checkbox"/>	B
7. Communication skills	Center staff needs to have good communication skills with patients and other staff.	Center staff has good communication skills with patients and other staff.	<input type="checkbox"/>	B
8. Quality management	Center needs to have a quality management system in place.	Center has a quality management system in place.	<input type="checkbox"/>	B
9. Structural documentation	Center needs to have structural documentation in place.	Center has structural documentation in place.	<input type="checkbox"/>	B
10. Critical incidents reporting and case management	Center needs to have a system for reporting and managing critical incidents.	Center has a system for reporting and managing critical incidents.	<input type="checkbox"/>	B
11. Assessment of current practice and needs	Center needs to have a system for assessing current practice and needs.	Center has a system for assessing current practice and needs.	<input type="checkbox"/>	B
12. In-house consultation	Center needs to have a system for in-house consultation.	Center has a system for in-house consultation.	<input type="checkbox"/>	B
13. Active participation of research funding and support for educational activities and education	Center needs to have a system for active participation of research funding and support for educational activities and education.	Center has a system for active participation of research funding and support for educational activities and education.	<input type="checkbox"/>	B

Requirement	Description	Subdescription	Yes/No	Gr.
14. Support of the ACARE network	Center needs to support the ACARE network.	Center supports the ACARE network.	<input type="checkbox"/>	A
15. Research and quality standards	Center needs to have research and quality standards in place.	Center has research and quality standards in place.	<input type="checkbox"/>	B

Requirement	Description	Subdescription	Yes/No	Gr.
16. Knowledge of and adherence to international guidelines and consensus documents for angioedema	Center needs to have knowledge of and adherence to international guidelines and consensus documents for angioedema.	Center has knowledge of and adherence to international guidelines and consensus documents for angioedema.	<input type="checkbox"/>	A
17. Knowledge and use of current evidence	Center needs to have knowledge and use of current evidence in the management of angioedema.	Center has knowledge and use of current evidence in the management of angioedema.	<input type="checkbox"/>	A
18. Knowledge and use of differential diagnosis algorithm	Center needs to have knowledge and use of differential diagnosis algorithm.	Center has knowledge and use of differential diagnosis algorithm.	<input type="checkbox"/>	A
19. Structured assessment and monitoring of disease activity, impact and quality of life	Center needs to have a system for structured assessment and monitoring of disease activity, impact and quality of life.	Center has a system for structured assessment and monitoring of disease activity, impact and quality of life.	<input type="checkbox"/>	A
20. Identification of comorbidities and underlying causes	Center needs to have a system for identifying comorbidities and underlying causes.	Center has a system for identifying comorbidities and underlying causes.	<input type="checkbox"/>	A
21. Family counseling and patient therapy	Center needs to have a system for family counseling and patient therapy.	Center has a system for family counseling and patient therapy.	<input type="checkbox"/>	A
22. Knowledge and use of therapeutic algorithms	Center needs to have knowledge and use of therapeutic algorithms.	Center has knowledge and use of therapeutic algorithms.	<input type="checkbox"/>	A
23. Counseling	Center needs to have a system for counseling patients and staff.	Center has a system for counseling patients and staff.	<input type="checkbox"/>	A

Requirement	Description	Subdescription	Yes/No	Gr.
24. Research	Center needs to have a research program in place.	Center has a research program in place.	<input type="checkbox"/>	A
25. Scientific excellence	Center needs to have scientific excellence in the management of angioedema.	Center has scientific excellence in the management of angioedema.	<input type="checkbox"/>	A
26. Scientific activity	Center needs to have scientific activity in the management of angioedema.	Center has scientific activity in the management of angioedema.	<input type="checkbox"/>	A
27. Scientific productivity	Center needs to have scientific productivity in the management of angioedema.	Center has scientific productivity in the management of angioedema.	<input type="checkbox"/>	A
28. Clinical trials	Center needs to have a system for conducting clinical trials.	Center has a system for conducting clinical trials.	<input type="checkbox"/>	A
29. Participation in registries	Center needs to have a system for participating in registries.	Center has a system for participating in registries.	<input type="checkbox"/>	A

Requirement	Description	Subdescription	Yes/No	Gr.
30. Education	Center needs to have an education program in place.	Center has an education program in place.	<input type="checkbox"/>	A
31. Educational activities	Center needs to have educational activities in place.	Center has educational activities in place.	<input type="checkbox"/>	A

Requirement	Description	Subdescription	Yes/No	Gr.
32. Network activities	Center needs to have network activities in place.	Center has network activities in place.	<input type="checkbox"/>	A

Audit result: All requirements fulfilled, no areas with a need for further improvement, center should be certified
 All requirements fulfilled, some areas require further improvement, center should be certified
 Area with a need for further improvement: _____

Most requirements fulfilled, center should be certified after _____
 providing documentation that the following requirements are fulfilled: _____

no audit in _____ months

Comments: _____

GALEN Requirements of the Angioedema Center of Reference and Excellence (ACARE) are part of the GALEN Centers of Reference and Excellence (GALEN CORE) Network and are subject to the GALEN CORE accreditation process. Centers for Excellence in the management of angioedema are invited to become a member of the GALEN CORE network. For more information, please contact the GALEN CORE Secretariat at: ga2len@ga2len.com or www.ga2len.com. The international consensus on the diagnosis and management of pediatric patients with hereditary angioedema with C1 inhibitor deficiency (HAE-C1) is available at: www.ga2len.com. The international consensus on the diagnosis and management of pediatric patients with hereditary angioedema with C1 inhibitor deficiency (HAE-C1) is available at: www.ga2len.com. The international consensus on the diagnosis and management of pediatric patients with hereditary angioedema with C1 inhibitor deficiency (HAE-C1) is available at: www.ga2len.com.

FIGURE 1 A and B, Audit checklist for GA²LEN/HAEi Angioedema Center of Reference and Excellence (ACARE) certification (A) and certificate awarded to GA²LEN/HAEi ACAREs upon a successful audit (B). A, The list shows and explains the requirements for becoming a GA²LEN/HAEi ACARE and the deliverables that are reviewed during the audit process. B, The certificate is awarded for 2 y and requires successful re-audit to be extended

What are the requirements for GA²LEN/HAEi ACAREs? ACAREs are required to demonstrate excellence in the management of angioedema, research activities, efforts in education, and advocacy activity. ACAREs need to fulfill 32 requirements, which are explained in the audit checklist (Figure 1A). This checklist includes specific deliverables for each requirement. For example, the requirement to know and follow international guidelines and consensus documents for angioedema (Requirement #16) entails that physicians and other ACARE healthcare professionals have read and understood the current versions of these guidelines and consensus documents and that their recommendations are implemented in their center.

These guidelines and consensus documents include, for example, the international WAO/EAACI guideline for HAE, the EAACI/GA²LEN/EDF/WAO guideline for urticaria, the International/Canadian hereditary angioedema guideline,²⁻⁵ the international consensus on the diagnosis and management of pediatric patients with hereditary angioedema with C1 inhibitor deficiency, the international consensus on the use of genetics in the management of HAE,⁶ and the international consensus and practical guidelines on the gynecologic and obstetric management of female patients with hereditary angioedema caused by C1 inhibitor deficiency.⁷ The deliverables for this requirement are that (a) current guideline and consensus document versions are present (paper or electronic version) at the center, (b) ACARE staff can answer questions on the recommendations these documents provide, and (c) ACARE physicians can show, upon request, by use of a patient file, that patient management decisions are based on guideline recommendations (Figure 1B).

This publication marks our intent to start the implementation of the GA²LEN/HAEi ACARE initiative. Specialty centers for angioedema have started to apply to become ACAREs, and audits and certifications are ongoing (Figure 1B). We expect that most GA²LEN UCARE centers and many angioedema specialty centers will become ACAREs in the near future. We predict and hope that by 2022, GA²LEN/HAEi ACAREs will be established in every continent. This will result in a strong global network of angioedema specialists, promote angioedema research, and harmonize and improve angioedema management worldwide. GA²LEN and HAEi will measure the impact of ACAREs over time and document and report the benefits of this initiative. ACARE network activities and a current list of ACAREs are posted on the network's website (www.acare-network.com).

ACKNOWLEDGMENTS

The GA²LEN/HAEi ACARE is supported by its twin network, the GA²LEN UCARE network (www.ga2len-ucare.com). We thank Beate



Schinzel for expert help with formatting and revising the manuscript as well as its submission.

CONFLICT OF INTEREST

Dr Maurer reports grants and personal fees from Allakos, personal fees from Aralaz, grants and personal fees from AstraZeneca, grants and personal fees from BioCryst, grants from Blueprint, grants and personal fees from CSL Behring, grants and personal fees from FAES, grants and personal fees from Genentech, grants from Kalvista, grants from Lilly, grants from Menarini, grants and personal fees from Novartis, grants from Leo Pharma, grants from Moxie, grants from Pharming, personal fees from Pharvaris, grants and personal fees from Roche, from Sanofi, grants and personal fees from Shire/Takeda, grants and personal fees from UCB, grants and personal fees from Uriach, outside the submitted work. Dr Aberer reports other from Takeda, other from CSL Behring, outside the submitted work. Dr Ansotegui reports personal fees from Mundipharma, personal fees from Roxall, personal fees from Sanofi, personal fees from MSD, personal fees from Faes Farma, personal fees from Hikma, personal fees from Astra Zeneca, personal fees from Stallergens, outside the submitted work. Dr Aygören-Pürsün reports personal fees from Adverum, grants and personal fees from BioCryst, grants and personal fees from CSL Behring, grants and personal fees from Kalvista, personal fees from Pharming, grants and personal fees from Shire/Takeda, during the conduct of the study. Dr Banerji reports grants from Takeda, BioCryst, personal fees from Takeda, BioCryst, CSL, Pharming, Pharvaris, Kalvista, outside the submitted work. Dr Aberer reports other from Takeda, other from CSL Behring, outside the submitted work. Dr Bernstein reports grants and personal fees from Shire/Takeda, grants and personal fees from CSL Behring, grants and personal fees from BioCryst, grants and personal fees from Kalvista, grants from IONIS, grants and personal fees from Novartis/Genentech, grants and personal fees from Astra Zeneca, grants and personal fees from Sanofi Regeneron, from HAEA MAB, during the conduct of the study. Dr Betschel reports personal fees from CSL Behring, personal fees from Takeda/Shire, during the conduct of the study; personal fees from Octapharma, grants from Green Cross, personal fees from Novartis, personal fees from CADTH, outside the submitted work; and Chair of the Canadian Hereditary Angioedema Network. Dr Bork reports personal fees from CSL, personal fees from Shire, outside the submitted work. Dr Busse reports personal fees from CSL Behring, grants and personal fees from Shire, personal fees from Pharming, personal fees from Pearl Therapeutics, personal fees from BioCryst, personal fees from CVS Health, personal fees from Novartis, personal fees from Law offices of Levin, Riback, Adelman and Flangel, outside the submitted work. Dr Bygum reports grants and other from CSL Behring, grants and other from Shire/TAKEDA, other from ViroPharma, from HAE Scandinavia, outside the submitted work. Dr Caballero reports personal fees and other from BioCryst, personal fees, non-financial support and other from CSL-Behring, personal fees from Merck, personal fees and other from Novartis, personal fees from Octapharma, personal fees, non-financial support and

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study. Dr Schmid-Grendelmeier reports personal fees from Takeda, during the conduct of the study. Dr Serpa reports speaker fees from Shire/Takeda, Novartis and Sanofi. Dr Sheikh reports other from Takeda, from CSL, outside the submitted work. Dr Smith reports personal fees from Takeda/Shire, personal fees from CSL/Behring, grants from Takeda/Shire, grants from BioCryst, outside the submitted work. Dr Soria reports personal fees from Novartis, personal fees from Sanofi Genzyme, personal fees from Abbvie, outside the submitted work. Dr Staubach reports personal fees and non-financial support from Takeda, personal fees and non-financial support from Shire, personal fees and non-financial support from Pharming, personal fees and non-financial support from CSL Behring, personal fees and non-financial support from Novartis, outside the submitted work. Dr Stobiecki reports personal fees from lectures given for CSL Behring, Takeda (Shire), personal fees from conducting clinical trials as a principal investigator for BioCryst, personal fees from consultant work for: BioCryst, CSL Behring, Takeda (Shire), Pharming, outside the submitted work. Dr Sussman reports grants and personal fees from Research grants from pharmaceutical companies. Novartis, Genentech, Amgen, Sanofi, CSL behring, Leo, Kedrion, Green Cross, DBV, Aimune. D'dConsulting and honoraria from Novartis, Novo, CSL Behring, Amgen., during the conduct of the study; grants from Novartis Pharmaceutical, grants from Genentech, grants from CSL behring, grants from Amgen, grants from Leo, grants from DBV, grants from Aimune, grants from Sanofi, non-financial support from Novartis, non-financial support from Novo, non-financial support from Pediapharm, non-financial support from Sanofi, grants from Kedrion, outside the submitted work. Dr Thomsen reports grants and personal fees from Novartis, grants and personal fees from Sanofi, grants and personal fees from UCB, grants and personal fees from Janssen, grants and personal fees from Abbvie, outside the submitted work. Dr Treudler reports personal fees from Shire-Takeda, personal fees from ALK-Abello, personal fees from Novartis, grants and personal fees from Sanofi-Genzyme, grants from Hautnetz Leipzig e.V., other from Fraunhofer Institut, outside the submitted work. Dr van Doorn reports personal fees from Leopharma, grants and personal fees from Novartis, personal fees from Abbvie, personal fees from BMS, personal fees from Celgene, personal fees from Lilly, personal fees from MSD, personal fees from Pfizer, personal fees from Sanofi-Genzyme, personal fees from Janssen Cilag, outside the submitted work. Dr Weber-Chrysochoou reports personal fees from Takeda and CSL Behring, outside the submitted work. Dr Zuberbier reports personal fees from AstraZeneca, personal fees from AbbVie, personal fees from ALK, personal fees from Almirall, personal fees from Astellas, personal fees from Bayer Health Care, personal fees from Bencard, personal fees from Berlin Chemie, personal fees from FAES, personal fees from HAL, personal fees from Leti, personal fees from Meda, personal fees from Menarini, personal fees from Merck, personal fees from MSD, grants and personal fees from Novartis, personal fees from Pfizer, personal fees from Sanofi, personal fees from Stallergenes, personal fees from Takeda, personal fees from Teva, personal fees from UCB, grants from Henkel, personal fees from

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.