

Original article

Establishing a standardized quality management system for the European Health Network GA²LEN*

Background: Quality management is increasingly important in clinical practice. The Global Allergy and Asthma European Network (GA²LEN) is a network of clinical and scientific excellence with originally 25 allergy centres in 16 European countries, a scientific society (European Academy of Allergology and Clinical Immunology), and a patient organization (European Federation of Allergy and Airways Diseases Patients' Associations). Although some allergy centres adhere to internal quality criteria, the implementation of a standardized quality management system for allergy centres across Europe was lacking.

Objectives: To implement standardized quality criteria among allergy centres organized within GA²LEN and thus ensure equal standards of diagnosis and care as well as to establish a culture of continuous quality improvement.

Methods: Quality criteria covering, e.g., diagnostic and therapeutic procedures, and emergency preparedness to assure patient safety were developed and agreed upon by all 25 participating centres. To assure implementation of quality criteria, centres were audited to check quality indicators and document deviations. A follow-up survey was used to assess the usefulness of the project.

Results: Deviations were documented mainly in the areas of emergency care/patient safety (27.3% lacked regular emergency training of doctors and nurses; 22.7% inadequate emergency intervention equipment; 22.7% lacked critical incidence reporting/root cause analyses) and handling of extracts/pharmaceuticals (31.8% lacked temperature logs of fridges; 4.5% inadequate check of expiration dates). Quality improvement was initiated as shown by findings of re-audits. Usefulness of the project was rated high.

Conclusion: The establishment of a quality management system with joint standards of care and harmonized procedures can be achieved in an international health network and ensures quality of care.

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The Global Allergy and Asthma European Network (GA²LEN) is a consortium of initially 25 leading allergy centres from 16 European countries with high clinical and scientific competence (now 31 partners and more than 50 collaborating centres) providing an ideal platform for educational activities and international collaboration. Additionally, the European Academy of Allergology and Clinical Immunology (EAACI) and the European Federation of Allergy and Airways Diseases Patients'

Associations (EFA) are partners of the EU-sponsored network GA²LEN. The overall objective of GA²LEN is to establish an internationally competitive network of excellence (NoE) to enhance the quality of research, address all aspects of allergic disease and, eventually, to decrease the burden of allergy and asthma throughout Europe. Quality management is one of the most important cross-sectional topics to improve integration of the partners within the network. The aim of the work package was to install a quality management system supervising both the work of the NoE and the quality of clinical care for allergies at the institutions of partners and collaborating centres.

In the light of a more integrated European health care system, standardization of care becomes more and more

Abbreviations: EAACI, European Academy of Allergology and Clinical Immunology; EFA, European Federation of Allergy and Airways Diseases Patients' Associations; ExCom, Executive committee; GA²LEN, Global Allergy and Asthma European Network; NoE, Network of excellence.

important. This has led to numerous guidelines dealing with therapy of common conditions e.g., asthma (1). Furthermore, in some instances, guidelines with respect to diagnostic approaches to some pathologies like aspirin hypersensitivity exist (2). Criteria to ensure certain standards of care have been established in organ-specific cancer centres (3) or for general certification of medical facilities. In the area of allergy care, however, there has been no overarching quality management system with a set of quality criteria. The measurement and comparison of the quality of care has shown to be helpful in improving health services (4). The establishment of quality indicators as measurement instrument can be used for benchmarking with a subsequent exchange of best practices from the leading centres to the ones lagging behind (4, 5). To measure performance quality indicators have to be valid and reflect the most relevant dimensions of health care (6). In some countries, e.g. Germany, quality reports are required by law and aim to provide more transparency thereby catalyzing quality improvements in health care (7). The Netherlands, in example, has used a national performance indicator framework to improve the performance of its health system in the form of the balanced score card. These cards monitor data on relevant indicators and have also been used as a management tool to measure whether an organization's goals are being achieved (8). Choosing indicators is a complex task, which has to balance the extra resources required for measuring these indicators with the usefulness of the collected data (9). Some simple indicators have been used successfully like e.g., the time until start of antibiotics in pneumonia patients or the use of beta-blockers after myocardial infarction (10). Allergic diseases often are very complex, and simple indicators are scarce. Additionally, in our context special attention to the different working environments and different health systems in the various countries had to be paid when discussing indicators like time to consultation in case of new allergic symptoms.

The main objective of the present project was to establish an international quality management system for clinical allergy centres, secondary aims were to create standardized quality criteria to be used for implementation in a network of allergy centres for improving and harmonizing the standards and quality of care.

Methods

Cooperating centres

Twenty-two allergy centres in 16 European countries participated in the quality management project (see Acknowledgment). The intention to install the quality management system established within the GA²LEN network was expressed by all 25 centres. However, because of different reasons like e.g., internal organizational re-structuring, three centres felt unable to implement a quality management system at the time.

Tools for assessing current quality standards and demand

To capture the current standard of quality management within the network, structured interviews were conducted by the coordinating centre with five centres and questionnaires gathered from another four centres. Assessment included 15 questions on the structure of the centre (type of departments present, pathologies treated, size), the current status of the quality management at the centres (quality management system established, audits conducted, certification achieved), as well as expectations towards the GA²LEN quality management system. Specifically, interviews inquired about the type of quality management system in use, the use of standard operating procedures as well as treatment pathways, the existence of a system on capturing improvement ideas or other quality improvement projects, the practice of assessing clinical outcomes, e.g., based on performance indicators, the assessment of patient satisfaction and employee satisfaction.

Establishment of quality criteria

To compile quality criteria, the following topics were rated as important: patient safety, evidence-based diagnostic/treatment, training of health workers. Accessibility of the health services was not included as improvement of this dimension was beside the influence of the centres. Disease-specific indicators were also excluded because centres had a different range of treated pathologies, and disease-specific assessment can be addressed by individual centres within clinical studies. A first draft of specific quality criteria was compiled by the quality management initiative and reviewed by an external expert. These standardized quality management criteria were circulated to all GA²LEN centres and feed-back requested. A second draft incorporating all feed-back was written and presented to the GA²LEN executive committee (ExCom). After ExCom approval, quality criteria were re-circulated to, and then approved by all GA²LEN centres. This process was repeated twice: once for basic quality criteria reflecting a basic standard of care that all allergy centres were asked to fulfill (level 1), and once for advanced quality criteria that selected centres could apply for reflecting an advanced spectrum of both clinical care and research (level 2, for detailed quality criteria see *Results* section).

Audits and audit reports

Prior to the initiation of the audits an expert in the field critically assessed and approved the predefined audit procedures for each of the defined quality criteria. Audits took place at the sites and included discussion with the team leader/consultant in the clinic (1–2 h), discussion with a nurse and visit to the allergy test facilities (30 min) and discussion with registrars and visit to the emergency intervention room (20 min). Audits were performed by members of the quality management work package with a specific training in quality management in health care. Each quality criterion was discussed, checked and deviations documented. Audit reports to document all findings, state deviations and include recommendations on potential improvements were written and sent to the respective centre as well as the GA²LEN head office.

Follow-up survey

A standardized five question survey was sent to all centres 3 years after the introduction of the quality criteria and the implementation of the quality management system. Answers were collected and assessed by the work package leader.

Results

Current quality standards and demand for quality management at GA²LEN centres

Interviews showed a wide spectrum of quality management status at the different centres with some having a quality management department with own projects and budget, e.g., Amsterdam, and others that have just started implementing quality management. Overall, only two centres had a formal quality management system at the beginning of the project whereas quality improvement projects on specific topics were implemented at all centres. Expectations were uniformly directed towards the:

- Exchange of expertise across Europe, i.e. that a reference centre could provide information on certain quality management subjects or direct questions to the respective expert and the
- Harmonization of procedures across Europe to make research and clinical results more comparable.

Specifically, centres wanted practical support to improve one's own services, e.g., by access to a 'reference centre'. Comparison with other centres and benchmarking was desired. Standardization of diagnosis and therapy was a key aim. Respondents objected to quality management measures that involved extra documentation efforts.

Establishment of quality criteria

Basic quality criteria were developed for the clinical centres to improve patient safety and to set quality standards for diagnostic and therapeutic procedures. Quality criteria cover fields like practice of evidence-based medicine and use of guidelines, training of staff, good clinical practice procedures, emergency intervention and error management (see Table 1). Furthermore, for selected centres advanced quality criteria were outlined (quality criteria level 2; see Table 2) reflecting a focus on translation of scientific findings, continuous updating of the knowledge of staff and patient satisfaction. Furthermore, quality indicators and audit procedures for all respective quality criteria were defined.

Altogether, 25 clinical centres in 16 European countries agreed on joint criteria with a focus on evidence-based medicine and patient safety to serve as standard for the GA²LEN network.

Implementation and auditing

To check whether the joint quality criteria were fulfilled, audits were conducted and quality indicators checked. Findings were documented in audit reports. In total, 22 centres were audited. The mean number of deviations was 1.4 deviations per centre. The areas that were mostly concerned were emergency preparedness (27.3%

of centres), in example the regular training of nurses and doctors in emergency intervention (see Table 3). Furthermore, emergency equipment was incomplete or not readily available in five out of 22 centres (22.7%). Storage and handling of extracts and pharmaceuticals were not performed correctly with missing temperature logs on fridges (31.8% of centres) and insufficient controls of expiration dates of medication and extracts (4.5%, see Table 3). Critical incidence reporting and root cause analyses, a measure to ensure patient safety, were not established according to the quality criteria in five out of 22 centres (22.7%). All audit reports contained recommendations for changes to comply with the standards.

Inputs from centres with own quality initiatives, e.g., structured training program for registrars in Athens, Greece or electronic drug check in Coimbra, Portugal, were documented for further reference for other centres (overview in Table 4). One of the key diagnostic tests in allergy was harmonized to introduce a Pan-European skin prick test to generate comparable data and ensuring surveillance of sensitization (11).

Results of the follow-up survey

To evaluate the usefulness of the implementation of this quality management system, a survey was conducted among the team leaders of the 22 centres. In the survey, the project was rated as very useful. The certification process was found to be useful or very useful by 19 out of 22 centres (86%; see Fig. 1A). Even the audits which are known to take up time and be cumbersome were seen as useful or very useful by 19 out of 22 centres (see Fig. 1B). With regard to motivation of staff, the project was still assessed as useful but not to such a large extent. Here, 14 out of 22 rated it to be useful or very useful (64%) while seven found it only slightly useful and one not really useful (see Fig. 1C). Even though the management system aimed to improve patient care and patient safety, we also included managerial questions. Regarding the usefulness for internal and external communication, the picture was mixed. It was stated to be useful or very useful by 13 and 11 centres for internal and external communication, respectively. Another six and seven centres found the quality management system slightly useful for internal and external communication (see Fig. 1D,E).

Discussion

This is the first report on an international quality management system for clinical allergy centres and demonstrates that the implementation of standardized quality criteria for a health network is essential and helps to improve as well as harmonize the standard of care. At the start of the project no joint quality management

Table 1. Quality criteria level 1

No.	Criteria	Explanation	Performance indicator	Audit	Details
1	Practice of official guidelines (e.g., WHO, EAACI)	Diagnosis and treatment should be based on evidence and consented guidelines	Guidelines exist for two relevant diseases	Check existence of guidelines or references	Ask three doctors for use of guidelines at the centre and let them give the reference
2	Compliance with guidelines/clinical pathways for two relevant diseases	Diagnosis and treatment should be based on evidence and consented guidelines	More than 80% of patients diagnosed/treated in compliance with guideline/pathway for e.g., allergic rhinitis, asthma, urticaria ≥6 Sessions/year	Check general compliance with guidelines/pathways	Take sample of 10 patients with specified disease and check compliance with guideline/pathway
3	Basic allergy training of doctors	Continuous medical education ensures standard of care	≥3 Sessions/year	Check training schedule	
4	Basic allergy training of nurses	Continuous medical education ensures standard of care	≥1 Sessions/year	Check training schedule	
5	Emergency intervention training of doctors and nurses	Repeating emergency interventions keeps knowledge up to date			
6	Critical incidence reporting/root cause analysis	Critical incidents (e.g., anaphylactic reactions, application of wrong medication/allergen extract or wrong dose) are reported, discussed, and the causes are analyzed. Actions to avoid future incidents are taken if necessary	Incidence report book documenting all incidents for internal and anonymous follow-up. Includes description and analysis of incidents and actions that have been taken for the future	Check report book and implementation of one of the actions	
7	Appointed internal responsible for quality issues (quality manager)	Contact person for quality matters and coordination of quality initiatives	Name of quality manager	Contact quality manager	
8	Practice of first expired first out (FEFO)	Storage and use of medication and extracts as to minimize expiration of drugs/extracts	Yes, practiced	Check how fridges are filled	Let responsible nurse explain how fridges are filled
9	Controls of expiration dates of all extracts and medication used	Control to ensure quality of drugs/extracts	One check per month	Check last control of expiration dates	Ask for last expiration date check and let nurse explain how it is performed
10	Temperature logs for all fridges	Control to ensure quality of drugs/extracts	Daily check (manual or electronic alarm) Daily check	Check temperature logs	
11	Availability of equipment for emergency intervention	Control to ensure effective emergency intervention if needed	Daily check	Check equipment for emergency intervention	Ask for last check of emergency equipment and let nurse explain how it is performed

EAACI, European Academy of Allergy and Clinical Immunology.

Table 2. Quality criteria level 2

No.	Criteria	Explanation	Performance indicator	Audit
1	Practice of guidelines (e.g., WHO, ARIA, Gina)	Diagnosis and treatment should be based on evidence and consented guidelines	Guidelines used for all treated diseases if available	List of guidelines in use
2	Full spectrum of allergology available	Coverage of all disease aspects including systemic allergic disease (anaphylaxis, food allergy, drug allergy)	Medical care for dermatological, pediatric and lung diseases	Check structure of centre
3	Quality control of diagnosis/treatment (patient record review)	Retrospective quality checks ensure elimination of errors	10 patient records reviewed per month by head of department or senior staff member	Check list of reviewed files
4	Quality of documentation in patient records	Notes in patient records with date and abbreviation of doctor/nurse who has documented	More than 90% of notes are dated and carry name of care provider	Check 20 randomly selected patient records for quality of documentation
5	Written protocols and manuals for testing and other procedures (standard operating procedures)	Protocols exist (can also be as reference to an article or a standard book) and employees are aware of them to ensure standardization of procedures	Protocols for skin prick test, skin patch test, intracutaneous testing, lung function, nasal provocation, application of immunotherapy, food and drug provocation test	Check existence of protocols and manuals
6	Excellence knowledge of allergology by team leaders	Maximum knowledge of team leaders ensures setting right guidelines and principles for medical care	Collegial interview with structured interview guidelines by telephone with other team leader on allergologic cases. Assignment of random interviewer by GA ² LEN office.	Check last interview and name of interviewer
7	Structured curriculum for allergology training	Structured training (including theoretical and practical knowledge and skills) of registrars/junior doctors ensures standard of training	Structured curriculum, e.g., UEMS curriculum for allergology or national curricula	Check whether curriculum is in use
8	Allergology knowledge of doctors	Up-to-date knowledge of doctors ensures complying with right guidelines and principles of medical care	Six internet-based questions for doctors to be answered once per year	Check results of survey
9	Basic allergology training of nurses	Continuous medical education ensures standard of care	≥4 Sessions/year	Check training schedule
10	Allergology knowledge of nurses	Up-to-date knowledge of nurses ensures complying with right guidelines and principles of medical care	Four internet-based questions for nurses to be answered once per year	Check results of survey
11	Emergency intervention training of doctors and nurses	Repeating emergency interventions keeps knowledge up to date	Participation in one emergency situation per year (training session or while on duty)	Check training documentation/documentation of ICU work or equivalent
12	Training of doctors for diagnostic and therapeutic guidelines	Continuous medical education ensures standard of care	1 Session/year	Check topics of the session
13	Communication skills in English language	Health care for European citizens not speaking native language ensured by availability of English speaking nurse and doctor on demand	Possibility to ask questions in English	Check names
14	Critical assessment of scientific literature	High quality care is ensured by continuous education with peer reviewed articles	Assessment of one centrally provided NonEuropean article (in cooperation with Cochrane) by all researchers	Check responses to article
15	Academic research	Participation in research ensures growth of body of knowledge and critical evaluation of results	At least 0.5 articles per year in a peer reviewed journal per researcher per year	Check publication list
16	Claim management	Continuous evaluation of claims and actions taken consequently ensure quality improvement in service delivery	Number of claims and number of actions taken	Check claim documentation
17	Patient interviews for evaluation of facility	Feed-back from patients on quality of care (including access, safe services, confidentiality, informed choice, comfort, continuity of care up) and subsequent changes ensure service improvements	40 patients interviewed in last 12 months (possibly by questionnaire)	Check actions taken as result of interviews

GA²LEN, Global Asthma and Allergy European Network.

system was employed by the 25 international centres, and only two centres had a formalized quality management system. Within the project joint quality criteria were

established among all allergy centres of the GA²LEN network. Twenty-two centres in 16 countries implemented these quality criteria, were audited and certified

Table 3. Deviations from quality criteria

No.	Criteria	No. of centres that showed deviation (<i>n</i> = 22)	Percentage of centres that showed deviation (%)
1	Practice of official guidelines (e.g., WHO, EAACI)	1	4.5
2	Compliance with guidelines/clinical pathways for two relevant diseases	0	0.0
3	Basic allergology training of doctors	0	0.0
4	Basic allergology training of nurses	2	9.1
5	Emergency intervention training of doctors and nurses	6	27.3
6	Critical incidence reporting/root cause analysis	5	22.7
7	Appointed internal responsible for quality issues (quality manager)	0	0.0
8	Practice of first expired first out (FEFO)	0	0.0
9	Controls of expiration dates of all extracts and medication used	1	4.5
10	Temperature logs for all fridges	7	31.8
11	Availability of equipment for emergency intervention	5	22.7
		1.4	6.5

EAACI, European Academy of Allergology and Clinical Immunology. Mean values are in bold.

according to the international GA²LEN quality management system. Main deviations were in the field of emergency preparedness and in handling of extracts and pharmaceuticals. The usefulness of this process was rated high in a follow-up survey.

An initial assessment of the status of quality management showed that centres lacked a common quality management system and wanted an exchange of expertise across Europe and a harmonization of procedures. Concerns from the team leaders in the GA²LEN network were that more bureaucracy could be created by the quality management system. This is in line with a previous study from Switzerland that documented that excessive administration was seen as a limiting factor for achieving good quality of care (12). While in the Swiss study, changes in the organization of the health care facility were not seen as a means to improve care – here only individual caregivers' expertise was rated as relevant – our interviewees were convinced that organizational changes could provide quality improvements. These differences might be because of the fact that we spoke mostly with department heads whereas Hudelson et al. (12) interviewed doctors and nurses.

It has been an ongoing debate, which approach most likely improves medical care: the organizational approach with quality management, assessment and accountability, or the approach centred around the care

Table 4. Overview of quality initiatives at GA²LEN centres

Topic	Project
Quality management system	ISO 9000 certification of hospital/department
System on capturing improvement ideas	Box to collect ideas, regular discussion with prioritization of ideas, actions and follow-up Personal meetings once a month to collect ideas and determine actions
Quality improvement projects	Improvement projects of organizational matters, i. e. how to organize the way the patient takes, how new visits are booked, how waiting times can be minimized
Patient satisfaction	Improvement of communication among doctors Survey conducted by the hospital as a whole via questionnaires and a box to place answers
Employee satisfaction	Patient interviews, e.g., by clinical studies group Individual meetings with employees where mutual feed-back is given every 6 months to 1 year Regular discussions with groups of employees regarding their satisfaction
Diagnostic standards	Pan-European skin prick test to generate comparable data and ensuring surveillance of sensitization (11)
Clinical outcome assessment	Assessment of clinical outcomes in the context of clinical studies Evaluation of clinical outcome in asthma at 4 centres in which asthma scores before and after treatment were assessed Patient record review for certain diagnoses Patient record review for the cases of new fellows Systematic process of reviewing all patient records in a team setting
Treatment pathways/Standard operating procedures	International guidelines (WHO, ARIA, GINA) Internal guidelines (departmental, institutional) Standard operating procedures (mainly for diagnostic procedures) Clinical pathways for certain diagnosis e.g., atopic dermatitis
Safety of drug application	Electronic drug check through specific software: drugs can only be prescribed from central hospital pharmacy upon check of patient allergies, interactions with already prescribed drugs, creatinine levels if applicable and dosage depending on size/weight
Training	Regular scheduled training sessions/lectures Patient record reviews used as training tool especially for new fellows Structured allergology training across Europe in cooperation with the European Union of Medical Specialists (http://www.uems.net)

GA²LEN, Global Asthma and Allergy European Network.

providers with a focus on evidence-based medicine, clinical practice guidelines and professional development (13). In the present study, we tried to tie these approaches together by integrating quality criteria of both approaches. Other quality systems use regulatory power (14), monetary incentives/punishment (15), or the publication of quality reports (16) to foster implementation of quality standards whereas this project had to rely on voluntary participation. Thus, the establishment

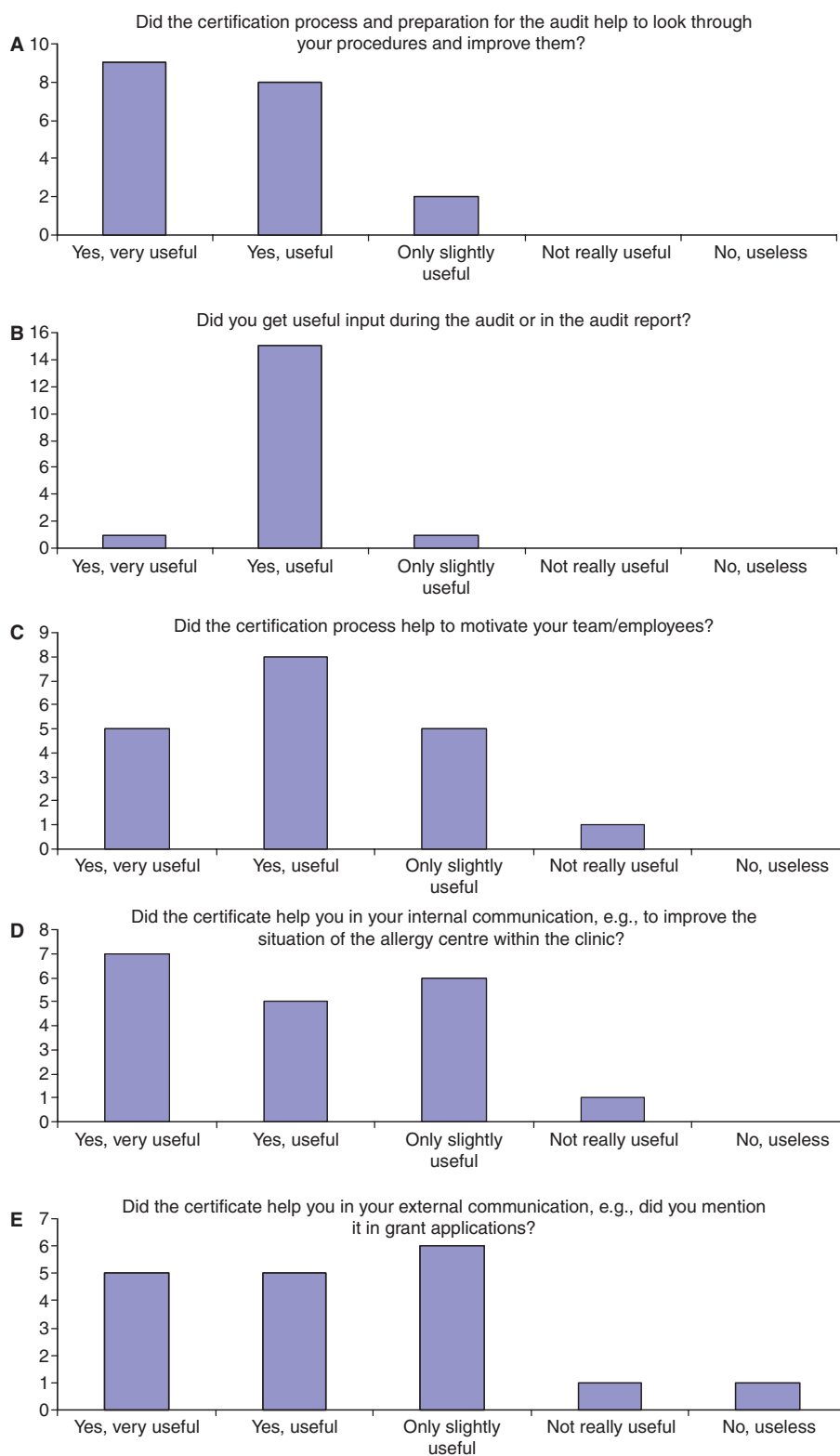


Figure 1. Evaluation of usefulness of quality management system. Absolute number of respondents are given ($n = 22$).

of quality management within the health network described here had to be a consent process. The main topics for quality criteria were agreed on in a partici-

pative process, which created a certain buy-in and engagement of the participating centres. Campbell et al. (6) report on methods to develop quality indicators and

state that acceptability is an a priori characteristic. Also, according to McGlynn (17), quality criteria should not impose undue burden on those providing data, help providers to improve care delivery and balance the need for continuous improvement with the stability of ongoing care. In our project, quality criteria included topics like e.g., training, use of guidelines, emergency preparedness and critical incidence reporting. These were included as they were considered crucial for patient safety (e.g., emergency preparedness and critical incidence reporting) and for harmonization of care (e.g., training, use of guidelines). While previous reports from other groups provide a sound theoretical basis, our study shows that the approach we took was acceptable and useful. Twenty-two out of 25 centres were certified and rated the implementation of the quality management system as useful or very useful.

Once quality criteria have been defined, audit and feedback have been shown as an effective means to improve professional practice (18, 19). However, in our experience audits at the centres were at first viewed very critical. These observations are in accordance with findings from the US where peer review organizations had to overcome their previous role as being adversarial and punitive (20). Reporting data back to facilities has to take into consideration various factors to contribute to improving performance (21). We took these into account to initiate quality improvement by constructive yet stringent audits, feed-back in the form of audit reports and the sharing of best practices. This follows the emphasis on continuous quality improvement that has been called for to improve quality of care (22) and proven useful in randomized trials (23, 24).

After implementation of the quality management criteria, team leaders stressed, the project was useful or very useful for the teams as shown in the subsequent survey. Centres stated that it was helpful to review their processes of care. Similarly, audits and the subsequent input through audit reports were rated as a useful tool to improve standard of care among the participating centres. Furthermore, preliminary data gathered in re-audits also indicate that improvement of the compliance with the quality criteria was achieved as the number of deviations was reduced (data not shown). This is in accordance with previous reports on quality improvement induced by quality programs (25). To objectively assess quality of care, the comparison of performance indicators is the gold standard. Harmonization of procedures is important to comparably assess performance indicators (26). The measurement of performance indicators has been especially useful in indications with very clear management guidelines and easily measurable indicators like diabetes (27), myocardial infarction (28), stroke (29, 30) or pneumonia (31).

In allergic diseases, the assessment of the quality of care is far more complex as a large part of care is guidance and consultancy (e.g., food allergy, drug reactions), and courses of disease are very diverse (e.g., allergic rhinitis, atopic dermatitis, anaphylaxis). Thus, objective performance indicators are harder to establish. Nonetheless, clear and reproducible performance indicators were defined during the current study ensuring an unbiased evaluation of procedures and outcomes. A prerequisite for gathering data is furthermore the standardization of assessment of disease. The harmonization of procedures among the European allergy centres is thus an essential achievement on the way to measuring quality of care in general or the impact of specific interventions by measuring performance indicators.

In summary, this project of the GA²LEN network for allergy and asthma contributed to the harmonization of the standard of care, improvement of patient safety and was seen as useful for internal quality improvements. It is the first study to show that establishment of joint quality criteria in an international health network is feasible and useful.

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