

INTRODUCTION TO EAACI CERTIFIED CLINICAL CENTRE (ECCC) ON DRUG ALLERGY

EAACI aims to improve quality of health care, research and education in allergy and clinical immunology. Targeting this aim, as one of its activities, EAACI intends to establish “**EAACI Quality Centres**”. Different type of centres including “Centre of Excellence” (ECE), EAACI Advanced Research Centre (EARC); and EAACI Certified Clinical Centre (plus Research) in certain fields of Allergy and Immunology.

EAACI Certified Clinical Centre (ECCC) defines the centres that fulfill the essential standards for delivering high-quality patient care in a specific area of Allergy and Immunology. As one level up category; **EAACI Certified Clinical and Research Centre (ECCRC)** defines the centres meeting both clinical standards but also some advanced standards particularly in research in that specific area. These centres are considered as conducting impactful research on that specific area.

EAACI guarantees that all processes related to Quality Centres will be managed under quality standards by covering planning, doing, checking and revising parts. This instruction provides information about the process AND standards for application for **EAACI Certified Clinical Centre** and **EAACI Certified Clinical and Research Centres**. All standards were prepared based on this quality approaches. Two different types of standards are being asked:

Essential (Basic) standards: All programs ask for the existence of specific standards based on recommendations on current guidelines and task force reports/position papers. The applicant centres should fulfill all essential standards. The rationale behind essential standards is to certify the centres who provide standardized and evidence-based care in that specific area.

Area for Improvement: These standards are not necessarily covered in the first application, but the centres will also be asked about their studies on providing the standards for “area for improvement” in the third-year evaluation. If the centres agree to apply for recertification after 5 years later, then they should fulfill both basic requirements and areas for improvement. The rationale behind “Area for Improvement” is to increase the extent and impact of the activities as well as scientific and educational collaboration and network of the centre throughout Europe.

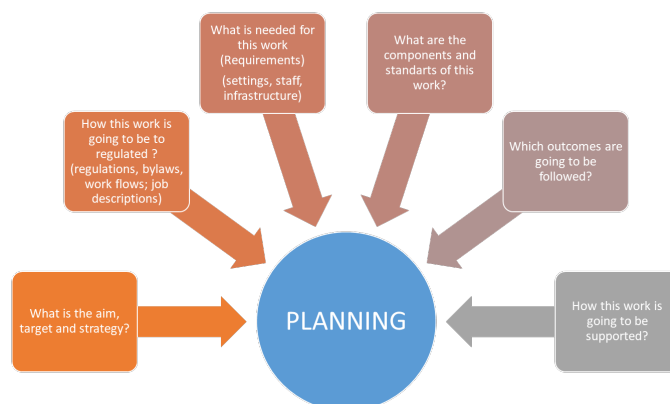
Please read the standards and check whether your centre fulfills all the basic requirements. If you fulfill the basic criteria, we kindly ask you to prepare a report on how you provide the basic standards and attach the evidence related to these standards in digital format (please see the specific checklist for further details), fill in the application form and submit your application electronically to the Quality Committee.

EAACI is aware of the diversity in regulations across countries, which may lead to a limitation for covering some of the basic standards. So, if any of the standards are not covered due to local regulations or data protection policy, please first contact the Quality Committee to evaluate the eligibility of your application.

Contact information: info@eaaci.org

We as the EAACI family are very happy to introduce this great initiative which will increase the impact of patient care, and research as well as our collaborations and network throughout Europe.

QUALITY STANDARD 1: PLANNING



1.1.AIM AND STRATEGY

1. The centre should have an aim, vision and mission for drug allergy diagnosis, and management
2. The centre should have a strategy/strategic plan compatible with this aim/vision and mission for drug allergy diagnosis, and management

EVIDENCES FOR BASIC STANDARDS

1. The statement of the centre about their aim, mission and vision
2. Strategic plan of the centre for drug allergy diagnosis, and management

1.2 REGULATIONS

1. The centre should have relevant bylaws, instructions and Standard Operation Procedures (SOP) related to management of drug allergy
2. Job descriptions should be available for each physician and staff working in the centre for the management of drug allergy
3. The centre should follow national or international drug allergy guidelines, position papers and practice parameters of EAACI
4. The centre should have the definition of the works and related workflows based on these sources

EVIDENCES FOR BASIC STANDARDS

1. Relevant instructions, SOP
2. Descriptions of works and workflows
3. Job descriptions of the staff working in the outpatient clinic
4. Statement of the centre about their sources (which guidelines or other sources are used)
5. Algorithms related to management of drug allergy

AREA FOR IMPROVEMENT

1. The centre should have an active quality management protocol including planning, doing, reviewing and revising the works of the outpatient clinic. This circle should be done on a regular basis

1.3. PATIENT CARE

1.3.1. Faculty and Staff

1. At least two of the members of the centre should have EAACI membership.
2. The centre should have at least two allergy&immunology specialists (adult and/or pediatric) with evidence of expertise* in drug allergy diagnosis/management.
3. It would be advisable to have one nurse for Drug Allergy diagnostic and eventually desensitization procedures.
4. The centres should have a “multidisciplinary approach” to the patient with relevant specialists (Anesthesiology, Pharmacology, ENT etc). When needed, the patients should be evaluated by this team and discussed for appropriate testing with the referring Specialist.

**Drug Allergy experts:: All experts should have documented professional activity in management of drug allergy for ≥ 5 years. Manuscripts and/or congress abstracts or authorship in guidelines, in review articles, position papers, members of working groups of drug hypersensitivity of national/international societies are valid as proof of expertise. The expert will be evaluated based on publications/abstracts and participation in drug allergy related working groups in international or national societies in the past 5 years following this scoring system : 2 points for participating in guidelines, 1-4 points for publications, 1-2 for abstracts, 2 points for participating in drug allergy related working groups in international or national societies. The experts need to obtain at least 5 points in evaluation.*

EVIDENCE FOR BASIC STANDARDS

1. Lists of the physicians, assigned physicians; nurses and technicians working in the Drug Allergy Outpatient Clinic, provided by the Hospital Administration or Local Departmental Leadership
2. CV of the experts (certificates of the allergy & immunology specialist, list of publications, talks, projects courses and/or training in general and related to drug allergy). A statement should also be included about providing the criteria for being considered as an expert in the field
3. Workflow and documents (reports, consultation notes etc) related to multidisciplinary approaches
4. List of the physicians in multidisciplinary team
5. Patient's notes (when available) or meeting reports showing the multidisciplinary approach

AREA FOR IMPROVEMENT

1. **Ongoing Staff Training:** Ensure that all staff regularly participate in training on updated drug allergy management protocols, new treatment approaches, and technological advancements
2. **Dedicated Drug Allergy Care Coordinator:** Appointment of a "Drug allergy care coordinator" to oversee patient follow-ups, manage comorbidities, and organize multidisciplinary approaches effectively
3. **Enhanced Proof of Expertise:** Ensure drug allergy specialists actively participate in national and international conferences, with regular documentation of their contributions
4. There should be at least one Pharmacist or technician assigned for Drug Allergy diagnostic and desensitization procedures for those drugs requiring dilution under safe conditions (e.g. chemotherapy, biologics)

1.3.2. Settings and infrastructure

1. There should be a drug allergy outpatient clinic working for at least one year AND with a minimum frequency of once a week and a day-hospital
2. Hospital administration or Local Departmental Leadership should approve this outpatient clinic officially

3. There should be a dedicated setting with emergency equipment necessary for drug tests and desensitization in the outpatient clinic/day hospital, with access to the ICU
4. The centre should have necessary diagnostic tools for drug allergy including skin prick test and intradermal tests with drugs, patch test with drugs, drug provocation, and desensitization with a dedicated room having a chemical hood for drug preparation, when needed (or a centralized procedure involving the hospital pharmacy)
5. The information on clinical history and physical examination as well as drug tests performed and desensitization should exist in case files

EVIDENCES FOR BASIC STANDARDS

1. An official document provided by the hospital administration or local departmental leadership on the existence of the Drug Allergy Outpatient Clinic, location of the clinic and staff list and support statement for application
2. List of the equipment available in the outpatient clinic
3. Pictures from the outpatient clinic
4. Documentation of the facilities of the clinic (skin prick test, intradermal tests, patch test, drug provocation test, advanced tests when available, statement and pictures of the laboratories)
5. Drug provocation and skin test forms
6. Drug desensitization form

AREA FOR IMPROVEMENT

1. There should be a standardized form to evaluate the patients. The form should include detailed drug allergy, test results, follow up of the patients in addition to general allergy work up
2. Risk evaluation and stratification should be assessed

1.4. PATIENT CENTERED APPROACH

1. A patients' centered approach should be followed up in the centre. The patients should be a part of the decision on management strategy related to themselves

EVIDENCES FOR BASIC STANDARDS

1. The statement of the centre of their policy on patient centered approach with examples

AREA FOR IMPROVEMENT

1. Organize regular feedback sessions to actively involve patients in shared decision-making regarding their treatment and management
2. Develop structured systems to collect and analyze patient feedback
3. Act on patient feedback, implement necessary improvements, and communicate these enhancements to the patients
4. Implement patient support networks and direct them to community-based resources for additional assistance and self-management strategies

1.5. IMPACT ON PUBLIC HEALTH AND HEALTH ADVOCACY

1. The centre should have released information to the public on drug allergy

EVIDENCE FOR BASIC STANDARD

1. Public releases on drug allergy of the centre (tv talks, newspapers, radio talks, social media posts, web page posts, leaflets)

AREA FOR IMPROVEMENT

1. The centre is encouraged to have an active webpage. In the clinical department webpage, the existence of the drug allergy clinic should be highlighted. The patients may apply for an appointment from the website
2. The website includes relevant information on referral paths, available testing and therapeutic options
3. The centres are encouraged to have an active social media account on drug allergy
4. The centres are encouraged to act as a health advocate in the drug allergy area

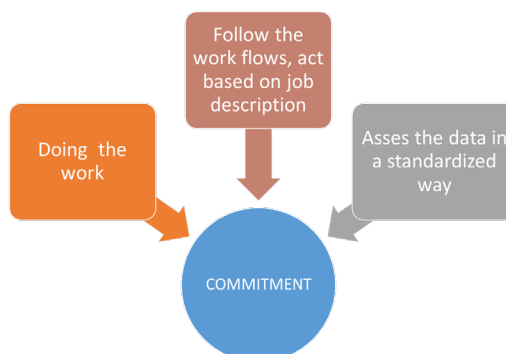
1.6. ARCHIVING AND DATA PROTECTION

1. The drug allergy outpatient clinic should have an electronic or physical data storage system that complies with local and national regulations
2. Patient data should be securely stored and managed according to applicable legal and institutional data protection policies

EVIDENCES FOR BASIC STANDARDS

- Document on data management and security overview, privacy and confidentiality policies

QUALITY STANDARD 2: DOING



2.1. PATIENT CARE

2.1.1. Clinical Practice

1. The centre should perform necessary drug allergy testings on a regular basis in the management of drug allergy
2. Information on drug allergy history and management and test results should be recorded in case files
3. Each centre should perform drug skin testing and/or DPTs for confirming or disproving allergy and finding safe alternative drugs
4. The centre should perform drug desensitization
5. A standardized protocol based on drug allergy guidelines/task force reports (and specific drug protocols, when available) should be used

EVIDENCES FOR BASIC STANDARDS

1. Documents on management algorithms
2. Consent form of the tests and desensitization
3. Examples of test forms of the cases (if it is permitted by local regulations)
4. List of drugs for which a desensitization procedure is available and written drug-specific desensitization procedures, including technical details for dilution preparation and administration and references
5. Examples from drug desensitization forms (case files) (if permitted by local regulations)

2.1.2 Long Term Management

1. Avoidance from culprit drugs also considering cross-reactivity should be recommended, each patient should be given a written “permission and avoidance” plan
2. A drug allergy passport should be provided

EVIDENCES FOR BASIC STANDARDS

1. Examples from written plans for the patients
2. Examples from Drug Allergy Passports

2.2. PATIENT CENTERED APPROACH

1. The centre should provide necessary information on drug allergy and its management to the patients and their relatives
2. This information could be provided in person, or in seminars or as written documents related to their drug allergy

EVIDENCES FOR BASIC STANDARDS

1. Documents, brochures, information sheets on drug allergy provided to the patients and their relatives
2. Agenda for seminars for the patients with drug allergy

2.3. FACULTY AND STAFF DEVELOPMENT PROGRAM

1. A regular seminar/literature/case discussion time on drug hypersensitivity should be done at least once a month

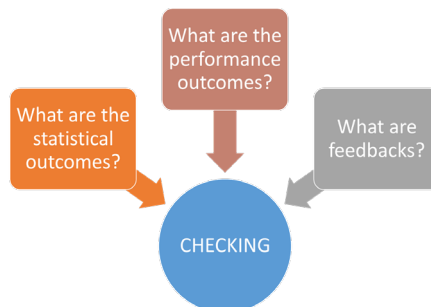
EVIDENCES FOR BASIC STANDARD

1. Agenda and the program of this educational sessions (yearly)

AREA FOR IMPROVEMENT

1. A standardized training program on drug allergy for working staff should be available in the centre
2. The physicians and other staff working in the outpatient clinic should have training on communication skills
3. Staff/faculty should have CME for the activities related to drug allergy and anaphylaxis
4. Staff/faculty are encouraged to join national and international courses on drug allergies

QUALITY STANDARD 3: REVIEWING



3.1. EVALUATION OF THE OUTCOMES

1. The centre should have assessment tools to follow up the performance of the clinic
2. The centre should collect all the relevant data for assessment of these predetermined outcomes

EVIDENCES FOR BASIC STANDARDS

1. Statistical reports related to outcomes and safety*(eg.number of the patients applying the outpatient clinic/year, number of the tests applied/year, number of desensitization procedures/year, number of adverse events in the tests/year)
2. Patients feedback (if it exists)
3. Staff feedback (if it exists)

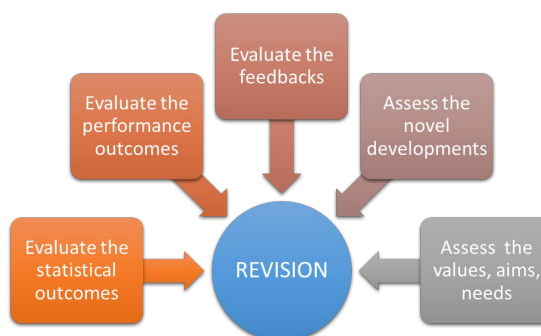
**Basic information is necessary, however, providing more specific data could be helpful*

AREA FOR IMPROVEMENT

1. The centre should have detailed/specific predetermined outcomes on activities of the outpatient clinic (statistical outcomes; performance data/safety data) and provide these outcomes at least annually
2. Patient feedback as well as satisfaction should be obtained by using questionnaires
3. Feedback from the physicians, nurses and allied healthcare workers should be obtained
4. The centre should also define strategic targets* in addition to descriptive analysis: these targets could be related to patient care; education and research as well as all activities under the umbrella of this outpatient clinic (like: increase the number of outpatient clinic days; increase the number of the patients without adverse drug reactions during tests/desensitization; increase the number of seminars organized for the patients; increase the number of publications; increase the patients' satisfaction)

**please define yours*

QUALITY STANDARD 4: REVISION OF THE PROGRAM



4.1 REVISION OF THE PROGRAM

1. The centre should review all the outcomes of the centre
2. These outcomes should be evaluated in regular time intervals (at least annually)
3. The centre should revise all the work of the outpatient clinic based on these outcomes and novel development and other requirements

EVIDENCES FOR BASIC STANDARDS

1. The reports on follow up criteria (based on data in part: Quality Standards #3)
2. The documents on how the centre evaluates the outputs
3. Meeting reports on evaluation of the centre
4. The documents on the decision on revision of the management of the outpatient clinic