

Allergen exposure chambers: harmonizing current concepts and projecting the needs for the future - an EAACI Position Paper.

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BACKGROUND:

Allergen exposure chambers (AECs) are clinical facilities allowing for controlled exposure of subjects to allergens in an enclosed environment. AECs have contributed towards characterizing the pathophysiology of respiratory allergic diseases and the pharmacological properties of new therapies. In addition, they are complementary to and offer some advantages over traditional multicentre field trials for evaluation of novel therapeutics. To date, AEC studies conducted have been monocentric and have followed protocols unique to each centre. Because there are technical differences among AECs, it may be necessary to define parameters to standardize the AECs so that studies may be extrapolated for driving basic immunological research and for marketing authorization purposes by regulatory authorities.

METHODS:

For this task force initiative of the European Academy of Allergy and Clinical Immunology (EAACI), experts from academia and regulatory agencies met with chamber operators to list technical, clinical and regulatory unmet needs as well as the prerequisites for clinical validation.

RESULTS:

The latter covered the validation process, standardization of challenges and outcomes, intra- and interchamber variability and reproducibility, in addition to comparability with field trials and specifics of paediatric trials and regulatory issues.

CONCLUSION:

This EAACI Position Paper aims to harmonize current concepts in AECs and to project unmet needs with the intent to enhance progress towards use of these facilities in determining safety and efficacy of new therapeutics in the future.

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KEYWORDS:

allergen exposure chambers; allergic; clinical trials; rhinitis; validation