

Letter to the editor

EAACI 'Standards for practical allergen-specific immunotherapy'

Gold standard

Standards are in general welcome. When things go well – for example, when systems work well and safely – then it is often 'because they conform to standards' (International Standardization Organization, ISO). The new EAACI standards (1) for allergen-specific immunotherapy (IT) were therefore awaited with great interest. Since the standards were produced to serve as a 'gold standard' they should be nothing but perfect. At the same time, it is stated in the new standard that 'the greatest problem encountered in trying to provide standards related to practical immunotherapy is the lack of evidence' (1). A 'gold standard' based on 'lack of evidence' is a contradiction and further discussion is needed before implementation of the standard locally.

The new grading system of side effect incorporates physician attitudes in the grading

There are several purposes of a grading system of side effects. The grading system can be used in trials as well as in the clinic, to carry out surveillance and for risk communication with the patients and authorities. The grading scale ought to be valid and its validity should be documented with regard to the results correctness and precision (inter- and intra-observer variance). It is acceptable to use an arbitrary

scale like the one in the new standard but data supporting its relevance are lacking (1, 2). In the new standard 'a more operational grading system based on the rate of onset and severity' is claimed but there is still no data on validity. Instead a new problem was introduced, since from now on, all cases where adrenaline was administered should be graded as 4 (anaphylaxis). This new factor (adrenaline) might reflect characteristics of the treating physician to a higher degree than characteristics of the reaction. As an example it might be possible that the experienced allergologist is more liberal when it comes to use of adrenaline than the nonexperienced treating the same grade reaction and bias might therefore be introduced. It will become difficult to compare side effects registered before and after implementation of the new standard. This can be avoided by adding a question on the use of adrenaline to the old grading system and keeping the rest unchanged. It will allow comparison of grade 4 reactions across EAACI standards until evidence based grading system is presented.

Problems with classification according to the EAACI standards

The grading system is unfortunately not explicit. Example is 'generalized urticaria' the same as nonlocalized and what does etc. mean in classification of grade 4 reactions?

Please clarify the following case. Three to five minutes after an IT injection a patient experienced local erythema and urticaria (injection site, arm) and also systemic urticaria (affecting the body generally) on the neck but not generalized (including a lot of things or subjects and not limited to only one or a few) (3). The scalp was itching (grade 4). Blood pressure was stable 155/80 mmHg (not grade 4). PEF fell from 500 to 350 l/min (30%). We classified the reaction as a grade 3 reaction complying with the 1993 classification. If adrenaline was used to infiltrate the injection site (not treatment of but maybe prevention of anaphylaxis) supplementary should the reaction then be classified as 4 according to the new standard?

Please clarify definitions of symptoms used in the standard ('generalized', 'practical etc.') and please comment on the impact of the change in classification for the epidemiology of serious side effects after IT. It has always been a big and important job to develop standards, especially gold standards. We should therefore attempt to improve the standards so this goal can be achieved. There are still room for improvement's (4) concerning allergen specific immunotherapy.

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References

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