In clinical trials, should we be blinded or masked? A proposal for becoming aware of the meaning behind words and concepts

To the Editor:

When reporting randomized clinical trials, literal translation of English into French reveals problems in the meaning of frequently used words, such as ‘blinded’ or ‘masked’. We submit to our fellow researchers that specifying these meanings in French might in turn be of interest to English-speaking readers.

Control of bias in randomized clinical trials allows a valid estimation of the effect of a new treatment compared to a standard one. Blinding (or masking) the nature of treatment to the patient, the investigator, and the individual in charge of measuring the endpoints, reduces assessment bias. Blinding has been literally translated into French by ‘à l’aveugle’. Because blinding implies that people do not know which treatment a given patient receives, it seems more appropriate to use ‘en insu’ (literally ‘without the knowledge of’). Using ‘en insu’ rather than ‘à l’aveugle’ may prevent confusions, especially when objective assessment of endpoints is not possible and needs the ‘eye’ of an independent investigator. For instance, it would not make sense to use a blind rheumatologist to measure joint functional indices or a masked radiologist to read an X-ray. Consequently, we believe that neither ‘blinding’ nor ‘masking’ are really satisfactory. We suggest using the phrase ‘without awareness of treatment’, which, although a little longer, is more precise.

Further confusion can occur in French when the adjective ‘ouvert’ (literally ‘open’) is used to qualify either a non-comparative trial (another synonym for ‘uncontrolled’) or a controlled trial with awareness of treatment (i.e., ‘open-labeled’, another synonym for ‘unblinded’ or ‘unmasked’). We suggest that ‘essai non comparatif’ and ‘essai sans insu du traitement’, respectively, are more appropriate. Our proposals of qualifiers of clinical trials (see Figure), meant to avoid these sources of confusion, are, of course, open ... to discussion.

Geneviève Chêne, Marianne Savès, Louis-Rachid Salmi

1. Unité de Soutien Méthodologique à la Recherche Clinique et Epidémiologique, Service d’Information Médicale, CHU de Bordeaux
2. INSERM Unité 330, 146 rue Léo-Saignat, 33076 BORDEAUX Cedex

Correspondence: Geneviève Chêne, INSERM Unité 330, 146 rue Léo Saignat, 33076 BORDEAUX Cedex. Fax: 00 33 557 57 11 72. E-mail: genevieve.chene@dim.u-bordeaux2.fr

REFERENCES