Correspondence on 'classification criteria: time for a rethink 'by D Porter *et al*'

We take the following three main messages from Porter and colleagues' thoughtful viewpoint article.[1]

1. Although disease classification criteria are developed for research purposes, they are commonly used for diagnosis in the clinic. This common practice is wrong since the prior probabilities for the targeted disease are always higher in the research and lower in clinical practice settings. Therefore, the use of the same criteria for diagnosis in general practice would cause an unacceptably high number of false positives in that setting.
2. The use of classification criteria for research purposes, the usual setting being enroling patients into clinical trials, is also problematic. Such criteria can not only cause exclusion of patients who would benefit from the drug used in the study, but also the inappropriate inclusion of patients with no disease into the formal study. The authors give suitable examples for both scenarios.
3. The authors conclude that since the current disease criteria represent much hard work by experts in the field we should not 'throw the baby out with the water'. The disease criteria could be used 'as a lens through which the study population can be viewed'.

First, we must point out the proposal to use the currently available criteria as a lens through which the study population can be viewed and will limit the use of the disease criteria only to better analyse what has already been published. We surely do not think that the authors' suggestion of using disease criteria at hand for future practice or research will be useful after the authors very clearly delineating their shortcomings.

We have on repeated occasions tried to highlight the shortcomings and thought barriers in the current classification versus diagnostic criteria discussion/debate.[2 3] Importantly, we had underlined that the cerebral activity composed of prior probability, sensitivity and specificity behind diagnostic and classification criteria are identical. Furthermore, there is invariably an element of uncertainty in both settings, a frank acknowledgement of which is essential for both science and patient care, while we all surely aspire to intimately connect the two.

So, in addition to the *lens use* of the criteria for judging previous work, we propose the following scheme for all future work:

1. We abandon the concepts of disease classification and diagnostic criteria altogether. For all research work, including drug trials and other and basic science studies, we specifically designate our criteria for that particular study as we clearly would have indicated in the study protocol. Surely identical criteria can be used for similar work. For example, the industry comes up with a new drug X for its use in disease Y. Our scheme proposes that the experts now design a set of study criteria for testing drug X in disease Y. Assuming that the drug has potentially few adverse events, this set of criteria can be very sensitive for its trial in disease Y as compared with a different set of criteria for the drug W with more adverse events, where we would surely desire less sensitive but more specific criteria for testing the drug W in the same disease Y. Again, in this scheme the same set of criteria can be used for identical studies in different geographies with more or less similar prior disease probabilities. Finally note that the *study-specific criteria* we propose does away with the *universal* disease classification criteria thus far published, the universality of which, we propose, has been the main mischief behind the problem at hand.
2. As for diagnosis, we propose that we abandon the designation of disease criteria for clinical work and construct and use *Diagnostic Guidelines* instead. This does not mean we should construct these guidelines in a less scientific manner. The concern for the elements of prior probability, sensitivity and specificity will surely need to be respected in these guidelines. For example, diagnostic guidelines for Behçet syndrome might well differ between different geographies and subspecialties based on prior probabilities.[2] In brief, in a diagnosis, you are telling patients the *implications of their symptoms and what to do about them*. In a scientific study on the other hand, starting with the scientific community, you are telling all the stakeholders *what has happened*. These two vastly different implications, we reason, deserve two separate and different designations.

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