Sensitive and Personalized Determinations of Likelihood of Being Helped or Harmed

To the Editor: We read Dr Andrade's recent article on likelihood of being helped or harmed (LHH) with interest.[1] In our view, this work raised important issues related to the need to make adequately sensitive and personalized number needed to harm (NNH) (thus LHH) determinations, as was originally intended by Dr Sharon Straus when she originated the idea in her evidence-based medicine classes some years ago.[2,3] There are many considerations regarding proximal and distal benefits and harms.[4]

Reasons for dropping out (or remaining in) clinical trials are complex, making the selection for individual patients of the optimal NNH for calculation of LHH complex. This is true particularly if the selected harm involves trial discontinuation (eg, all-cause discontinuation or adverse effect discontinuation), as patients may be more reluctant to discontinue participation in a clinical trial than to discontinue a clinically administered medication. This could undermine the sensitivities of harms involving trial discontinuation.

Spontaneously reported adverse events for common problems such as sedation, weight gain, or akathisia (eg, for second-generation antipsychotics) may be more sensitive harms but may be too sensitive (ie, reflecting harms with insufficient severity to be actionable) or, once again, susceptible to complex causes. Adverse events leading to discontinuation may address the former sensitivity (but not the latter complexity) challenge. Adverse events thresholded for potential clinical significance (eg, ≥ 7% weight gain) may address both challenges, but may not be relevant for all patients. Thus, it appears to these authors that it is particularly important to make adequately sensitive and personalized NNH (thus LHH) determinations when using these tools.[5]

References

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