LETTERS

Patient Engagement and Shared Decision-Making

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To the Editors:—We agree with the excellent points Drs. Hoffman and McNaughton-Collins make in their commentary regarding our Users' Guide to Non-Inferiority trials.¹ In particular, we enthusiastically endorse shared decision-making (SDM).² Our Users' Guide explicitly states "the decision must rest with each individual patient."³ Nevertheless, the commentary authors' perception that we neglected SDM suggests that we have not communicated successfully.

In the third edition of the associated Users' Guides textbooks, the relevant revised section of the text will read as follows:

The non-inferiority threshold implies a trade-off between the advantages of the experimental treatment and the potential loss in effectiveness. Making this trade-off is not fundamentally different from other patient-management decisions: they all involve value and preference judgments, and it is the preferences of the individual patient that must drive the decision. When the trade-off between desirable and undesirable consequences is a close one, SDM represents the best way to ensure the chosen course of action is right for the individual.

In preparing for SDM with your patients, and being cognizant of the limited time you may have to spend on this activity, it may be worthwhile to reflect on the values and preferences of your typical patient and the implications for the noninferiority threshold.

If, given the benefits and harms of an experimental intervention, you perceive that virtually all patients would make the same decision, you and your patient may be able to come to a fully satisfactory decision quickly. If the desirable and undesirable consequences are more closely balanced, you will require a detailed discussion.

Considering the most appropriate non-inferiority margin will help distinguish between these two situations. First, consider the maximum increase in risk of the primary outcome that your typical patients would be willing to accept in exchange for the experimental treatment's reduction in harms or burden—your patients' non-inferiority margin.

If the upper boundary of the confidence interval is substantially greater than that threshold, and very few of your patients would choose the intervention, decision-making may be expeditious. If, however, the upper boundary is near your threshold, ensuring the right decision will involve full exploration of your patient's views of the trade-off at hand.

We trust that this revised description of our guidance will remove the discordant note and allow this Users' Guide to take its place with the other guides that Drs. Hoffman and McNaughton-Collins describe as the bible of evidence-based care.

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