LETTERS TO THE EDITOR

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EFFECTS OF PATIENT EDUCATION

To the Editor:

We enjoyed the paper by Howland et al (*Howland JS, Baker MG, Poe T: Does patient education cause side effects? A controlled trial. J Fam Pract 1990; 31:62–64*). We were especially gratified to see an important clinical question addressed in the office of the private practitioner. This seems to us a well-designed and well-executed study that contributes to our knowledge of patient education; however, a careful inspection of Table 3 suggests some possibilities for interpretation beyond those offered by the authors.

It is true that there are no statistically significant differences between the two groups for any of the outcomes reported. This is so whether comparing simple post-treatment percentages or pretreatment–post-treatment difference scores, and whether analyzed by simple chi-square analysis, Fisher's exact test, or log linear analysis. There is a definite trend toward more side effects, however, for the group receiving patient education: abdominal discomfort increased by 12% (vs 5% for the uninformed group), abdominal cramps increased by 18% (vs 8%), and diarrhea increased by 14% (vs 8%). Nausea increased slightly in the informed group (by 2%) and decreased slightly in the uninformed group (by 1%). One might consider that the difference of 8% observed between the two groups in abdominal discomfort after treatment would be clinically significant if it was true of the population at large. This suggests that a power analysis would be in order to assess the likelihood of a type II error—that the "no difference" reported here is erroneous. In fact, the likelihood of a type II error under these conditions ($\alpha = .05$, $\delta = .08$) would be about 84%; the power of the test for this sample size, and under this threshold for detection of a difference, is only .16. To move it up to the customary but stringent .80, the sample would have to contain 380 subjects in each group, an enormous increase in expenditure and effort. Even if one set a difference of 15% as the minimum necessary to detect, it would take a sample containing 84 subjects in each group before we could accept a finding of "no difference" as 80% likely to reflect a true difference between the groups of 15% (with α at .05). This suggests that the finding of no difference may well be in error, but that it would be expensive to reduce substantially our uncertainty.

This certainty does not mean that an inadequate sample size has obscured the fact that patient education most likely increases the incidence of side effects. On the contrary, the reported finding of no difference between the two groups can be accepted within the probability of a type II error detailed above. We merely wish to suggest that the question addressed by this study—whether patient education about potential side effects actually increases those side effects—is still an open one, and that reporting the power of the test would augment the reader's ability to interpret the authors' findings.

Again, we wish to thank Howland et al for their contribution to our understanding of this problem.

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The preceding letter was referred to Dr Howland, who responds as follows:

The comments of deGruy and Dickinson are appreciated. Their point is well taken. As was stated in the paper, the sample size was relatively small. There were differences in the occurrence of individual side effects between the uninformed and informed groups, but they did not reach statistical significance. A larger study might conclude otherwise. This is true of almost any research project.

The most important finding of the study was that 10% (5 of 48 subjects) in the uninformed group said the erythromycin caused them a side effect vs 8% (4 of 50) in the informed group. We felt these data warranted the conclusion that informing patients about side effects of therapy did not have any detectable adverse effects. Although a much larger study might show a small adverse effect, it would be unlikely to be of clinical significance.

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