Correspondence

We will try to publish authors' responses in the same edition with readers' comments. Time constraints may prevent this in some cases. The problem is compounded in the case of a bimonthly journal where continuity of comment and redress is difficult to achieve. When the redress appears 2 months after the comment, 4 months will have passed since the original article was published. Therefore, we would suggest to our readers that their correspondence about published papers be submitted as soon as possible after the article appears.

Post-Transfusion Purpura

To the Editor: I would like to correct a statement made in "Post-Transfusion Purpura" by Drs. E. Chris Vincent and Tracy Willett (J Am Board Fam Pract 1991; 4:175-8). In the case report, the authors state that the patient had no risk factors for human immunodeficiency virus (HIV) infection. On the contrary, the patient was a known illicit drug user and sexually active as evidenced by her pregnancy and prior two children. Hematologic abnormalities including purpura are associated with HIV infection. In a patient with (and without this patient's) HIV risk history, this possibility should have been explored further.

As family physicians, we must be aware of and ready to consider HIV infection in our patients.

J. Greenway, M.D.
Tucson, AZ

The above letter was referred to the authors of the article in question, who offer the following reply:

To the Editor: At the time of this patient's hospitalization (August 1989), the acquired immunodeficiency syndrome (AIDS) was predominantly a disease of homosexual or bisexual men and intravenous (IV) drug users. Our patient denied sexual contact with homosexual or bisexual men and denied IV substance abuse.

We now recognize more fully the rising incidence of AIDS in women and the role of heterosexual HIV transmission independent of other risk factors. As of July 1991 there have been 84 AIDS cases in women in Washington state and 18,201 cases in women in the United States (personal communication, Washington State Department of Health, Office of HIV/AIDS Epidemiology and Surveillance). Nationally 33 percent of women with AIDS identify heterosexual contact as the only risk factor. Of these women, most have had sexual contact with a person who either (1) used illicit IV drugs, (2) was homosexual or bisexual, (3) was born in a country where heterosexual transmission dominates, or (4) had received a blood transfusion.

In retrospect, it probably was an oversight not to screen our patient for HIV disease. It is interesting to note that although the patient was asked about HIV risk factors, none of the 4 housestaff, 2 family practice faculty, and 4 consultants who cared for this patient ever suggested testing for HIV infection. We agree with Dr. Greenway that the *current* standard of care should include HIV testing for any sexually active adult who has unexplained thrombocytopenia.

Chris Vincent, M.D.
Tracy Willett, M.D.
Seattle, WA

Dietary Calcium and Hypertension

To the Editor: I would like to comment upon the clinical trial by Tanji, Lew, and Wong, et al. (Dietary calcium supplementation as a treatment for mild hypertension. J Am Board Fam Pract 1991; 4:145-50). In an otherwise well-designed and well-described study, I believe the authors fail to address fully a crucial area of their design. In a "negative" study ($P > 0.05$), careful attention must be directed to the power of the trial. As noted by Freiman, et al.,[1] "Many of the therapies labeled as 'no different from control' in trials using inadequate sample sizes have not received a fair test." The power of a study, defined as one minus the probability of a type II error ($1-\beta$), is the chance of finding the detectable difference (δ) that you are seeking. To determine the sample size required for a desired power in a study such as this, you must specify (1) the probability of type I error (α), (2) β, (3) the standard deviation of the measurement (s), (4) δ, and (5) the ratio of treatment groups (m).[2] An example of this is given in the well-described methods section of one of the authors' references.[3] The authors, however, state only, "To determine the sample size for the group, the P value was 0.5 and the power value was 0.5." I am confused as to what ". . . P value was 0.5 . . . " means (perhaps $\alpha = 0.05$?). In any case, the reader is not informed what was used for s or δ to arrive at the β of 0.5.

I have made power calculations for this study using the computer program referenced above. If $\alpha = 0.05$, $\beta = 0.5$, $s = 14$ mmHg, $n = 10$ (in each group), and $m = 1$, the detectable difference the authors decided to look for was approximately 14 mmHg for systolic blood pressure. In other words, drops (or gains) in systolic blood pressure of the treatment group of less than 14 mmHg would not be considered clinically significant. By way of comparison, van Berestyn set $\delta = 3$ mmHg.[3] If this study were to use this δ (grantedly rather stringent), the power of this study

is 0.08. Even a more reasonable (to me) 6 = 10 mmHg yields a power for this study of 0.31.

This is an exciting and controversial area. A replication of this trial with a larger sample size would be of interest. I have no opinion on the efficacy of dietary calcium for hypertension and agree that more investigation is warranted. My concern is only that such studies have a reasonable chance of addressing the issue.

Brian H. Feighner, M.D., M.P.H.
Laurel, MD

References

1. Freiman JA, Chalmers TC, Smith H Jr, Kuebler RR. The importance of beta, the type II error and sample size in the design and interpretation of the randomized control trial. Survey of 71 "negative" trials. N Engl J Med 1978; 299:690-4.
2. Dupont WD, Plummer WD Jr. Power and sample size calculations: A review and computer program. Controlled Clin Trials 1990; 11:116-28.
3. van Beresteyn EC, Schaafsma G, deWaard H. Oral calcium and blood pressure: a controlled intervention trial. Am J Clin Nutr 1986; 44:883-8.

To the Editor: Tanji, et al. are to be congratulated for their painstakingly designed and executed study (Dietary calcium supplementation as a treatment for mild hypertension. J Am Board Fam Pract 1991; 4:145-50). However, this work points up a serious limitation of such studies, particularly in the family practice literature.

More than 100 numbers and ranges are presented in this report, including four tables and two figures. Unfortunately, all of these numbers were generated from the observation of only 19 subjects. According to the authors, the power of the study was only 0.5 (they do not provide all of the details of their power analysis); i.e., the study had only a 50 percent a priori chance of detecting a real effect. So what can we legitimately conclude from these negative results? Sadly, not much.

The study by Tanji, et al. confirms my own limited experiences with family practice residency-based studies. It can be surprisingly difficult to recruit substantial numbers of subjects. One therefore ends up publishing a report that has too few subjects to provide conclusive answers to the questions asked. Perhaps some residents have benefited in the process, but the benefits to our literature and to subsequent medical decision making are debatable.

So should family practice residencies stop doing studies? Hardly. But more attention needs to be paid toward choosing studies appropriate to the patient population at hand. Let's count our subjects before they're matched.

David W. Goldman, M.D.
Portland, OR

The above letters were referred to the author of the article in question, who offers the following reply:

To the Editor: I appreciate the opportunity to respond to the two letters regarding "Dietary Calcium Supplementation as a Treatment for Mild Hypertension" and further welcome the content and the spirit of the letters by both authors.

I want to address first the issue of the number of subjects selected for the study. Given the stated pretest condition of an α value of 0.05 and a β value of 0.5, the results of the study are statistically valid. However, I confess that, in spite of the issue of mathematically demonstrated validity, I too am skeptical of extrapolating study results from a small study group to the population at large. Much of my research time is spent in the Human Performance Laboratory at our university, where I engage in collaborative work with exercise physiologists. Many studies in the field of exercise physiology are hampered by the flaws of a limited number of subjects who are self-selected, are at an elite level of physical conditioning, and tend to overrepresent the male sex. One of the defenses to the criticism of sample size is that with the number of tests and the frequency of data collection common in such studies, it is impractical to study a large population. A major contribution to research by family medicine is to question the clinical validity of studies with limited numbers and on such selected populations. This contribution naturally occurs not only because of the ties among family medicine, public health, and epidemiology, but also because of the practical perspective of the family physician for what is relevant for an individual patient. I wish to validate the author's concern about the small size of the study population.

The second issue is the question of the power of this trial. The α value of the study was set at 0.05. The text is in error ("*P* value at 0.5") and I apologize for the confusion in this oversight. Our deliberations paralleled Dr. Feighner's, and we alternatively weighed γ values of 3–15 mmHg. We arbitrarily chose a higher γ value (14 mmHg) than Dr. Feighner (10 mmHg) might have chosen; in retrospect, either value would have resulted in the same outcome.

I agree that a replication of this trial with a larger sample size would be interesting and am most appreciative of the feedback provided through this forum.

Jeffrey L. Tanji, M.D.
Sacramento, CA

Management of Streptococcal Pharyngitis

To the Editor: In the May–June 1991 issue of *JABFP*, Bryars, et al. describe the effect the rapid strep test has had on physician management of streptococcal pharyngitis. Physicians in their clinics are being much more selective, prescribing antibiotics only for those patients with a positive rapid strep test or culture. They are proceeding on the assumption that there are no other bacterial pathogens that cause acute pharyngitis or that such bacteria as may be present are of no consequence.