Can You Believe What You Read in Medical Journals?

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The Editor of the ACP Journal Club, Dr. R. Brian Haynes, maintains that "About 90 percent of any journal will be publications of preliminary studies. Only a small proportion will be studies that should be applied in clinical practice. Physicians have to be able to detect those that are appropriate for clinical practice among quite a variety that aren't."1

Do physicians have the ability to detect the differences between clinically relevant and premature studies? Apparently they lack this capacity or perhaps they do not have the time because Dr. Haynes concludes, "Most practicing physicians do not have enough time to sort critically through the medical literature themselves."1 Dr. Haynes and his colleagues identify the existence of a serious problem. Their solution, for the constituency they represent, the practicing internist, is to choose for the reader studies that they consider to be appropriate for clinical practice. Editor Haynes stresses, "We would only abstract an article on a treatment study if the study is a randomized trial with at least 80 percent follow-up of patients."2

A totally different solution is suggested by Dr. John Fisher, an obstetrician in Jacksonville, Florida. He believes that reports of original research are not appropriate for "working doctors" and, therefore, he states that journals for clinicians should contain only information that has been "tested and approved."2 One of the results of this approach would be the division of medical societies into two segments: one half for practicing clinicians and the other for, (in the words of Dr. John Fisher), "Those who profess rather than practice their art, the teachers." Thus, there would have to be a minimum of two journals in each society, one a review journal and the other for ivory tower men and women.

I disagree with this approach. Apparently Dr. Fisher embraces the premise that physicians should accept "authoritative" conclusions without reservation. Members of my Editorial Board and I ask authors to provide fully quantitative information in order to let the readers judge the clinical significance of each article. We have faith in the ability of the physician to be a critical reader.

I am espousing, therefore, an editorial philosophy which resembles neither the approach of Dr. Brian Haynes nor that of Dr. John Fisher. The critical reader is not dead and he need not restrict his reading to articles chosen by a journal club editorial board; and most assuredly, the bedside clinician (the working doctor of Dr. Fisher's paradigm) should not place major emphasis upon journals which contain only review articles, the so-called tested and approved studies of Dr. Fisher.

I would agree with Dr. Haynes that most clinical studies are preliminary reports, but only when one considers the contributions yet to be made by the discretionary clinician reader. Publication in a peer-review medical publication can signify the onset of dialogue in the establishment of medical truths. The role of the practitioner in this ongoing relationship among investigators, editors, and clinicians is dramatized by an evaluation of postmarketing drug surveillance. Today's postmarketing drug surveillance is that stage IV drug evaluation which occurs when a drug has already been released on the market and is being used by practicing physicians. Many drug firms spend enormous sums of money for systematic, structured programs and projects to evaluate drugs once they are being used in clinical practice. Recent studies have shown, however, that so-called spontaneous reporting by practitioners who submit information from their office and hospital patients provides data superior to those of formal, industry supported programs. The thousands of clinicians who currently submit information to the FDA and pharmaceutical firms about adverse drug reactions offer proof that the clinician can be a lifelong teacher as well as a lifelong student.

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The ability of a clinician to be a discriminating reader is linked with the requirement that he/she possesses a clear understanding of the scientific method and the fundamentals of clinical research. One cannot evaluate clinical research reports unless one can discriminate between descriptive studies and explanatory research. A descriptive study is best represented by a case report or a series of case reports. During my tenure as Chief Editor of the Archives of Internal Medicine of the AMA, I labeled our case report section “Clinical Observations.” The author had observed something, but the report was still anecdotal whether one patient is described or 500 case reports are cited. The category is “descriptive” or “observational” if one element is missing and that is the use of comparisons. Without comparisons, descriptive studies cannot explain causes of disease or scientific phenomena and they cannot offer evidence that one therapy is superior to another. Comparison groups are basic to the strategy of explanatory studies. The gold standard in explanatory studies is the controlled clinical trial which involves the active intervention of the investigator. A classic example would be the study of a new drug by structuring a study group and a placebo or control group. Randomizing these groups would be the initial step and an investigator would follow both groups prospectively. I have just described the randomized, prospective, (possibly double-blind) clinical trial.

Physicians in Great Britain introduced the controlled clinical trial in the early 1950s when they were studying the use of chemotherapeutic agents in the treatment of tuberculosis. It is the introduction of this study design that changed medicine from an empirical discipline to a scientific endeavor. Assuredly, this is why Dr. Haynes and the other editors of the ACP Journal Club provide top priority for randomized clinical research. There is very little disagreement on the desire to achieve this ideal in clinical investigation. However, in many, many instances, variations of the “ideal” investigational protocol are necessary with deletion of some of the elements described above.

How should the editor view descriptive studies, i.e., case reports or a series of case reports? I have defended the publication of descriptive case control studies based upon reasoning which resulted from the following episode. We received a manuscript entitled “The Use of Hydrocortisone in the Treatment of Acute Myocardial Infarction.” A distinguished biostatistician studied the paper and reported as follows, “This manuscript represents the result of a supposedly well-controlled double-blind study. The problem, of course, is that it is not such a study. The patients were not randomized even though random allocation had been stated in the paper. Even if the patients had been randomly allocated, there were other major differences between the two groups which might account for differences in mortality. The groups may have differed in age, sex, physical condition, obesity, and cholesterol levels. In addition, the treatment groups differed by the type of physician, anticoagulant therapy and many other factors.” The disposition of the paper? The detailed criticisms were sent to the investigators who took into account all of the objections raised by the Editorial Board and our out-of-office consultants. They rewrote the manuscript and included a discussion section that made it possible for the reader to render his own judgment. The biostatistician studied the final version of the paper and noted, “I would be very happy if all papers published in Chest, (and in other medical journals) were in the form that this manuscript is at the present time. Unfortunately, many manuscripts hide the deficiencies and the reader believes the results. In this case, the reader is placed on his guard (as well he should be), and I am afraid that is all we can ask of any good investigator.” The statistician recognized that no experiment performed in the real world of man can be perfect. Every study, no matter how well designed, will have limitations which the reader must take into account when he assesses the validity or clinical relevance of the conclusions. We ask only that the limitations of each investigation be clearly identified. Published with these guidelines the preliminary study cited above may have been of sufficient promise to warrant a randomized double-blind study.

In the evaluation of study designs, the discriminating clinical reader must be able to differentiate another type of research structure. The reader should understand the difference between the standard randomized controlled trial and the historical controlled trial. An historical controlled trial compares a series of patients given a particular treatment under study to patients
previously treated with the standard regimen. Chalmers and associates have demonstrated that historical controlled trials appear likely to conclude that any new therapy is better than that used in the historical controlled group no matter what the therapy is. In general, randomized controlled trials seem to conclude that few new therapies are better.

Therefore, the reader should keep in mind the high false positive rate in historical controlled trials and the need for further study, preferably a randomized trial. If a new therapeutic agent is found effective by well-designed randomized controlled trials, there is much less need for confirmation. However, the clinician should look closely to see if the investigator studied a sample size sufficiently large enough to detect clinically important differences. Thus, the great defect in randomized controlled trials is the high false negative rate where an inadequate sample size exists.

In this discussion of the role of the clinician as a critical reader, I have described the clinician-reader as an indispensable element in the establishment of medical truths. A sophisticated investigator appreciates the contributions which readership can make.

Critical evaluation of medical research is one of the few disciplines that is not taught in medical schools and postgraduate training years!

Dr. Chen of Denver returned a revised manuscript to my office with these comments, "We hope that your readers will be as critical as your referees have been so that the quality of our studies can be continuously examined." This view is counter to the views of Dr. Fisher and others who have encouraged physicians to believe without reservation every review or "how to" article. Editorial boards of peer-reviewed journals provide the initial judgment, but it is the individual experiences of the clinician which must serve as a final arbiter in the evaluation of the validity and clinical value of published data.

The title of this commentary raises the query—can you believe what you read in medical journals? An appropriate answer would be—yes, but be a skeptical reader! Authors, editors, and discretionary readers, all three constituencies are necessary in the evolution of medical science and practice. Are practitioners currently familiar with basic scientific methodology so that they can participate in this triumvirate? If many are not, it is because critical evaluation of medical research is one of the few disciplines that is not taught in medical schools and postgraduate training years! This is a deficiency that should be corrected. The clinician who is not a critical reader and who places as much credence in unsophisticated studies as in excellent ones cannot practice optimal medicine and indeed may be responsible for the initiation or perpetuation of medical myths.

REFERENCES
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