

A Note to Family Medicine Researchers

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In this issue, two studies report on the quality of clinical trials published in *The Journal of Family Practice* from 1974 to 1991 and on all clinical trials published in US family medicine journals from 1987 to 1991.^{1,2} These studies follow the methods first outlined by Chalmers in 1981 to critically assess and compare the methodologic rigor of randomized controlled trials (RCTs).³ The literature in other medical disciplines has been similarly critiqued. What is known from these studies is that for all journals and disciplines, the average clinical trial is hopelessly deficient. This raises the obvious question: "What constitutes good research?"

First the bad news. Sonis and Joines reviewed the trials published in *The Journal of Family Practice* beginning with the first issue in 1974. On average, these trials met only 35% of Chalmers's criteria for a rigorous clinical trial, with a range of 5% to 73%. By eyeballing the results from the 25 previously published reviews of clinical trials from other disciplines (Figure 2, page 232), I find that *The Journal of Family Practice* is a little below the average of 40%. The year of publication was the strongest predictor of "quality." Although this may reflect better science over time, it is probably the result of changes in publication practices brought on in part by interest in Chalmers's work.

Silagy, Jewell, and Mant avoid this problem by examining RCTs from a recent 5-year period published in the four research-oriented US family medicine journals. They report that the number of randomized trials is increasing but remains small, averaging only about one per month in all of the US family medicine literature. Like Sonis and Joines, they found many opportunities for improvement in both research methods and reporting. Interestingly, 42% of the clinical trials were for nonpharma-

cologic interventions (ie, patient education). Using a randomized controlled design to study such interventions can be either heroic or foolish.

I worry that we have entered into a period of medical science that can best be characterized as the "tyranny of the RTC." For too many, there is no truth unless there is double-blinding, randomization, and a sufficiently impressive *P* value. RCTs are held out by epidemiologic gurus as the "gold standard" method of evaluation, regardless of the question at hand. The occasional counter-intuitive RCT finding is usually cited as evidence for this research design's awesome power, such as the higher rate of sudden death in ventricular tachycardia patients treated with flecainide as compared with placebo.⁴ Such believers organize their faith in science into tidy, hierarchal rules of evidence, with the RCT as the only path to truth. This narrow view is a particular problem in the grant review process, where methodologic fascism buries innovation.^{5,6}

Research designs are tools. As such, RCTs have unique attributes that make them extremely valuable for some types of scientific work. However, when you need a screwdriver, a hammer will not do. Many of those in medical science today not only discount the screwdriver, they have never even heard of the wrench. As the old saying goes, if all you have is a hammer, then everything starts to look like a nail.

RCTs are best at showing that one drug is better than another or better than no drug at all. It is precisely because of this that many of the RCTs that are done (and done well) are dull and of marginal consequence: ie, they are of the "new-oral-cephalosporin-compared-with-amoxicillin-in-the-treatment-of-otitis-media" variety. The most interesting aspect of RCTs is the consistently high efficacy of placebos. In many studies, they compare very favorably to the drug of interest, but this efficacy is ignored or dismissed by the study authors. A detailed study of the placebo effect demonstrated in a large number of RCTs could tell us a great deal about both the natural history of many diseases and patient perceptions of their symptoms.

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Table 1. *The Journal of Family Practice* Papers from 1981 to 1993 That Have Been Cited Most Frequently in the Medical Literature (compiled by the Institute for Scientific Information, Philadelphia)

Rank	No. of Citations	Title	Authors	JFP Citation Year/Vol/Pages
1	71	The Structure and Content of Family Practice: Current Status and Future Trends	Rosenblatt RA, Cherkin DC, Schneeweiss R, et al	1982; 15:681-722
2	54	A Critical Review of Adult Health Maintenance. Part 3: Prevention of Cancer	Frame PS	1986; 22:511-20
3	46	A Critical Review of Adult Health Maintenance. Part 1: Prevention of Atherosclerotic Diseases	Frame PS	1986; 22:341-6
4	44	Family Physicians' Beliefs about Breast Cancer Screening by Mammography	Cummings KM, Funch DP, Mettlin C, Jennings E	1983; 17:1029-34
5	40	A Critical Review of Adult Health Maintenance. Part 4: Prevention of Metabolic, Behavioral, and Miscellaneous Conditions	Frame PS	1986; 23:29-39
6	36	Panic Disorder: Epidemiology in Primary Care	Katon W, Vitaliano PP, Russo J, et al	1986; 23:233-9
7	35	Falls Among the Elderly Living in High-Rise Apartments	Perry BC	1982; 14:1069-73
8	32	Screening Guidelines in a Family Medicine Program: A Five-Year Experience	Mandel IG, Franks P, Dickinson JC	1982; 14:901-7
9	32	Mental-Health Activities of Family Physicians	Cassata DM, Kirkman-Liff BL	1981; 12:683-92
10	31	Influence of Stereotypes in the Diagnosis of Depression by Family Practice Residents	Seller RH, Blascovich J, Lenkei E	1981; 22:849-54
11	30	A Critical Review of Adult Health Maintenance. Part 2: Prevention of Infectious Diseases	Frame PS	1986; 22:417-22
12	30	Improving Physician Compliance with a Health Maintenance Protocol	Frame PS, Kowulich BA, Llewellyn A	1984; 19:341-4
13	29	Characteristics of the Initial Medical Interview Associated with Patient Satisfaction and Understanding	Smith CK, Polis E, Hadac RR	1981; 12:283-302
14	27	Validity and Reliability of the Family APGAR as a Test of Family Function	Smilkstein G, Ashworth C, Montano D	1982; 15:303-11
15	26	Controlled Trial of Imipramine for Chronic Low Back Pain	Alcoff J, Jones E, Rust P, Newman R	1982; 14:841-6
16	24	The Maximin Strategy in Modern Obstetrics	Brody H, Thompson JR	1981; 12:977-86
17	22	Hospital Privileges for Family Physicians: A National Study of Office Based Members of the American Association of Family Physicians	Clinton C, Schmittling G, Stern TL, Black RR	1981; 13:361-71
18	22	Teaching the Family System Concept in Family Medicine	Christie-Seely J	1981; 13:391-401
19	22	Hospital Privileges for Graduates of Family Practice Residency Programs	Stern TL, Schmittling G, Clinton C, Black RR	1981; 13:1013-20
20	22	Continued Assessment of Flexible Sigmoidoscopy in a Family Practice Residency	Johnson RA, Quan M, Rodney WM	1984; 18:723-7

If the methodologic design itself cannot be used to characterize a gold standard for research, then what should be used? It could be argued that the most frequently cited articles are the "best," since citations are an indication of the impact of an article on subsequent sci-

ence. With this in mind, we have recently compiled a list of *The Journal of Family Practice* articles from 1981 to 1993 that have been cited most frequently in the medical literature (Table 1). Because of the normal delay in the citation process, most of these articles were published in

Table 2. Recent Studies from *The Journal of Family Practice* That Asked "Gold Standard" Questions

- Hueston WJ. A comparison of albuterol and erythromycin for the treatment of acute bronchitis. *J Fam Pract* 1991; 33:476-80.
A microbiologic treatment (erythromycin) was compared to bronchodilator therapy (albuterol) in patients with acute bronchitis. Albuterol was more effective in eliminating cough at 7 days.
- Morelli D, Koenigsberg MR. Sample medication dispensing in a residency practice. *J Fam Pract* 1992; 34:42-8.
The "sample closet" in a family practice center was monitored for a month. Nearly \$20,000 worth of drugs were available of which \$4,154 worth were "dispensed." Nearly one fourth of the samples were used by physicians, their families, or the center staff.
- Miller WL. Routine, ceremony, or drama: an exploratory field study of the primary care clinical encounter. *J Fam Pract* 1992; 34:289-96.
Two "exemplary" family physicians were interviewed by their partner to see how they managed a busy office practice. These physicians organized patient encounters into "routine visits," "ceremonies," and "drama." Each type of encounter implied a different role as healer.
- Mold JW, Holtgrave DR, Bisonni RS, et al. The evaluation and treatment of men with asymptomatic prostate nodules in primary care: a decision analysis. *J Fam Pract* 1992; 34:561-68.
The literature on prostate nodules and prostate cancer was combined in a decision analysis to determine whether asymptomatic men should be screened by rectal examination. Such screening could increase a patient's average life expectancy by 1 month, but because of incontinence and impotence resulting from treatment, he would lose 3.5 quality-adjusted months of life.
- Calman NS, Hyman RB, Licht W. Variability in consultation rates and practitioner level of diagnostic certainty. *J Fam Pract* 1992; 35:31-8.
The consultation patterns of 8 clinicians in a single practice were studied. There was an overall fivefold variation in consultation rates, with even greater variation in consultation rates to specific specialties (ie, referrals to a cardiologist). Unexpectedly, consultation increased as the clinicians' expertise in a specialty increased.
- Ely JW, Burch RJ, Vinson DC. The information needs of family physicians: case-specific clinical questions. *J Fam Pract* 1992; 35:265-9.
Thirty family physicians were observed in their offices to see how they answered clinical problems that came up in the care of patients. Such questions came up once per 15 patient encounters. Most questions were answered by asking colleagues or referring to the *Physicians' Desk Reference*.
- Olson M, Klerman GL. The treatment of depression: prescribing practices of primary care physicians and psychiatrists. *J Fam Pract* 1992; 35:627-35.
Do primary care physicians properly prescribe antidepressants? The data sets from the 1980, 1985, and 1989 National Ambulatory Care surveys were analyzed to study prescribing practices. Primary care physicians prescribed antidepressants much more commonly for depression than did psychiatrists. By 1989, psychiatrists approached the rate of antidepressant prescribing of primary care physicians.
- Zubialde JP, Lawler F, Clemenson N. Estimated gains in life expectancy with use of postmenopausal estrogen therapy: a decision analysis. *J Fam Pract* 1993; 36:271-80.
The literature on postmenopausal estrogen therapy was combined in a decision analysis. All women showed gains in life expectancy, primarily because of a reduction in CAD. Women at high risk for CAD benefitted the most, with an average of 2.3 additional years of life.
- Vinson DC, Lutz LJ. The effect of parental expectations on treatment of children with a cough: a report from ASPN. *J Fam Pract* 1993; 37:23-7.
This study evaluated parental expectation for an antibiotic and found that such expectations were strongly associated with a diagnosis of bronchitis (ie, when the doctor and patient agree on the diagnosis, the patient gets better.)
- Proudfoot ML. A critique of the practice-expense values of the resource-based relative value scale. *J Fam Pract* 1993; 37:57-67.
An analysis of HCFA's practice-expense payment under Medicare shows that office-based physicians are underpaid while hospital-based physicians are overpaid. By 2001, office based physicians will work for HCFA for free.

the early half of the 1980s. It is interesting that while 13 of the 20 most frequently cited articles are research articles, only one is a randomized clinical trial.

My own sense is that we have become all too impressed with our *research tools* and pay too little attention

to the quality of our *research questions*. Great science must be based on great questions. Often such questions lead to new methods or the application of methods from other scientific disciplines into entirely new fields.

With this in mind, I have reviewed the past 4 years of

Table 3. An Index for Evaluating the Quality of Research Questions

	No. of Points
1. The question examines a previously unstudied problem.	+1
2. The question examines a well-studied problem but in an entirely new way that threatens current dogma.	+2
3. An institutional research administration says of it, "This is not real research."	+2
4. The question is important, ie, would have a noticeable impact on people's lives.	+3
5. The question "pops" into your head when you are doing something unrelated to research.	+1
6. The question comes to you fully formed while you sleep, wakens you, and forces you out of bed to write it down.	+2
7. You must look to databases other than MEDLINE to see if the question has been previously studied.	+1
8. You must talk with someone in a nonmedical discipline to find out if it <i>can</i> be studied.	+2
9. The research question could be understood by a 7-year-old child.	+1
10. The child would find it interesting.	+2
11. It is unlikely that any research-granting organization would fund it.	+1
12. It was suggested in a recent NEJM article to be a "fertile area for future research."	-2

Index interpretation:

Score of -2 to 7: Life's too short.

Score of 8 to 12: CV Builder

Score of 13 to 18: What are you waiting for?

The Journal of Family Practice to find research articles that asked high-quality questions. Table 2 is an annotated list of these studies. The variety of research methods used in these studies is impressive.

Not to be outdone by the Chalmers's index, I have also formulated a similar index to rate the quality of research questions (Table 3). I encourage its use in prioritizing your valuable and limited time.

References

1. Sonis J, Joines J. The quality of clinical trials published in *The Journal of Family Practice*, 1974-1991. *J Fam Pract* 1994; 39:225-35.
2. Silagy CA, Jewell D, Mant D. An analysis of randomized controlled trials published in the US family medicine literature, 1987-1991. *J Fam Pract* 1994; 39:236-42.
3. Chalmers TC, Smith H Jr, Blackburn B, et al. A method for assessing the quality of a randomized clinical trial. *Controlled Clin Trials* 1981; 2:31-49.
4. The Cardiac Arrhythmia Suppression Trial (CAST) Investigators. Preliminary report: effect of encainile and flecainide on mortality in a randomized trial of arrhythmia suppression after myocardial infarction. *N Engl J Med* 1989; 321:406-12.
5. Horrobin DF. The philosophical basis of peer review and the suppression of innovation. *JAMA* 1990; 263:1438-41.
6. Glantz SA, Bero LA. Inappropriate and appropriate selection of "peers" in grant review. *JAMA* 1994; 272:114-6.