patient who felt poorly yesterday is more likely to feel poorly today), which causes some methodologists to advocate caution when using them.

How useful and practical are n-of-1 RCTs in clinical practice? In many situations, physicians will continue to rely on open, unmasked, before-after studies — the trial of therapy. Although this traditional approach is fraught with the limitations that we have outlined, it has one major advantage: it is easy. On the other hand, n-of-1 RCTs require more time and effort from both clinician and patient. Are they worth it? Our experiences in more than 70 n-of-1 RCTs, as well as that of others elsewhere,[5] suggest that they are. Treatment frequently changes,[3] and both patients and physicians report increasing confidence in the ultimate management decisions.[3,6] Even though conducting n-of-1 RCTs requires additional time and effort, their execution is feasible in day-to-day practice, and guidelines for conducting them are available.[7]

The n-of-1 RCT provides physicians and their patients with a set of tools that can advance the science of the art of medicine and result in both improved and more consensual clinical care. It will be interesting for readers of the *Journal* to follow the extent to which the n-of-1 approach is integrated into family practice in the future. Studies like that of Nuovo, et al. suggest that this approach has much to offer primary care physicians and their patients.

Roman Jaeschke, M.D.
Deborah Cook, M.D.
David L. Sackett, M.D.
Hamilton, Ontario

References

1. Nuovo J, Ellsworth AJ, Larson EB. Treatment of atopic dermatitis with antihistamines: lessons from a single-patient, randomized controlled trial. J Am Board Fam Pract 1992; 5:137-42.
2. Guyatt GH, Sackett D, Taylor DW, Chong J, Roberts R, Pugsley S. Determining optimal therapy — randomized trials in individual patients. N Engl J Med 1986; 314:889-92.
3. Guyatt GH, Keller JL, Jaeschke R, Rosenbloom D, Adachi JD, Newhouse MT. The n-of-1 randomized controlled trials: clinical usefulness. Our three-year experience. Ann Intern Med 1990; 112:293-9.
4. Larson EB. N-of-1 clinical trials. A technique for improving medical therapeutics. West J Med 1990; 152:52-6.
5. Larson EB, Ellsworth AJ. Randomized trials in single patients. Our two-year experience. Clin Res 1991; 39(2):316A.
6. Jaeschke R, Adachi JD, Guyatt GH, Keller JL, Wong B. Clinical usefulness of amitriptyline in fibromyalgia: the results of 23 N of 1 randomized controlled trials. J Rheumatol 1991; 18:447-51.
7. Guyatt G, Sackett D, Adachi J, Roberts R, Chong J, Rosenbloom D. A clinician's guide for conducting randomized trials in individual patients. Can Med Assoc J 1988; 139:497-503.

Teamwork And Informed Consent

The Cotsonas article[1] in this issue is a welcome addition to the literature on informed consent in primary care. It emphasizes that the essence of informed consent is meaningful communication rather than formalistic disclosure. It acknowledges that the tort law can send misleading messages to physicians (especially family physicians) about what sort of consent process is optimal. And it points out that ethical obligations to patients can suggest broader and more proactive responsibilities for education and consent than do minimal legal requirements.

Cotsonas offers many items of illuminating advice for family physicians. I wish here to draw out for further elaboration a theme that is implicit or explicit in much of her discussion — the idea of optimal informed consent as teamwork. I will ask who should be a member of this "team" and what their respective roles ought to be.

Cotsonas explicitly notes the importance of good communication and collaboration between the family physician and the specialist performing the procedure or consultation. Implicit in her analysis is the role of the patient as an essential team member — in effect, the most efficient and critical "messenger" between primary

Submitted 21 November 1991.

From the Department of Family Practice, Michigan State University, East Lansing. Address reprint requests to Howard Brody, M.D., Ph.D., Department of Family Practice, B-100 Clinical Center, Michigan State University, East Lansing, MI 48824-1315.

care physician and consultant. (The consultant can articulate to the family physician what was told to the patient, but only the patient can communicate back what he or she actually heard.)

Cotsonas proposes a practical division of labor among the two physicians. The consultant should be best situated to answer detailed patient questions about the risks and benefits of the procedure. The family physician, on the other hand, has a special obligation to be educated as to the acceptable alternative treatments for the patient's condition and to counsel the patient regarding those alternatives in a way that highlights their suitability for the patient's individual values and circumstances.

In some cases the patient and family physician will have agreed upon a preferred alternative before the patient sees the consultant; the patient simply retains a veto in the event that the risks explained by the consultant seem greater than what the patient had previously thought. In other cases the patient and the family physician begin the discussion of alternatives, but the patient feels the need for more detail before making a final choice. The patient then goes to the consultant for a more detailed disclosure of risks and benefits and finally returns to the family physician to discuss these data. (The good family physician, of course, will have communicated clearly to the consultant the purpose of the consultation before the patient arrives.)

How can the patient now be fully integrated as a member of the informed consent team? One approach is to suppose that the family physician has an extra 10 minutes to devote to this patient, who is about to see the consultant. The physician could spend the 10 minutes reading up a bit more about the risks, benefits, and alternatives of the contemplated procedure, or the physician could spend the 10 minutes "coaching" the patient on how most effectively to use the time with the consultant and what sorts of questions to ask.

While both actions have appeal, I am drawn to the course of trying to make the patient a more active participant in the overall process of information gathering. Data suggest that patients who are more involved and assertive in their own care actually have better health outcomes.[2] Furthermore, this strategy promises to make the notion of "empowerment" of patients something more than a popular buzzword and instead builds the sort of relationship in family practice in which both physicians and patients are better able to address and resolve health problems.[3]

Finally, what about the other members of the team? If the family-practice–friendly concept of "transparency"[4] is to become a reality, the essential ingredients are that patients believe that they are active participants in decisions and that they are encouraged to ask questions until they feel adequately informed. The challenge for us as family physicians is how to structure our office practices in such a way that questions and participation in decisions are encouraged consistently by all aspects of the office encounter. This means in turn that all staff members, including the office nurse and receptionist, play a critical role in creating this positive environment. Any hint that the physician is too busy to answer questions or that the patient who arrives with a list of questions is likely to be labeled as a hypochondriac and a troublemaker will effectively derail this goal. The receptionist, for example, who is sensitive to the ideal model can do much to promote a positive working relationship by scheduling adequate time for the patient who has such a list of questions.

Informed consent, properly construed, is an essential feature of good family practice rather than a bothersome legal distraction. With the right sort of teamwork among family physician, patient, consultant, and office staff, it will flow smoothly and naturally as a part of comprehensive and continuous care.

Howard Brody, M.D., Ph.D.
East Lansing, MI

References

1. Cotsonas CE. Informed consent: law, clinical reality, and the role of the family physician. J Am Board Fam Pract 1992; 5:207-14.
2. Greenfield S, Kaplan S, Ware JE. Expanding patient involvement in care: effects on patient outcomes. Ann Intern Med 1985; 102:520-8.
3. Brody H. The healer's power. New Haven: Yale University Press, 1992.
4. *Idem*. Transparency: informed consent in primary care. Hastings Cent Rep 1989; 19(5):5-9.