



Why are we doing so little clinical research?

Part 1: Clinical descriptive research

I.R. McWhinney, OC, MD, FRCGP, FCFP

Family medicine is a clinical discipline. So why are so few family physicians doing clinical research? Certainly there are notable exceptions to that generalization. But if you look at our publication record as a whole, clinical descriptive research is only a small part. Yet it is an important issue, with consequences for our place in medical schools.

In this editorial, I want to address this issue and hope to stimulate discussion about how we can raise the profile of this field of research. I will define clinical descriptive research, discuss the four cornerstones on which it is built, suggest some reasons for our neglect, and try to convey the rich opportunities that exist in our day-to-day clinical experiences.

Our neglect of clinical research is puzzling. Of all types of research, this area is for clinicians the most fitting, the most practical, and the most enjoyable. We are also heirs to a rich tradition of clinical research in general practice.¹ It is fitting because it can be part and parcel of our clinical practice and need not require blocks of segregated time. Once we have decided which patients to study, it will add only a few minutes to the consulting time for these patients and will add some record keeping.

Because our interventions are no different from our usual care, clinical research does not pose ethical problems. Although it does need thought and preparation, it does not call for complicated research designs.² Because we do not need research assistants, large grants are not necessary. Clinical research is enjoyable because we are looking at our own work and our own patients. If you look very closely at a group of your patients over time, I can almost promise that you will find things that are not in the books or that are in the books but are wrong. As a result you will experience the joy of discovery.

Four cornerstones of clinical research

In a classic paper on the natural history of disease, John Ryle³ defined the cornerstones of clinical research as observing, recording, classifying, and analyzing.

Observing. The observer is the patient's own doctor: a clinician who has developed the skills of accurate

observation. When we think of research training today, we think of training in methodology. It used to mean training in observation. When Michael Livingston embarked on his studies of neck and back pain, he honed his examination skills by studying with physicians and other practitioners who had an interest in musculoskeletal disorders.⁴ Training in observation is an old idea, but there is also something new about the position of the observer, and I think family medicine is leading the way here. We used to see ourselves as detached from patients and their illnesses—looking in from the outside. The change in perspective became clear to me when we were planning our group study of the natural history of headache.⁵ When we were discussing what data should be recorded, a member of the group said, "Let's record whether we like the patient." I do not think we realized at the time what a revolutionary step this was. It turned out that liking the patient was strongly associated with recovery at 1 year, as was the patient's perception of having been listened to.

Leaving aside the question of whether our likes and dislikes *should* affect the outcome, we were observing ourselves as part of the natural history of the illness. Is there a danger that we might lose our objectivity as observers? The greater danger, I think, is that we continue to delude ourselves that complete detachment is possible in any scientific work, especially when our subjects are living beings, and even more so when they are people.⁶ As primatologists have shown, certain knowledge can be gained only by personal involvement.

Recording. In clinical research, record keeping is not separate from the record of patient care. It is unlikely, however, that our usual records will be sufficient, except for the most basic data. We will need some additions but not so many that they distort the process of care or add more than a few minutes to the consulting time. Patients can become our partners in the study by completing self-assessment records. Computers have made it possible to assemble and analyze large data sets, but these are not a substitute for accurate observations.

Classifying. Classification is central to all clinical disciplines. In family practice we must be aware of the limitations and contradictions involved when we place unique individuals into categories. Yet it is taxonomic research, validated by long-term studies of outcome, that gives diagnosis its predictive power and provides the basis for therapeutic intervention. Classification is the map that guides us through diagnosis, prognosis, and therapy.

There is a political dimension to classification. If we do not have a map of our own territory, we are ripe for colonization, and the colonizing power will expect us to use its map and its language. The link between classification and power has been tacitly understood whenever knowledge has been categorized, whether in an index, catalog, or encyclopedia, or in the departmental structure of a university. In medicine the equivalent would be *Index Medicus*, the *International Classification of Diseases (ICD)*, and the *Diagnostic and Statistical Manual (DSM)*.

We tend to accept uncritically disease categories handed down to us from other disciplines, without regard to the differences in context. For example, we are told that we misdiagnose 50% of cases of major depression as defined in the DSM. Of course we all miss cases of depression, as we do of early cancer. But could there not be other explanations for this finding?

The context of family practice is different from the context of psychiatric practice, for which the DSM was designed, especially in the relationship between doctor and patient. Could it not be that we call depression different names and manage it differently, based on our personal knowledge of a patient? There are substantial differences between these types of illness in general practice and psychiatric practice.⁷

In the DSM, depression is categorized separately from anxiety, whereas in general practice they frequently occur together. Depression according to the DSM is defined by numbers of symptoms, not by severity. This might be appropriate for psychiatrists who see only more severe cases, but not for family physicians, who see the whole spectrum, from mild to severe. Nease and colleagues⁸ recently investigated a severity-based classification of mood and anxiety symptoms in family practice patients. Using an existing data set, they did a cluster analysis of responses to a 15-item questionnaire on mood and anxiety symptoms. Analysis revealed four unique groups, differentiated by severity and association between depression and anxiety. There were important differences in the strength of the association between the groups and measures of health-related quality of life. The real test is whether these categories predict long-term outcomes, and this can be done only by

observing patients over time. We have much to learn from other disciplines, and much to teach them, but we must always be prepared to critically appraise their teachings before we assume that they are applicable in a family practice context.

The political factor is important, but we must not confuse political aspects with scientific aspects of taxonomic research. Our categories have no validity unless they have predictive power, and validating their predictive power is what descriptive science is all about.

Analyzing. Analysis in descriptive research is quite straightforward. The basic method is dividing the cohort into subgroups, identifying factors that predict different outcomes. These are comparisons between groups within the cohort. We also have the option of identifying a control group from outside the cohort.

Conclusion

Research based on these four cornerstones is within the reach of any family physician. The method is simple and straightforward. It can be done without big research grants, and it does not require knowledge of advanced statistics.

I began this article by asking why we were doing so little clinical research. In Part 2, I will discuss some of the fallacies that deflect us from continuing this research tradition, which has such strong historical roots in our discipline. ♦

Based on the Martin Bass Lecture delivered at the Trillium Research Conference at the University of Toronto in Ontario, June 12, 1999.

Dr McWhinney is Professor Emeritus in the Department of Family Medicine at the University of Western Ontario in London.

Acknowledgment

I thank Bette Cunningham for preparing the manuscript.

Correspondence to: Dr I.R. McWhinney, Centre for Studies in Family Medicine, Suite 245, 100 Collip Circle, London, ON N6G 4X8; telephone (519) 858-5028; fax (519) 858-5029; e-mail irmcwhin@uwo.ca

References

1. McWhinney IR. Family medicine as a science. *J Fam Pract* 1978;7(1):53-8.
2. Donner-Banzoff N, Kunz R, Rosser W. Studies of symptoms in primary care. *Fam Pract* 2001;18(1):33-8.
3. Ryle J. The physician as naturalist. In: Ryle J. *The natural history of disease*. London, Engl: Oxford University Press; 1936. p. 1-23.
4. Livingston M. *Common whiplash injury*. Springfield, Ill: Charles C. Thomas; 1999.
5. Headache Study Group of The University of Western Ontario. Predictors of outcome in headache patients presenting to family physicians—a one year prospective study. *Headache* 1986;26(6):285-94.
6. Polanyi M. *Personal knowledge: towards a post-critical philosophy*. New York, NY: Harper and Row; 1964.
7. van Weel-Baumgarten E, van den Bosch W, van den Hoogen H, Zitman FG. Ten year follow-up of depression after diagnosis in general practice. *Br J Gen Pract* 1998;48:1643-6.
8. Nease DE Jr, Volk RJ, Cass AR. Investigation of a severity-based classification of mood and anxiety symptoms in primary care patients. *J Am Board Fam Pract* 1999;12(1):21-31.