

that seek to publish clinical research. Recalling some of the great discoveries from research in general practice, Dr McWhinney suggests journals need to develop standards that provide space for novel findings based on clinical observation. He suggests that plausibility, support from the basic sciences and appropriate literature, clarity of the concepts, and reproducibility of the procedures may be more important than traditional methodological standards if research journals are to provide a forum for, rather than squelch, new discoveries. The *Annals* is enthusiastic about seeking out and supporting the dissemination of the kind of emergent discoveries based on careful clinical observation that Dr McWhinney describes. We look forward to receiving more submissions of this kind and to asking our peer reviewers to consider them in particular for the potential importance and novelty of their discoveries.

Please share your insights by joining the *Annals* online discussion at <http://www.AnnFamMed.org>.

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EDITORIAL

Assessing Clinical Discoveries

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General practice has a long, though tenuous, history of clinical research, carried out often by single practitioners working with their own patients. Recent experience has convinced me that this is still the case, even though very little clinical research is published in the journals of family medicine and general practice. After a thorough review of the journal's first 2 years, the editors of the *Annals of Family Medicine* concluded, with good reason, that much had been achieved in most aspects of the journal, but they

regretted that very little clinical research had been published. They wrote: "Our discipline must do a lot more work to bring rigor and relevance together."¹

Is there a place for clinicians' observations, hunches, and insights in family medicine and general practice journals? Having recently been in touch with practitioners who I believe have made important discoveries, but whose work has been rejected by family medicine journals, I welcomed the opportunity to give thought to the problem.

UNDERSTANDING CLINICAL INSIGHTS

I believe the fundamental problem is that journals attempt to put clinical insights in the wrong category. Clinical insights do not fit any of the research categories; they are not cohort studies, or randomized controlled trials, or qualitative studies. Unlike clinical insights, these more traditional forms of research are prepared in advance and designed to add to our knowledge of phenomena that have already achieved plausibility within a paradigm.

In Kuhnian terms, what we call research is "mopping up"² after a discovery has been made, followed by a change of paradigm. In some sciences, the investigator is supposed to be at a distance from the object, which of course is impossible for a practitioner and, as Polanyi would say, is impossible for any scientist in the human sciences.³ To understand humans, as well as the higher animals, we have to hang out with them. That is the lesson Jane Goodall taught in her work with chimpanzees when she discovered they were tool-using animals. She was told that her methods were unscientific.

How then can we describe clinical discoveries? First, they are not planned in advance. They do not begin as research; they arise in the course of practice. Second, clinical discoveries are iterative. A certain clinical observation attracts the physician's attention. He or she takes notes (not prepared in advance) and looks out for other cases, with each case adding more information. As time goes on, the observations coalesce, and the physician may have an intuitive insight. Such insights are often not the result of logic; rather, they are perhaps a key observation that has been overlooked. Roentgen's discovery of x-rays is an example. Pasteur said: "Chance favors the prepared mind."

Clinical insights should have a category of their own, called perhaps "Discoveries." How should this work be judged? Editors and reviewers must have criteria. I suggest 4 criteria: plausibility, support from the basic sciences and appropriate literature, clarity of the concepts, and reproducibility of the procedures.

Why should work be published at this unfinished stage? Because no work is ever finished. In his book,

The Genesis and Development of a Scientific Fact, Ludwik Fleck, a precursor of Kuhn, describes how discoveries evolve through many years, even centuries, before they become scientific facts. He coined the term *thought collective* for the groups of workers who carry ideas from age to age, each collective adding some knowledge until there is some consolidation as a fact.⁴

CLINICAL OBSERVATIONS THROUGHOUT HISTORY

The publication of clinical observations has played a crucial role in medicine. Alexander Fleming's discovery was a single observation: the accidental effect of mold on a petri-dish containing bacterial culture. His paper was published but ignored. About 10 years later, Howard Florey and Ernst Chaim found his paper while doing a literature search and, with further work, produced a stable, reproducible form of penicillin. Would we have penicillin if Fleming's paper had been rejected?

James Mackenzie's early papers on heart disease were published as he worked his way through his studies of arrhythmias. His first publication, "The Significance of the Pulsations in the Veins,"⁵ was published only 12 years after his entry into general practice, long before his major discoveries of auricular fibrillation and ventricular extrasystole. He was helped by the polygraph he perfected, which enabled him to record the pulses graphically. More important, however, were his observations of his patients over long periods, which enabled him to distinguish arrhythmias and murmurs that were benign from those with a poor prognosis.

Mackenzie's discoveries on digitalis were a continuation of those by William Withering and others. Mackenzie was able to clarify the effect of digitalis on the heart. In his own words,

So long as the heart beat a rate under 80, these patients were pretty well ... when the rate exceeded 110, they gradually showed increasing signs of heart failure. I therefore tried in each case, how much digitalis was required to keep the heart in check and was frequently able to regulate the dose which kept the rate under 80 and thus enabled patients to pursue their occupations for years. ...⁶

Although Mackenzie's work on digitalis was not final, and his observations were superseded by others, they were one more step in the understanding of digitalis and the heart. Mackenzie himself said:

The discovery of a new fact or a new method must not be the end of the enquiry. ... Rather it must be looked upon as a means to an end ... a stepping stone to help a further advance. ...

This is the essence of general practice—indeed of all clinical discovery. It can be done only by clinicians

working with their patients. The early work of our original thinkers is being mistaken for lack of rigor. Their work is as good as can be found under the conditions of practice. If we believe that an author is on to something, his or her work should not be rejected. These physicians are not living in the protected world of a university department. They are not funded by grants. They take rejection as rejection, and they might simply give up the struggle. Of course, there are risks in publishing such work, but I would rather take this risk than lose touch with our grass roots. If we dam the stream at its source, we will end up with mediocrity.

THE TRUE MEANING OF RIGOR

I believe we are misusing the concept of rigor.

The essence of our discipline is an unconditional commitment to patients who have put their trust in us. We will see them for any problem they may bring to us. Without this generalist role, we cease to exist as a discipline. Our commitment is open-ended: we are still available to patients even if they are referred to specialists.

This committed relationship enables us to know our patients over the long term. Because every patient is different, we know them as individuals. We do try to classify their illnesses into categories that have predictive and explanatory power, but outside these categories, there are many variations, and we try to fit our therapy to each patient's needs.

We come to know our patients by living with them over time, listening to them, and sharing their confidences.

As I read the journals, I am struck by how often research relies on existing databases and on questionnaires completed by patients. Information is arrived at without knowing anything about those who are represented in the data. The investigator knows nothing

about the most important work the physician has done: listening to the patient.

If information is gained only from questionnaires, and the investigator has no contact with the patient, he has to interpret the words himself without gathering the patient's meaning in the course of a dialogue. This is not a rigorous procedure.

I think we must be very careful in how we use the term rigor. Either we should acknowledge that all research lacks rigor in some way, even when the results are presented in the form of statistics, or we should stop using it. The rules of research are not universal; they are different for each category of research. They must be designed to fit the circumstances of each category. The rules for clinical research on our own patients must be different from the rules in a laboratory.

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