I reckon the term “clinical research” no longer passes the tests of consistency, reality and utility. It is inconsistent because it distinguishes neither bench research among bits of plants and animals from bedside research in intact humans, nor molecular medicine from clinical decision analysis. It became unrealistic when the proportion of clinicians who identified themselves as “clinical researchers” in the 1960s and 1970s began to decline1 as the knowledge and skills they needed for success at the bench moved ever further from those they needed for competency and safety at the bedside; increasingly they have been replaced by PhD fulltime bench researchers.2 Their previous attractiveness as role models for medical students declined in parallel with their diminishing clinical skills, and many became more comfortable at the blackboard than at the bedside. Finally, “clinical research” by clinicians has lost its utility as fears have grown about its “virtual or real extinction.”3

This same period witnessed a phenomenal rise in clinician-led “clinical-practice” research into the practical problems of caring for patients. Because the methods used in clinical-practice research are determined by the questions posed, they range from randomized experiments among tens of thousands of patients to qualitative research inquiries among a handful of them.4 Nonetheless, the growth of clinical-practice research is most strikingly documented in the geometric growth of therapeutic trials. Carried out at about 1 per decade in the first half of the 20th century, the latest edition of the Cochrane Controlled Trials Register contains records for more than 270,000 reports of them, and reports of or about randomized trials are currently being published at a rate of 200 per week.5 Confined to pharmacologic and a few surgical interventions in their early years, their focus has more recently broadened in 2 dimensions. First, although they often evaluate therapeutic leads discovered at the bench, the array of interventions put to the test has expanded to include behavioural, educational, organizational and alternative medicine strategies. Second, the unit of randomization has expanded from a principal focus on individual patients to families, practices, hospitals, communities and provinces. As governments and voluntary health organizations recognize the risks of leaving the design, conduct and especially the interpretation of randomized trials to the pharmaceutical industry, proper support for independent trials is increasing. Clinicians from every health profession, at every stage of training and experience, are now designing, leading and running randomized trials, and core undergraduate and postgraduate clinical training has changed to emphasize the integration of their results with individual patients’ risks, responsiveness, values and expectations. When limitations were recognized in the validity of broad therapeutic recommendations based on individual trials, clinicians began to join methodologists and patients in conducting systematic reviews of the effects of health care, opening another field of clinical-practice research. These systematic evaluations of the effects of health care, opening another field of clinical-practice research. These systematic
reviews are often major undertakings, must adhere to rigorous scientific principles if they are to be valid and credible, and are important both as guides to current therapy and as a basis for defining the question that should be posed in the next trial.

Research into the accuracy, precision and usefulness of diagnostic manoeuvres has grown much more slowly, hampered by a less well-developed methodology that is still struggling to integrate the multiple elements of any diagnostic decision, a natural reluctance to abandon the “art” of medicine and the difficulties of recruiting sufficient numbers of appropriate patients within individual practices or institutions. As a result, progress in this branch of clinical-practice research is found in individual examples rather than overall volume. For my first example, a collaboration between clinicians in Ottawa and Halifax identified 9 elements of the history and physical examination of patients with clinically suspected deep vein thrombosis whose combination was so definitive that it could be used to question and even overrule the conclusions of the “gold-standard” of compression ultrasound. For a second example, an international collaboration of clinicians led from Toronto and Edmonton but joined by clinicians from every continent (whose rising numbers passed 675 as this editorial was being written) have come together to design and execute studies to accomplish the “Clinical assessment of the reliability of the examination” (CARE). In their initial pilot study of the examination for airflow limitation, the CARE consortium recruited 309 patients in 1 month (over 20 times the accrual rate of the best previous study) and documented likelihood ratios of over 8 and 0.13 when all 4 items of a quick history and physical examination were present and absent, respectively. This example also demonstrates how isolated clinicians far from academic medical centres can instantly become part of a collegial group of clinician-researchers, engage in and even lead clinical-practice research. For a third example of the impact of diagnostic research, a clinical decision rule developed in Ottawa for predicting which patients with ankle injuries need x-rays has since been validated in Sweden, Singapore, the Netherlands, the United States and France, extended to children and applied in sports medicine clinics, found to reduce costs (even when patients whose fractures are missed sue!), and shown to be equally effectively applied by nurse-practitioners.

Why has clinical-practice research become so popular? I can think of 4 reasons. First, its synergy with clinical practice is very attractive to practical, inquiring minds. The questions posed in clinical-practice research arise from clinical observations and especially from clinical frustrations (for example, our compliance trials arose from our frustrations in attempting to help our patients control their blood pressures). Moreover, and in sharp contrast to most bench research, the results of clinical-practice research are immediately applicable (for example, within 24 hours of announcing that our trial of carotid endarterectomy demonstrated a clinically important reduction in major stroke and death, a control patient in Quebec underwent the operation). The intimate linkage of research topics and methods with clinical diagnosis, therapy and management mean that becoming a clinical-practice researcher makes you a better, not worse, clinician. Moreover, affiliation with both clinical and methodology departments nurtures continuing development of both essential elements of the clinical-practice researcher.

Second, academic opportunities for clinical-practice researchers are abundant and often have outstripped the supply of qualified investigators. For example, it took several years for the chair of Canada’s leading academic department of surgery to achieve his goal of recruiting at least 1 clinical-practice researcher to every division of his department. New faculty posts and endowed chairs in clinical-practice research are being created almost every month, and my mailbox is overflowing with requests for the names of clinical epidemiologists who might be movable. This process is likely to accelerate further as increasing numbers of clinical-practice researchers are appointed to the chairs and deanships that identify recruitment priorities. This increase in academic posts for clinical-practice researchers has been paralleled by an increase (albeit only recently catching up in Canada) in the availability of funding for research projects and career-development awards.

Third, the opportunities to lead or collaborate in clinical-practice research aren’t confined to academic health sciences centres. No special buildings, labora-
tories or animal care facilities are required, and the start-up costs are small. When we launched research at the then-new McMaster medical school in 1968 we discovered that it cost 10 times as much to establish a bench researcher as a clinical-practice researcher. I’ll wager that this multiplier has doubled since then as the soaring costs of ever more sophisticated laboratory equipment further dwarf the falling costs of ever more sophisticated laptop computers and electronic communication. Not surprising, then, that some of the most innovative clinical-practice research is conducted in remote areas and that it is not uncommon for more patients to be investigated and enrolled in collaborative diagnostic and treatment studies from outlying areas than from major centres.

Finally, the opportunities for becoming a clinical-practice researcher are rapidly expanding. Graduate programs in applied research methods have been established at most faculties of health science across Canada. Moreover, training in clinical-practice research methods has become an optional (or even mainstream) component of modern postgraduate training (especially in the subspecialties), further integrating research and practice. All of these graduate programs provide role models of successful clinical-practice researchers, and many of them also provide the mentoring and instruction in time-management that are essential to subsequent academic success and healthy lifestyle.

Competing interests: Dave Sackett has been wined, dined, supported, transported and paid to speak by countless pharmaceutical firms for over 40 years, beginning with 2 research fellowships and interest-free loans that allowed him to stay to finish medical school. Dozens of his randomized trials have been supported in part (but never in whole) by pharmaceutical firms, who never received or analyzed primary data and never had veto power over any reports, presentations or publications of the results. He has twice worked as a paid consultant to advise pharmaceutical firms whether their products caused lethal side effects; on both occasions he told them “yes.” He has testified as an unpaid expert witness for a stroke victim who successfully sued a manufacturer of oral contraceptives and has been paid by a second to develop “levels of evidence” for determining the causation of adverse drug reactions. His wife inherited and sold stock in a pharmaceutical company. While head of a division of medicine he enforced the banning of drug detail personnel from clinical teaching units (despite the threat of withdrawal of drug industry funding for resident research projects). He received the Pharmaceutical Manufacturers’ Association of Canada Medal of Honour (and cash) for “Contributions to Medical Science in Canada” for the decade 1984-94.

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References


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