

Clinical assessment of the reliability of the examination (CARE)

Diagnostic tests are of crucial importance in clinical care and can help to determine the most appropriate therapy for individual patients, to monitor and modify ongoing treatment, and to determine prognosis. The critical details in deciding whether or how to use a diagnostic test are its precision and accuracy. Unfortunately, evidence to support these data is often difficult to find and frequently is not available at all. Further, although we are all taught that “a good history and physical examination” have considerable value, little evidence exists to support the diagnostic utility of the clinical findings.

In a primary care setting, 88% of all diagnoses were established by the end of the initial history and physical examination (1), and similar results have been observed in a general medicine clinic (2). However, despite the importance of the history and physical examination to the clinical setting, their accuracy and precision have rarely been subjected to rigorous evaluation. Using the definition of a high-quality diagnostic study applied by such evidence-based journals as *Evidence Based Medicine* and *ACP Journal Club* (independent blinded comparison with the reference standard among an appropriate spectrum of patients), few such studies of the clinical examination can be identified. *JAMA* began the Rational Clinical Examination series with the objectives of summarizing the literature on elements of the clinical examination and drawing attention to those areas in which there was an evidence gap. Only half of the reviews originally commissioned have been completed because the investigators were unable to locate high-quality evidence relevant to their research question (3). More than half of the published reviews identified major gaps in the literature within their subject area (3, 4), and the studies that were found were often small and inconclusive (4).

Why aren't there better studies of the clinical examination? Several reasons have been offered (4, 5). First, these studies are challenging to design and difficult to execute. Second, the specificities of symptoms and signs are often low in the usual study sites (tertiary-care academic centers). Third, diagnosis seldom arises from 1 symptom or sign, and significant methodologic skills are needed to successfully carry out multivariate analyses that look simultaneously at several signs and symptoms. Fourth, with the pressure to see more patients in less time in many situations, it is more efficient for the clinician (but not for the health care system) to order the “definitive investigation.”

One way to progress is to conduct large, methodologically robust studies on the precision and accuracy of the clinical examination. These studies should be done among patients in primary-, secondary-, and tertiary-care settings to document any changes in accuracy as patients move along the referral pathway. Further, the studies must involve the broad spectrum of real-world clinicians, with various levels of training and experience, who are the targets for what is learned.

INTRODUCING THE CARE GROUP

In response to this challenge and building on the success of practice-based research networks in primary care (6–8), we have helped to form an international collaborative group to design and execute large, simple studies of the accuracy and precision of the clinical examination. We have borrowed from the terminology and expertise of clinical trialists in mounting simple studies by enrolling unselected consecutive patients and collecting a minimum of data (9). We hope that by keeping these studies quick and simple, participation will not be too onerous for either busy clinicians or patients.

The CARE (Clinical Assessment of the Reliability of the Examination) group was initiated 2 years ago, and since then > 600 clinicians from 35 countries have joined. The group is open to health care professionals at any stage of training or experience who are working in any practice setting. Any member can suggest symptoms or signs for possible evaluation and distribute them to the rest of the group by e-mail. Members who share an interest in any of these topics come together electronically to develop the protocol, enroll patients in the study, and report their results through the Internet to the study coordinating center (www.carestudy.com). All participating investigators are required to adhere to local clinical and ethical practice. Use of the Internet for data entry allows instantaneous data checking and editing. The electronic network also allows the study results to be analyzed and disseminated to the investigators within hours of study completion.

TESTING CARE'S FEASIBILITY

To test the feasibility of this idea, we completed 2 studies of the accuracy of a few clinical items used in diagnosing chronic obstructive airways disease (COAD) validated against independent blind spirometry (10; Unpublished data—to be reviewed in the November/December issue of *ACP Journal Club*). In our first study, 332 patients were recruited in just 5 weeks, and 177 more patients were recruited in a second COAD study done 2 months later. Multivariate regression was used to develop a simple 4-variable model that will be tested in an independent set of patients in a third COAD study, which is scheduled for this fall.

Now that the feasibility of this network has been established, other studies of the clinical examination have been developed and are currently under way, such as assessment of the accuracy of a simple tool for predicting falls in elderly persons. Bandolier highlighted an observation by Lundin-Olsson and colleagues (11) that patients living in a long-term care facility who stopped walking when a conversation was initiated were more likely to fall within the next 6 months (likelihood ratio of 10) than those who were able to continue walking and talking. This screening test is simple, fast, inexpensive, and requires no special equipment. Further, this simple maneuver, if validated in larger studies in various settings, could allow clinicians either to identify the people who would

benefit most from interventions proved to decrease the risk for injury from falls or to find participants for randomized trials of interventions that might decrease that risk.

NEXT STEPS

Although several studies have been done to derive risk predictions for perioperative cardiac risk (12–14), few have rigorously evaluated the prediction of pulmonary risk (15, 16). Indeed, we are unaware of any published prediction rules for assessing the risk for perioperative pulmonary complications. To meet this need, CARE investigators are currently enrolling patients in a study designed to determine the accuracy of selected elements of the history, the physical examination, and the routine preoperative tests for predicting postoperative pulmonary complications in patients having nonthoracic surgical procedures.

It is our goal to expand CARE to a size and scope that would facilitate large (> 100 clinicians enrolling > 1000 patients), simple (< 2 min per patient and < 15 patients per participating clinician), and fast (< 2 wk) studies of the clinical examination. Please join us in this fun and exciting project dedicated to improving our knowledge and performance of the clinical examination.

*Sharon E. Straus, MD
University of Toronto
Toronto, Ontario, Canada
E-mail: sestraus@home.com*

*Finlay A. McAlister, MD
University of Alberta
Edmonton, Alberta, Canada
E-mail: finlay.mcalister@ualberta.ca*

*David L. Sackett, MD
Trout Education and Research Center at Irish Lake
Markdale, Ontario, Canada
E-mail: sackett@bmts.com
on behalf of the CARE group*

References

1. Crombie DL. Diagnostic process. *J Coll Gen Pract.* 1963;6:579-89.
2. Sandler G. The importance of the history in the medical clinic and the cost of unnecessary tests. *Am Heart J.* 1980;100:928-31.
3. Simel DL, Rennie D. The clinical examination. An agenda to make it more rational [Editorial]. *JAMA.* 1997;277:572-4.
4. McAlister FA, Straus SE, Sackett DL, on behalf of the CARE-COAD1 (Clinical Assessment of the Reliability of the Examination-Chronic Obstructive Airways Disease) Group. Why we need large, simple studies of the clinical examination: the problem and a proposed solution. *Lancet.* 1999;354:1721-4.
5. Sackett DL, Rennie D. The science of the art of the clinical examination [Editorial]. *JAMA.* 1992;267:2650-2.
6. Niebauer L, Nutting PA. Primary care practice-based research networks active in North America. *J Fam Pract.* 1994;38:425-6.
7. Green LA, Hames CG Sr, Nutting PA. Potential of practice-based research networks: experiences from ASPN. *J Fam Pract.* 1994;38:400-6.
8. Froom J, Culpepper L, Grob P, et al. Diagnosis and antibiotic treatment of acute otitis media: report from International Primary Care Network. *BMJ.* 1990;300:582-6.
9. Yusuf S, Held P, Teo KK, Toretzky ER. Selection of patients for randomized controlled trials: implications of wide or narrow eligibility criteria. *Stat Med.* 1990;9:73-86.
10. Straus SE, McAlister FA, Sackett DL, Deeks J, on behalf of the CARE-COAD1 Group. The accuracy of patient history, wheezing and laryngeal measurements in diagnosing obstructive airway disease. *JAMA.* 2000;283:1853-7.
11. Lundin-Olsson L, Nyberg L, Gustafson Y. "Stops walking when talking" as a predictor of falls in elderly people [Letter]. *Lancet.* 1997;349:617.
12. Lee TH, Marcantonio ER, Mangione CM, et al. Derivation and prospective validation of a simple index for prediction of cardiac risk of major non-cardiac surgery. *Circulation.* 1999;100:1043-9.
13. Goldman L, Caldera DL, Nussbaum SR, et al. Multifactorial index of cardiac risk in noncardiac surgical procedures. *N Engl J Med.* 1977;297:845-50.
14. Detsky AS, Abrams HB, McLaughlin JR, et al. Predicting cardiac complications in patients undergoing non-cardiac surgery. *J Gen Intern Med.* 1986;1:211-9.
15. Lawrence VA, Page CP, Harris GD. Preoperative spirometry before abdominal operations: a critical appraisal of its predictive value. *Arch Intern Med.* 1989;149:280-5.
16. Lawrence VA. Evidence about preoperative risk assessment: why aren't there better studies? *ACP J Club.* 1993;119:A16-8.