Respiratory clinical trials in Canada – slow, steady progress toward effective, evidence-based health care

Shawn D Aaron MD FRCPC

In the current issue of the *Canadian Respiratory Journal*, Tacon et al (1) (pages 181-184) present intriguing data regarding the frequency of respiratory clinical trials conducted in Canada. They used a clinical trial database to search for respiratory-based drug trials conducted in Canada between 2001 and 2011. Their results are somewhat encouraging, suggesting that in the past decade Canada has emerged from an awful nadir in 2001, when clinical trials in respiratory medicine were almost absent, to a point in which today, respiratory clinical trials are more prevalent.

Randomized clinical trials are vital to the practice of evidence-based medicine. When performed properly, trials will determine which treatments or strategies work best for particular diseases, or for particular patient groups. Importantly, clinical trials can also determine whether a therapy may cause harm. In many cases, medical and surgical therapies, such as hormone replacement therapy for postmenopausal women or lung volume reduction surgery for chronic obstructive pulmonary disease, have been widely applied to patients without convincing clinical trial evidence suggesting benefit. Randomized controlled trials of these therapies later demonstrated that these treatments were potentially harmful, leading to widespread changes in clinical practice (2,3).

The numbers tell the story. In 2001, only 22 respiratory clinical trials were conducted in Canada and, of these, only three were investigator-driven trials conducted independent of industry. Thankfully, in the past several years the numbers have increased and, in 2010/2011, an average of 61 respiratory trials per year were conducted in Canada, with an average of 16 per year being conducted independent of industry. Reassuringly, Tacon et al (1) found that the number of respiratory clinical trials conducted in Canada has increased at an average rate of 4.5 per year over the past decade.

Tacon et al did not explore the reasons for this encouraging trend. One explanation for the modest surge in nonindustry sponsored respiratory trials conducted in Canada may involve the creation of the Canadian Institutes of Health Research (CIHR) in 2000/2001. The mandate of the CIHR embraces the four pillars of health research: biomedical, clinical, health systems and services, and population health. The CIHR created a specific committee to review clinical trial protocols and this undoubtedly helped spur clinical trial initiatives by independent academic investigators, and by investigators working in organized collaborative groups such as the Canadian Critical Care Trials Network. This funding initiative was ultimately responsible for sparking many important clinical trials conducted in respiratory and critical care medicine within the past decade (4-7). These trials were 'Designed and Made in Canada' and, for this achievement, the Canadian respiratory and critical care communities and CIHR should be proud.

The study by Tacon et al is, however, not all good news. The data suggest that collaborative trials, in which an independent investigator obtains industry funding for his/her trial, have fallen at a rate of 0.4 trials per year. Similarly, the number of industry-sponsored trials in Canada

hit a high point in 2008, but these numbers are now declining, suggesting that the pharmaceutical industry may be withdrawing from research investment in Canada. Again, the reasons for this are not clear, but global trends suggest that industry is investing proportionally more money in clinical trials in Eastern Europe and Asia, where costs are lower, patients are plentiful and often relatively undertreated for their chronic respiratory diseases, and where the regulatory environment may make clinical trials easier to initiate and complete in a timely fashion (8).

In summary, the study by Tacon et al (1) suggests that our relatively terrible performance at the start of the millenium has improved this past decade, and more Canadian investigators and Canadian patients, have the opportunity to participate in respiratory and critical care clinical trials of new medicines and new treatment procedures. However, there are threats on the horizon. Threats include a proposed revamping of CIHR's funding strategies and review processes, which may impact future funding opportunities for respiratory clinical trials. Investment from the pharmaceutical industry in Canada's clinical trial infrastructure also appears to be slowing. Physicians, researchers, industry and government share the responsibility to keep our clinical trial infrastructure strong so that Canadian health care professionals can continue to strive to provide effective, cutting-edge, evidence-based care to our patients with respiratory disease.

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Division of Respiratory Medicine, The Ottawa Hospital, Ottawa, Ontario

Correspondence: Dr Shawn D Aaron, Division of Respiratory Medicine, The Ottawa Hospital, 501 Smyth Road, Ottawa, Ontario K1K 8L6.

Telephone 613-739-6636, e-mail saaron@ohri.ca