"You randomize. We analyze."

Malcolm Maclure, ScD Research Consultant, Policy Outcomes, Evaluation and Research Pharmaceutical Services Division BC Ministry of Health

British Columbia has a need for a statistical centre for low-cost pragmatic randomized trials using de-identified central administrative databases within the Ministry of Health's new informatics architecture for protecting data privacy.

Many health care interventions and policies are implemented that could be rapidly rigorously evaluated using randomized control groups. Randomized controls are rarely used because controlled trials are widely regarded as expensive. Over the past decade in BC, a series of low-cost pragmatic randomized trials have been done in BC demonstrating that randomization costs next to nothing. Often the most important outcome data – major health events and health care utilization – are virtually free, insofar as they are routinely collected. There is very little additional cost associated with merging with those databases a list of Personal Health Numbers or Practitioner Numbers, and dates, for the Intervention Group and the Control Group.

The biggest current impediment to low-cost trials is cumbersome data access procedures designed to protect data privacy. However, these procedures could be greatly streamlined if trial investigators do not want raw data. Often investigators want only 'Table 1' (baseline comparisons), 'Table 2' (outcome comparisons) and 'Figure 1' trends in the Intervention versus the Control Group. Such presentations of aggregated data usually can be released without risk of violating data privacy.

If a fast-track stream for approving release of such aggregate data can be created, then the rate limiting step will be the production of tables and figures. This could be done by a group of skilled statisticians who have special access to encrypted Ministry databases and who function like the statistical coordinating centre for a clinical trials network. The Pharmaceutical Services Division of the BC Ministry of Health is interested in exploring the possibility of creating such a platform for low-cost randomized trials and controlled cohort studies.