Effect of participation in a primary care cluster randomized controlled trial on the dyslipidemia prescribing practices

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Randomized controlled trials (RCT) evaluating medical practices almost always require that health care professionals be the unit of allocation. This is known as cluster or group allocation. TEAM study is an on-going cluster RCT funded by CIHR and designed to compare the management of statin therapy in an integrated primary care (IPC) intervention model, in which physicians and pharmacists are co-responsible for managing statin therapy, to the usual care (UC) intervention. During the review process, CIHR evaluators raised the possibility that the participation of physicians in the UC group may improve their dyslipidemia prescribing practices. The change in clinical practices associated with the participation in a RCT is called the "***trial effect***". The trial effect may be attributed to the impact of the tested intervention. However, it may also be associated with various aspects of the trial other than exposure to the tested intervention. This is called the "***participation effect***". This effect may be due to a ***protocol effect***, a ***care effect*** as well as a ***Hawthorne effect***. Very few studies, mainly in classical RCT in the field of oncology, have compared patient's outcomes between trial and non-trial participants.

Primary objective: To evaluate the ***participation effect***, compare changes in lipid-lowering-prescribing practices of UC trial physicians to the changes in lipid-lowering-prescribing practices of a matched group of non-trial physicians between the year preceding the TEAM study and the period of the study. Secondary objectives: (1) To evaluate the persistence of the ***participation effect***, compare changes in lipid-lowering-prescribing practices of UC trial physicians to the changes in lipid-lowering-prescribing practices of a matched group of non-trial physicians between the year before the TEAM study and the year after the study. (2) To evaluate the potential for a selection bias, compare the lipid-lowering-prescribing practices of UC and IPC physicians to those of matched non-trial physicians during the year preceding the TEAM study. (3) To evaluate the ***trial effect***, compare changes in lipid-lowering-prescribing practices of IPC trial physicians to the changes in lipid-lowering-prescribing practices of a matched group of non-trial physicians between the year before the TEAM study and the period of the study. (4) To evaluate the persistence of the ***trial effect***, compare changes in lipid-lowering-prescribing practices of IPC trial physicians to the changes in lipid-lowering-prescribing practices of a matched group of non-trial physicians between the year before the TEAM study and the year after the study.

Study design: A 4-year cohort study comparing the dyslipidemia prescribing practices of trial and non-trial physicians during three observation periods: (1) the year preceding TEAM study (January 2005 to December 2005); (2) during TEAM study (January 2006 to December 2007); and (3) the year after TEAM study (January 2008 to December 2008). Each trial physician accepting to participate in this cohort study will be matched to 30 non-trial physicians within the same geographic area according to gender, year of graduation, the annual number of prescriptions and proportion of prescriptions for patients at age 45 or more. All trial and non-trial physicians will be family physicians. IMS Health Canada will provide, free-of-charge, physician dyslipidemia prescribing practices information. The unit of observation in the IMS database is the prescription. For each prescription, information includes the: date of the transaction; medication name, dosage, and quantity; code for a new prescription or a renewal; duration of treatment; number of refill authorized; age and gender of patient; and the physician medical permit number.