

## Use of the CANHEART 'big data' registry to conduct a large randomized registry clinical trial to improve lipid management in Ontario, Canada

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### Introduction

Creation of registries using linked population-based databases could potentially be used to conduct large registry-based clinical trials. As part of the CANHEART-Strategy for Patient-Oriented Research (SPOR) innovative clinical trials initiative, we explored the practicality of using the linked CANHEART registry to conduct a cluster-randomized trial aimed at improving lipid management.

### Objectives and Approach

The CANHEART registry ([www.canheart.ca](http://www.canheart.ca)) was created through the linkage of 19 population-based health databases in Ontario, Canada, providing individual-level socio-demographic, geographic, hospitalization, disease testing/screening, mortality, prescription medication, and behavior/lifestyle information. Using CANHEART defined eligibility criterion, small and medium-sized, high cardiovascular-risk health regions (defined as having acute myocardial infarction, stroke or cardiovascular death rates greater than the Ontario average) are being randomly allocated to receive either the intervention (availability of a lipid management 'toolbox') or standard care. Cohort linkages to additional years of data will occur regularly over the 3-year trial to ascertain the primary outcome of appropriate statin prescribing rates.

### Results

Record linkage enabled us to determine baseline characteristics of 835,345 patients aged 40-75 as of January 2016, being treated in the 28 study-eligible regions by 2,012 family physicians. Preceding the study, the baseline statin use rate was 35.7% (in 66-75 year olds) across these regions and the cardiovascular event rate ranged from 3.78-5.64 events/1000 person-years. A randomization procedure yielded 14 regions in both the intervention and control arms which did not differ significantly in socio-demographic characteristics, traditional cardiovascular risk factors, disease history, prevalence of statin use, or access to healthcare indicators. Working groups have

been established to operationalize the lipid management tools that will be made available in the intervention regions. Analysis of newly linked participant data will permit outcome ascertainment at trial completion.

### Conclusion/Implications

Our work demonstrates the feasibility of using the CANHEART 'big data' registry to conduct a large, cluster-randomized clinical trial aimed at improving lipid management, without requiring any primary data collection. Broader use of this methodology has the potential to change the existing paradigm for conducting pragmatic clinical trial research.

