

# Making Informed CHOICES: The Launch of a “Big Data” Pragmatic Trial to Improve Cholesterol Management and Prevent Heart Disease in Ontario

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## Abstract

**Cholesterol-lowering statin medications are a safe and effective therapy to lower cholesterol and reduce the risk of cardiovascular events. Yet physician prescribing patterns and patient adherence remain suboptimal in Canada and the United States, often due to pervasive misconceptions. The Community Heart Outcomes Improvement and Cholesterol Education Study (CHOICES) is a pragmatic, registry-based, cluster randomized controlled trial that aims to improve cholesterol management through appropriate statin use in adults and to ultimately reduce cardiovascular events in high-risk communities across Ontario. The trial uses an innovative, multicomponent intervention and implementation approach that includes audit and feedback reports for family physicians and educational materials and tools for patients.**

## The Issue

Cardiovascular disease (CVD) remains a highly prevalent chronic disease in Canada and costs the province of Ontario alone approximately \$10.5 billion in direct healthcare spending annually (Chu et al. 2019). Statins are a class of medications commonly used to reduce the level of low-density lipoprotein, sometimes referred to as “bad” cholesterol, and have been shown to reduce the risk of first (i.e., primary prevention) and recurrent (i.e., secondary prevention) cardiac events in high-risk middle-aged adults by about 25% (Cholesterol Treatment Trialists’ Collaborators 2005 2010). Despite the well-established benefit of cholesterol-lowering statin therapy and frequently touted reputation as the “wonder drug” for CVD prevention, therapeutic cholesterol management by means of statin prescribing and adherence remains suboptimal in both Canada and the United States (Hennessy et al. 2016; Sparrow et al. 2019a, 2019b). For instance, patients who are eligible for statin therapy often report never being offered statins by their physician or report discontinuing their therapy due to perceptions and fear of side effects (Bradley et al. 2019). For patients on statins, many are often not on the guideline-recommended dosage that achieves the greatest preventive impact (Navar et al. 2017).

The Community Heart Outcomes Improvement and Cholesterol Education Study (CHOICES) is an innovative, real-world, cluster randomized trial that leverages Ontario’s investment in routine health data collection (“big data”) and aims to improve cholesterol management and reduce CVD events in those at risk (ClinicalTrials.gov Identifier: NCT04067297). To address this aim, we have developed a set of dynamic, multicomponent interventions that will be periodically launched over the five-year study period to inform and improve cholesterol management and statin use among patients and family physicians and prevent CVD among Ontarians. The study is funded by the Canadian Institutes of Health Research Strategy for Patient-Oriented Research and primarily conducted at ICES (formerly the Institute for Clinical Evaluative Sciences) and Women’s College Hospital in Toronto. The intervention strategy to improve cholesterol management will include passive and active dissemination of targeted strategies across a number of intervention communities, including annual community-level report cards on cholesterol risk management for family physicians, print and digital patient education materials on cholesterol screening and management and many more dynamic approaches. We hypothesize that those communities in Ontario selected to receive a multicomponent cholesterol management intervention will experience a significant increase in guideline-recommended statin therapy among those at risk compared to communities in regions that do not receive the intervention.

## The Approach

### Barriers and facilitators

Although barriers to optimal cholesterol management have been identified in other jurisdictions, an Ontario-based study of community-specific factors was warranted to help optimize our intervention. During the study’s first six months, the Team for Implementation, Evaluation and Sustainability with the Knowledge Translation Program at the Li Ka Shing Knowledge Institute of St. Michael’s Hospital conducted a formative

assessment of barriers and facilitators to optimal cholesterol management in high-cardiovascular-risk communities. The assessment consisted of telephone interviews with a purposive sample of patients and family physicians. Findings from these interviews helped identify implementation strategies that may be considered for improving uptake of cholesterol management activities. These included but were not limited to the following:

- use of mass media campaigns to encourage cardiovascular risk assessment and adherence to cholesterol medications;
- distribution of educational materials to empower patients to be active participants in their cholesterol management activities, including in clinic waiting rooms as a patient-mediated strategy also targeting physicians; and
- use of audit and feedback tools that are prepared at a community level for primary care.

The recommendations yielded from the assessment of barriers and facilitators helped inform the intervention strategies used for the CHOICES trial.

### **Patient engagement**

Because patient engagement is key to all facets of the trial work, we established a CHOICES patient partner panel of eight individuals from across Ontario who will be involved in the project over its life cycle. The panel's role is to offer insight on various aspects of the project, including intervention materials and implementation strategies, and provide a public lens on the real-world implications of cholesterol management in different parts of the province.

### **Outcome measurement**

The CHOICES trial interventions target adults without a history of CVD who are living in Ontario communities that have higher than average rates of cardiovascular events. A group of control communities will not receive the intervention tools to rigorously assess the impact of care patterns and outcomes. Our Cardiovascular Health in Ambulatory Care Research Team (CANHEART) "big data" registry, created through linkage of more than 19 population databases housed at ICES, has attracted increasing attention as a novel, less costly and more efficient method for conducting clinical trials in health research (Tu et al. 2015). The registry will be used in place of primary data collection to measure outcomes in the intervention and control communities.

The primary trial outcome will be the proportion of residents (aged 66 to 75) in each community at intermediate and high risk of CVD taking statins, as measured using the CANHEART registry at the beginning and completion of the three-year intervention period. Secondary process of care outcomes will also be measured at baseline and study

completion, including clinical events and ongoing process measures that will track the number of downloads of our cholesterol management resources, the number of visits to the study website and other measures of knowledge translation available through online analytics.

Process evaluations will be conducted by the Team for Implementation, Evaluation and Sustainability to aid in evaluating the implementation strategies throughout the course of the study and to better understand implementation quality at each site from the perspectives of those who are directly and indirectly involved with implementation. A pre- and post-implementation survey will also be conducted to measure knowledge, attitudes, confidence and intentions related to cholesterol management and cardiovascular health.

### **The Intervention**

In the fall of 2019, we launched the first phase of our multicomponent intervention strategy, which was aimed at both patients and family physicians. The launch consisted of a targeted implementation of a cardiovascular risk management physician report card on the status of cardiovascular preventive care in each community and tailored patient education materials on cholesterol management and cardiovascular health. The cardiovascular risk management report cards will be issued annually to family physicians in the intervention communities for the next three years and will provide community-level data on nine main indicators of cardiovascular risk management. Each community is provided with its overall ranking compared to all 76 health regions in Ontario (except two with inadequate amounts of data), as well as indicators on risk factor screening. The report cards also provide rates of statin use among 66- to 75-year-olds in various subgroups at high risk for CVD and an indicator on statin adherence and cholesterol treatment target achievement.

Benchmarks are an important part of the report cards as these provide family physicians with high but achievable goals in their own practice for the included indicators. In addition to providing the community with their own data, each indicator also reports:

1. the Achievable Benchmark of Care (ABC) representing the value for the top 10% of performers (Weissman et al. 1999),
2. the value for the top performer in each indicator and
3. the highest reported values in a comparable health system from existing literature.

In addition to providing community-level data and benchmarking, two pages of the report are devoted to providing tips on improving cholesterol screening and statin prescribing and adherence. Information included in this section is based on the Canadian Cardiovascular Society's 2016 guidelines for dyslipidemia (Anderson et al. 2016), which are evidence based and the

current Canadian standard of practice. Preliminary results of the primary and secondary outcomes will become available as data linkage is updated across the CANHEART databases and as respondents complete process evaluation surveys.

Our team has also developed patient-centred print materials (e.g., waiting room posters, one-page flyers and 12-page booklets) that can educate the public about the indications for cholesterol screening, heart disease risk and benefits and risks of cholesterol-lowering therapy. Materials specifically address the barriers and facilitators of optimal cholesterol management identified from our qualitative patient interviews and are meant to empower patients with actionable resources and encourage informed discussions with their physicians. Our materials also include general advice about CVD risk reduction (e.g., smoking cessation, diet and physical activity), although the primary focus is on cholesterol and statins.

As part of our dissemination of the patient and physician “toolbox” of cholesterol management resources, we chose a two-pronged approach of both digital and print distribution to allow for maximum reach. Our CANHEART website serves as the hub for accessing study materials, whereas print copies of patient materials and report cards were mailed, respectively, to various community organizations and family physician practices. On our website, a designated URL ([www.canheart.ca/choices](http://www.canheart.ca/choices)) will provide general study information, link to the patient materials and physician reports accessible to those with a postal code in the intervention regions and highlight the work of our patient partner panel and investigator team. In addition, we have created a three-and-a-half-minute promotional video that explains the purpose of the project and is available on YouTube (<https://youtu.be/QF285N3ytO8>). We also have a Twitter feed (@CANHEART\_News) for sharing promotional materials, information on the study and general research and new data on cholesterol and cardiovascular health by our co-investigators and partners.

## Moving Forward

We hope that this work can ultimately serve as a flagship project for prompt feedback of care across communities in Ontario, across Canada and beyond. Our interventions are pragmatic and interactive, with the ability to serve as a learning health system to inform evidence-based practice and policy changes. By improving the implementation of guideline-recommended preventive therapy among those at risk of experiencing a cardiovascular event, we hope to inevitably save direct costs associated with in-patient care, cardiac rehabilitation and ambulatory services and indirect costs attributed to loss of work and premature death. Our study may also improve patient experience and quality of care by empowering patients with access to real-time, evidence-based information on the

benefits and risks of statins in cardiovascular health. We will launch our next phase of study interventions in 2020 and 2021, and all study interventions will be made publicly available at the conclusion of the study in late 2022. For more information, visit [www.canheart.ca/choices](http://www.canheart.ca/choices).<sup>1</sup> **HQ**

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## Note

1. In memory of Dr. Jack Tu (1965–2018), former principal investigator of the CANHEART CHOICES initiative.

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