

# A cluster randomised trial to assess the impact of opinion leader endorsed evidence summaries on improving quality of prescribing for patients with chronic cardiovascular disease

<b>Submission date</b> 04/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/06/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/09/2007	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00175279

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

### Study objectives

We propose having locally-nominated opinion leaders generate and endorse one-page evidence summaries for two common and chronic cardiovascular conditions. These evidence summaries, linked with specific patient-level medication profiles (generated at the community pharmacy), will be distributed to practicing physicians and attached to their patients chart. Our hypothesis is that this will act as both a source of credible and convincing information and a specific reminder for action at the next patient encounter. Our study is designed to test this hypothesis, by assessing the impact of this intervention on the quality of prescribing for patients with Heart Failure (HF) or Ischaemic Heart Disease (IHD).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

## Participant information sheet

### Health condition(s) or problem(s) studied

Heart failure, ischaemic heart disease

### Interventions

The intervention consists of a disease-specific and patient-specific one-page evidence summary. It will be a patient-specific letter addressed to the patients primary care physician, along with a description of the potential risks of undertreatment and current evidence-based treatment recommendations. The letter will be signed and endorsed by all five of the study opinion leaders. Accompanying the letter will be the most recent pharmacy record of medications

dispensed to the study patient. It is intended that the evidence summary and the pharmacy medication profile will become part of the patients medical record and act as a reminder or prompt at the next patient visit. These materials will be faxed to the primary care physician directly from the patients community pharmacy.

Control: usual care

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

The primary outcome measure will be the 'improvement' of prescribing for efficacious therapies in patients with a chronic cardiovascular disease within 6 months of the intervention. By study design, none of the study patients will be taking the medications of interest. For HF, starting any ACE inhibitor or angiotensin receptor blocker will be considered a positive outcome. For IHD, starting any statin will be considered a positive outcome. For the primary outcome all positive study-related medication changes will be pooled for an overall estimate of effect, compared with usual care controls.

### **Secondary outcome measures**

1. Condition-specific 'improvement' in prescribing after 6 months
2. 'Optimization' of dosage for each of the medications prescribed (i.e. ACE inhibitors or angiotensin receptor blockers and statins)
3. Patient adherence (using prescription refill rates based on dispensing records)
4. Potential influence of age and sex on outcomes

### **Overall study start date**

01/01/2002

### **Completion date**

30/06/2005

## **Eligibility**

### **Key inclusion criteria**

Patients with HF or IHD who are not currently taking the study medications of interest (Angiotensin-Converting Enzyme [ACE] inhibitors/angiotensin receptor blockers for HF or statins for IHD), and whose primary care physician of record is part of the study. For patients who happen to be eligible for both HF and for IHD, only one condition will be selected at random.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

**Target number of participants**

160

**Key exclusion criteria**

1. Decline enrolment
2. Unable or unwilling to give informed consent
3. Have previously taken the study medications according to dispensing records
4. Have a documented allergy or intolerance to study medications according to pharmacist records
5. Are in long-term care facilities or institutions
6. Do not confirm on the basis of self-report that they have a diagnosis of either HF or IHD
7. Primary care physician has already contributed 5 patients to the study

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

30/06/2005

## **Locations**

**Countries of recruitment**

Canada

**Study participating centre**

**2E3.07 WMC**

Edmonton, Alberta

Canada

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## **Sponsor information**

**Organisation**

Alberta Heritage Foundation for Medical Research (Canada)

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.ahfmr.ab.ca>

**ROR**

<https://ror.org/006b2g567>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Alberta Heritage Foundation for Medical Research (Canada)

**Alternative Name(s)**

AHFMR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Canada

**Funder Name**

Institute of Health Economics (Canada)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	Protocol	27/06/2005		Yes	No
<a href="#">Results article</a>	Results	01/01/2007		Yes	No