CHOLESTABETES

CHOLESTerol lowering in type 2 diABETES QuERI

PROGRAM OVERVIEW

For an in-depth summary, please reference the CHOLESTABETES QuERI Protocol

CANADIAN HEART RESEARCH CENTRE

The Care-Gap Analysis

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- **Lowering of the total and LDL cholesterol (LDL-C) has been shown to be a key step in lowering the risk of cardiovascular morbidity and mortality in patients at risk [1].**
- **Despite clear guideline recommendations [2, 3], up to 50% of high-risk Canadian patients are not achieving the recommended LDL-C target [4-6] and may therefore benefit from implementing strategies, including utilization of combination therapy, to achieve more optimal outcomes.**

1. Baigent C, Keech A, Kearney PM, et al; Cholesterol Treatment Trialists (CTT) Collaborators. Efficacy and safety of cholesterol-lowering treatment: prospective meta-analysis of data from 90,056 participants in 14 randomized trials of statins. Lancet 2005;366:1267-78.
2. Anderson, Todd J. et al; 2012 Update of the Canadian Cardiovascular Society Guidelines for the Diagnosis and Treatment of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult Canadian Journal of Cardiology , Volume 29 , Issue 2 , 151 – 167
3. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes 2013;37(suppl 1):S1-S212.
4. Yan AT, Yan RT, Tan M, et al. Contemporary management of dyslipidemia in high-risk patients: targets still not met. Am J Med 2006;119:676-83.
5. Hackam DG, Leiter LA, Yan AT, et al. Missed opportunities for secondary prevention of cardiovascular disease in Canada. Can J Cardiol 2007;23:1124-30.
6. L.A. Leiter et al; Canadian Journal of Diabetes, vol. 37, 2013, p. 82-89.

A1C, LDL-C and Blood Pressure Guideline Targets Achieved in Patients with Diabetes

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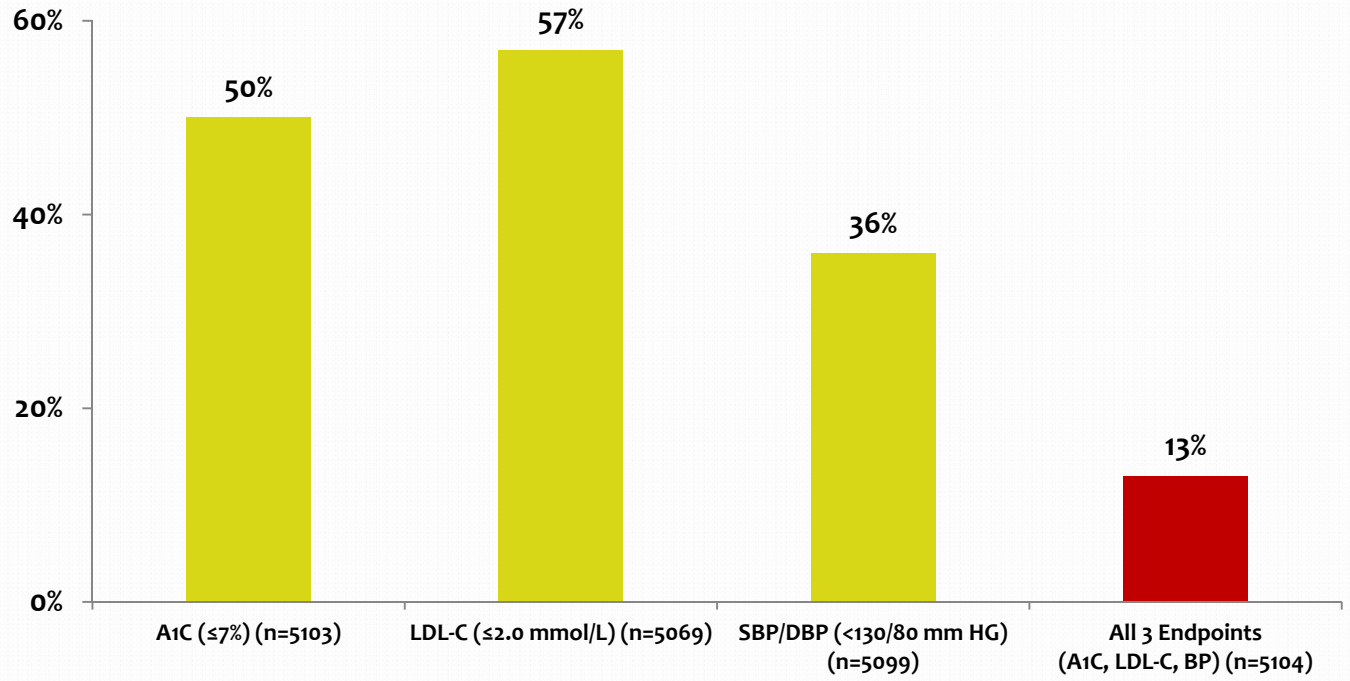
- **DM-SCAN, a recent survey by the Canadian Heart Research Centre among 479 Canadian physicians involving over 5,000 patients with type 2 diabetes mellitus, has revealed an even greater care-gap in the comprehensive care of high-risk patients whereby only 13% of patients achieved a triple target of glycemic, LDL-C, and blood pressure control**



L.A. Leiter et al; Canadian Journal of Diabetes, vol. 37, 2013, p. 82-89.

DM SCAN

Program Background

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- **The CHOLESTABETES QuERI is an observational quality enhancement initiative which provides program participants with evidence-based management strategies and feedback on patients with T2DM who are not achieving guideline-recommended LDL-C and A1C targets**
- **The Program Design:**
  - *Aims to identify challenges Canadian physicians experience in managing patients with diabetes*
  - *Addresses the existing care-gap and the need for greater control of risk factors in high-risk patients*
  - *Provides an interactive feedback algorithm to help facilitate evidence-based management strategies, including appropriate utilization of combination therapy, to achieve guidelines recommended targets*
- **The decision to follow the evidence-based recommendations are left to the participating physician's discretion**

Program Scope

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Participants:	75 Primary Care Physician Participants
Recruitment:	5 Patients per Participant
Enrollment:	375 Eligible Patients
Duration:	24±6 Weeks
Number of Visits:	3 (Routine Clinical Practice)
Approval Process:	Central Research Ethics Board - Approved

Eligibility Criteria

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ALL of the criteria must be present

1. **Male and female patients older than 18 years of age**
2. **Diagnosis of hypercholesterolemia and type 2 diabetes mellitus**
3. **High-risk for cardiovascular disease defined as one of:** (at least ONE must be present)
   - 10-year risk of cardiovascular event ≥20% based on the Framingham Risk Score
   - Prior diagnosis of CAD (PCI, CABG, MI, Stenosis > 50% on angiogram)
   - Prior diagnosis of CeVD (TIA, CVA, Carotid disease on ultrasound > 50%)
   - Prior history of Abdominal Aortic Aneurysm surgery
   - Prior history of PAD (AFB, Stent, or ABI <0.7 with symptoms of intermittent claudication)
4. **LDL-C > 2.0 mmol/L despite on optimal statin therapy (e.g. Atorvastatin ≥ 20 mg, Rosuvastatin ≥ 10 mg, Simvastatin ≥ 40 mg)**
5. **A1C > 7.0% and < 9.0% on optimal metformin therapy (e.g. ≥ 1500 mg / day)**
6. **Patient's Consent to Participate**

Exclusion Criteria

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None of the criteria present

1. Patients with clinically significant concomitant illness or co-morbid condition (e.g. cancer)
2. Liver, muscle or kidney abnormalities (e.g. compromises patient management according to physician)
3. Secondary causes of hypercholesterolemia (e.g. hypothyroidism, nephrotic syndrome)
4. Contraindications or intolerance to combination therapy

Participant Responsibilities and Remuneration

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Participating Physician Responsibilities

- ✓ Complete the Needs Assessment Survey and the Payee Form;
- ✓ Read and understand the Memorandum of Understanding (MOU) and the CHOLESTABETES QuERI program materials, timelines and ensure that all person(s) in your practice who may be associated with the CHOLESTABETES QuERI program also understand these materials;
- ✓ Maintain chart notes that were used for the CHOLESTABETES QuERI submitted data until you are notified by the CHRC that the program is completed;
- ✓ Complete the e-CRFs and feedback forms on patients that meet the program eligibility criteria in adherence with the program timelines;
- ✓ Obtain and retain a copy of an Informed Consent Form for each eligible patient included in the program;
- ✓ To provide a copy of a current curriculum vitae and medical license if requested from the CHRC;
- ✓ Exercise reasonable and diligent efforts and professional expertise in the conduct and completion of the program documents in an efficient and timely manner and in compliance with the program instructions;
- ✓ Be available to answer data queries

Remuneration

- **Visit 1 (Baseline Visit) - $125.00 per interactive e-CRF**
  (**up to $625.00** for completing interactive e-CRFs on 5 patients)
- **Visit 2 (14±6 weeks) - $ 75.00 per interactive e-CRF**
  (**up to $375.00** for completing interactive e-CRFs on 5 patients)
- **Visit 3 (24±6 weeks) - $ 50.00 per interactive e-CRF**
  (**up to $250.00** for completing interactive e-CRFs on 5 patients)

e-CRF - Data Collection Variables

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Evaluation	Visit 1	Visit 2	Visit 3
Informed Consent	√		
Eligibility verification	√		
Patient ID assignment	√		
Demographics (age, gender)	√		
Functional Assessment / Symptoms	√	√	√
Co-morbidities and Medical History	√		
Vital signs including body weight	√	√	√
Medications to date	√	√	√
Cholesterol panel	√	√	√
Glycemic assessment	√	√	√
Other Lab Values if abnormal • AST • ALK PHOS • Creatinine • e-GFR • ACR	√	√	√
Evidence-based considerations / additional therapy	√	√	√

All of the program data points may not be required at every visit

e-CRF - Interactive Considerations, Recommendations & Feedback Forms

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The Interactive component of the e-CRF consists of two parts:

Considerations & Recommendations Form:

- Compares current management strategy and patient characteristics to guideline recommended strategies and targets
- Summarizes evidence-based considerations and recommendations for the participating physician to consider in order to achieve guideline recommended targets

Participating Physician Feedback Form:

Based on the Considerations and Recommendations, the participating physician:

- Specifies the change(s) implemented to the current management strategies based on the considerations and recommendations

OR

- Provides reason(s) for not following the considerations and recommendations

Summary

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Benefit of Participation:

- Improved care of high-risk patients through interactive tools and guideline recommended reminder systems
- Better care consequently leads to improved patient outcomes
- Decision to follow the recommendations and all treatment strategies are left to the physician's discretion - no formal intervention or mandated treatment
- Better understanding of current barriers in the management of patients with T2DM in Canada and better adherence to evidence-based recommendations to help close the care-gap

Canadian Heart Research Centre (CHRC)

- The Canadian Heart Research Centre is a federally incorporated not-for-profit, full service academic research organization
- ***Mission Statement:*** The CHRC is the national leader in the design, conduct and management of clinical trials, quality enhancement research initiatives and innovative physician educational programs in North America
  - *Over 18 years of experience in integrating evidence-based recommendations into clinical practice which has resulted in measurable and sustainable behavior changes at point of care*
  - *Established long standing relationships and a vast network of collaborators: from thought leaders, universities and academic institutions to CME content experts and health care professionals across specialities*

Selected CHRC Programs

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Program	Clinical Setting	Nº Sites	Nº Patients	Status
ACS I	Acute Coronary Syndromes	51	5,312	Sep 99-Jun 01
ACS II	Non-ST ↑ ACS	36	2,359	Jan 03-Dec 03
ISH	Isolated Systolic Hypertension	72	693	Jul 01-Aug 03
InsigHT	High-risk Hypertension	99	1,141	Jan 02-Mar 03
VP	High-risk Vascular	278	5,100	Dec 01-Nov 04
GOALL	High-risk Vascular	255	4,726	Mar 03-Dec 04
STENT	PCI	14	734	Sept 04-Feb 07
DRIVE	Type 2 Diabetes	229	3,017	Feb 05-Mar 07
PAH QuERI	Pulmonary Hypertension	160	823	Ongoing
Scleroderma QuERI	Scleroderma	27	212	Apr 06-Sept 07
T2DM	Type 2 Diabetes	386	6,155	Mar 06-Sept 08
GUIDE	Dyslipidemia	225	2,704	Dec 05-Oct 07
GUIDANC	Dyslipidemia	172	2,334	Oct 07-Dec 09
FREEDOM AF	Atrial Fibrillation	507	4,962	2010 - 2012
CANREDUCE-CMR	Type 2 Diabetes	100	2,500	2011 - 2012
DM-SCAN	Type 2 Diabetes	478	5,123	2012
CONNECT AF	Atrial Fibrillation	620	6,500	2012 - 2014
ACS III QuERI	Acute Coronary Syndromes	40	800	On-Going
CHOLESTABETES QuERI	Type 2 Diabetes	75	375	Starting