# **ACHORD**

## Alliance for Canadian Health Outcomes Research in Diabetes

Volume 6 Issue 2 July 2006

### IHE Consensus Development Conference for Self-Monitoring in Diabetes

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In November 2006, ACHORD and the IHE will be hosting an international Consensus Conference for Self-Monitoring in Diabetes in Edmonton. The objective is to develop a consensus statement on the benefits and costs of testing supplies for self-monitoring of blood glucose in diabetes, to inform policies of financial coverage.

This will be the first in a series of IHE Consensus Conferences. These will be modeled on the National Institute of Health Consensus Development Program from the US. The purpose of an IHE Consensus Conference is to evaluate the available scientific information on a health issue and develop a statement that advances understanding of the issue under consideration and will be useful to health professionals and the public. The panel is typically an independent, broad-based, non-government, advocacy group with social awareness on broad policy issues. The panel weighs the evidence presented by invited experts and comments from the general audience information, then composes a statement that addresses a set of predetermined questions. This statement is an independent report of the panel and is not a formal policy statement of any government.

For this very first IHE Consensus Conference, the ACHORD Group was asked to identify a topic and organize the program around a relevant health policy issue for diabetes in Canada. One line of research we have undertaken relates to policies and the cost of supplies for self-monitoring in diabetes. We are aware that the supplies for self-monitoring are one of the top line-item expenditures for each of the provincial health care systems that provide financial coverage for these supplies. Further, there is debate amongst the clinical community as to the effectiveness of self-monitoring in all patients with diabetes. This is evidenced by organized debates on this topic, such as at the recent American Diabetes Association meeting in Washington in June 2006, and the upcoming CDA/CSEM Annual meeting in Toronto in October 2006, where ACHORD investigator Dr. Sumit Majumdar will present the CON arguments.

The IHE Consensus Conference Program Planning Committee includes Dr. Jeffrey Johnson, Dr. Egon Jonsson (IHE), Ms. Karen Phillips (CDA), Ms. Dawn Friesen (Alberta Health and Wellness) and Judy Wry (Buksa Conference Management). Mr. Michael Decter will chair the panel for this first consensus conference.

# ACHORD: Seen and Heard

### **Recent Publications**

Hubacek J, Galbraith PD, Gao M, Humphries K, Graham MM, Knudtson ML, Ghali WA; APPROACH investigators. External validation of a percutaneous coronary intervention mortality prediction model in patients with acute coronary syndromes. *Am Heart J* 2006 Feb;151(2):308-15.

Southern DA, Knudtson ML, Ghali WA; APPROACH Investigators. Myocardial infarction on snow days: incidence, procedure, use and outcomes. *Can J Cardiol* 2006 Jan;22(1):59-61.

Maddigan SL, Feeny DH, Majumdar SR, Farris KB, Johnson JA. Health Utilities Index Mark 3 demonstrated construct validity in a population-based sample with type-2 diabetes. *J Clinical Epidemiology* 2006;59:472-477.

Brown LC, Majumdar SR, Newman SC, Johnson JA. Type 2 diabetes does not increase risk of depression. *CMAJ* 2006;175:42-46.

Simpson, SH, Eurich DT, Majumdar SR, Padwal RS, Tsuyuki RT, Varney J. Johnson JA. A Meta-Analysis of the Relationship between Drug Therapy Adherence and Mortality Risk. *BMJ* 2006 Jul 1;333(7557):15.

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# Report from the Chair



Jeffrey A. Johnson

I am happy to take this opportunity to report on recent activities of the ACHORD Group. We continue to be productive in generating and disseminating diabetes health outcomes research. I am happy to report that our group is growing again, with several new people joining in recent times. Ms. Sherry Lydynuik has joined us as our Research Administrative Assistant. Sherry comes to us with 10 years of experience at the Faculty of Medicine at University of Alberta. Ms. Stephanie Vermeulen has also joined our group as Project Manager, and will have primary responsibility for organizing the Alberta Diabetes Surveillance System (ADSS). Stephanie is a nurse and is just completing her MSc in Epidemiology, a background which will be a welcome addition to the group.

Our research trainees continue to progress. Samantha Bowker recently presented her research on health status of people with diabetes and cancer at the American Diabetes Association meeting in Washington DC. We were excited for PhD student Dean Eurich, and his wife Michelle, who welcomed their new daughter Rikki last month. We have two new trainees joining the group later this year. Dr. Carolyn Green will be starting a CIHR funded Post-Doctoral Fellowship this summer, working with myself and Dr. Scot Simpson on the Vascular Intervention Program, and JM Gamble, a U of A Pharmacy grad, will be starting an MSc in Clinical Epidemiology this fall.

The past few months have been busy for me, in ramping up activities for the ADSS and planning for the upcoming IHE Consensus Conference in November. In September I will be attending the European Association for the Study of Diabetes (EASD) meeting in Copenhagen/Malmo, where I will be participating in a panel discussion on the role of oral antidiabetic agents in improving long-term survival.

# **Project Hightlight:**

<u>Patients with Heart Failure ANd Type 2 Diabetes Treated with Placebo Or Metformin</u>
(PHANTOM) Pilot Study

Research Team: Dean Eurich, Richard Lewanczuk, Sumit Majumdar, Finlay McAlister, Ross Tsuyuki, Jeffrey Johnson

Heart failure (HF) is a common complication of type 2 diabetes. Unfortunately, there are limited treatment options for glycemic control in patients with HF and diabetes. Although metformin is considered a safe and effective medication, it is currently not recommended in patients who have HF due to a perceived increased risk of lactic acidosis, although there is limited evidence linking metformin to lactic acidosis. Indeed, the near-absence of any cases of lactic acidosis suggests that metformin may be "an innocent bystander" in sick patients rather than a causal agent. We recently completed a large observational study that suggested metformin therapy is associated with lower morbidity and mortality and appears to be safe in this population.

It is important to consider, however, that the currently available evidence supporting the use of metformin in patients with heart failure is based solely on observational data. As a result, we have designed the *PHANTOM Study* to rigorously assess the safety and efficacy of metformin in a blinded randomized placebo controlled trial (RCT). We are conducting a *PHANTOM Pilot Study* to evaluate the feasibility of a large RCT in

this population and to generate initial morbidity and mortality estimates. The pilot study is being completed as part of a component of Dean Eurich's PhD dissertation research.

We are aiming for 100 subjects (i.e., approximately 10% of the anticipated number of subjects for a full RCT) who will be randomly assigned to either metformin or matching placebo therapy and followed for 6 months. The primary outcome of the study is a combined endpoint of all-cause mortality and all cause-hospitalization. Secondary endpoints include the individualized components of the primary outcome, development of lactic acid, change in A1c, change in six-minute walk, and change in health related quality of life measures. We are currently enrolling subjects into the study at the University of Alberta Hospital. It is anticipated that enrollment at the Misericordia Community Hospital and several emergency departments within the Capital Health Region will be commencing within the near future. The results of this pilot study will be used to assess the feasibility of conducting a large multicentre study and to secure funding through various funding agencies, including CIHR and the Heart & Stroke Foundation.

Metformin may be "an innocent bystander" in sicker patients, rather than an agent that causes lactic acidosis itself.

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### Recent Literature: Brown LC, Majumdar SR, Newman SC, Johnson JA Type 2 diabetes does not increase risk of depression. CMAJ 2006;175:42-46.

#### What was the study about?

The aim of this study was to evaluate whether people with type 2 diabetes are at an increased risk of developing depression compared to people without diabetes. Many cross-sectional studies have demonstrated an increased association between depression and diabetes, and longitudinal studies have demonstrated an increased risk of type 2 diabetes in people with depression or high depressive symptoms. Little information is available, however, evaluating the risk of depression in people with type 2 diabetes. As people with diabetes and comorbid depression have increased functional disability, decreased self-care activities including adherence to medications and diet and exercise programs, increased micro- and macrovascular complications, and an increased risk of mortality independent of increased complications compared to people with diabetes who do not have depression, investigating the temporal relationship between depression and diabetes is necessary.

### What were the results of the study?

After adjusting for age, sex, number of physician visits in the year following study index date, presence of comorbidities associated with depression (including coronary artery disease, cerebrovascular disease, peripheral arterial disease, cancer, and arthritis), and insulin use as a marker for severity of diabetes, diabetes was not associated with an increased risk of depression compared to not having diabetes. However, complications associated with diabetes including cerebrovascular disease and peripheral arterial disease were associated with a significantly increased risk of depression (HR: 1.73; 95% CI: 1.41 - 2.13 and HR: 1.79; 95% CI: 1.20 - 2.66, respectively).

### What are the implications of the study?

The results of this study have important implications in terms of the temporal relationship between depression and diabetes, and in terms of screening patients with diabetes for depression. This study found that people who are recently diagnosed with type 2 diabetes are not at an increased risk of developing depression compared to people without diabetes. As a result, routine screening for depression in people with type 2 diabetes is not warranted, and should be evaluated on a case-by-case basis. Complications associated with diabetes such as cerebrovascular disease and peripheral arterial disease do appear to increase the risk of depression. Therefore, it is important that patients with diabetes and cardiovascular comorbidities are closely monitored for development of depression.

Routine screening depression in people with recent onset type diabetes is not warranted. Depression may be more likely later in the disease, associated with long term complications.

# Meet the Staff: Stephanie Vermeulen, BSN.

In 1997, Stephanie graduated from a diploma Stephanie also had the opportunity to be program at N.A.I.T in Business specializing in Marketing. She soon realized that she was more interested in health, and decided to follow her mother's footsteps and enroll in nursing. Stephanie completed her Bachelor's of Science in Nursing at the University of Alberta in 2001. After graduation, she worked as a bedside nurse, first in neurosurgery and then in pediatric cardiology from 2002 to 2005. In 2003, Stephanie decided to pursue a Masters degree in the Department of Public Health Sciences specializing in Epidemiology. In addition to being a full-time student, she maintained part-time employment as a research assistant at the Stollery Children's Hospital and with the Western Canadian Children's Heart Network. The research projects were mostly qualitative in nature, but

involved with some of the quantitative components.

Presently, Stephanie is in the process of completing her Master's Thesis, under the supervision of Dr. Linda Carroll, where she is assessing the performance of a self-report comorbidity scale that was used in a large population-based study. As she nears the completion of her thesis, she welcomes the opportunity to join the ADSS as Project Manager on a part-time basis. She is excited to join ACHORD on a full-time basis as soon as her thesis is complete. Stephanie is planning to maintain her clinical practice on a part time basis as a Registered Nurse at the Stollery Children's Hospital.



Stephanie Vermeulen

### ACHORD Chair

### Dr. Jeffrey Johnson

University of Alberta Institute of Health Economics

### Staff & Research Trainees

Ms. Samantha Bowker Ms. Lauren Brown Mr. Dean Eurich Ms. Sherry Lydynuik Dr. Sheri Pohar Ms. Stephanie Vermeulen



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#### Address

#1200, 10405 Jasper Avenue Edmonton, Alberta Canada T5J 3N4

### **Phone**

(780) 448-4881

#### Fax

(780) 448-0018

#### Websites

http:/www.achord.ca http:/www.ihe.ca

# ACHORD: Seen and Heard (cont)

#### **Recent Presentations**

Shrive F, Ghali WA, Johnson JA, Manns B. Comparison of UK and US Scoring Algorithms for the EuroQol-5D: Effect on the Findings of an Economic Evaluation. Society of General Internal Medicine 29th Annual Meeting, Los Angeles, CA, April 26 – 29,

Rabi D, Shrive F, McAlister FA, Majumdar SR, Sauve R, Johnson JA, Ghali WA. Effect of Peri-Operative Glucose-Insulin and Potassium In fusion on Atrial Fibrillation and Mortality after Coronary Artery Bypass. Society of General Internal Medicine 29th Annual Meeting, Los Angeles, CA, April 26 – 29,

Brown LC, Majumdar SR, Newman SC, Johnson JA. Type 2 diabetes does not increase risk of depression. Canadian Therapeutics Congress, May 10 – 13, 2006.

of type 2 diabetes in people taking antidepressant therapy. Canadian Therapeutics Congress, May 10 - 13, 2006.

Bowker SL, Pohar SL, Johnson JA. Health Related Quality of Life Deficits in Individuals with Comorbid Diabetes and Cancer. American Diabetes Association 66th Scientific Sessions, June 9 - 13, 2006, Washington, DC. Diabetes 2006;55(Suppl 1):A206.

Johnson JA, Pohar SL, Majumdar SR. Health Care Utilization and Costs in the Decade Following Diagnosis of Type 1 and Type 2 Diabetes. American Diabetes Association 66<sup>th</sup> Scientific Sessions, June 9 – 13, 2006, American Diabetes Association 66th Scientific Sessions, June 9-13, 2006, Washington, DC. Diabetes 2006;55(Suppl 1):A556.

Johnson JA, Pohar SL, Secnik K, Yurgin N, Hirji Z. Utilization of Diabetes Medication and Cost of Testing Supplies in Saskatchewan Prescription Drug Plan, 2001. American Diabetes Association 66<sup>th</sup> Scientific Sessions, Brown LC, Majumdar SR, Johnson JA. Risk June 9 - 13, 2006, Washington, DC. Diabetes 2006;55(Suppl 1):A553.

# Why this Newsletter?

The purpose of the ACHORD Newsletter is to keep you updated on the activities of the ACHORD group and to provide reviews of recent, relevant diabetes literature. The newsletter is published three times a year.

If you have any questions about the newsletter, please call Jeffrey Johnson or any of the ACHORD staff at the Institute of Health Economics at (780) 448-4881.

You can expect to see the following in every

- Report from the Chair
- ACHORD Project Highlights
- ACHORD Seen and Heard
- Review of Recent Literature

### **ACHORD Events**

**IHE Consensus Development Conference** For Self-Monitoring in Diabetes November 14-16, 2006 Westin Hotel Edmonton, Alberta, Canada