

# Diabetes Experience

*More than 20 staff with experience in diabetes projects including*

Keith Davis, MA  
Sr. Director, Health Economics  
kldavis@rti.org

Catherine Johannes, PhD  
Director, Epidemiology  
cjohannes@rti.org

Lori McLeod, PhD  
Head, Psychometrics  
lmcleod@rti.org

## Contact

RTI Health Solutions  
Research Triangle Park, NC, USA  
+1.800.262.3011

Ann Arbor, MI, USA  
+1.734.213.5372

Barcelona, Spain  
+34.93.241.7766

Lund, Sweden  
+46.706.58.3442

Manchester, UK  
+44(0)161.447.6000

Sheffield, UK  
+44(0)114.213.3390

Waltham, MA, USA  
+1.781.434.1700

rtihealthsolutions@rti.org  
www.rtihs.org

## A Wealth of Experience

At RTI Health Solutions, we have collaborated with our clients on over 75 projects researching diabetes, diseases related to diabetes, or complications of diabetes. Our experience includes:

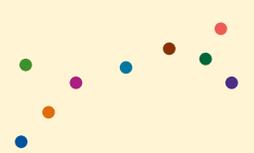
- Type 1 diabetes
- Type 2 diabetes
- Microvascular complications in diabetes including:
  - Diabetic retinopathy
  - Diabetic nephropathy
  - Peripheral neuropathy
- Macrovascular complications including:
  - Cardiovascular events related to diabetes
  - Peripheral vascular disease
  - Diabetic foot ulcers
- Obesity

## Types of Projects

We have assisted our clients with numerous types of projects to inform their strategies in the diabetes market and to develop and gain market access for products to treat diabetes and complications arising from diabetes. Our projects have included:

- Disease prevalence, including prevalence of diseases related to the onset of diabetes
- Assessment of the impact of weight loss among obese individuals
- Therapy adherence studies
- Economic burden of illness studies
- Costs of treatment studies
- Summaries of existing therapies
- Preparation of value dossiers to gain formulary access
- Stated-choice studies between products for the treatment of diabetes
- Literature reviews
- Research gap analysis and publication planning
- Database analyses using cross-sectional and longitudinal databases
- Development of the value proposition for drugs indicated for diabetes
- Review of the disease state and the reimbursement and market access environments
- Patient-reported outcomes studies
- Development of survey instruments to assess symptoms and treatment options
- Development of decision-analytic models to predict disease prevalence and the budget impact and cost-effectiveness of treatment options
- Commercial assessment of products indicated for diabetes

*(continued)*



## See How We've Helped Others

### Database Study Evaluates Incretin Therapies

Using data from the GE Centricity database, we implemented a retrospective cohort study to evaluate if use of incretin therapies contributes to weight loss and associated improved glycemic control, blood pressure and lipids in patients with type 2 diabetes. The study showed that weight loss in patients on incretin therapy had beneficial effects on these cardiovascular risk biomarkers. Outcome trials are needed to determine whether an improvement in these biomarkers translates into a reduction in cardiovascular events in patients with type 2 diabetes. Study results were published in *Diabetes Care*, 2010; 33(8):1759-1765

### Stated Preference Study

We conducted a stated preference study to analyze factors that improve patient adherence to oral medications for Type 2 diabetes. As part of the study, patients completed a web survey that included a series of choice-format questions about two hypothetical medications, each defined by improvements in glycated haemoglobin, frequency of mild-to-moderate hypoglycaemia, water retention, weight gain, stomach upset and medication-related cardiovascular risk. Patients were also asked to indicate how likely they would be to miss or skip doses of each hypothetical medication. We found that weight gain and cardiovascular risk had significant negative effects on patient adherence. Study results were published in *Diabetic Medicine*, 2009; 26(4):416-424.

### Cost-Effectiveness of a Treatment

We developed a decision-analytic model to evaluate the cost-effectiveness of duloxetine when considered as an additional treatment option for UK-based patients suffering from diabetic peripheral neuropathic pain. The cost-effectiveness of duloxetine was evaluated as an additional first-, second-, third- or fourth-line therapy over a 6-month treatment period. 2008 study results were published in *Current Medical Research and Opinion* 2008; 24(2):385-399.

### Diabetes Treatment Patterns

Using data from The Health Improvement Network (THIN) database, which collects records from general practices throughout the UK, we implemented a retrospective cohort study to estimate the time to insulin initiation in patients with Type 2 diabetes inadequately controlled on oral glucose-lowering agents (OGLAs). The study found that 25% of patients with Type 2 diabetes had insulin initiation delayed for at least 1.8 years, and 50% of patients delayed starting insulin for almost 5 years after failure of glycemic control with OGLA polytherapy, even in the presence of diabetes-related complications. Interventions that reduce this delay to insulin initiation are required to help achieve and maintain recommended glycemic targets in patients with Type 2 diabetes. Study results were published in *Diabetic Medicine* 2007; 24(12):1412-8.

## Selected Recent Publications By Our Staff

Anderson RT, Girman CJ, Pawaskar MD, Camacho FT, Calles J, Kelly WS, **DeMuro C**, Balkrishnan R. Diabetes Medication Satisfaction Tool: a focus on treatment regimens. *Diabetes Care* 2009;32(1):51-3.

**Barrett AM**, Lucero MA, LeT, Robinson RL, Dworkin RH, Chappell AS. Epidemiology, public health burden, and treatment of diabetic peripheral neuropathic pain: a review. *Pain Medicine* 2007;8(Suppl 2):S50-62.

Beard SM, **McCrink L**, LeTK, Garcia-Cebrian A, Monz B, Malik RA. Cost effectiveness of duloxetine in the treatment of diabetic peripheral neuropathic pain in the UK. *Current Medical Research and Opinion* 2008;24(2):385-99.

**Candrilli SD**, **Davis KL**, Kan HJ, Lucero MA, Rousculp MD. Prevalence and the associated burden of illness of symptoms of diabetic peripheral neuropathy and diabetic retinopathy. *Journal of Diabetes and Its Complications* 2007;21(5):306-14.

Horton ES, Silberman C, **Davis KL**, Berria R. Weight loss, glycemic control, and changes in cardiovascular biomarkers in patients with type 2 diabetes receiving incretin therapies or insulin in a large cohort database. *Diabetes Care* 2010;33(8):1759-65.

**Johannes CB**, Koro CE, Quinn SG, **Cutone JA**, Seeger JD. The risk of coronary heart disease in type 2 diabetic patients exposed to thiazolidinediones compared to metformin and sulfonylurea therapy. *Pharmacoepidemiology and Drug Safety* 2007;16(5):504-12. DOI: 10.1002/pds.1356.

**Johannes CB**, Seeger JD, Koro CE, **Cutone JA**, Quinn SG. Response to a comment on 'the risk of coronary heart disease in type 2 diabetic patients exposed to thiazolidinediones compared to metformin and sulfonylurea therapy'. *Pharmacoepidemiology and Drug Safety* 2007;16(10):1073-4.

Lee LJ, Fahrback JL, **Nelson LM**, **Mcleod LD**, Martin SA, Sun P, Weinstock RS. Effects of insulin initiation on patient-reported outcomes in patients with type 2 diabetes: Results from the DURABLE trial. *Diabetes Research and Clinical Practice* 2010; 89(2):157-166.

Rubino A, **McQuay L**, Gough SC, Kvasz M, **Tennis P**. Delayed initiation of subcutaneous insulin therapy after failure of oral glucose-lowering agents in patients with Type 2 diabetes: a population-based analysis in the UK. *Diabetic Medicine* 2007;24(12):1412-8.

Rubino A, Rousculp MD, **Davis K**, Bastyr EJ, Tesfaye S. Diagnosis of diabetic peripheral neuropathy among patients with type 1 and type 2 diabetes in France, Italy, Spain, and the United Kingdom. *Primary Care Diabetes* 2007;1(3):129-34.