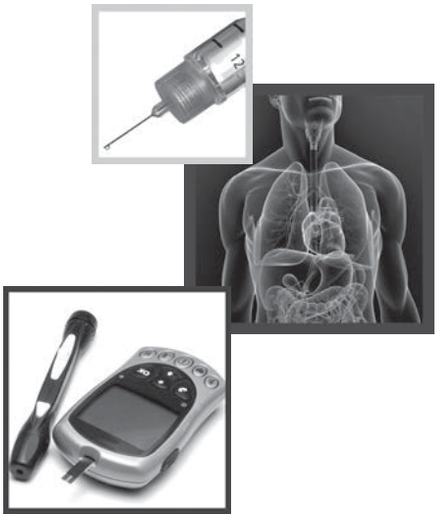

Strategies to deliver safe, effective and affordable diabetes care

Patrick J O'Connor* speaks to Natasha Leeson, Assistant Commissioning Editor: Dr Patrick J O'Connor is a primary care physician and chronic disease epidemiologist who serves as Senior Clinical Investigator at HealthPartners Institute for Education and Research in Minnesota (MN, USA). Dr O'Connor has a longstanding interest in diabetes epidemiology, treatment and outcomes. He is principal investigator of numerous NIH grants involving diabetes and related chronic diseases. He has been a coauthor of the national American Diabetes Association diabetes care guideline for 5 of the last 12 years, and also coauthors regional Institute for Clinical Systems Integration (ICSI) clinical guidelines on treatment of hypertension, dyslipidemia, diabetes, obesity, and on lifestyle prevention of common chronic diseases. Dr O'Connor has over 200 peer-reviewed publications and has served on numerous NIH study sections and advisory panels as well as similar panels for Centers for Disease Control and Prevention (CDC), Center for Medicare and Medicaid Services (CMS), National Quality Foundation (NQF), Agency for Healthcare Research and Quality (AHRQ), Patient Centered Outcomes Research Institute (PCORI), the Indian Health Service (HIS), the Institute of Medicine (IOM), the Minnesota Department of Health (MDH) and other organizations. His most satisfying professional accomplishment has been helping to orchestrate major improvements in quality of diabetes care in managed care organizations from 1995 to 2012 using electronic medical record-based clinical decision support, new care models, and patient and provider behavior change interventions.

Q How did your career lead you to working in diabetes?

After I completed my training in family medicine, I went to work on the Navajo Indian reservation in a remote area of northern Arizona (AZ, USA) where we had 600 patients with diabetes. I knew from my training how to take care of diabetic ketoacidosis and hospitalized patients with diabetes, but I had very little experience in treating outpatients with diabetes over long periods of time. This is what spurred my interest in diabetes – I knew very little about its ambulatory management and I wanted to learn more. By working with more experienced doctors, I was able to learn from them and utilize their clinical experience. Diabetes was becoming an even bigger problem on the Navajo reservation, so it was at this time when I also began to do research on it. We looked at the care we were delivering for diabetes patients on the reservation and thought about ways we could improve this.

Q Were there any particular colleagues that you worked with who really influenced the path your research has taken?

A major turning point for me was during medical school – I decided to take an extra year out to study public health at the

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University of North Carolina (NC, USA). While there I had the good fortune of having Ed Wagner as an advisor, and he has continued to be a mentor and an advisor to me ever since. After working on the Navajo reservation, I then moved to the University of Connecticut (CT, USA) and worked with Benjamin Crabtree and William Miller, who are both anthropologists. Ben and I led a research unit in the family medicine department. At that time, neither one of us had ever published a paper, so we worked together and learned research the hard way, but it worked. Although I got tenure, I left academia and moved to do research in a care delivery system at HealthPartners in Minneapolis (MN, USA), where the organization really valued primary care and was actively looking for ways to actively improve diabetes care. In retrospect, it was a good decision for me career-wise to leave academia and one of the best things that happened to me.

Q What do you consider to be the biggest achievements in your career so far?

The biggest thing is working in this large delivery system and large network with other large health maintenance organizations to improve care, which has been very successful. I started working here in 1993, and by 1994 we had organized initiatives in HealthPartners to improve diabetes care, which have been sustained ever since. By 1999, we had median glucose levels less than 7% (53 mmol/mol) in all our 10,000 diabetes patients; this was achieved simply by carrying out system improvements and we have maintained those excellent levels of glucose control ever since. Also starting in approximately 1999, we put emphasis on blood pressure and low-density lipoprotein cholesterol control, and patient levels of these have also improved dramatically to this point. My involvement in these improved outcomes is very satisfying. In diabetes patients in the last 7 years, we have documented an 18% reduction in mortality and a 35% reduction in heart attacks.

Another satisfying achievement was participating in the ACCORD trial. I was involved in planning the study and then, later on, I was involved in providing care for approximately 300 of the participants, which was a terrific experience. I think that the results of the ACCORD study, which showed that extremely aggressive management of blood pressure, glucose and lipids conferred little or no benefit to patients, were very important for all three of these things. That was a very important study and has really framed a new and more personalized approach to diabetes care ever since.

Q You have recently published a paper on the effectiveness of four distinct glucose-control strategies in patients with Type 2 diabetes. Can you tell me a bit about this study?

One very important question that needs to be addressed is the cardiovascular safety of glucose-lowering medication. Out of the ten or more classes of glucose-lowering medication now available, only three classes have reasonably good long-term studies that demonstrate a positive impact on cardiovascular events: metformin, sulfonylureas and human insulins. These results come largely from older studies, such as the UK PDS study. Since there are approximately 48 cardiovascular deaths among diabetes patients for every one renal disease death, it is clear that the main goal of Type 2 diabetes care needs to be reduction of cardiovascular risk. It is imperative that we know that the medicines we prescribe for glucose control have some cardiovascular benefits. The ACCORD and ADVANCE studies raised some questions about the safety of glucose-lowering medications, so we are now very aware of this.

Our study on the treatment strategies that were involved in ACCORD demonstrated that the same treatment strategies give the same results across entire diabetes populations, and although more intensive efforts to lower glucose do confer some renal benefits, they do not reduce cardiovascular events. Consequently, our study showed that results of the ACCORD study applied very broadly to all patients with Type 2 diabetes in primary care settings, not just those at high risk.

Q There have been several recent publications regarding cardiovascular risk of glucose-lowering medications. How important are these studies?

A positive development is that the US FDA has mandated that new glucose-lowering drugs be assessed for cardiovascular safety. However, a more important practical question is: "What is the impact of treatment combinations on cardiovascular safety?" The majority of patients with Type 2 diabetes take more than one glucose-lowering medicine, so it is important that there are studies on individual classes of medicines. However, it is also important that investigators use large databases and other research methods to look at the cardiovascular impact of common combinations of medicine. The attention of the diabetes community has turned markedly and people are thinking about it in a very careful way, which is terrific. One way to address this problem is studying large groups of patients. For example, in our network of health maintenance organizations, we have a registry of approximately 1.5 million individuals with diabetes. Using this resource, it is possible to examine and identify the relevant impact of treatment patterns on outcomes such as mortality and cardiovascular events. In the past, statistical methods made some of those analyses difficult to do in terms of validity, but newer methods, such as marginal structural modeling, have some promise for improving the validity of these large database analyses and this is a source of information that should be seriously considered.

Q The prevalence of Type 2 diabetes is rising. What strategies can we put in place to help prevent, or slow, the onset of diabetes?

It is important to consider that if you reduce complication rates by half but the prevalence of the disease doubles, you will have just as many amputations or heart attacks as you had to begin with, which would be a very undesirable scenario. Even though there has been progress in the management of Type 2 diabetes, and there have been impressive reductions in the number of associated heart attacks and mortality in recent years, it is still important to focus on primary prevention of

diabetes. I am very disappointed in the lack of creativity in the research community on this issue. Most researchers automatically try to extend the results of the Diabetes Prevention Program, which was successful in delaying the onset of diabetes using a variety of strategies, but those types of strategies typically targeted individuals who already had prediabetes or impaired glucose tolerance. In my opinion, it is much more important to get primordial prevention of diabetes – to take individuals before they even develop risk factors, and intervene at that point. For example, we should focus weight control strategies on individuals with a BMI in the 24–27 kg/m^2 range, rather than waiting for their BMI to reach 30–31 kg/m^2, they already have prediabetes and developing diabetes is largely a matter of time. I think that these efforts to prevent diabetes need to move further upstream and into younger age groups. I believe that there are several productive strategies that could be applied there, for example, lifestyle interventions. In addition, there are other strategies that could be deployed such as patient incentives and policy changes to make it more expensive to do the things that are detrimental to health, such as smoking, and less expensive to do the things that are healthier, such as physical activity. This could decrease the problems of Type 2 diabetes in the long run.

Q Are different strategies needed for adults compared with children?

Strategies in children are very important and we have done some large studies in children that demonstrate that approximately 22% of 3-year-olds are overweight or obese. Consequently, there is a lot that needs to be done during pregnancy and the first couple of years of life to try to reduce the burden of obesity in young children. I think the notion that a 'bigger baby at birth is a better baby' is something that could be addressed. Furthermore, the school system offers opportunities to reach children and adolescents but it is harder to reach adults. Work-site programs are very much under utilized at this point in time.

Q Do you think that education is one of the biggest problems we face in managing diabetes?

For individuals who do not have diabetes, there is a lot of innovation; recently a number of studies have shown positive results for educational weight programs, both within the healthcare system and outside of it. However, when it comes to individuals with diabetes, the educational approach is, in my opinion, too rigid. I think the role of the Certified Diabetes Educators (CDE), needs to radically change in the next 10 years – the CDE need to be more flexible. Current studies indicate very marginal benefits from diabetes patient education, which is clearly an important part of diabetes care. However, the current approach is not very effective and because of licensing and reimbursement structures, there tends to be a lack of innovation and experimentation to improve this approach. I hope that CDE-related organizations will recognize this and encourage change and innovation, and encourage CDEs to broaden their clinical domain from glucose control to a broad emphasis on all aspects of risk prevention, such as smoking, blood pressure management and lipid management, in addition to glucose control.

Q What do you think are the biggest challenges we currently face in regards to managing diabetes? Is more work needed to improve how care is organized?

There is a lot of movement toward patient-centered care, and this is a very positive development. I think one of the key elements to allow patients to independently and accurately manage their condition is that they are well informed. There are so many things that are important in diabetes care: glucose, blood pressure, lipids, weight, aspirin use, renal care and eye care are just some of the things that you need to think about all the time. Some of these domains of care are in good shape and some less so, therefore, it is important for patients to know where they stand within these various clinical domains. They need to understand what the potential benefit to their health would be if they made certain changes with respect to their glucose or lipids or blood pressure, and which changes can be made to give the most benefit in terms of outcomes, such as reducing their risk of a stroke, heart attack and extending their life. Patients who have this type of information are more informed and may make different choices than their counterparts who do not have that same information.

Q How important are electronic medical records in clinical decision support?

Electronic medical records (EMRs) are, perhaps, the only way to prioritize the benefit of alternative treatment choices. Using EMRs and risk engines we can quite easily develop and implement programs to improve care. They identify to patients and providers which of these many clinical domains (glucose, blood pressure, lipids, aspirin, smoking, weight, screening for foot, eye and kidney problems) is likely to provide the patient with the most benefit. EMRs can also take information on current treatments, patient allergies to certain treatments and the distance from goal glucose, blood pressure or low-density lipoprotein levels patients are, and make treatment recommendations. They also prioritize the benefits of different clinical actions, based on reduced risk of major complications.

As we identify and develop new biomarkers for risk of complications and for the effectiveness of certain types of medicines in an individual, the use of these algorithmically driven EMR-based clinical decision systems is going to become more and more essential in primary care. The use of these EMR-based clinical decision systems also could be helpful for diabetes care educators, pharmacists, nurse practitioners and others because the algorithms can standardize a treatment plan, so treatment can adapt to the patient's current state. For example, if the patient's blood pressure changes, the recommendation for blood pressure management will also change. These algorithms that can be embedded in the EMR to provide a dynamic, evolving care plan. They will also serve the important function of coordinating care across the many providers that may be part of an individual's diabetes care team. It will help coordinate care, as well as personalize and standardize care at the same time. In addition, you can output

the clinical decision support information to patients in ways that are intelligible to most patients.

Furthermore, EMR-based decision systems can be hosted on websites, so the algorithms can be updated overnight. Consequently, the idea that it takes 17 years for changes in evidence to get into practice could now take 17 hours. That is a major shift in diffusion of information and updating care plans. It is very exciting what can be done with new technologies – it is a cutting edge area of research right now.

Q There is quite a lot of media attention regarding the healthcare costs associated with managing diabetes. Do you think the hype is justified and more can be done to curtail the costs?

There are several components of diabetes-related care costs to consider. First, they are related to the number of individuals with diabetes. If you control the costs but double the number of individuals with diabetes, you're still going to be spending more money on diabetes. This emphasizes the importance of primary prevention. Second, it is important to recognize that most of the excess costs associated with individuals with diabetes are related to cardiovascular disease. We have done some studies that demonstrate that if you take two individuals with diabetes (one with heart disease and one without), the patient with heart disease has costs that are three- to four-times higher than their counterpart without heart disease. Primary prevention of coronary heart disease in individuals with diabetes is a critically important task, and blood pressure control, lipid control, smoking and aspirin use are critical to that task. Third, the cost of the medication is an issue. We achieved median glucose levels of 7% in the year 2000, using only metformin, sulfonylureas and human insulin. Since then, the cost of drugs have doubled but the glucose levels have not necessarily improved, we just use more and more expensive medications; sometimes newer medications with unproved safety records that drive up the costs. My recommendation to other healthcare providers is to use older, more reliable treatments, such as metformin, which have established safety records and tend to be less expensive, rather than newer medications that have no long-term safety records, are much more expensive and may have unknown side effects, such as bladder cancer or pancreatitis that may not even be recognized as problems for another 5 years.

Recent studies on saxagliptin showed that there was no reduction in cardiovascular events in diabetes patients, rather there was a significant increase in congestive heart failure hospitalizations at 2 year follow-up. Therefore, we need to find glucose-lowering medications that actually reduce the burden of cardiovascular disease. As far as I am aware, the best option is metformin, which is recommended first in most guidelines. The second best drug is still for the taking.

Q Where do you see the field of diabetes research going in the next 5–10 years?

I think the cardiovascular risk of glucose-lowering medications and the cardiovascular risk of combinations of these drugs are very important to focus on. It will not be possible to carry out randomized trials for all these different combinations, but there is a wealth of information sitting in the EMRs around the country that can be utilized, and new statistical methods are available that can help us make more reasonable inferences about the impact of various combination treatments on cardiovascular events and mortality. I think these should be important components of future research.

Another important component of future research would be to find the second and third-line glucose-lowering control agents that actually have cardiovascular benefits. It could be some of the drugs that are already on the market, we just do not know yet. If we can identify such an agent it could have huge potential implications for patient well-being and long-term clinical outcomes. However, we are currently operating with incomplete information.

I think that care delivery for individuals with diabetes, probably both in the UK and in the US, depends a lot on primary care providers. The ongoing efforts to improve diabetes care in primary care settings are of utmost importance. This will include larger roles for educators, dieticians, nurse practitioners, pharmacists and others in the future, so I think that developing organizational strategies within clinics that facilitate the sharing of patient care will ensure that all team members are up to speed. Diabetes care is an ongoing challenge, and I have enjoyed working with thousands of other individuals who recognize that challenge and are engaged in addressing it.

Disclaimer

The views expressed in this article are those of the interviewee and do not necessarily reflect the views of Future Medicine Ltd.

Financial & competing interests disclosure

PJ O'Connor is supported in part by funding from NIH grants R01HL089451, R01HL102144-01, R01HS019859, R18DK079861 and P30DK092924. PJ O'Connor and others hold a US patent (8,388,348 B2) issued 5 March 2013 entitled 'Disease Treatment Simulation'. PJ O'Connor has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.