# PCDS Primary Care Diabetes Society

The latest news and views from the Primary Care Diabetes Society

## Incretin-based diabetes therapies: Updated statement from the PCDS Committee



David Millar-Jones
GP in Cwmbran, Wales,
and Chair of the PCDS
On behalf of the PCDS Committee

fter reviewing the evidence relating to incretin-based therapies and pancreatic disease, the PCDS Committee issued a statement back in June on its website www.pcdsociety.org. Here, following the subsequent publication of a number of additional statements, we have updated our own statement below. Broadly, the message remains the same.

#### **Updated statement**

The Committee of the Primary Care Diabetes Society (PCDS) is aware that healthcare professionals and people with type 2 diabetes may have concerns regarding recent publications and media announcements in relation to a possible association between incretin-based therapies (dipeptidyl peptidase-4 inhibitors and glucagon-like peptide-1 receptor agonists) and pancreatic disease.

These include findings from a group of independent academic researchers suggesting an increased risk of pancreatitis (inflammation of the pancreas) and precancerous cellular changes called pancreatic-duct metaplasia in patients with type 2 diabetes treated with incretin-based therapies (Butler et al, 2013). The study involved examination of a small number of pancreatic tissue samples obtained from organ donors with and without diabetes, who died due to causes other than diabetes.

The PCDS Committee questions whether the recent reports add anything further to our current knowledge of these therapeutic agents, which remain an important and very useful addition to our diabetes formularies.

After reviewing the emerging evidence, the PCDS Committee currently advises that healthcare professionals make no changes

to their current practice in relation to these agents. The European Medicines Agency (EMA, 2013), the US Food and Drug Administration (FDA, 2013) and the Medicines and Healthcare Products Regulatory Agency (2013) have made similar recommendations, and this is also reflected in a joint statement issued by the American Diabetes Association, the European Association for the Study of Diabetes and the International Diabetes Federation (American Diabetes Association, 2013). The PCDS Committee has reached this conclusion on the basis of the following factors.

- The potential link between these therapies and pancreatitis
  has been known for several years, and is reflected in the
  current prescribing information.
- In late July, the EMA (2013) announced that it had finalised a review of incretin-based diabetes therapies. Its conclusion was that currently available data do not confirm recent concerns over an increased risk of pancreatic adverse events with these medicines. Current EMA advice is that these drugs remain available treatments to NHS patients and there is no need for people with diabetes to stop taking their medicines.
- American regulatory authorities are currently also reviewing the evidence (FDA, 2013).
- The SAFEGUARD study (http://clinicaltrials.gov/ct2/show/ NCT01744236 [accessed 01.08.13]) is currently underway to further investigate this issue.

Furthermore, the Committee makes the following additional recommendations to healthcare professionals when prescribing these agents.

 All patients should be adequately screened regarding their potential risk of pancreatitis (hypertriglyceridaemia, alcohol intake, presence of gallstones, past medical history of pancreatitis).

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 All patients should be advised about pancreatitis and informed of how to recognise early symptoms and to seek medical advice should these occur.

The Committee will continue to monitor the available and emerging evidence and issue further statements if its opinion changes.

American Diabetes Association (2013) ADA/EASD/IDF Statement Concerning the Use of Incretin Therapy and Pancreatic Disease. ADA, Alexandria, VA, USA. Available at: http://www.diabetes.org/for-media/2013/recommendations-for.html (accessed 01.08.13)

Butler AE, Campbell-Thompson M, Gurlo T et al (2013) Diabetes 62: 2595-604

European Medicines Agency (2013) Investigation into GLP-1 based diabetes therapies concluded. EMA, London. Available at: http://www.ema.europa.eu/ema/pages/news\_and\_events/news/2013/07/news\_detail\_001856.jsp (accessed 01.08.13)

Medicines and Healthcare products Regulatory Agency (2013) Statement on CLP-1 medicines used to treat diabetes. MHRA, London. Available at: http://www.mhra.gov.uk/NewsCentre/CON286853 (accessed 01.08.13)

US Food and Drug Administration (2013) FDA Drug Safety Communication: FDA investigating reports of possible increased risk of pancreatitis and pre-cancerous findings of the pancreas from incretin mimetic drugs for type 2 diabetes. FDA, Silver Spring, MD, USA. Available at: http://1.usa.gov/16ux8TG (accessed 01.08.13)

## New online toolkit launched to help tackle growing bill for diabetes complications



Paul Downie

GP Partner, Ross-on-Wye, and Hospital Practitioner in Diabetes for Gloucestershire Hospitals NHS Foundation Trust n order to help health professionals tackle the challenge of diabetesrelated complications, the PCDS has launched an online toolkit, in partnership with Sanofi Diabetes.

Poor management of diabetesrelated complications can have a serious negative effect on the quality of life of people with diabetes, causing unnecessary and preventable hospital admissions. Improving the management of diabetesrelated complications would also help the NHS to meet its savings

challenge over the coming years. The cost of treating avoidable complications currently equates to 80% of the NHS spending on diabetes and stands at £7.7 billion per year (House of Commons Public Accounts Committee, 2012). This could rise to as much as £13.5 billion by 2036 (Hex et al, 2012).

The launch of the Complications Toolkit, available at www.diabetestoolkit.co.uk, marks the culmination of the 2-year *Keeping People with Diabetes out of Hospital* (KPDOH) project, which aimed to identify best practice in treating complications and highlight some of the most effective ways of helping people with diabetes to avoid unnecessary hospital admissions.

Despite there being clear treatment guidance in place, variation in the thoroughness of the local application of this guidance is common. In 2010, the number of people who received all nine of their NICE-recommended annual checks ranged from 6% to 69% across primary care trusts (Diabetes UK, 2012).

Furthermore, it is known that, overall, only 54.3% of people with diabetes in England received all of these essential care processes (National Diabetes Audit, 2012).

The Complications Toolkit has been designed to provide GPs, hospital doctors and commissioners with practical tools to prevent the development of common complications. It includes case studies on preventing complications, where possible, through integrated care models. Additionally, people with diabetes can identify the performance of their local health service in treating complications via a mapping tool, helping them to identify any problems in their local care provision.

The recent extensive changes to the NHS's commissioning structures have led to some confusion over the responsibility for the delivery of diabetes care, with some health professionals warning of the risks of fragmentation and the breaking of established working relationships. The toolkit website provides a clear guide to the responsibilities of the new NHS organisations, as well as links to other commissioning and treatment resources elsewhere on the web.

The toolkit provides an invaluable "one-stop shop" for commissioners to access advice on effective methods for avoiding diabetes complications. The PCDS and Sanofi would urge the diabetes clinical community to make use of this new resource and contribute with any examples of effective care on the ground that can be added to the toolkit.

Diabetes UK (2012) State of the Nation 2012. Diabetes UK, London

Hex N, Bartlett C, Wright D et al (2012) Diabet Med 29: 855-62

House of Commons Public Accounts Committee (2012) The management of adult diabetes services in the NHS. www.parliament.uk, London

National Diabetes Audit 2010-2011 (2012) Report 1: Care Processes and Treatment Targets. Health and Social Care Information Centre, Leeds



## PCDS Committee elections: Call for candidates

since its creation in 2004, the PCDS has built a large membership of healthcare professionals working in primary care diabetes, run numerous highly successful educational conferences, played a role in the development of various toolkits and other healthcare intiatives, and worked in liaison with other professional groups and in lobbying politicians.

PCDS Committee posts are elected on a 3-yearly basis, with the cycles staggered across the representatives. The Committee is always interested to hear from Society members who are seeking to take a more active role, and one way in which this can be achieved is via membership of the Committee. Elected members generously give their own time. Much of the work is done by



email, but there are approximately four Committee meetings each year, typically held on Saturdays in Birmingham with preparatory meetings on the Friday evening.

#### How to stand for election to the PCDS Committee

To stand for election, please submit a resumé of up to 150 words to pcds@sbcommunicationsgroup.com, along with a recent photograph, both of which will be published in the next issue of this journal in the list of candidates. Please also note the following points:

- You must be a current member of the PCDS who is involved in the professional care of people with diabetes in a primary care setting.
- Your proposal needs to be supported by another PCDS member.
- The deadline for submitting your resumé is Monday 23 September.
- The Committee's constitution seeks to ensure a balance between clinicians from medicine, nursing and allied professions and also some geographical balance.

Voting will take place, and results announced, at the 9<sup>th</sup> National Conference of the PCDS, which is being held in Birmingham on 7–8 November.

Keep an eye on your inbox as September will see the launch of a new e-newsletter service from the PCDS for its members. Titled *Diabetes Distilled*, this regular email will have the aim of filtering the latest developments in diabetes, from major clinical trials down to local guidelines, into a time-efficient, and hopefully highly engaging, read.

#### **CALL FOR POSTERS**: 9<sup>th</sup> National Conference of the PCDS

- The deadline for poster submissions has been extended to 4 October
  - To submit a poster abstract, please visit: http://bit.ly/1annC8X
- For further details, please email: pcds@sbcommunicationsgroup.com

The poster component of the conference is supported by Novo Nordisk

## New study seeks to develop questionnaire for assessing dietary habits in type 2 diabetes

s part of a new study, researcher Clare England (a Specialist Diabetes Dietitian and National Institute for Health Research Clinical Doctoral Research Fellow, University of Bristol) is developing a brief questionnaire that assesses dietary habits relevant to type 2 diabetes. The final goal is to create a tool that includes no more than 15 questions, takes approximately 5 minutes to complete, can be scored and will be tailored for use in clinical practice in the UK.

Clare is currently recruiting healthcare professionals to participate in an online Delphi survey. They will be invited to provide expert

opinion on the content and design of this brief dietary habits questionnaire. It is anticipated that the survey will involve two rounds, although if the views of the panel differ widely it may be necessary to increase this up to a maximum of four rounds. Each round should take no more than 30 minutes to complete.

#### Can you help?

At this stage, Clare is asking anyone interested in finding out more to contact her at clare.england@bristol.ac.uk or on 0117 331 1096 for an information sheet and survey access details.



## Heralding the imminent 9th National Conference of the PCDS in Birmingham: Back to the future

ovember 2005 was a month in which medicine was very much in the headlines: the world's first successful face transplant operation took place in France while in Britain, Andrew Stimpson received a negative HIV test result after previously being diagnosed positive, thereby defying conventional wisdom in the area.

During the same month, in the Warwickshire village of Wishaw, healthcare professionals with an interest in primary care diabetes convened for a day and a half of presentations and workshops – the inaugural conference of the PCDS.

The range of themes was both broad and clinically focused, thus setting a template for the success of future conferences: this event is all about day-to-day clinical practice and is open to members and non-members alike. Among the topics in 2005, Dr Peter

Holden spoke on the new General Medical Services contract and the achievements that had been seen in the first round of the Quality and Outcomes Framework.

At the time, diabetes care in the UK was already undergoing a shift from hospital to community. And the trend, we now know, was set to continue. In summarising his thoughts, Dr Holden

correctly foresaw the importance that was to be placed on practice-based commissioning.

Since then, the shift has continued apace. All the while, the PCDS has been plotting a course through this ever-changing landscape via its ever-growing set of educational offerings – in person, in print and online.

Today, it is clear that the newly instituted concept of clinical commissioning groups now sits at the core of the Government's health and social-care strategy. As such, the focus for diabetes in the primary care setting has never been sharper.

It is against this background that the PCDS National Conference on 7–8 November 2013 will, for the first time, offer a programme comprising two full days. Over 12 hours' accredited CPD is on offer via 22 sessions and multiple tracks, with associated online



A session at the 8th National Conference of the PCDS.

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more than ever before,

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learning opportunities offering the scope – more than ever before – for delegates to plot a truly personalised path.

The agenda has been designed for a broad range of professional groups, including GPs, clinical leads, nurse practitioners, practice nurses, diabetes specialist nurses and pharmacists. There is a breadth of learning opportunities in a variety of formats,

with a mixture of refresher sessions for attendees wanting to review the basics and more advanced sessions for those seeking a challenge.

As ever, delegates will be encouraged to network with peers in order to solve problems and share best practice. In

addition, attendees will receive a free workbook for their personal development portfolios, supported by associated in-print and online educational materials, aimed at helping with that all-important translation of learning into practice.

It is difficult to predict what might be hitting the headlines this November, but we are confident that there will be no better place to keep abreast of the latest developments in primary care diabetes than at the 9<sup>th</sup> National Conference of the PCDS.