

# Diabetes & Primary Care

Vol 18 Suppl A 2016

The journal for healthcare professionals with an interest in primary care diabetes

## Supplement A

### POSTER ABSTRACT BOOK

# 12<sup>th</sup> National Conference of the Primary Care Diabetes Society

Birmingham, 24–25 November 2016

*Diabetes & Primary Care* is  
published in association with the  
Primary Care Diabetes Society

**PCDS**  
Primary Care Diabetes Society

- The abstracts in this supplement have been edited minimally from the submitted versions, primarily for house style on units.
- For full authorship details, please refer to the posters.
- Funding declarations are presented only where explicitly supplied with the abstracts. For full details, please refer to the posters.

## P1

### Developing a specialist diabetes practice nurse group as a resource for practice nurses for support, sharing best practice and improving care

Submitting author: *Nightingale S, Croft Medical Centre, Leicester*

**Background:** The group was set up by senior practice nurses, who run nurse-led diabetic clinics within Solihull, following a GPN conference that empowered nurses to be proactive in diabetes care within the primary care setting. The was a need for support for nurses who were prescribers and insulin initiators. **Aims/Objectives:** Develop a group that would have a representative from primary, community and secondary diabetes care, invite GPs with a specialist interest in diabetes care, a dietitian and a pharmacist to attend along with practice nurses who were just starting out in diabetes care to ensure a broad spectrum of experience to share knowledge. **Methods:** Part of the monthly meetings would involve an educational element decided at the previous meeting, the meeting would allow time for questioning the experts and discussion and interaction. Part of the meeting would be set aside for projects to be set for members to work on within a set time scale. **Results:** We now meet regularly and our numbers are growing, we are developing protocols and competencies after researching all the evidence. We developed a WhatsApp group, Twitter page and Facebook closed page to help keep people informed. **Conclusion:** Nurses can work together across primary and secondary care to appreciate the complexities of diabetes care in each setting, develop new ways of working, improve links and conversations, and strive to improve insulin safety and patient compliance. ■

## P2

### Evaluation of ability to recognise patients with pre-diabetes and offer appropriate lifestyle reviews in primary care

Submitting author: *Saied A, Warwick Medical School, Warwick*

**Background:** As a key facet of type 2 diabetes prevention in the UK, current NICE guidelines recommend that GPs and other primary healthcare providers “keep an up-to-date register of people’s level of risk” and “At least once a year, review the

lifestyle changes people at high risk have made [...] to help reinforce their dietary and physical activity goals, as well as checking their risk factors”. **Aims:** To measure how well GPs comply with NICE guidance on identifying patients with “pre-diabetes”, and offering lifestyle reviews to those at high risk of developing type 2 diabetes. **Methods:** Using data from our local GP practice, 207 electronic health records of patients with an HbA<sub>1c</sub> of 42–47 mmol/mol (6%–6.4%) were examined to determine compliance with current NICE guidelines. **Results:** Forty (19.32%) patients with HbA<sub>1c</sub> of 42–47 mmol/mol were correctly coded as having pre-diabetes. Thirty-five (16.91%) patients with a HbA<sub>1c</sub> of 42–47 mmol/mol had a record of having been offered lifestyle advice in the previous 12 months. **Conclusions:** Prior to an educational intervention, GPs were not very good at identifying patients as having pre-diabetes, with many GPs incorrectly coding patients as having impaired glucose tolerance or impaired fasting glucose. Because of this, GPs were not very good at offering high-risk patients regular lifestyle advice. ■

## P3

### Patient perspectives on insulin initiation and maintenance in T2DM

Submitting author: *Hadjiyanni I, Diabetes Lilly Deutschland GmbH, Bad Homburg, Germany*

**Background:** Persistence to insulin therapy is often poor, which may affect clinical outcomes and costs. Understanding patient experiences may help improve persistence and clinical outcomes. **Aims/Objectives:** To describe the experiences of patients with type 2 diabetes mellitus (T2DM) from basal insulin initiation through to 6-months’ post initiation. **Methods:** A sample of patients with T2DM (aged 18+ years, initiating basal insulin between July 1, 2012, and July 3, 2015) was identified from claims associated with a large commercial US-based health plan. Contacted, consenting patients who qualified for the study and self-reported as persistent users ( $n=167$ ) completed a cross-sectional survey by telephone or online. **Results:** Mean patient age was 58.4 years; 51% were male; and respondents were predominantly white (84%). Mean time since T2DM diagnosis was 9.8 years. Only 34% of patients indicated that insulin was discussed at their initial diagnosis. Approximately 57% of patients indicated that their input was taken into consideration “very much” or “fully” when the decision was made to initiate insulin. At initiation, most patients reported feeling fear that they would develop other diabetes-related health problems (78% agree/strongly agree) and a fear that their diabetes was getting worse (75% agree/strongly agree). Approximately half of all respondents (49%) indicated that their health care provider gave them instructions on titration when they initiated basal insulin. **Conclusions:** Study results identify areas where health care provider input might be especially helpful to

insulin-naïve patients with T2DM. ■

## P4

### Lixisenatide therapy in older patients with type 2 diabetes inadequately controlled on their current anti-diabetic treatment: The GetGoal-O study (NCT01798706)

Submitting author: *Baradez C, Sanofi, Surrey*

**Abstract:** This is an ENCORE Abstract. **Aim:** To evaluate the efficacy and safety of adding the once-daily glucagon-like peptide-1 receptor agonist lixisenatide versus placebo in non-frail older patients with type 2 diabetes inadequately controlled on their current treatment regimen. **Methods:** Patients aged >70 years were randomised to receive lixisenatide 20 µg once daily ( $n=176$ ) or placebo ( $n=174$ ) concomitantly with their existing therapy for 24 weeks. Patients at risk of malnutrition or with moderate-to-severe cognitive impairment were excluded. Primary endpoint was mean change in HbA<sub>1c</sub> from baseline to week 24. **Results:** Of the patients randomised, 37% were >75 years old, 43% were obese and almost a third had moderate renal impairment. One third were treated with basal insulin, one third were receiving sulfonylurea and one third other oral anti-hyperglycaemic drug(s). Mean HbA<sub>1c</sub> at baseline was 8%. Placebo-adjusted least-squares mean change (95% confidence interval) in HbA<sub>1c</sub> from baseline to week 24 was -0.64% (-0.81, -0.46;  $P<0.0001$ ), largely due to a decrease in postprandial glucose. Least-squares mean difference for body weight versus placebo was -1.32 kg, with no impact on nutritional status. The safety profile of lixisenatide in this older population was consistent with the known profile observed in other lixisenatide studies, including nausea and vomiting. The number of patients with symptomatic hypoglycaemia was 7.4% in the lixisenatide group versus 5.7% in the placebo group. **Summary:** In non-frail older patients uncontrolled on their current anti-diabetic treatment, lixisenatide was superior to placebo with respect to HbA<sub>1c</sub> reduction and targeting postprandial hyperglycaemia. Lixisenatide patients showed low risk of hypoglycaemia and no unexpected safety finding. **Declaration:** This study was sponsored by Sanofi and was presented at Diabetes UK Professional Conference, 2–4 March 2016 in Glasgow, Scotland. ■

## P5

### Improving attendance and patient experience for type 2 diabetes structured education

Submitting author: *Gough H, Bentley Medical Centre, Walsall*

**Background:** Walsall has traditionally struggled with poor uptake of structured education for people with newly diagnosed type 2 diabetes – referral to attendance

rate has averaged 25% since 2011. Following a service review the team redesigned the education pathway from referral to delivery. **Aim:** To redesign the structured education pathway for type 2 diabetes. **Objectives:** To increase referral to attendance rate and to develop a more flexible, cost effective programme tailored to meet needs of local population. **Method:** The administration process was mapped from receipt of GP referral to appointing, in order to highlight delays and constraints in the system. The programme content was redesigned based on a review of similar education programmes, patient feedback and best practice guidance. The new programme was launched on 1 October 2016, attendance data and patient evaluations were compared pre- and post-implementation. **Results:** The first 6 months of data (October–March) revealed a significant improvement in the referral to attendance rate when compared to previous years. The attendance rate for structured education increased from 21% to 47%. The programme content, timings and resources were redesigned. The new programme has evaluated extremely well, with 96% of patients reporting that they enjoyed the session and 82% responding that the session would impact positively on their health and wellbeing. **Conclusions:** A combination of administrative changes has significantly improved attendance rates. The programme is more cost effective to deliver and more flexible, allowing for easy update of the curriculum in response to emerging clinical evidence. ■

## P6

### Clinical impact of titratable fixed-ratio combination of insulin glargine/lixisenatide versus each component alone in type 2 diabetes inadequately controlled on oral agents: LixiLan-O Trial (NCT02058147)

*Submitting author: Baradez C, Sanofi, Surrey*

**Abstract:** The efficacy and safety of iGlarLixi, a novel titratable fixed-ratio combination of insulin glargine (iGlar-100) with lixisenatide (LIXI), was compared with iGlar-100 and LIXI in T2DM inadequately controlled on metformin (MET) ± a second oral glucose-lowering drug. After a 4-week run-in to stop sulfonylureas and increase MET, participants ( $n=1170$ ) were randomised (2:2:1) to once-daily iGlarLixi or iGlar-100 titrated to fasting plasma glucose 4.4–5.6 mmol/L (maximum 60 units/day), or lixisenatide (20 µg maintenance dose) continuing with MET for 30 weeks. iGlarLixi showed greater reductions in HbA<sub>1c</sub> from baseline (8.1%) versus iGlar-100 and LIXI (–1.6%, –1.3%, –0.9%, respectively;  $P<0.0001$ ), reaching mean HbA<sub>1c</sub> levels of 6.5%, 6.8%, 7.3%, respectively, at week 30. More subjects reached target HbA<sub>1c</sub> <7% with iGlarLixi (74%) versus iGlar-100 (59%) or LIXI (33%). Mean body weight increased with iGlar-100 (+1.1 kg), and decreased with iGlarLixi (–0.3 kg, difference 1.4 kg;  $P<0.0001$ ) and LIXI (–2.3 kg). Documented symptomatic hypoglycaemia ( $\leq 3.9$  mmol/L) was similar with iGlarLixi (1.44 events/year [E/Y]) and iGlar-100 (1.22 E/Y), but lower with LIXI (0.34 E/Y). **Conclusion:** iGlarLixi

meaningfully improved glycaemic control with no weight gain and without increase in hypoglycaemia risk compared with iGlar-100, and with many fewer nausea and vomiting events than LIXI. **Declaration:** This study was sponsored by Sanofi and presented at the ADA conference, 10–14 June 2016 in New Orleans, USA. ■

## P7

### Improving diabetes care: The next step for the National Diabetes Audit

*Submitting author: Lewis J, Betsi Cadwaladr University Health Board, North Wales*

**Background:** The National Diabetes Audit (NDA) results show there is variation in the performance in process and care target indicators, and there is the potential for general practices to improve their care. **Aim:** The CIRC programme used a “train-the-trainers” model with structured mentorship using QI methodology as described in the 2015 RCGP publication *Quality Improvement for General Practice* to improve diabetes care and outcomes at a practice level. **Methods:** Three CCGs and one Welsh Health Board were selected with their clinical leads for diabetes to be involved in this project. They were supported by two RCGP clinical QI leads through training and mentoring to enable them to work with up to six practices each. Practices were usually selected where there was seen to be room for improvement as demonstrated by their NDA data. Each practice was to choose at least one area for improvement and, using quality improvement methods and tools, introduce an intervention, plan its introduction and test its effectiveness. **Results:** The poster describes our experience of the programme, giving examples of how QI has been used to improve care and the factors that impacted on individual practice success. **Conclusion:** Collecting and displaying the results from the NDA may be the first step in improving diabetes care and showing where is further action needed. QI tools in this project have been shown to be one way to achieve further improvement. Contextual factors such as a changing workforce and high workload had a significant impact on maintaining the momentum through the improvement projects. ■

## P8

### Effective Diabetes Education Now (EDEN) is health care professional (HCP) diabetes training, which aims to increase competency and knowledge, thereby improving patient outcomes

*Submitting author: Sennett J, Leicester Diabetes Centre, Leicester*

**Abstract:** EDEN was created to address the challenges of delivering high-quality diabetes care in an area with high diabetes prevalence, significant levels of deprivation, a

multi-ethnic population and large variation in standards of care across city practices. A needs analysis tool was used to review the knowledge, skills and confidence of all primary care staff at baseline, then repeated yearly for a 3-year period. Optic recognition software automates the process of inputting results, from which individualised training recommendations can be emailed back to staff. Our comprehensive database allows us to audit against performance indicators. EDEN competency-based modules are accredited and highly rated by the Royal College of General Practitioners. Uniquely, a mentorship programme supports the implementation of learning into practice. EDEN constantly evolves, updating and reflecting the dynamic nature of diabetes, and currently there are 15 modules. In excess of 2000 staff have attended over 150 taught modules. Evaluation of modules by delegates gives an average score of 92%. EDEN sessions are now a regular feature at the monthly PLT sessions. Following requests from external organisations, EDEN has been delivered in Lancashire, Lincolnshire, Stafford, Cannock, Essex and Gibraltar. We are also in negotiation with countries as far away as India to run EDEN. In 2016, we developed the train-the-trainer programme, which allows external organisations to run EDEN locally using our resources. As an NHS organisation, we believe that EDEN is a unique and innovative programme. ■

## P9

### Effect of empagliflozin on bone fractures in patients with type 2 diabetes

*Submitting author: Kohler S, Boehringer Ingelheim Ltd, Ingelheim, Germany*

**Objective:** To assess the effect of empagliflozin, a sodium–glucose cotransporter 2 inhibitor, on bone fractures in patients with T2DM using pooled placebo-controlled trial data and data from a head-to-head study versus glimepiride (EMPA-REG H2H-SU). **Methods:** Pooled safety data were analysed from patients randomised (1:1:1) to receive empagliflozin 10 mg, 25 mg or placebo in 15 Phase I–III clinical trials (including EMPA-REG OUTCOME), plus four extension studies. In EMPA-REG H2H-SU, patients received empagliflozin 25 mg or glimepiride as add-on to metformin for 104 weeks and could participate in a 2-year extension. Bone fracture adverse events (AEs) were evaluated through a search of investigator-reported AEs and analysed descriptively. **Results:** In the pooled analysis, 4221, 4196 and 4203 patients received empagliflozin 10 mg, 25 mg and placebo, respectively (median exposure: 698, 699 and 658 days, respectively). Bone fracture AEs were reported in 119 (2.8%), 105 (2.5%) and 123 (2.9%) patients, respectively; corresponding to a rate of 1.55, 1.36 and 1.69/100 patient-years, respectively. In EMPA-REG H2H-SU, 765 and 780 patients received empagliflozin 25 mg and glimepiride, respectively. Bone fracture AEs were reported in 31 (4.1%) and 33 (4.2%) patients,

respectively; corresponding to a rate of 1.28 and 1.40/100 patient-years, respectively. There were no changes from baseline in calcium or phosphate in any group in the pooled analysis or in EMPA-REG H2H-SU. **Conclusion:** In a pooled analysis of >12 000 patients with T2DM, empagliflozin did not increase the risk of bone fracture versus placebo. In a 4-year head-to-head study, empagliflozin did not increase the risk of bone fracture versus glimepiride. ■

## P10

### Effect of empagliflozin on cardiovascular death in subgroups by age: results from EMPA-REG OUTCOME

*Submitting author: Fitchett D, University of Toronto, Ontario, Canada*

**Objective:** In the EMPA-REG OUTCOME trial, empagliflozin added to standard of care significantly reduced 3-point major adverse cardiovascular events (composite of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke), cardiovascular death and all-cause mortality versus placebo in patients with type 2 diabetes (T2DM) and high cardiovascular risk. We investigated the effect of age on the reduction in cardiovascular death with empagliflozin. **Methods:** Patients in EMPA-REG OUTCOME were randomised to receive empagliflozin 10 mg, empagliflozin 25 mg or placebo. Cardiovascular death was analysed in a Cox regression model including sex, baseline BMI, baseline HbA<sub>1c</sub>, baseline estimated glomerular filtration rate, region, treatment, age group, and treatment by age group interaction, in the pooled empagliflozin group versus placebo in subgroups by baseline age (<65, 65 to <75, ≥75 years). **Results:** A total of 7020 patients were treated. Median observation time was 3.1 years. Mean (SD) age at baseline was 63.2 (8.8) years in the placebo group and 63.1 (8.6) years in the empagliflozin group. The benefit of empagliflozin versus placebo on cardiovascular death was consistent across age categories. Across age subgroups, reported adverse events were consistent with the known safety profile of empagliflozin. **Conclusion:** Empagliflozin, added to standard of care, reduced the risk of cardiovascular death in patients with T2DM and high cardiovascular risk irrespective of age. ■

## P11

### Effect of empagliflozin on diabetic ketoacidosis in patients with type 2 diabetes: pooled clinical trial data

*Submitting author: Lund S, Boehringer Ingelheim Ltd, Ingelheim, Germany*

**Objective:** To assess the incidence of diabetic ketoacidosis (DKA) with empagliflozin versus comparators using pooled clinical trial data. **Methods:** Safety data were pooled from patients with type 2

diabetes treated with empagliflozin 10 mg or 25 mg in 18 randomised, Phase I–III clinical trials of 8 days' to 4 years' duration (including the cardiovascular outcomes trial EMPA-REG OUTCOME), plus six extension studies. Based on adverse events (AEs) reported by the investigators, DKA was assessed through a search of three Medical Dictionary for Regulatory Activities-preferred terms (diabetic ketoacidosis; diabetic ketoacidotic hyperglycemic coma and ketoacidosis) and analysed descriptively. **Results:** Total exposure was 8368, 11 017, and 10 472 patient-years in the empagliflozin 10 mg, 25 mg and comparator groups, respectively. DKA AEs were reported in 5 (0.1%), 2 (<0.1%), and 5 (0.1%) of patients in the empagliflozin 10 mg, 25 mg and comparator groups, respectively; corresponding to a rate of 0.06, 0.02, and 0.05/100 patients-years, respectively. Serious DKA (as reported by the investigator) was reported in 5 (0.1%), 1 (<0.1%), and 4 (0.1%) patients in the empagliflozin 10 mg, 25 mg, and comparator groups, respectively; corresponding to a rate of 0.06, 0.01, and 0.04/100 patients-years, respectively. All patients with DKA AEs in empagliflozin groups recovered, except for one patient (empagliflozin 10 mg; post-treatment AE) scheduled for hospital discharge but lost to follow-up. Two patients discontinued treatment with empagliflozin due to DKA AEs. **Conclusion:** In an analysis of pooled data with >19 000 patient-years' exposure to empagliflozin, the incidence of DKA was low and comparable between groups. ■

## P12

### Improved glycaemic control and weight loss with once weekly dulaglutide versus placebo, both added to titrated daily insulin glargine, in type 2 diabetes patients (AWARD-9)

*Submitting author: Pozzilli P, Bio-Medico University, Rome, Italy*

**Aims:** This double-blind, 28-week study compared the once-weekly GLP-1 receptor agonist dulaglutide 1.5 mg and placebo when added to titrated once-daily insulin glargine (± metformin), in type 2 diabetes patients with inadequate glycaemic control (HbA<sub>1c</sub> ≥53 mmol/mol [≥7.0%] and ≤91 mmol/mol [≤10.5%]). **Methods:** Patients (n=300; mean baseline characteristics: age 60.4 years; HbA<sub>1c</sub> 68 mmol/mol (8.4%); BMI 32.7 kg/m<sup>2</sup>; glargine dose 39 units [0.42 units/kg]) were randomised (1:1) to dulaglutide 1.5 mg or placebo; glargine was titrated to fasting plasma glucose target (3.9–5.5 mmol/L); primary objective was HbA<sub>1c</sub> change from baseline at week 28 tested for superiority. Least squares (LS) mean changes from baseline [SE] are presented, unless stated otherwise. **Results:** At week 28, dulaglutide 1.5 mg resulted in significantly greater reductions versus placebo in HbA<sub>1c</sub>: -15 mmol/mol [1] (-1.4% [0.09]) versus -8 mmol/mol [1] (-0.7% [0.09]; P<0.001) and FSG: -2.5 mmol/L [0.23] (45 mg/dL [4]) versus -1.6 mmol/L [0.23] (29 mg/dL [4];

P<0.001). Body weight decreased with dulaglutide 1.5 mg and increased with placebo (-1.9 kg [0.30] versus +0.5 kg [0.30]; P<0.001). Hypoglycaemia rate (plasma glucose ≤3.9 mmol/L [70 mg/dL] and/or symptoms) was 7.69 and 8.56 events/patient/year for dulaglutide 1.5 mg and placebo, respectively (P=0.488); severe hypoglycaemia events were (n): dulaglutide 1.5mg (1), placebo (0). A statistically greater increase in glargine dose was observed with placebo versus dulaglutide 1.5 mg (25.9 units [2.3] versus 12.8 units [2.3]; P<0.001). Nausea and diarrhoea were more common with dulaglutide 1.5 mg (12.0%, 11.3%) versus placebo (1.3%, 4.0%). **Conclusions:** Once-weekly dulaglutide 1.5 mg compared to placebo, both add-on to titrated daily glargine, resulted in better glycaemic control and weight loss without significantly increasing the risk of hypoglycaemia. ■

## P13

### Efficacy and safety by duration of diabetes with once-weekly dulaglutide in the AWARD Programme

*Submitting author: Gallwitz B, University of Tübingen, Tübingen, Germany*

**Aims:** To evaluate the efficacy and safety of dulaglutide 1.5 mg and 0.75 mg in T2D patients by duration of diabetes (DoD) <5 years, ≥5 and <10 years, and ≥10 years. Dulaglutide, a once-weekly GLP-1 receptor agonist, demonstrated significant HbA<sub>1c</sub> reduction and potential for weight loss in patients with type 2 diabetes (T2D), in the AWARD clinical trial programme. **Methods:** We conducted a post-hoc analysis on the completed studies AWARD-1, 2, 5, 6 and 8 at 6 months. AWARD-3 and 4 were not included because, due to the populations studied, small numbers of patients had DoD ≥10 years in AWARD-3 and DoD was <5 years in AWARD-4. **Results:** Across all studies, the proportions of patients with dulaglutide treatment were similar among DoD subgroups. The ranges of HbA<sub>1c</sub> reductions for patients with DoD <5 years, ≥5 and <10 years, and ≥10 years, respectively, were: dulaglutide 1.5 mg: -13.0 mmol/mol (-1.19%) to -16.8 mmol/mol (-1.54%), -12.7 mmol/mol (-1.16%) to -17.1 mmol/mol (-1.56%) and -11.4 mmol/mol (-1.04%) to -16.4 mmol/mol (-1.50%); dulaglutide 0.75 mg: -9.9 mmol/mol (-0.91%) to -14.0 mmol/mol (-1.28%), -10.3 mmol/mol (-0.94%) to -13.2 mmol/mol (-1.21%) and -9.0 mmol/mol (-0.82%) to -15.1 mmol/mol (1.38%). HbA<sub>1c</sub> changes were similar from the pooled analysis for DoD <5 years, ≥5 and <10 years, and ≥10 years: dulaglutide 1.5 mg: -14.3 mmol/mol (-1.31%), -13.9 mmol/mol (-1.27%) and -12.8 mmol/mol (-1.17%); dulaglutide 0.75 mg: -11.2 mmol/mol (-1.02%), -10.2 mmol/mol (-0.93%) and -10.7 mmol/mol (-0.98%), respectively. Effects on weight were similar among DoD subgroups at both doses. Dulaglutide treatments were well tolerated. **Conclusions:** Irrespective of DoD, dulaglutide demonstrated similar HbA<sub>1c</sub> reduction, weight change and an acceptable safety profile. ■

**P14****Similar efficacy and safety of LY2963016 insulin glargine and insulin glargine (Lantus®) in patients with type 2 diabetes in age groups (<65, ≥65 years)**

*Submitting author: Poltom RK, Eli Lilly and Company, Indianapolis, USA*

**Aims:** In ELEMENT-2, a 24-week, phase 3, randomised, double-blind study involving patients with type 2 diabetes (T2D), LY2963016 insulin glargine (LY IGLar) had a similar efficacy and safety profile to insulin glargine (Lantus®, IGLar). Our aim was to further investigate the similarity of LY IGLar and IGLar, which have identical amino acid sequences. **Methods:** Subgroup analyses based on age at study entry (<65 years, ≥65 years) were performed to compare the efficacy and safety of LY IGLar and IGLar in patients from ELEMENT-2. **Results:** At baseline, patients ≥65 years ( $n=214$ ) had significantly longer diabetes duration, lower baseline HbA<sub>1c</sub>, body weight and BMI, and were more likely to report pre-study IGLar use than those <65 years ( $n=542$ ;  $P<0.05$  for all). No significant treatment-by-age interactions ( $P\geq 0.05$ ) were observed for any of the clinical efficacy and safety outcomes, including incidence and rate of documented symptomatic hypoglycaemia ( $P=0.459$  and  $P=0.769$ , respectively), incidence of treatment-emergent adverse events ( $P=0.714$ ), serious adverse events ( $P=0.487$ ) and insulin antibodies (% binding;  $P=0.331$ ). These data indicate no significant differential treatment effect between LY IGLar and IGLar across the two age groups. Moreover, no treatment differences ( $P>0.05$ ) were observed within each age group for any of the clinical efficacy and safety outcomes. **Conclusions:** LY IGLar and IGLar exhibit similar efficacy and safety in younger and older patients with T2D.

**P15****Insulin initiation experiences in people with type 2 diabetes mellitus with different patterns of persistence**

*Submitting author: Peyrot M, Loyola University Maryland, Baltimore, USA*

**Aims:** To assess the impact, across persistence pattern subgroups, of insulin therapy among insulin-naïve people with type 2 diabetes mellitus (T2DM) who had initiated basal insulin therapy 3–24 months previously. **Methods:** People with T2DM ( $n=942$ ) from the United States, France, Germany, Spain, United Kingdom, Brazil and Japan completed an online survey. Respondents were classified as “Continuers” (no gaps of  $\geq 7$  days in basal insulin treatment), “Interrupters” ( $\geq 1$  gap of  $\geq 7$  days in therapy, then restarted basal insulin) or “Discontinuers” (stopped using basal insulin for  $\geq 7$  days and had not restarted by the time of the survey). **Results:** The majority of respondents in each group received

training during initiation on self-injection, titration, insulin therapy in general, diet/exercise and diabetes in general. In each group, the proportion of patients agreeing/strongly agreeing with having specific concerns related to insulin (e.g. glycaemic control, self-injections, inconvenience) tended to decrease from initiation to 1 week post-initiation; the proportion of Continuers agreeing/strongly agreeing with having specific concerns was consistently lower versus Interrupters and Discontinuers. Furthermore, Continuers had the lowest proportion of patients reporting specific challenges (e.g. checking blood sugars, adjusting dose and the ability to treat hypoglycaemia) during the first week of therapy. Compared with Discontinuers, Continuers and Interrupters were more likely to report a somewhat, or very positive, impact of insulin use on specific aspects of life (e.g. glycaemic control, physical wellbeing or emotional wellbeing). **Conclusion:** Understanding patient concerns, challenges and feelings during basal insulin initiation may help clinicians provide individualised care and support, which may improve persistence.

**P16****Efficacy and safety by baseline HbA<sub>1c</sub> with once-weekly dulaglutide in the AWARD Programme**

*Submitting author: Dagogo-Jack S, University of Tennessee Health Science Center, Tennessee, USA*

**Aims:** Dulaglutide, a once-weekly GLP-1 receptor agonist, was studied in the AWARD clinical trial programme in adult patients with type 2 diabetes (T2D) and demonstrated significant HbA<sub>1c</sub> reduction and potential for weight loss. Our aim was to evaluate the efficacy and safety of dulaglutide 1.5 mg and dulaglutide 0.75 mg in T2D patients by baseline HbA<sub>1c</sub> <69 mmol/mol (<8.5%) or  $\geq 69$  mmol/mol ( $\geq 8.5\%$ ). **Methods:** We conducted a post-hoc analysis on AWARD-1 to 6 and 8 at 6 months. **Results:** Across seven studies, 55–82% of the dulaglutide-treated patients had a baseline HbA<sub>1c</sub> <69 mmol/mol (<8.5%) and 18–45% had a baseline HbA<sub>1c</sub>  $\geq 69$  mmol/mol ( $\geq 8.5\%$ ). The ranges of HbA<sub>1c</sub> reductions for patients with baseline HbA<sub>1c</sub> <69 mmol/mol (<8.5%) and  $\geq 69$  mmol/mol ( $\geq 8.5\%$ ), respectively, were dulaglutide 1.5 mg:  $-7.32$  mmol/mol ( $-0.67\%$ ) to  $-13.66$  mmol/mol ( $-1.25\%$ ) and  $-13.34$  mmol/mol ( $-1.22\%$ ) to  $-25.91$  mmol/mol ( $-2.37\%$ ); dulaglutide 0.75 mg:  $-5.79$  mmol/mol ( $-0.53\%$ ) to  $-11.70$  mmol/mol ( $-1.07\%$ ) and  $-14.98$  mmol/mol ( $-1.37\%$ ) to  $-23.94$  mmol/mol ( $-2.19\%$ ). The HbA<sub>1c</sub> reduction from the pooled analysis was greater in patients with baseline HbA<sub>1c</sub>  $\geq 69$  mmol/mol ( $\geq 8.5\%$ ) than patients with baseline HbA<sub>1c</sub> <69 mmol/mol (<8.5%), respectively, dulaglutide 1.5 mg:  $-20.33$  mmol/mol ( $-1.86\%$ ) and  $-11.15$  mmol/mol ( $-1.02\%$ ); dulaglutide 0.75 mg:  $-19.13$  mmol/mol ( $-1.75\%$ ) and

$-9.07$  mmol/mol ( $-0.83\%$ ). Dulaglutide treatments were well tolerated among baseline HbA<sub>1c</sub> subgroups. **Conclusions:** Across the AWARD programme, dulaglutide 1.5 mg and dulaglutide 0.75mg demonstrated significant HbA<sub>1c</sub> reductions in both subgroups with an acceptable safety profile. Compared to patients with baseline HbA<sub>1c</sub> <69 mmol/mol (8.5%), patients with baseline HbA<sub>1c</sub>  $\geq 69$  mmol/mol (8.5%) had greater HbA<sub>1c</sub> reduction. ■

**P17****AI in diabetes healthcare professional education**

*Submitting author: Jones P, Leicester Diabetes Centre, Leicester*

**Abstract:** Leicester has one of the highest prevalence rates of diabetes in the UK at around 8%; therefore, diabetes education for Leicester's doctors and nurses is critical. Failure to meet practices' training needs means variable levels of care for patients and can lead to more hospital admissions, complications and specialist care referrals. We needed a technology intelligent enough to analyse training needs assessments and make individual training recommendations to thousands of HCPs while monitoring uptake. We developed an intelligent database application based around artificial intelligence (AI) algorithms that systematically analyses HCPs' knowledge and confidence levels in 73 key diabetes skill areas. The application identifies their strengths and weaknesses, determines the right training for them, and it scans through attendances and booking records before emailing its recommendations to them. We can track response rates, and we have even developed tools to automate course reminders and booking confirmations sent out via email. We embrace digital technologies and have adopted optic recognition software to minimise data input while actively developing our accompanying e-learning platform. The app aggregates datasets together in a single place to enable comparison between such diverse datasets as population growth, type 1 and 2 prevalence, training and mentoring uptake, QOF performance indicators (such as HbA<sub>1c</sub>), and knowledge and confidence levels within different groups of healthcare professional. We utilise cutting-edge data warehousing techniques, alongside AI and mapping to effectively deliver tailor-made diabetes training to HCPs. Our training needs analysis service has now been utilised by a number of CCGs. ■

**P18****Drivers of and barriers to optimal basal insulin (BI) titration: Results of a quantitative survey**

*Submitting author: Baradez C, Sanofi, Surrey*

**Background and aims:** To evaluate the drivers of,

and barriers to, optimal BI titration in the USA, France and Germany. **Materials and methods:** Online survey of 386 healthcare professionals (HCPs) and 318 patients with type 2 diabetes (T2DM) on long-acting BI for 6–36 months, including 243 current BI users (95 users currently self-titrating), and 75 users who had discontinued BI within the past 12 months. **Results:** Fasting self-monitored plasma glucose (SMPG) targets as outlined in country-specific guidelines were not used by all HCPs; instead, HCPs preferred higher fasting SMPG targets than recommended by these guidelines. For current BI users, mean start dose was 15 units and mean current dose was 25 units. A dose increase of <10 units was seen by 27 months for 62% of current BI users, despite 49% of them reporting not reaching HbA<sub>1c</sub> target. Main barriers to optimal titration for current BI users not reaching HbA<sub>1c</sub> target were concerns over weight gain (52%), frustration over time to reach goal (43%), perception that dose increase meant worsening diabetes (38%) and fear of hypoglycaemia (37%). HCPs perceived the main barriers to target attainment in self-titrating patients to be fear of hypoglycaemia (74%) and low patient involvement/motivation (63%). Overall, 26% of current BI users indicated that they preferred self-titrating their BI; the percentage of current BI users self-titrating was 39%. **Conclusion:** Generally, HCPs prefer a slow, safe approach to titration to higher glucose targets compared to recommended targets to avoid hypoglycaemia. However, patients not at target are frustrated about the time taken to reach target and are less concerned about hypoglycaemia than HCPs. Preference for self-titration needs improving and patients need encouraging to self-titrate. **Declaration:** This market survey project was conducted by Hall & Partners US LLC, funded by Sanofi. This study was presented at the EASD conference, 12–16 September 2016, Munich, Germany. ■

## P19

### Untreated CVD risk burden in patients with pre-diabetes using QRISK

*Submitting author: Hussain AR, Boultham Park Medical Practice and Lincoln County Hospital, Lincoln*

**Introduction:** Over 300 million people are at-risk of developing diabetes (“prediabetes” [PDM]) as per IDF figures, and it is envisaged that these numbers will continue to grow. Various cardiovascular disease (CVD) risk calculators are used to assess CVD risk, including QRISK, Framingham risk score and UKPDS. None of these take PDM or glycaemic burden into account as an independent risk factor of CVD risk. **Aims/Objectives:** To study undiagnosed CVD risk burden in a UK inner-city practice. **Methodology:** A retrospective observational study was carried out on a total of 9534 patients registered using SystemOne. Analysis was performed for each variable used in QRISK calculator. WHO criterion was used to diagnose

PDM (HbA<sub>1c</sub> 42–47 mmol/mol). **Results:** In all, 448 patients (41% male, 59% female) were identified to be at risk of developing diabetes. A total of 147 patients were found to be CVD-naïve (i.e. without any CV risk factors: AF, CKD, CVD). Their median BMI was 29.03 kg/m<sup>2</sup>, median systolic blood pressure (BP) was 130 mmHg, median HDL/cholesterol ratio was 3.8 and median QRISK was found to be 11.91%. Forty-three patients were found to have systolic BP at 140mmHg or higher (not diagnosed and without treatment), and the QRISK score of 93 patients out of 147 was above 10%, while 49 patients had a QRISK score of 20% or higher. **Conclusion:** The results reveal that PDM remains underestimated and an under-treated entity. Addressing clinical inertia and modifying CVD risk factors in the management of PDM can yield positive health outcomes. ■

## P20

### Diabetes and conjunctivitis

*Submitting author: Ansari AS, University of Surrey, Guildford*

**Background:** Acute red eyes frequently present to primary care (almost 1% of all primary care consultations are due to conjunctivitis). More than 5 million episodes are seen annually in the United States and 1 million are seen in the United Kingdom. Identification of risk factors could, therefore, provide targets for reduction of disease burden and alterations of management. **Aims:** We aimed to see if propensity to prescribe treatment for conjunctivitis varied between types of diabetes and if it was influenced by age, smoking, ethnicity, sex and diagnosis of connective tissue disorder or retinopathy stage. **Methods:** A retrospective cohort study was carried out using the Royal College of General Practitioners Research and Surveillance Centre (RCGP RSC) database over a 5-year period. Logistic regression modelling was carried out incorporating specific inclusion and exclusion criteria and adjusted for relevant confounders. We identified 14871 patients who were prescribed treatment in the general population and 1301 in the diabetic population. We initially looked to see the variation in risk between type 1 and type 2 diabetes; subsequently we stratified patients by age, ethnicity, diagnosis of connective tissue disorder and retinopathy stage or presence of maculopathy. **Conclusions:** Age-influenced propensity to prescribe in a linear manner with the highest risk seen in those above 75 years of age. Retinopathy stage did not influence propensity to prescribe or infection risk. Conversely, diagnosis of maculopathy and connective tissue disorder did have a statistically significant influence, suggesting a proportion of patients are unnecessarily being prescribed treatment. ■

## P21

### Improving cholesterol targets by using

### quality improvement methodology

*Submitting author: Askey A, St John's Medical Centre, Walsall*

**Background:** Treating cholesterol to target, a key objective in managing diabetes, may be affected by media reports of adverse effects of statins. **Aims:** To improve the number of patients reaching cholesterol targets of 4 and 5 mmol/L in primary care setting. **Methods:** EMIS protocols were developed to prompt treating to a target cholesterol of 4 mmol/L. Quality improvement methodology was used to increase the number and percentage of patients reaching cholesterol targets of both 4 and 5 mmol/L. The number of patients taking a statin was recorded monthly, allowing calculation of the percentage of different statins prescribed. Run charts and cumulative charts were used to display treatment targets and statin prescribing results. **Results:** In early 2014, the percentage of patients reaching cholesterol target of 5 mmol/L in a GP diabetes clinic fell from 75% to only 45%. EMIS protocols were developed to prompt intensification of statins. Improvement was shown within 6 months. The practice was part of the RCGP quality improvement project in 2015–16 and used quality improvement methodology, including the use of run charts to report on progress monthly. The percentage of patients reaching cholesterol of 5 mmol/L increased from 45% in 2014 to 85% in 2016, while the percentage reaching cholesterol of 4 mmol/L increased from 22% to 45%. **Conclusions:** Using quality improvement methodology achieved an increase in the number and percentage of people with diabetes taking appropriate statins and reaching both cholesterol targets. ■

## P22

### Incidence of hypoglycaemia with the dipeptidyl peptidase-4 inhibitor linagliptin in type 2 diabetes patients with renal impairment

*Submitting author: von Eynatten M, Boehringer Ingelheim GmbH, Ingelheim, Germany*

**Background:** Patients with type 2 diabetes (T2D) and renal impairment (RI; eGFR <60 mL/min/1.73 m<sup>2</sup>) have a significantly increased risk for hypoglycaemia. This can lead to a reluctance to intensify management in these patients, thus compromising glycaemic control. In this context, the addition of a dipeptidyl peptidase (DPP)-4 inhibitor is a potentially attractive alternative. **Aims/Objectives:** To evaluate the incidence of hypoglycaemic events in randomised, placebo-controlled trials with the DPP-4 inhibitor linagliptin, specifically in participants with RI. **Methods:** Participants with T2D and RI were identified from 20 trials (duration 12–52 weeks) of linagliptin 5 mg once daily as monotherapy or add-on therapy. The incidence of pre-defined overall and confirmed hypoglycaemic events was determined. **Results:** In

all, 1155 participants with T2D and RI were identified (linagliptin,  $n=669$ ; placebo,  $n=486$ ; mean exposure  $>6$  months). Most (80%) had an eGFR between 30 and  $<60$  mL/min/1.73 m<sup>2</sup>. Overall, participants were aged  $66\pm 9$  years, had a prolonged diabetes duration and frequent vascular comorbidities, and 44% were treated with insulin. Mean baseline HbA<sub>1c</sub> was 8.2%. Linagliptin significantly lowered HbA<sub>1c</sub> versus placebo ( $-0.53\%$  at 52 weeks;  $P<0.0001$ ). Although background incidence of hypoglycaemia was high ( $>30\%$ ), there was no increase in pre-defined hypoglycaemic event categories. Incidence risk ratio of any confirmed hypoglycaemic event for linagliptin versus placebo was 0.99 (95% CI, 0.79–1.24). Severe hypoglycaemia occurred in 1.3% and 1.0% of linagliptin and placebo participants, respectively ( $P=ns$ ). **Conclusions:** These findings support the addition of linagliptin for improving glycaemic control in patients with T2D and RI without increasing the risk for hypoglycaemia. **Support:** Boehringer Ingelheim. ■

## P23

### Safety and efficacy of linagliptin in patients with type 2 diabetes and coronary artery disease: Analysis of pooled incident investigator-reported events from Phase 3 trials

*Submitting author: Lehrke M, University Hospital Aachen, Aachen, Germany*

**Background:** Patients with type 2 diabetes (T2D) continue to have increased coronary artery disease (CAD) morbidity and mortality. **Aims/Objectives:** To evaluate safety and efficacy data of the dipeptidyl peptidase-4 inhibitor linagliptin in T2D patients with CAD (standardised MedDRA query “embolic and thrombotic events”). **Methods:** Data from linagliptin 5 mg, randomised placebo-controlled trials were pooled. Patients with  $\geq 12$  weeks (safety trials [ $n=19$ ]; linagliptin,  $n=451$ ; placebo,  $n=272$ ) or  $\geq 24$  weeks (efficacy trials [ $n=12$ ]; linagliptin,  $n=328$ ; placebo,  $n=198$ ) of treatment were included. **Results:** Overall, among the safety set of trials, baseline mean $\pm$ SD age, BMI $\pm$ SD and HbA<sub>1c</sub> $\pm$ SD were  $64.7\pm 9.2$  years,  $30.6\pm 4.9$  kg/m<sup>2</sup> and  $8.1\pm 0.9\%$ , respectively. Approximately 50% of patients in each group received at least two additional background anti-diabetes drugs. Median (range) exposure to linagliptin and placebo was 169 (6–707) days and 170 (1–706) days, respectively. Use of cardiovascular (CV) non-study drugs and baseline CV risk factors/history were well matched between both groups. The overall incidence of adverse events (AEs) was numerically lower with linagliptin than with placebo (65% versus 75%). Cardiac AEs were reported by 9% of patients in both groups. In the efficacy set of trials (baseline mean $\pm$ SD HbA<sub>1c</sub>,  $8.2\pm 0.9\%$ ), the placebo-adjusted mean HbA<sub>1c</sub> change from baseline at week 24 with linagliptin was  $-0.57\%$  (95% CI,  $-0.70$ ,  $-0.43$ ;  $P<0.0001$ ). Although patients were more likely to achieve HbA<sub>1c</sub>  $<7\%$  with

linagliptin versus placebo (OR, 3.70;  $P<0.0001$ ), the incidence of hypoglycaemia was 20.8% with linagliptin and 24.6% with placebo. **Conclusions:** Linagliptin was well tolerated and efficacious in T2D patients with known CAD. **Support:** Boehringer Ingelheim. ■

## P24

### Appropriate dosing of dipeptidyl peptidase-4 inhibitors (DPP-4) in patients with type 2 diabetes and reduced renal function: A CPRD study

*Submitting author: Lee S, Boehringer Ingelheim Ltd, Bracknell*

**Background:** Four out of five DPP-4 inhibitors (saxagliptin, alogliptin, sitagliptin and vildagliptin) should be dose adjusted in patients with type 2 diabetes and renal impairment, in accordance with their respective summary of product characteristics (SPCs). **Aims/Objectives:** To determine if recommended dose adjustments are made in clinical practice. **Methods:** This is a retrospective cohort study using the UK Clinical Practice Research Datalink (CPRD) of patients with a diagnosis of type 2 diabetes and renal impairment, who were initiated on a DPP-4 inhibitor between 2013 and 2015. The study protocol was approved by the MHRA Independent Scientific Advisory Committee (Ref: 15\_184Mn). **Results:** This study identified 3425 patients who were diagnosed with both type 2 diabetes and renal impairment and were initiated on a DPP-4 inhibitor. Average age at the time of treatment initiation was 74.15 years, history of type 2 diabetes was 11.8 years, average HbA<sub>1c</sub> level was 8.32% and there was a similar divide between men and women. The percentages of patients who were on an inappropriate dose of DPP-4 inhibitors for their level of renal impairment was 48%, 43%, 41% and 27% for saxagliptin, alogliptin, sitagliptin and vildagliptin, respectively. **Conclusions:** The evidence suggests that a large proportion of patients with type 2 diabetes did not receive the recommended dose of saxagliptin, alogliptin, sitagliptin and vildagliptin based on their level of renal impairment. Therefore, it is important to raise awareness that with the exception of linagliptin all other DPP-4 inhibitors require dose reduction for patients with moderate or severe renal impairment. ■

## P25

### Reasons for different patterns of basal insulin persistence after initiation among people with type 2 diabetes mellitus (T2DM)

*Submitting author: Peyrot M, Loyola University Maryland, Baltimore, USA*

**Aims:** People with T2DM who initiate basal insulin therapy often interrupt or stop therapy soon after initiation. This study assessed reasons for different

persistence patterns (continuers, interrupters or discontinuers) among insulin-naïve people with T2DM who initiated basal insulin therapy within the previous 3–24 months. **Methods:** An online survey was completed by 942 respondents from the US ( $n=154$ ), France ( $n=137$ ), Germany ( $n=131$ ), Spain ( $n=150$ ), UK ( $n=131$ ), Brazil ( $n=156$ ) and Japan ( $n=83$ ), who were identified from the Harris Panel and third-party panels.

**Results:** Continuers were on average significantly older than interrupters and discontinuers (46, 37, and 38 years, respectively;  $P<0.05$ ). Significantly lower proportions of continuers and discontinuers were men (62% and 58%) compared with interrupters (78%). Benefits of basal insulin therapy motivated continuers. Experienced or potential side effects were most often noted as factors for interruption or discontinuation. Instruction by the healthcare provider (HCP) was often a reason for continuing/stopping/restarting therapy. HCPs persuaded 71% of interrupters to restart therapy. **Conclusions:** Persistence on basal insulin is often influenced by HCP actions, and understanding patient experiences that affect persistence may help clinicians increase persistence to therapy in T2DM. ■

## P26

### Effect of patient–physician relationship on insulin progression, diabetes distress, adherence and HbA<sub>1c</sub> control over time: Insights from the MOSA1c study

*Submitting author: Linetzky B, Eli Lilly and Company, Buenos Aires, Argentina*

**Aims:** This analysis investigates how aspects of the patient–physician relationship are associated with insulin treatment progression, patient-reported outcomes, adherence and HbA<sub>1c</sub> levels over 2 years using data from the MOSA1c study, a prospective cohort study of patients with type 2 diabetes (T2D) on insulin therapy. **Methods:** Patients with T2D  $\geq 18$  years and taking insulin  $\geq 3$  months were included. Extensive clinical, demographic and psychosocial data were collected at each visit. Multivariable linear or logistic regression models examined the effect of baseline interpersonal process of care (IPC) sub-scale scores on the diabetes distress scale (DDS), diabetes knowledge test (DKT), self-monitoring blood glucose (SMBG), adherence, insulin treatment progression and HbA<sub>1c</sub> level at Year 2. **Results:** We enrolled 4299 patients (mean [SD] age, 60.9 [11] years; mean [SD] HbA<sub>1c</sub> 8.1% [1.9%]; 50.2% women). At 2 years, post-baseline hurried communication was associated with higher levels of diabetes distress ( $=0.16$ ;  $P<0.001$ ), lower levels of diabetes knowledge ( $=-0.06$ ;  $P<0.03$ ), less frequent SMBG ( $=-0.11$ ;  $P<0.001$ ) and self-reported adherence to insulin ( $=-0.04$ ;  $P<0.001$ ). A higher report on eliciting patient concerns ( $=0.06$ ;  $P=0.008$ ), and on explaining results ( $=0.07$ ;  $P=0.009$ ) was associated with higher DKT scores at Year 2. **Conclusions:** Improvements in various aspects of the patient and health care provider relationship were

associated with a lower level of diabetes-related distress, higher diabetes knowledge scores, better self-reported adherence to insulin treatment and SMBG, and an increase in progression of diabetes therapy. However, this did not translate to significant changes in HbA<sub>1c</sub> levels at study completion. Analysis is ongoing. ■

## P27

### Comparable efficacy and safety of dulaglutide in T2D patients ≥65 and <65 years of age

Submitting author: *Boustani MA, Indiana University, Indiana, USA*

**Objectives:** Dulaglutide (DU), a once-weekly GLP-1 receptor agonist, demonstrated significant HbA<sub>1c</sub> reduction and potential for weight loss in adult patients with T2D in the AWARD clinical trial programme. We compared the efficacy and safety of DU in patients ≥65 and <65 years of age. **Methods:** This pooled analysis used 26-week data from the intent-to-treat populations of six published AWARD clinical trials (AWARD-1 to 6) to evaluate efficacy (HbA<sub>1c</sub> reduction and percent to goal HbA<sub>1c</sub> <64 mmol/mol [8%]) and safety (GI tolerability) of DU 1.5 mg and 0.75 mg in patients with T2D who were ≥65 and <65 years of age. The trials, which incorporated different background therapies, included non-insulin comparators (four trials: metformin, sitagliptin, exenatide BID, liraglutide) and insulin comparators (two trials). **Results:** Mean age differed by -17 years between age groups for both DU doses. For each DU dose, change in HbA<sub>1c</sub> from baseline, percentage of patients achieving HbA<sub>1c</sub> <64 mmol/mol (8%), and GI adverse event rate were similar between age groups. In the DU 1.5 mg-treated patients, nausea, diarrhoea and vomiting occurred in 20.3%, 11.6% and 10.1% of the older age group respectively, and in 22.6%, 14.2% and 10.4% of the younger age group respectively. In DU 0.75 mg-treated patients, percentages affected by nausea, diarrhoea and vomiting in the older group were 12.3%, 8.9% and 6.3% respectively and in the younger group, 13.2%, 8.9% and 8.5% respectively. Severe hypoglycaemic events were infrequent. **Conclusions:** Both DU doses were well tolerated and improved glycaemic control with comparable efficacy in patients with T2D who were ≥65 and <65 years of age. ■

## P28

### Improving diabetes care by increasing the percentage of people achieving treatment targets

Submitting author: *Askey A, St John's Medical Centre, Walsall*

**Background:** The National Diabetes Audit reported that in 2013–14, only 41.4% of adults with type 2 diabetes reached targets for HbA<sub>1c</sub>, cholesterol and blood pressure,

with no further increase in 2015–16. The Quality and Outcomes Framework measures these same indicators but with different targets and does not report for the combined target. **Aims:** To increase the percentage of patients achieving all three National Diabetes Audit treatment targets using quality improvement methodology. **Methods:** Analysis of National Diabetes Audit data at practice level confirmed there was room for improvement. Process mapping identified areas where it was thought improvement could be made. Data were analysed monthly for individual treatment targets and annually for the combined target. **Results:** Data from a primary care diabetes clinic were analysed for individual treatment targets and for all three treatment targets. For 3 consecutive years, improvement was seen in individual treatment targets, and the overall results for all three treatment targets increased from 37% in 2013–14, to 41% in 2014–15 and 43% in 2015–16. **Conclusions:** A change of emphasis in diabetes care considering all three treatment targets, rather than individual targets as in the Quality and Outcome Framework, can lead to measurable improvements in diabetes care. ■

## P29

### Improving diabetes care by increasing screening for microalbuminuria

Submitting author: *Askey A, St John's Medical Centre, Walsall*

**Background:** Screening for microalbuminuria in people with diabetes has been done less routinely since this indicator was removed from the Quality and Outcomes Framework. Six practices in one PCT were involved in the RCGP project to improve quality of care in people with diabetes, with a focus on improving microalbuminuria screening. **Aims:** To improve consistency of ACR screening in diabetes in six practices using quality improvement methodology, with a combined list of about 1800 people with diabetes. **Methods:** Each practice used process mapping to identify how they could improve microalbuminuria screening. EMIS prompts were used to facilitate the process of testing. Various practical methods were adopted to increase testing. The number of tests performed was reported monthly and displayed both as cumulative and run charts. Results were reported for each individual practice and as combined results for all six practices. **Results:** In 2014, only 1085 out of 1800 people with diabetes in this group of practices had a microalbuminuria screen performed. This increased to 1800 in 2015. Each practice was able to demonstrate improvement, and the combined results show the impact of small changes in a larger context. **Conclusion:** Identifying specific areas of care where improvement is needed using quality improvement methodology significantly increased the consistency of microalbuminuria screening in a group of six practices. The impact could be even greater if these simple measures were adopted on a larger scale. ■

## P30

### Clinical perspectives from the BEGIN and EDITION programmes: Trial-level meta-analyses outcomes with either degludec or glargine 300 units/mL versus glargine 100 units/mL in T2DM

Submitting author: *Baradez C, Sanofi, Surrey*

**Background/Aims:** The BEGIN and EDITION programmes included a broad population of adults with T2DM on basal–bolus or basal–oral therapy, as well as those who were insulin naïve. Efficacy and safety of insulin degludec (IDeg) and insulin glargine 300 units/mL (Gla-300) were compared with insulin glargine 100 units/mL (Gla-100) in the BEGIN and EDITION programmes, respectively. **Materials and methods:** HbA<sub>1c</sub>, fasting plasma glucose (FPG) and hypoglycaemia incidence with IDeg or Gla-300 versus Gla-100 were explored in two trial-level meta-analyses of clinical trials in T2DM. **Results:** HbA<sub>1c</sub> reduction was significantly greater for Gla-100 versus IDeg, despite FPG reduction being significantly more pronounced with IDeg. HbA<sub>1c</sub> reduction was comparable with Gla-300 and Gla-100, whereas FPG reduction was significantly greater with Gla-100 in the fixed but not random effect model. Risk of ≥1 confirmed hypoglycaemic event (<3.1 mmol/L) or severe hypoglycaemic event was lower with IDeg versus Gla-100 at night (00:01–05:59 h) but comparable at any time (24 h). Risk of ≥1 confirmed (<3.0 mmol/L) or severe hypoglycaemic event was lower with Gla-300 versus Gla-100 at night (00:00–05:59 h) and also at any time (24 h). Furthermore, the risk of ≥1 documented symptomatic hypoglycaemic event (≤3.9 mmol/L) with IDeg or Gla-300 versus Gla-100, both at night and at any time, closely reflected that of confirmed (<3.1 or <3.0 mmol/L) or severe events. Risk of ≥1 severe hypoglycaemic event was comparable with IDeg or Gla-300 versus Gla-100. **Conclusion:** In trial-level meta-analyses in T2DM, Gla-100 reduced HbA<sub>1c</sub> more than IDeg despite IDeg having a greater FPG-lowering effect. Hypoglycaemia risk was lower with IDeg versus Gla-100 for nocturnal but not anytime events. Gla-300 provided comparable glycaemic control to Gla-100 with lower risk of anytime and nocturnal hypoglycaemia. Head-to-head trials of IDeg versus Gla-300 are warranted. Trial-level meta-analyses was supported by Sanofi and presented at the EASD conference, 12–16 September 2016, Munich, Germany. ■

## P31

### Glycaemic control and hypoglycaemia benefits with insulin glargine 300 units/mL (Gla-300) extend to people with type 2 diabetes (T2DM) and mild-to-moderate renal impairment

Submitting author: *Baradez C, Sanofi, Surrey*



**Abstract:** EDITION 1, 2 and 3 showed that over 6 months, Gla-300 provided comparable glycaemic control to glargine 100 units/mL (Gla-100) and less hypoglycaemia in people with T2DM. Renal impairment increases the risk of hypoglycaemia in people with T2DM. The effects of Gla-300 versus Gla-100 on HbA<sub>1c</sub> reduction and hypoglycaemia were assessed in renal function subgroups (baseline eGFR  $\geq 30$  to  $< 60$  mL/min/1.73 m<sup>2</sup>,  $\geq 60$  to  $< 90$  mL/min/1.73 m<sup>2</sup> and  $\geq 90$  mL/min/1.73 m<sup>2</sup>) in a post-hoc patient-level meta-analysis of data from EDITION 1, 2 and 3. Most participants (56%) had baseline eGFR  $\geq 60$  to  $< 90$  mL/min/1.73 m<sup>2</sup>. Non-inferiority for HbA<sub>1c</sub> reduction (defined in the EDITION studies) was shown for Gla-300 and Gla-100 regardless of renal function; no evidence of heterogeneity of treatment effect was demonstrated across subgroups ( $P=0.46$ ). Risk of confirmed ( $\leq 3.9$  mmol/L) or severe hypoglycaemia was significantly lower for nocturnal events and comparable or lower for anytime (24 h) events for Gla-300 versus Gla-100 across subgroups. Renal function did not affect the lower rate of nocturnal or any-time hypoglycaemia (no evidence of heterogeneity of treatment effect across subgroups:  $P=0.73$  and  $P=0.27$  respectively). Gla-300 provided comparable glycaemic control and consistently reduced nocturnal hypoglycaemia versus Gla-100 in participants with T2DM, regardless of renal function, with no increase in any time hypoglycaemia. **Declaration:** The study was supported by Sanofi and was presented at ADA, 10–14 June 2016 in New Orleans, USA. ■

### P32

#### Factors associated with insulin adherence among patients with type 2 diabetes: The MOSA1c study

*Submitting author: He M, Brigham and Women's Hospital, Boston, USA*

**Aims:** Insulin is the most effective glucose-lowering therapy. Reported rates of adherence vary widely and few studies have investigated this issue over an extended period. This analysis explores factors associated with sub-optimal insulin adherence within the MOSA1c study, a 2-year prospective cohort study. **Methods:** Patients with type 2 diabetes (T2D),  $\geq 18$  years old and on insulin for  $\geq 3$  months in 18 countries were included. Extensive demographic, clinical and patient-reported data were collected at baseline and over 2 years within the normal course of care. Sub-optimal adherence was defined as missing any insulin injections in the 7 days prior to a clinic visit and was self-reported. Multivariable logistic regression and multiple imputation were used in the analyses. **Results:** Among 4213 (of 4299 total) patients with evaluable data (mean [SD] age, 61 [11] years; 50% female), 943 (22%) reported sub-optimal insulin adherence at the end of study. These patients were younger ( $P<0.0001$ ), with lower diabetes knowledge test scores ( $P=0.03$ ), likely to be non-adherent at baseline ( $P<0.0001$ ), use mixed insulin ( $P=0.0002$ ), inject  $>1$  time per day ( $P=0.002$ ), have a worse experience with their insulin delivery system

( $P=0.03$ ) and have poorer communication with their healthcare provider compared to fully adherent patients. After adjustment, age and baseline insulin adherence status remained significantly different between the two groups along with some geographic variations. **Conclusion:** Our study indicates that among patients with T2D utilising insulin, younger patients with a history of poor adherence are less likely to be adherent over time. Future analysis will explore geographic and cultural differences among these findings. ■

### P33

#### Delivery of diabetes care for people with severe mental illness: A survey of health professionals

*Submitting author: Mulligan K, School of Health Sciences, City, University of London*

**Background:** People with severe mental illness (SMI), such as schizophrenia and bipolar disorder, are at an increased risk of developing diabetes and experience poorer outcomes than people who have diabetes alone. **Aims/Objectives:** To identify factors that influence health professionals' management of type 2 diabetes mellitus (T2DM) in people with SMI. **Methods:** An anonymous online survey was distributed in NHS trusts and by publicising the survey through professional organisations and social media. **Results:** Participants were 103 mental health nurses and 93 psychiatrists. Of these, 72.3% reported having access to people in primary care to help manage T2DM. Diabetes monitoring was reported by most participants to be the responsibility of GPs, but 46% to 70% of mental health staff also saw it as part of their role to monitor blood pressure, cholesterol, weight and kidney function and to provide advice on nutrition and physical activity. However, less than 17% reported responsibility for foot checks or referral to retinopathy screening. Barriers to managing diabetes included lack of confidence with only 41% feeling confident in managing diabetes and 71% reporting a need for more training. Organisational barriers included a need for more integrated IT systems (reported by 68% of participants). Family support was seen as an important enabler by 53%. **Conclusions:** Mental health professionals report that the main responsibility of diabetes care in people with SMI should rest with primary care. However, they are willing to take responsibility for other health aspects, but they report a need for more training to help them in this role. ■

### P34

#### A comparison between a local audit of services provided for women with pre-existing diabetes in a general hospital with a high-risk, low socioeconomic population against the National Diabetes in Pregnancy Audit (2014)

*Submitting author: McLatchie K, Medway*

*Maritime Hospital, Gillingham*

**Aim:** To review the local incidence of diabetes in pregnancy (DiP) and benchmark this against national statistics to develop local NHS services. **Methods:** A retrospective audit that collated local data from 2013–2015 benchmarking against National DiP data (2014) to assess outcomes against NICE (2015) guidance. **Results:** The local incidence of type 1 (T1) DiP has increased by 50% since 2013 compared to a 29.6% decrease of type 2 (T2) DiP over the same period. Locally, 85% of T1 and 72% of T2 saw DiP services by 12 weeks, compared to 82% and 75% nationally. Pre-conceptually, 30.7% of the cohort received 5 mg of folic acid (FA), 9.38% received 400 mcg, and 59.9% received no FA. Of T2 women, 20% had a first trimester HbA<sub>1c</sub>  $\leq 48$  mmol/mol compared to 35.8% nationally, while 11.6% of T2 women had an HbA<sub>1c</sub>  $\geq 86$  mmol/mol, which is above NICE recommendations. T1 women were equitable to national results with 15% of women having an HbA<sub>1c</sub>  $\leq 48$  mmol/mol; however, 30% had an HbA<sub>1c</sub>  $\geq 86$  mmol/mol, compared to 25.7% nationally. The average BMI was 28.8 kg/m<sup>2</sup> for T1 women compared to 26.8 kg/m<sup>2</sup> nationally, and similarly, average BMI for T2 women was 35.2 kg/m<sup>2</sup> versus 33 kg/m<sup>2</sup> nationally. The cohort caesarean rate was 74.5% (T2) and 77.5% (T1) compared to 52% (T2) and 66.9% (T1) nationally. Of the 51% babies delivered before 37 weeks, 74% needed neonatal care. Of the 46% of babies born between 37–38 +6 weeks of pregnancy, 87% received normal care. **Conclusions:** Key development areas include adaptations to the pregnancy referral to identify women requiring early contact, establishing partnerships with primary services to provide pre-conceptual care and further auditing of indication for caesarean/premature delivery. ■

### P35

#### Empagliflozin (EMPA) as add-on to linagliptin (LINA) and metformin in patients with type 2 diabetes (T2DM): A 24-week randomised, double-blind, double-dummy, parallel-group trial

*Submitting author: Søfteland E, Haukeland University Hospital, Bergen, Norway*

**Background:** Metformin often fails to maintain glycaemic control as T2DM progresses. **Aims/Objectives:** To investigate the efficacy and safety of EMPA 10 mg and 25 mg versus placebo (PBO) as add-on to LINA 5 mg and metformin in patients with T2DM. **Methods:** Patients with HbA<sub>1c</sub>  $\geq 8.0$  and  $\leq 10.5\%$  while receiving stable-dose metformin were treated with open-label LINA 5 mg ( $n=606$ ) for 16 weeks. Subsequently, those with HbA<sub>1c</sub>  $\geq 7.0$  and  $\leq 10.5\%$  were randomised to double-blind treatment with a single-pill combination of EMPA 10 mg/LINA 5 mg ( $n=112$ ) or EMPA 25 mg/LINA 5 mg ( $n=111$ ), or PBO plus LINA 5 mg ( $n=110$ ) for 24 weeks. Endpoints included changes from baseline (randomisation) in HbA<sub>1c</sub>, FPG and weight

after 24 weeks of double-blind treatment. **Results:** At week 24, EMPA 10 mg and 25 mg significantly reduced HbA<sub>1c</sub> from baseline compared with PBO as add-on to LINA 5 mg and metformin: difference versus PBO was -0.79 (95% CI, -1.02, -0.55;  $P < 0.0001$ ) for EMPA 10 mg and -0.70 (95% CI, -0.93, -0.46;  $P < 0.0001$ ) for EMPA 25 mg. FPG and weight were also significantly reduced with EMPA 10 mg and 25 mg compared with PBO at week 24 (all  $P < 0.0001$ ). Confirmed hypoglycaemia occurred in 0%, 2.7% and 0.9% of the EMPA 10 mg, EMPA 25 mg and PBO groups. **Conclusions:** In T2DM patients inadequately controlled with LINA and metformin alone, EMPA 10 mg and 25 mg improved glycaemic control and weight versus PBO as add-on to LINA 5 mg and metformin for 24 weeks and were well tolerated. ■

### P36

#### Non-attendance in diabetes education in diabetes education centres: Perspective of practitioners

*Submitting author: Lawal M, University of West London, Brentford*

**Background:** Structured patient education plays a vital role in reducing the physical, social and economic burdens of diabetes. Whilst, there are several education programmes to promote awareness of the medical condition, non-attendance presents a major challenge. **Objective:** To explore referring practitioners' views about causes of non-attendance and identify ways to reduce some of the barriers to advancing government policy of education for all patients with diabetes. **Method:** A qualitative approach was adopted using semi-structured individual face-to-face interview ( $n=8$ ) of practice nurses in six GP surgeries in the South East of England. **Findings:** This final stage of a four-tier sequential study revealed four main themes: (1) Organisation of care, (2) Personal circumstances of the patient, (3) Perceptions and attitudes of patients to diabetes education and (4) Strategies to aid attendance. **Conclusion:** The findings from this phase of the project are similar to the previous phases and indicated that the pressure of time and the drive to meet government target seem to play a significant role in the referral process. Although the inclusion of payment incentives in the QOF 2013/14 for referring patients to the diabetes education centres has led to increase in the referral rate, it appears that it has not resulted in the desired outcome. ■

### P37

#### Older people with type 2 diabetes and chronic kidney disease are commonly overtreated with therapies associated with severe hypoglycaemia

*Submitting author: Hambling CE, Bridge Street Surgery, Norfolk*

**Background:** Chronic kidney disease (CKD) contributes to hypoglycaemia risk amongst older people with type 2 diabetes. The International Diabetes Federation and International Society for Nephrology advise against intensive glycaemic management to HbA<sub>1c</sub>  $< 7.0\%$  (53 mmol/mol) in older people with CKD, advocating less stringent targets aimed at minimising hypoglycaemia. **Aim:** To evaluate glycaemic management and prevalence of overtreatment with sulfonylurea (SU) and insulin therapies in older people with type 2 diabetes, with and without CKD. **Method:** A cross-sectional observational study of people with type 2 diabetes (aged  $\geq 70$  years, registered from 16 practices and prescribed SU or insulin therapies within the previous 90 days). Data collected included age, sex, last recorded HbA<sub>1c</sub> and renal function. **Results:** From a cohort of 1379 people, 644 (47.8%) had CKD. People with CKD were older (median age 80 years;  $P < 0.001$ ). Whilst prescribing of SU therapies decreased across worsening CKD staging, prescribing of insulin or combined insulin and SU therapies increased ( $P \leq 0.001$ ). There was no difference in median HbA<sub>1c</sub> or treatment to HbA<sub>1c</sub>  $< 7.0\%$  between those with or without CKD. In all, 193 (30.3%) people with CKD had HbA<sub>1c</sub>  $< 7.0\%$  versus 205 (29.5%) without CKD ( $P = 0.351$ ). **Conclusion:** Almost half of older people with type 2 diabetes who are prescribed SU or insulin therapies had CKD. Those with CKD were older and more commonly prescribed insulin, yet intensively managed as commonly as people without CKD. Further research is warranted to inform guidance that promotes safe glycaemic management in older people with complex comorbidity. ■

### P38

#### Overtreatment of older people with therapies associated with hypoglycaemia

*Submitting author: Hambling CE, Bridge Street Surgery, Norfolk*

**Background:** Severe hypoglycaemia in older people with type 2 diabetes causes serious harm and is associated with increased mortality. Low HbA<sub>1c</sub> is a marker for potential overtreatment, increasing the risk for severe hypoglycaemia. International Diabetes Federation guidance advises against treating older people with type 2 diabetes to HbA<sub>1c</sub>  $< 7\%$  (53 mmol/mol) with therapies associated with severe hypoglycaemia. **Aim:** To determine the proportion of older people with type 2 diabetes overtreated with therapies associated with severe hypoglycaemia. **Method:** A cross-sectional observational study of people with type 2 diabetes (aged  $\geq 70$  years and who are registered with 16 participating practices). We collected data on the proportion of people who had received a prescription for any sulfonylurea or insulin therapy within the previous 90 days. Data collected included age, sex, last recorded HbA<sub>1c</sub> and data for renal function. **Results:** From a population of 24 661 people aged  $\geq 70$  years, 3863 (15.7%) patients had a diagnostic

code for type 2 diabetes. Of these, 1379 (35.7%) patients had received a prescription for any sulfonylurea or insulin therapy. The median age of these patients was 78 years (range 70–102 years). Overall, 1339 (97.1%) patients had an HbA<sub>1c</sub> measurement within the previous 18 months. Median HbA<sub>1c</sub> was 7.5% (IQR 6.8–8.5%, range 5.0–17.7%). In total, 400 (29.9%) patients had a HbA<sub>1c</sub>  $< 7\%$  (53 mmol/mol), with 162 (12.1%) treated to a HbA<sub>1c</sub>  $< 6.5\%$  (48 mmol/mol). **Conclusion:** Nearly a third of older people with type 2 diabetes are potentially overtreated with therapies associated with risk of hypoglycaemia. Further research should include intervention programmes aimed at reducing the risk of severe hypoglycaemia within this vulnerable population. ■

### P39

#### Elderly people with type 2 diabetes and dementia are managed to similar glycaemic targets as those without dementia

*Submitting author: Hambling CE, Bridge Street Surgery, Norfolk*

**Background:** Dementia contributes to the complexity of glycaemic management in older people with type 2 diabetes, increasing the risk for hypoglycaemia. As a consequence, International Diabetes Federation guidance advises less stringent glycaemic targets, accepting HbA<sub>1c</sub> up to 8.5% (70 mmol/mol) and proposing HbA<sub>1c</sub>  $< 7.0\%$  (53 mmol/mol) as indicative of overtreatment, placing patients at unnecessary risk. **Aim:** To evaluate glycaemic management among older people with type 2 diabetes and dementia (with therapies that may put patients at risk of hypoglycaemia) and to compare them to those without dementia. **Method:** A cross-sectional observational study of people with type 2 diabetes (aged  $\geq 70$  years and who are registered with 16 participating practices), who had received a prescription for any sulfonylurea or insulin therapy within the previous 90 days. Data collected included age, sex, last recorded HbA<sub>1c</sub>, renal function and diagnostic code for dementia. **Results:** From an identified cohort of 1379 patients, 60 (4.35%) patients had a co-existing diagnostic code for dementia. Compared to those without dementia, patients with dementia were significantly older, median age 83 years (IQR 76–87) versus 78 (IQR 73–83) years ( $P = 0.001$ ). There was no difference in median HbA<sub>1c</sub> between patients with and without dementia. A greater proportion of patients with dementia had HbA<sub>1c</sub>  $< 7.0\%$  (36.8%) compared to those without dementia (29.6%), although this difference did not reach statistical significance. **Conclusion:** In spite of more advanced age, patients with dementia on sulfonylurea or insulin therapies are managed to similar glycaemic targets as patients without dementia. Overtreatment appears common and may place these very elderly and particularly vulnerable patients at unnecessary risk of hypoglycaemia. ■

Notes

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

This abstract book will  
be published online  
as a supplement to  
*Diabetes & Primary Care*  
Vol 18 No 6  
This will be available at:  
[www.diabetesonthenet.com/dpc](http://www.diabetesonthenet.com/dpc)

*Diabetes & Primary Care* is  
published in association with the  
Primary Care Diabetes Society

**PCDS**  
Primary Care Diabetes Society