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P1

Improving quality: the impact of formal impaired glucose regulation reviews in the primary care setting

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Background: Against the backdrop of an expanding diabetes population and its associated burdens, prevention of type 2 diabetes (T2D) is becoming increasingly important. Persons most at risk are those with impaired glucose regulation (IGR). IGR has become more readily diagnosed since HbA_{1c} tests have been introduced and included within NHS health checks. We now have an identifiable IGR population which affords the opportunity to deliver preventative lifestyle advice and intervention. **Aims/objectives:** To quantify the impact of formal consultations giving lifestyle advice and intervention in improving outcomes for persons with IGR. **Methods:** Persons with HbA_{1c} 42–47 mmol/mol inclusive were invited for review in 20-minute clinics with a practice nurse. Explanation of IGR was given, BP, pulse and BMI measurements were taken, and kidney function and lipids profile were reviewed. Advice regarding lifestyle, signs and symptoms of T2D and smoking cessation advice (where appropriate) was given. The population was reviewed again after 12 months. The study includes data from 95 persons. **Results:** In the second review: 55% had reduced HbA_{1c} with 37% having a normal HbA_{1c}. Three per cent had progressed to T2D. Sixty per cent had reduced BMI, of which 31% had reduced more than 5 kg. Initially, 44% had cholesterol higher than 5 mmol/L, falling to just 18% during second reviews. Four per cent were found to have hypertension and three persons were identified as having irregular heart rhythms. **Conclusion:** Formal reviews of the IGR population appear to trigger positive lifestyle changes in the majority of the population, reducing their risk of developing T2D and cardiovascular disease. ■

P2

A nurse-led community renal clinic for people with diabetic nephropathy

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Background: Diabetes is the single largest cause of end-stage renal failure and is linked to increased cardiovascular disease. **Aims/objectives:** To assess the effectiveness of a renal nurse-led clinic by reducing deterioration of nephropathy and cardiovascular disease by optimising medication and addressing life-style issues. This was achieved by reducing blood pressure and albumin excretion using ACE-inhibition to the maximum tolerated doses. Cardiovascular risk was assessed and managed by addressing smoking cessation, weight loss and physical activity. HbA_{1c} targets were individually assessed with a target of 48 mmol/mol. Self-management was encouraged with the use of a hand-held record book. **Methods:** Twenty-six patients were seen at chronic kidney disease (CKD) 3a, 3b, and 4 and followed up at monthly intervals. Two questionnaires were completed on three occasions – initial clinic, 3 months and 6 months. The patient's test results were completed by the nurse and a WHO (Five) Well-Being Index (1998 version) was completed by the patient. A patient experience survey was completed after the 6-month clinic. The GP and diabetes consultant were kept informed of the patient's progress after each consultation. **Results:** At 6 months systolic and diastolic blood-pressure had significantly improved ($P \leq 0.0037$; $P \leq 0.0015$). For the albumin creatinine ratio: $P \leq 0.06$. For the protein creatinine ratio: $P \leq 0.23$. The patient experience survey suggested that all patients had an improvement in their knowledge of renal disease since coming to the clinic. **Summary:** Our data reveal that there were improvements in blood pressure which has a significant effect in reducing diabetic nephropathy and cardiovascular disease. ■

P3

Are X-PERT centres meeting the NICE structured patient education (SPE) key criteria for Quality Assurance?

***Deakin T**, X-PERT Health, West Yorkshire*

Aim: To comply with NICE guidance, X-PERT Educators are assessed with the X-PERT Quality Assurance Programme within their first year of delivery. **Method:** The X-PERT Quality Assurance Programme contains 62 standards that are linked to learning outcomes. Each standard is either fully, mostly, partly or not met. Guidance defines the criteria required for each category and points are allocated accordingly. Delivery to patients is assessed via direct observation or videos. Educators receive a report and constructive feedback. If Educators score below 198 (80%) a timed action plan is prepared and the quality assurance process repeated within 1 year. **Results:** 431 X-PERT Diabetes Educators were eligible to be assessed by 20/2/14. Number of Educators who have: completed the QA process = 260 (60.3%); are in progress = 86 (19.9%); have not done it = 77 (17.8%); are on long-term leave = 8 (1.8%). Mean score = 221/248 (89%, SD 6.7%) with scores ranging from 167 (67%) to 248 (100%). Six Educators (2.3%) required a timed action plan to increase score. Lost marks were mainly due to lack of interpersonal/facilitation skills to support group education and goal setting. **Conclusion:** Adherence to quality standards for delivery of X-PERT Diabetes ensures that patients receive a high standard of structured education. Three hundred and forty-six X-PERT Educators (80.2%) have either been assessed or are currently going through the process. The remaining Educators will be assessed during the following 12 months or removed from registration. A handbook has been prepared to assist Educators in developing the relevant interpersonal/facilitation skills. ■

P4

Are X-PERT centres meeting audit standards for structured patient education?

***Deakin T**, X-PERT Health, West Yorkshire*

Aim: X-PERT Structured Education has demonstrated improved clinical, lifestyle and psychosocial outcomes. To ensure national implementation replicates results from the randomised controlled trial and standards identified in NICE Guidance, continuous audit is conducted. **Methods:** X-PERT Educators collect and enter patients' baseline, 6-month and annual results onto the X-PERT Audit Database. **Results:** Seventy-nine X-PERT Centres (100%) have submitted data for 42 823 people with new or established diabetes. Ethnicity: 84% white and 16% BAME groups. Time to access education from diagnosis: 8% within 1 year, 58% within 5 years, 14% within 10 years and 20% more than 10 years. Audit standards have been met with excellent attendance scores: 95.7% attend at least one session and 81.9% four sessions or more; patient evaluation scores of 95%; empowerment scores increased by 22.9%; HbA_{1c} reduction of 6.7 mmol/mol (95% CI, 6.2–7.2 mmol/mol) at 6 months and 6 mmol/mol (95% CI, 5.5–6.5 mmol/mol) at 1 year; weight loss of 2.1 kg (95% CI, 1.4–2.6 kg) at 6 months and 3.7 kg (95% CI, 2.8–4.1 kg) at 1 year; 2.5 cm (95% CI, 1.6–3.3 cm) waist circumference reduction at 6 and 12 months; 1.6 mmHg (95% CI, 1.1–2.1 mmHg) reduction in systolic and 2.3 mmHg (95% CI, 2.0–2.6 mmHg) reduction in diastolic blood pressure at 1 year; 0.3 mmol/L reduction in total/LDL cholesterol and 0.2 mmol/L reduction in triglycerides at 1 year. **Conclusions:** National implementation of the X-PERT Programme has met audit standards. X-PERT is well attended and evaluated, and results in improved clinical and empowerment outcomes amongst people with newly diagnosed and existing diabetes. ■

P5

Natural History of Renal Function with Exenatide usage in Diabetes – An Observational Audit

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Background: Exenatide is a glucagon-like peptide-1 (GLP-1) agonist. It is cleared by renal excretion, with renal impairment being a contraindication. Case studies

have reported occurrences of acute and reversible renal impairment in some GLP-1 agonist users. **Aim:** To monitor the natural history of renal function in patients on exenatide therapy and to also measure the incidence of acute renal impairment. **Methods:** Patients identified were using exenatide alone or with insulin. Patients were divided according to pre-treatment renal function using the Modification of Diet in Renal Disease (MDRD) formula (n=448). Adverse renal events, discontinuation and changes in weight, BMI, systolic blood pressure, and HbA_{1c} were monitored and compared between renal groups over a 12-month period. **Results**: Median values of eGFR and creatinine remained stable in both the exenatide-only and exenatide–insulin groups. Four patients were identified with criteria fulfilling acute renal impairment. However, patient notes further clarified that these were merely fluctuations with no significant deterioration. In terms of weight, the groups had a median reduction of 6.6 kg and 10.2 kg for exenatide–insulin and exenatide-only groups respectively with subsequent improvement in BMI. Blood pressure improved in both groups. HbA_{1c} values for the group comprising exenatide only showed a percentage drop of 1.4% (P<0.05), while the exenatide–insulin had no change at 12 months. **Conclusion**: In contrast to existing literature, exenatide therapy was not consistent with a decline in renal function. The risk of acute renal failure was apparent in patients who suffered from other dose-related adverse effects such as diarrhoea and vomiting. ■

P6

Stepping Up: Exploring the impact and implementation of a new model of care for insulin initiation in general practice

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Background: Stepping Up is a cluster randomised controlled trial testing a new model of care for insulin initiation in general practice in which the role of the practice nurse is enhanced. **Aims/objectives:** To explore the views of GPs and practice nurses (PNs) about the impact of this model of care and factors affecting its implementation. **Methods:** Purposive sampling identified six GP–PN pairs in the intervention arm of Stepping Up. The aim was to achieve maximal variation based on factors such as location and previous experience with insulin initiation. Individual semi-structured interviews were analysed using an applied thematic approach. **Results:** Three overarching themes were identified. 1: GPs identified clinical benefits from participating, for example related to the study tools and clinical resources. However, 2: The realities of generalist care and organisational issues are barriers to a focus on a single condition such as diabetes and the PN's role. And 3: Mentoring and Credentialed Diabetes Educator-Registered Nurse (CDE-RN) support were essential elements for PN involvement in insulin initiation. However, PNs highlighted additional needs, including further education and support to further develop relationships with local CDE-RNs. **Conclusion:** Engagement of local CDE-RNs, organisational ± structural changes in clinics and additional practice nurse education are important factors in increasing insulin initiation in general practice. These issues will need to be addressed at both the individual (relational) and practice (organisational) level and have implications for the provision of services such as by Primary Health Care Networks. ■

P7

Assessing Cardiometabolic Risk in Middle-Aged Adults Using Body Mass Index and Waist-Height Ratio – Are Two Indices Better Than One?

Millar SR, *University College Cork, Cork, Ireland*

Objectives: A novel obesity classification method has been proposed utilising BMI and waist–height ratio (WHtR) together. In this study we compare the metabolic profiles in subjects defined as overweight or obese by both measures. We examine a range of metabolic risk features, pro-inflammatory cytokines, acute-phase response proteins, coagulation factors and white blood cell counts to determine whether a combination of both indices more accurately identifies subjects at increased cardiometabolic risk. **Methods:** This was a cross-sectional study involving a random sample of 2047 men and women aged 50–69 years. Metabolic and anthropometric profiles were assessed in study participants. Independent t or Mann–Whitney U tests were used to compare lipid, blood pressure, glycaemic and inflammatory biomarker levels between BMI and WHtR tertiles. Multinomial logistic regression was performed to determine cardiometabolic feature and biomarker risk factor associations for BMI and WHtR groupings. **Results:** In both overweight and obese groups, the combination of BMI and WHtR tertiles identified consistent metabolic variable differences relative to those characterised on the basis of one index. Similarly, odds ratios for cardiometabolic risk factors were noticeably increased in subjects classified as overweight or obese by both indices when compared to study participants categorised by either BMI or WHtR individually. In obese subjects within the highest BMI and WHtR percentile, the prevalence of high blood pressure, insulin resistance and pre-diabetes was 81%, 55% and 17% respectively. **Conclusions:** Risk stratification using a composite index may provide a more effective and precise method for identifying high-risk subjects. ■

P8

Optimal Central Obesity Measurement Site for Assessing Cardiometabolic and Type 2 Diabetes Risk in Middle-Aged Adults

Millar SR, *University College Cork, Cork, Ireland*

Objectives: Despite recommendations that central obesity assessment should be employed as a marker of cardiometabolic health, no consensus exists regarding measurement protocol. This study examined a range of anthropometric variables and their relationships with cardiometabolic features and type 2 diabetes in order to ascertain whether measurement site influences discriminatory accuracy. In particular, we compared waist circumference (WC) measured at two sites: (1) below the lowest rib (WC rib) and (2) between the lowest rib and iliac crest (WC midway), which has been recommended by the World Health Organization. **Methods:** This was a cross-sectional study involving a random sample of 2002 men and women aged 50–69 years. Metabolic profiles and WC, hip circumference, pelvic width and BMI were determined in study participants. Logistic regression and area under the receiver operating characteristic curve analyses were used to evaluate obesity measurement associations and discrimination of metabolic risk phenotypes and type 2 diabetes. **Results:** Rib measurements displayed the strongest associations with non-optimal lipid profiles, high blood pressure, insulin resistance, impaired fasting glucose, a clustering of metabolic risk features and type 2 diabetes. Rib-derived indices improved discrimination of type 2 diabetes by 3–7% compared to BMI and 2–6% compared to WC midway (in men) and 5–7% compared to BMI and 4–6% compared to WC midway (in women). **Conclusions:** WC rib is easier to measure and is a better method for determining obesity-related cardiometabolic risk than WC midway. The clinical utility of rib-derived indices as potentially more accurate predictors of type 2 diabetes requires further investigation. ■

P9

The Prevalence and Determinants of Undiagnosed and Diagnosed Type 2 Diabetes in Middle-Aged Irish Adults

Millar SR, *University College Cork, Cork, Ireland*

Objectives: The prevalence of type 2 diabetes within the Republic of Ireland is poorly defined, although a recent report suggested 135 000 cases in adults aged 45+, with approximately one-third of these undiagnosed. This study aims to assess the prevalence of undiagnosed and diagnosed diabetes in middle-aged adults, and compare features related to either condition, in order to investigate why certain individuals remain undetected. **Methods:** This was a cross-sectional study involving a sample of 2047 men and women, aged 50–69 years, randomly selected from a large primary care centre. Logistic regression was used to explore socio-economic, metabolic and other health-related variable associations with undiagnosed or diagnosed diabetes. A final multivariable analysis was used to determine

odds ratios and 95% confidence intervals for having undiagnosed compared to diagnosed diabetes, adjusted for gender, age and significant covariates determined from univariate models. **Results:** The total prevalence of diabetes was 8.5% (95% CI, 7.4–8.8%); 72 subjects (3.5%) had undiagnosed diabetes (95% CI, 2.8–4.4%) and 102 subjects (5.0%) had diagnosed diabetes (95% CI: 4.1%–6.0%). Obesity, dyslipidaemia, and family history of diabetes were positively associated with both undiagnosed and diagnosed type 2 diabetes. Compared with diagnosed subjects, study participants with undiagnosed diabetes were significantly more likely to have low levels of physical activity and were less likely to be on treatment for diabetes-related conditions or to have private medical insurance. **Conclusions:** A considerable proportion of diabetes cases were undiagnosed (41%), emphasising the need for more effective detection strategies and equitable access to primary healthcare.

P10

Associations of iron indices with impaired fasting glucose and diabetes among Korean adults

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Background and aims: Previous studies indicated that excessive iron stores induce organic damage, leading to diabetes. This study evaluated the relationship between iron indices – serum ferritin and transferrin saturation (TSAT) – and impaired fasting glucose (IFG) and diabetes. **Methods:** We performed a cross-sectional study of a representative sample of South Korean adults aged ≥19 years using data from the Korean National Health and Nutrition Examination Survey 2010–2012. In total, 14 468 participants were included after excluding those who were pregnant and those with chronic liver disease, chronic kidney disease, or anaemia. The subjects were classified into the following three groups: normal fasting glucose, IFG (defined as fasting glucose, 100–125 mg/dL), and diabetes. We also measured fasting plasma glucose, HbA_{1c}, serum ferritin, and TSAT (percentage of iron-saturated transferrin). **Results:** IFG increase and diabetes prevalence were related to increasing ferritin quartiles and decreasing TSAT quartiles. After adjusting for age, education level, smoking, drinking, and BMI, IFG was significantly elevated in the highest ferritin quartile compared with the lowest quartile in women (adjusted OR, 1.37; 95% CI, 1.05–1.78) and men (adjusted OR, 2.12; 95% CI, 1.66–2.71). Diabetes prevalence was also significantly higher in the highest quartile group, in women (adjusted OR, 1.88; 95% CI, 1.32–2.69) and men (adjusted OR, 2.08; 95% CI, 1.55–2.79). In contrast, IFG and diabetes were less prevalent in the highest TSAT quartile for both sexes. **Conclusion:** Increased serum ferritin and decreased TSAT levels are independently associated with IFG and diabetes among Korean men and women.

P11

Reviewing the care planning of diabetes care within a mental health trust

Wiltshire L, *Birmingham and Solihull Mental Health Foundation Trust, West Midlands*

Aims/Objectives: To review if the implementation of a diabetes service and education around diabetes has had an impact on the quality of care plans for service users with diabetes within a mental health trust. **Method:** All inpatient units within Birmingham and Solihull mental health trust were audited in 2012 and re-audited in 2014 to assess if they were having their service users with diabetes given appropriate "diabetes care plans" and if it was relevant to their needs. Care plans were observed for the individual "9 care processes" in 2012 and 2014; however, 2014 also reviewed for an overarching diabetes care plan. **Results:** In both 2012 and 2014, patients had some individual care plans for individual elements of diabetes; there has been an improvement in HbA_{1c} and weight/BMI care planning in 2014; however, there had been little impact on the other care processes, suggesting the staff still don't consider these elements to be diabetes related. However, in 2014 over 68% has an overarching diabetes care plan and another 18% had diabetes included in a physical health care plan, which is a considerable improvement. **Conclusion/Summary:** It is recognised that there has been minimal improvement in the care-planning of the individual elements of the diabetes "9 care processes" within a mental health trust. However, diabetes is an area which is being actively care-planned, and there has been an improvement in overarching general diabetes care plans and including diabetes in the physical health care plans.

P12

A Safer Ramadan: promoting safer fasting during Ramadan

Northern A, *Leicester Diabetes Centre, Leicester*

Aims: To develop a toolkit to aid primary care organisations to educate communities, staff and patients with diabetes about fasting safely during the holy month of Ramadan. **Method:** Based on principles of the DESMOND Programme an education package of three components was written and piloted in five primary care organisations in the UK: 1) Community Awareness – designed to increase awareness of the impact of diabetes during Ramadan throughout communities. 2) Healthcare Professional Training – a chance for healthcare professionals to discuss how best to manage their patients before, during and after Ramadan. 3) Patient Self-Management Education: a) Understanding Diabetes for Ramadan – 2-hour session looking at the basics of how the body works and what diabetes is; b) A Safer Ramadan – 2.5-hour session designed to provide knowledge of how to observe Ramadan safely. **Results:** In the pilot seven Community Awareness sessions were delivered to groups of up to 20 people, seven Healthcare Professional Training events took place and there were 10 patient education sessions. Positive feedback was received by attendees from all three components about the impact of the intervention. In addition, 19 patients were followed up and showed weight reduction at 8 weeks post-attendance and mean HbA_{1c} had not deteriorated post-Ramadan. **Conclusion:** Providing a "whole systems approach" to raising awareness of fasting safely during Ramadan is the key. It addresses the patient needs, healthcare professional needs and the needs of the wider community all at once, whilst positively impacting on patient outcomes and levels of self-management.

P13

Similar Efficacy and Safety With LY2963016 Insulin Glargine Compared With Lantus Insulin Glargine in Patients With T1DM: The ELEMENT 1 Study

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PRESENTING NON-AUTHOR: ***Balogh E****, Eli Lilly and Company, Windlesham, UK*

Background: LY2963016 (LY IGlar) and Lantus® (IGlar) are both insulin glargine products, with identical amino acid sequences. Even with identical primary structure, protein-based therapeutics manufactured by distinct processes must be shown to be clinically similar. **Aims/objectives:** The aim was to test the non-inferiority of LY IGlar to IGlar. **Methods:** A 52-week, Phase 3, randomised, open-label, parallel study was undertaken to compare the efficacy and safety of LY IGlar QD versus IGlar QD in combination with pre-meal insulin lispro TID in patients with T1DM (HbA_{1c} ≤11.0%). The primary aim was to test the non-inferiority of LY IGlar to IGlar (0.4% non-inferiority margin and if 0.4% was met then 0.3% was tested) as measured by change in HbA_{1c}, from baseline to 24 weeks. Safety assessments included hypoglycaemia, AEs and antibody responses. **Results:** Both treatment groups had within-group statistically significant (P<0.001) decreases in mean HbA_{1c} values from baseline. The change in HbA_{1c} from baseline with LY IGlar was non-inferior to IGlar (-0.35% versus -0.46%, respectively; least square mean difference [95% CI] of 0.108 [-0.002 to 0.219]). Non-inferiority of IGlar to LY IGlar was also demonstrated; thus, the criteria for

equivalence in clinical efficacy between LY IGlar and IGlar were met. There were no treatment differences in secondary efficacy or safety outcomes including hypoglycaemia. AE frequency was the same with LY IGlar (62%) and IGlar (62%) (P>0.999). **Conclusions:** LY IGlar compared with IGlar, used in combination with lispro, provided equivalent efficacy and a similar safety profile in patients with T1DM. ■

P14

A health economic assessment of Exenatide once weekly versus Insulin glargine for patients with type 2 diabetes mellitus based on 3-year clinical trial data and a 6-year follow-up study

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Objective: When patients start their first injectable therapy, clinicians can choose between GLP-1 receptor agonists and basal insulins. The relative efficacy and costs of exenatide once weekly, a GLP-1 receptor agonist, compared with insulin glargine were assessed in patients inadequately controlled with metformin (± sulfonylureas) based on long-term clinical evidence and a health-economic modelling framework. **Methods:** Clinical inputs were derived from a 26-week randomized clinical trial (DURATION 3) comparing exenatide once weekly (ExQW) versus insulin glargine once daily. The durability of the treatment effects was taken from 3- and 6-year follow-up (DURATION 3/DURATION 1) of patients treated with ExQW. These clinical parameters were included in a health-economic model and were combined with costs associated with drug treatment, diabetes-related complications and other healthcare resources. Total Quality-Adjusted Life-Years (QALYs) and total costs, along with the incremental cost-effectiveness ratio (ICER), were calculated for a lifetime horizon. The uncertainty around the model inputs was analysed by means of sensitivity analyses. **Results:** Long-term treatment with ExQW was well tolerated and associated with sustained glycaemic control and sustained weight loss over at least 3 years. Compared to glargine, ExQW in combination with metformin was associated with an incremental benefit of 0.123 QALYs (95% CI, 0.057–0.178) at an additional cost of £1722 (95% CI, £1396–£2089), resulting in an ICER estimate of £13 967/QALY. **Conclusion:** ExQW in combination with metformin (± sulfonylureas) was shown to be a cost-effective treatment option as first injectable therapy in patients inadequately controlled with metformin. The robustness of this statement has been addressed and confirmed within extensive sensitivity analyses. ■

P15

Can Type 2 Diabetes Mellitus Be Reversed With Very Low Calorie Diets: A Systematic Review

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Background: There is recent evidence suggesting that type 2 diabetes mellitus (T2DM) is reversible with certain diets. This has ignited the interest of medical and patient communities. **Aims:** This systematic review explores whether there is evidence that T2DM can be reversed with very low calorie diets (VLCDs), and whether any effects on glycaemia and bodyweight are sustained in the longer term. **Methods:** A systematic review was undertaken to investigate the effects of a VLCD intervention conducted in T2DM populations. PubMed, Medline and Web of Knowledge were searched from database start to September 2013. In all, 2516 publications were screened and 36 studies included using the criteria of a VLCD intervention comprising less than 800 kcal daily, in those with T2DM regardless of age, duration of disease or bodyweight. **Results:** There was a strong association between weight loss and improved glycaemic control in the short term. Four of the 36 included studies reported reversal of T2DM using the WHO 2011 diagnostic criterion of HbA_{1c} <6.5%. Thirteen of the 36 included studies reported reversal of T2DM using the WHO 2006 diagnostic criterion of FBG <7 mmol/L. Six of the 36 included studies reported glycaemic outcome measures spanning greater than 12 months. These studies did not report reversal of T2DM, or a sustained reduction in bodyweight after a VLCD. **Conclusions:** VLCDs can improve glycaemia in the short term. However, there is no evidence of a sustained improvement in glycaemic control or maintenance of weight loss. There remains a great need for robust longer-term outcome data. ■

P16

Physicians' Challenges When Discussing the Type 2 Diabetes Diagnosis With Patients: Insights From a Cross-National Study (IntroDia™)

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Aims: Physician communication at diagnosis of type 2 diabetes (T2D) may impact patient self-care, quality of life, and outcomes. IntroDia™ is a survey of ~17 000 T2D patients and physicians in 26 countries to investigate early physician–patient communication and its potential consequences. **Methods:** As part of IntroDia™, we surveyed 6753 physicians from Asia, Europe, America, Africa, and Australia using an online survey that included a novel questionnaire of 12 challenges that physicians may encounter at T2D diagnosis, and the Jefferson Scale of Physician Empathy. **Results:** Across countries, 76–100% of physicians (88% overall) agreed that conversations with patients at T2D diagnosis impact on patients' disease acceptance and treatment adherence. Ninety-two per cent of physicians wanted tools to help patients sustain behavioural change. Using factor analysis, the 12 items resulted in loading onto two factors: Discouraged with Patients at Diagnosis (DPD; α=0.87), comprising eight related challenges, and Frustrated with Situation at Diagnosis (FSD; α=0.72), comprising four challenges. Correlation between these two factors suggested related, but distinct, groups of challenges (r=0.64, P<0.0001). Factor scores varied globally (DPD highest in France; FSD in Japan). Upon adjusting for demographic/clinical practice variables, regression models showed a negative relationship between physician empathy and perceived challenges for total score (all 12 items) as well as DPD and FSD (all P<0.0001). **Conclusion:** Many physicians, especially those scoring lower on empathy, report significant challenges and frustrations during conversations with patients at diagnosis of T2D. Most physicians wanted tools to help patients sustain behavioural change. Supporting use of empathy-related skills may contribute to better patient outcomes. ■

P17

Development of a Continuing Professional Development website to raise awareness of preconception counselling and pre-pregnancy care for Women with Diabetes

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Aims: Pre-pregnancy care reduces the risk of adverse pregnancy outcomes in women with diabetes, yet the majority of women receive suboptimal care due to poor preconception counselling rates and a lack of awareness about the importance of specialised pre-pregnancy care. The primary aim was to develop a continuing professional development (CPD) resource for healthcare professionals (HCPs) who work with women with diabetes to facilitate preconception counselling with this group. **Methods:** The website was developed under the direction of a multidisciplinary team, adhering to NICE guidelines. The tone, key messages and format are informed by the "Women with Diabetes" preconception counselling website, www.womenwithdiabetes.net, an existing resource which is effective in helping women to be better prepared for pregnancy. **Results:** This e-learning resource will

give HCPs the necessary knowledge and tools to prepare women with diabetes to plan for pregnancy. The website features women with diabetes sharing their views and experiences, alongside an evidence-based commentary and key messages from research papers and clinical guidelines. It comprises two modules: "Planning for Pregnancy", focusing on contraception, risks and planning; and "Diabetes and Pregnancy", focusing on support during pregnancy with an overview of each trimester of pregnancy. **Conclusion:** This website will be a useful CPD resource for all HCPs working with women with diabetes, providing a certificate on completion. This resource will empower HCPs to engage in preconception counselling with women with diabetes by providing the HCP with a greater understanding of the specific needs of women with diabetes both preconception and during pregnancy. ■

P18

Delaying Insulin treatment through the use of newer anti-diabetic agents, dapagliflozin followed by exenatide once weekly; a health economic assessment from a UK NHS perspective

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Objective: New anti-diabetes drug classes may delay the onset of insulin treatment. The relative efficacy and costs were assessed for a treatment pathway consisting of dapagliflozin + metformin as first line of treatment, followed by exenatide once weekly + metformin as second line and insulin regimens as third line, compared with a treatment pathway that commences with sulphonylurea (SU) + metformin, followed by the addition of insulin in patients inadequately controlled with metformin alone. **Methods:** Clinical inputs for dapagliflozin versus SU, and exenatide versus insulin regimens were derived from relevant head-to-head clinical trials and long-term follow-up studies (dapagliflozin: 4-year data; exenatide: 6-year data). These were included in a health-economic model and were combined with costs associated with drug treatment and other healthcare resources. Total Quality-Adjusted Life-Years (QALYs) and costs, along with the incremental cost-effectiveness ratio (ICER) were calculated over a lifetime horizon. The uncertainty around the outcomes was determined through sensitivity analyses. **Results:** The long-term follow-up studies showed the durability of the treatment effects of dapagliflozin and exenatide. The health economic analysis demonstrated that sustained HbA_{1c} level control can delay the onset of insulin treatment by 5–6 years. Compared to the traditional clinical practice, treatment with dapagliflozin + metformin followed by exenatide + metformin was associated with a benefit of 0.343 QALYs (95% CI, 0.239–0.450 QALYs) at an additional cost of £2827 (95% CI, £2352–£3267), resulting in an ICER estimate of £8233/QALY. **Conclusions:** The proposed alternative treatment sequence is a cost-effective treatment option in patients inadequately controlled with metformin alone. The robustness of this statement has been addressed within extensive sensitivity analyses. ■

P19

Combinations of Empagliflozin/Linagliptin for 24 Weeks as Add-on to Metformin in Subjects with Type 2 Diabetes

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Aim: To evaluate the efficacy and safety of empagliflozin/linagliptin as add-on to metformin in subjects with type 2 diabetes (T2DM). **Methods:** In a Phase III study, subjects were randomised to receive empagliflozin 25 mg/linagliptin 5 mg (n=137), empagliflozin 10 mg/linagliptin 5 mg (n=136), empagliflozin 25 mg (n=141), empagliflozin 10 mg (n=140) or linagliptin 5 mg (n=132) for 52 weeks. The primary endpoint was change from baseline in HbA_{1c} at week 24. **Results:** Mean baseline HbA_{1c} was 7.90–8.02%. At week 24, adjusted mean (SE) changes from baseline were -1.19% (0.06%) with empagliflozin 25 mg/linagliptin 5 mg, -1.08% (0.06%) with empagliflozin 10 mg/linagliptin 5 mg, -0.62% (0.06%) with empagliflozin 25 mg, -0.66% (0.06%) with empagliflozin 10 mg and -0.70% (0.06%) with linagliptin 5 mg. Adjusted mean (95% CI) difference in change from baseline in HbA_{1c} with empagliflozin 25 mg/linagliptin 5 mg versus empagliflozin 25 mg was -0.58% (-0.75 to -0.41) and versus linagliptin 5 mg was -0.50% (-0.67 to -0.32), and with empagliflozin 10 mg/linagliptin 5 mg versus empagliflozin 10 mg was -0.42% (-0.59 to -0.25) and versus linagliptin 5 mg was -0.39% (-0.56 to -0.21); all P<0.001. Significantly greater proportions of subjects with HbA_{1c} ≥7% at baseline reached HbA_{1c} <7% at week 24 with empagliflozin/linagliptin (57.8%–61.8%) versus the individual components (28.0%–36.1%; all P<0.001). Adverse events occurred in 54.7%, 54.4%, 63.1%, 57.1% and 54.5% of subjects on empagliflozin 25 mg/linagliptin 5 mg, empagliflozin 10 mg/linagliptin 5 mg, empagliflozin 25 mg, empagliflozin 10 mg and linagliptin 5 mg, respectively, over 24 weeks. **Conclusions:** As add-on to metformin in subjects with T2DM, empagliflozin 25 mg/linagliptin 5 mg and empagliflozin 10 mg/linagliptin 5 mg for 24 weeks significantly reduced HbA_{1c} versus linagliptin 5 mg and versus the respective empagliflozin components. Treatments were well tolerated. ■

P20

Retrospective evaluation of HbA_{1c} & body weight in patients converted from pioglitazone to DPP-4 inhibitor in a primary care setting

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Background: Weight increase is a recognised undesirable effect of pioglitazone but not of DPP-4 inhibitors. **Aims:** To investigate if conversion from pioglitazone to DPP-4 inhibitor results in comparable blood glucose control with a better effect on body weight. **Methods:** Retrospective identification of patients switched to DPP-4 inhibitor from pioglitazone with a 9- to 12-month post-switch HbA_{1c} and body weight measure was performed on a single practice patient record database. Mean values at time of conversion in the 31 evaluable patients found were: age, 61 years; duration of diabetes, 9 years; and pioglitazone treatment, 5 years. Baseline HbA_{1c} and weight were 57.1 mmol/mol and 94.8 kg respectively. Analysis of pre- and post-conversion HbA_{1c} and weight was performed. The paired t-test was used for the analysis of both outcomes. **Results:** No statistically significant difference in the pre and post HbA_{1c} values was found (mean change, 0.8 mmol/mol [95% CI, -2.5 to 4.1 mmol/mol; P=0.64]). However, there was a significant change in weight after switching, reducing by a mean of 5.1 kg (95% CI, -6.3 kg to -3.9 kg; P<0.001]. Three patients were converted back to pioglitazone due to deterioration of HbA_{1c} post-switch. One case of hypoglycaemia was documented in the patient record database during the 9–12 months post-switch, but this was thought to be not drug related. **Conclusions:** Conversion from pioglitazone to DPP-4 inhibitor in patients with type 2 diabetes may in the majority of cases result in a comparable HbA_{1c} control with a significant reduction in body weight. ■

P21

What do patients and health practitioners think of diabetes prevention efforts offered in primary care? Findings from a qualitative systematic review on diabetes prevention in primary care

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Background: Type 2 diabetes is on the rise; however, many future cases can be prevented through lifestyle interventions. Primary care is an important setting for diabetes prevention because it is a patient's primary point

of contact with the health care system and lifestyle advice could be integrated into care. **Aim:** To explore patient and practitioner views of diabetes prevention interventions in primary care for patients at risk of developing type 2 diabetes. **Methods:** This systematic review took on an iterative approach which included using several databases (Medline, CINAHL, ASSIA) and a stacking of terms approach. Narrative and thematic analysis were utilised to identify emerging themes. **Results:** A database of 6646 records was screened, and 24 papers (qualitative and quantitative) were included in this synthesis. Findings suggest that diabetes prevention interventions in primary care are well received by patients and practitioners; however, the primary care environment and a patient's understanding and motivation for change can impact on delivery and uptake. In addition, the evidence suggests that patients do not easily understand or follow advice. The data also point to targeted and tailored advice with appropriate follow-up. While primary care can be an ideal setting for prevention messages, practitioner can face several challenges in providing prevention advice such as knowledge barriers, lack of time and resources, for example. **Conclusions:** Providing a rich account of patient and practitioner experiences in this area has the potential to highlight what is working well, as well as suggested areas for improvement in diabetes prevention efforts in primary care. ■

P22

Barriers associated with uptake of diabetes group education: a survey of patients' opinion

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Background: Although the NHS has a good record of improving the health of its citizens, the absence of simple solutions for longstanding diseases such as diabetes presents a challenge. A key component of diabetes management in the UK is empowerment of patients through effective education and support. However, one of the challenges of this management option is the degree of non-attendance at the education centres. **Aims:** The aim of this study was to identify the barriers associated with attendance in diabetes education centres (DECs). **Method:** A purposive sample of 105 newly diagnosed patients with diabetes identified from the hospital database was surveyed. Postal questionnaires were sent to elicit data from these patients, who were referred for structured patient education in four DECs in the South East of England. **Results:** One hundred and five (46 male, 59 female) patients participated in the survey. Seventy (67.3%) believed in taking responsibility for self-care, 70 (67.3%) believed in adequacy of other sources of information such as the internet, and 59 (57.8%) do not have flexible working conditions. Almost half, 50 (46.7%), believed that their diabetes is mild and they do not require additional information while 30 (28.6%) neither agree nor disagree. Although the education was offered in the morning, 32 (32%) preferred the evening, 28 (28%) preferred the afternoon and 17 (17%) preferred the weekend. **Conclusion:** These findings identified perceptions and beliefs of patients, personal problems, inconvenient location and time as barriers. The study suggested that offering flexible times and locations coupled with effective practitioner–patient therapeutic relationship are possible interventions to aid attendance. ■

P23

EDEN – Effective Diabetes Education Now; Primary Diabetes Care in Leicester

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Aim: Sixty-one practices within Leicester City CCG have been supported through the project to deliver either a competency-based enhanced diabetes service or core care to their patients with diabetes. This is based on increasing knowledge and skills confidence through training and mentorship. **Method:** Annual assessment was undertaken at each practice. A bespoke package of education was available including training modules and mentorship at practice level. Backfill was provided to contribute towards training. A core data set was agreed to measure outcomes, covering QOF data, and local/national agreed key performance indicators. A training overview database was set up to record and monitor the progress of each practice. The TOD Data warehouse also provides us with suggested study sessions so that the relevant training is targeted at those who will most benefit. **Results:** EDEN has just come to the end of its second year, and, from the training and mentorship already provided, in Year 2: module bookings are up 43% and there is an 11.2% increase in average knowledge and confidence, with enhanced practices increasing by 36.8% (38% of practices now have enhanced status). Feedback from participants is a consistent 4.6/5 on training. **Summary:** EDEN has increased the competences of HCPs to deliver a high standard of care and support the transformation of care closer to home delivered by a knowledgeable and confident workforce. Clinical data are in the process of being analysed. ■

P24

Structured education for Type 2 diabetes – a toolkit for Optimal delivery

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Background: Structured education (SE) is an effective and cost-efficient self-management tool to help people with type 2 diabetes understand and manage their life-long condition. Yet uptake is shockingly low at 2% despite recommendations in NICE and a QOF indicator. Access to SE is also poor with unacceptable variation across London. Not attending a course is wasteful, in terms of finance, and also a lost opportunity for people with diabetes. **Aims and objectives:** The Health Innovation Network (HIN) is a membership organisation and the Academic Health Science Network has a remit of driving lasting improvements in patient and population health outcomes by spreading the adoption of innovation into practice across the health system. When people with diabetes, service providers, referrers and commissioners work collaboratively, real change can happen allowing education to reach a greater number of the population, as has been demonstrated in the London boroughs of Bexley, Southwark and Lambeth. **Methods:** The HIN brought these groups together in a number of engagement events, collaborative meetings and task and finish groups to produce a London-wide toolkit for optimal delivery of SE. **Results and conclusion:** This practical, interactive web-based toolkit highlights the views of people with diabetes and shares best practice, provides meaningful metrics to benchmark performance and gives key performance indicators. It can be amended according to local needs with a menu of options allowing access to the range of structured education available and provides programmes to suit the "harder to reach" individuals. ■

P25

Dapagliflozin compared to DPP-4 inhibitors as triple therapy in the treatment of type 2 diabetes mellitus in the UK

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Aims/Objectives: To compare dapagliflozin, the first-in-class sodium–glucose co-transporter-2 inhibitor, with the dipeptidyl peptidase-4 inhibitor (DPP4i) class, as triple oral therapy with metformin and a sulphonylurea (met + SU) for patients with type 2 diabetes mellitus (T2DM) and inadequate glycaemic control on met + SU alone. **Methods:** A systematic review of third-line therapies for T2DM and subsequent network meta-analysis of the clinical effectiveness of dapagliflozin and DPP4is were conducted. An established cost-utility diabetes model combining relevant clinical parameters with costs of drug treatment, diabetes-related complications and healthcare resources was used to investigate the cost-effectiveness of dapagliflozin from a UK perspective, over a 40-year time horizon. **Results:** Dapagliflozin provides a similar level of glycaemic

control (HbA_{1c} reduction) to DPP4is, and is associated with a statistically and clinically significantly better weight profile at Week 24 of treatment. In the cost-utility model, dapagliflozin was more effective than the DPP4i class at an additional cost of £253, resulting in an incremental cost-effectiveness ratio (ICER) of £10 995 per Quality-Adjusted Life-Year gained. **Conclusion:** Despite current treatment options, many patients fail to meet the Quality and Outcomes Framework glycaemic target of 7.5%. Weight management is also important for T2DM patients; a high proportion of T2DM patients are overweight, which impacts on cardiovascular risk and quality of life. Prescription of dapagliflozin as triple therapy in combination with met + SU can promote glycaemic control and help T2DM patients manage their weight, providing important clinical benefits to patients. Dapagliflozin was shown to be a cost-effective treatment option with an ICER well below the NICE threshold. ■

P26

Effect of Lixisenatide vs Liraglutide on Glycemic Control, Gastric Emptying, and Safety Parameters in Optimized Insulin Glargine T2DM ± Metformin

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Aims: The meal test-related pharmacodynamics of lixisenatide (LIXI) 20 µg and liraglutide (LIRA) 1.2 and 1.8 mg QD were compared in this 8-week, randomized, open-label, three-arm parallel trial in T2DM ± metformin after optimal insulin glargine (IG) titration. **Methods:** The primary endpoint was change from baseline in incremental area under the glucose curve for 4 hours after a standardized solid breakfast (postprandial glucose area under the curve [PPG-$AUC_{00.30–04.30\ h}$]). **Results:** LIXI reduced PPG-$AUC_{00.30–04.30\ h}$ (LS mean [SE] -240.2 h·mg/dL [20.0 h·mg/dL]) more than LIRA 1.2 and 1.8 mg (-131.8 h·mg/dL [20.2 h·mg/dL] and -157.1 h·mg/dL [21.0 h·mg/dL], respectively; $P<0.0001$). LIXI delayed gastric emptying more than LIRA 1.2 and 1.8 mg ($P<0.0001$). HbA_{1c} decreased significantly from baseline in all groups with similar reductions with LIXI and LIRA 1.2 mg and small but significantly greater reductions with LIRA 1.8 mg (by -0.16%). Mean ambulatory monitored 24-hour increase in heart rate was greater with LIRA 1.2 and 1.8 mg (by 6 beats/min) versus LIXI ($P<0.0001$). Symptomatic hypoglycaemia was slightly more frequent with LIXI, and LIRA had more GI AEs reported. There were greater increases in amylase and lipase levels with LIRA versus LIXI, and one patient in the LIRA 1.8 mg group developed asymptomatic oedematous pancreatitis. **Conclusion:** LIXI and LIRA + IG improved glycaemic control in T2DM ± metformin, albeit with differing gastric emptying mechanisms of action and safety/tolerability profiles. ■

P27

Empagliflozin as Add-On to Metformin Plus Sulfonylurea in Patients with Type 2 Diabetes

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Aim: To assess long-term safety and efficacy of empagliflozin as add-on to metformin plus sulphonylurea versus placebo in patients with type 2 diabetes. **Methods:** Of 666 patients treated with empagliflozin 10 mg, empagliflozin 25 mg or placebo in a 24-week study (EMPA-REG METSU™), 71.2% continued in a Phase III double-blind extension trial (EMPA-REG EXTEND™ METSU) for ≥52 weeks (until the last person had been treated for 76 weeks). Exploratory efficacy endpoints were changes from baseline (of EMPA-REG METSU™) in HbA_{1c} and body weight at week 76. **Results:** At baseline, mean HbA_{1c} was 8.15%, 8.07% and 8.10% and mean weight was 76.2 kg, 77.1 kg and 77.5 kg in the placebo, empagliflozin 10 mg and empagliflozin 25 mg groups, respectively. Compared with placebo, adjusted mean (95% CI) changes from baseline in HbA_{1c} at week 76 were -0.72% (-0.87% to -0.56%) with empagliflozin 10 mg and -0.69% (-0.85% to -0.53%) with empagliflozin 25 mg (both $P<0.001$), and in weight were -1.8 kg (-2.3 kg to -1.3 kg) with empagliflozin 10 mg and -1.6 kg (-2.2 kg to -1.1 kg) with empagliflozin 25 mg (both $P<0.001$). Adverse events (AEs) were reported in 81.3%, 81.7% and 82.0% of patients on placebo, empagliflozin 10 mg and empagliflozin 25 mg, respectively. Hypoglycaemic AEs (glucose ≤3.9 mmol/L and/or requiring assistance) were reported in 15.6%, 23.7% and 19.4% of patients on placebo, empagliflozin 10 mg and empagliflozin 25 mg, respectively; one patient each on placebo and empagliflozin 10 mg required assistance. **Conclusion:** Empagliflozin as add-on to metformin plus sulphonylurea was well tolerated and reduced HbA_{1c} and weight compared with placebo. ■

P28

Oral Glucose Lowering With Linagliptin Plus Metformin is a Viable Initial Treatment Strategy in Patients With Newly Diagnosed Type 2 Diabetes and Marked Hyperglycaemia

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Aims: Newly diagnosed type 2 diabetes (T2D) patients commonly present with marked hyperglycaemia. This condition has rarely been studied for novel oral diabetes drugs and insulin is often proposed as the preferred starting therapy. **Methods:** We explored oral glucose-lowering combination therapy in newly diagnosed (≤12 months) T2D patients with marked hyperglycaemia (n=316) utilising prespecified exploratory subgroup analyses from a randomised double-blind study of initial combination of linagliptin + metformin versus linagliptin. Baseline mean (± SD) age and HbA_{1c} was 48.8 ± 11.0 years and 9.8% ± 1.1%, respectively. The primary endpoint was HbA_{1c} change from baseline to week 24. **Results:** Mean (± SE) HbA_{1c} reduction was -3.4% ± 0.2% versus -2.5% ± 0.2% with linagliptin + metformin and linagliptin, respectively, in patients with baseline HbA_{1c} ≥9.5%, and -2.1% ± 0.2% versus -1.4% ± 0.2% in patients with baseline HbA_{1c} <9.5%. Similar HbA_{1c} reductions occurred in all subgroups of age, BMI, renal function, race, and ethnicity. Hypoglycaemia was rare (1.9% and 3.2% of patients, respectively) with no severe episodes. **Conclusion:** In our analysis of newly diagnosed T2D patients presenting with marked hyperglycaemia, initial linagliptin + metformin elicited consistent HbA_{1c} reductions across different subgroups. Oral glucose-lowering combination therapy may be a viable initial alternative to insulin for effective treatment of these patients. ■

The abstracts in this supplement have been edited minimally from the submitted versions, primarily for house style on units.