QOF, toe amputation risk, heart failure drug, and preventing type 1 diabetes

Stay abreast of the latest news that could influence diabetes care. Pam Brown, Editor-in-Chief of *Diabetes & Primary Care*, rounds up the latest national and international news and clinical research stories.

QOF around the nations

As Scotland enters its second year maintaining diabetes care without the direct challenge of the Quality and Outcomes Framework (QOF), there are changes to the framework in the other three devolved nations.

England

In England, there are no changes to the indicators or thresholds compared to 2016/17, and a 3.6% uplift in the value per point achieved, similar to other nations. As in Scotland, practices must continue to undertake care as clinically appropriate for so-called "indicators no longer in QOF" (INLIQ). For diabetes, these are the previously retired indicators for albumin:creatinine ratio, retinopathy screening and erectile dysfunction. It is a contractual requirement for practices in England to facilitate data collection for the INLIQ.

Wales

In Wales, there is perhaps the greatest shake up, following on from the option to claim "relaxation" of a significant proportion of clinical indicators at the end of the 2016/17 year (as occurred in Northern Ireland). For 2017/18, 40 points have been retired (no diabetes indicators), 40% have been made inactive (including all diabetes indicators [50 points] apart from the register [2 points, as previously]), and roughly 50% of indicators remain active. Payment for inactive indicators will be made at the adjusted year-end payment figures for 2016/17, uplifted by prevalence factor and Contractor Population Index figure as of 1 January 2018. This was negotiated to free up clinician time to manage individual patients rather than simply ticking boxes and remove some unnecessary workload pressures. The inactive indicators will continue to be captured and reviewed by clusters, with a specific focus on diabetes and chronic obstructive pulmonary disease (COPD). In addition, Welsh GP practices will engage with the National Diabetes Audit, which most participated in previously.

Points from the retired indicators have been added to the cluster working domain (now worth 200 points – around £30 000 per practice), which incentivises practices to work in groups to develop population healthcare. Within this are included 50 points for "Quality Assurance – Clinical Information Governance and peer review of inactive QOF indicators", which requires contractors to peer review the inactive indicators within practice and at designated cluster meetings twice during the year. The outcome of this work will be included in the cluster annual report and used to inform future QOF developments within Wales as the entire contract is up for review.

Northern Ireland

At the end of 2016/17, Northern Ireland, like Wales, allowed for QOF payments to be made on the average of the previous 2 years, after negotiation between the Department of Health and Northern Ireland General Practitioners Committee. This reflected the increased pressure on general practice in the province, particularly acute in the West with practice closures and others at risk of closure with pending retirements. The full details of how this QOF "holiday" works out is still debatable as there may be implications for future years if QOF targets were not met or fully reported by individual practices. Details of the final arrangements for 2017/18 were still to be confirmed as the Journal went to press.

Possible increased risk of lower limb amputations with SGLT2 inhibitors

The European Medicines Agency (EMA; 2017) again highlighted the possible risk of lower limb amputation (mainly toes) with sodium–glucose cotransporter 2 (SGLT2) inhibitors on 24 February 2017, advice reiterated in the recent MHRA Safety Update (MHRA, 2017). Healthcare professionals are encouraged to remind people taking these drugs to check their feet regularly, follow preventive care, and report any wounds or discolouration or if their feet are tender or painful. The EMA states that an increased risk has not been seen in studies with other medicines in the same class, dapagliflozin and empagliflozin. However, data available to date are limited and the risk may also apply to these other medicines. The product information for the three drugs in the class will be revised to include a warning of possible increased risk. No changes to prescribing are recommended. The prescribing information for canagliflozin will also include lower limb amputation as an uncommon side effect (occurring in <10 patients per 1000). Healthcare professionals are advised to carefully monitor people receiving canagliflozin who have risk factors for amputation, such as poor control or problems with heart or blood vessels, and to consider stopping canagliflozin if patients develop foot complications such

as infection, skin ulcers, osteomyelitis or gangrene. After consideration of outcomes in the CANVAS study where the amputation risk was identified, the EMA recommended the study should continue.

Heart failure drug has small benefit on glycaemia

The PARADIGM-HF trial (*n*=8399; McMurray et al, 2014) compared sacubitril/valsartan with enalapril in patients with heart failure with reduced ejection fraction (HFrEF). *Post hoc* analysis of data from the 3778 patients with known diabetes or HbA_{1c} ≥48 mmol/mol (6.5%) at baseline (published online March 2017; Seferovic et al, 2017) showed small, persisting improvements in glycaemic control over the 3-year study, as well as 29% reduction in insulin initiation and reduced oral hypoglycaemic drug initiation in those treated with sacubitril/valsartan compared to those treated with enalapril. HbA_{1c} reductions were small and there was no reduction in the pre-specified outcome of new-onset diabetes. However, the authors propose the glucose-lowering effect may be large enough to necessitate reducing the dose of antihyperglycaemic therapies when sacubitril/valsartan is initiated if there is a risk of hypoglycaemia.

Nearly a quarter of those found to have an HbA_{1c} ≥48 mmol/mol (6.5%) at entry to the trial were not known to have diabetes previously, highlighting the ongoing burden of undiagnosed diabetes in those with HFrEF.

The PARADIGM-HF study demonstrated reduced cardiovascular death, hospital admission for heart failure and all-cause mortality compared with enalapril.

Risk of type 1 diabetes not reduced by extensively hydrolysed cow's milk-based formula

Rather than reducing the risk of islet autoimmunity development, use of extensively hydrolysed cow's milk-based formula appears to be associated with increased risk compared to other formulas, particularly if this is introduced in the first 7 days of life, according to new data published from TEDDY (The Environmental Determinants of Diabetes in the Young) study (Hummel et al, 2017). Infant formulas containing hydrolysed cow's milk protein are recommended for infants at increased allergy risk in some countries and these have been hypothesised to reduce the risk of developing islet autoimmunity, although previous studies have been inconsistent.

After mean follow up of 8 years, the study demonstrated no increased risk of developing autoimmunity in those fed partially hydrolysed or non-hydrolysed formula as the first formula during the first 3 months of life, but increased risk (adjusted hazard ratio 1.57 [95% confidence intervals, 1.04–2.38]) from the extensively hydrolysed formula use in the first 7 days of life (which occurred mainly in Finland). Using a partially hydrolysed or other formula, or exclusively breast feeding during the first 7 days had no impact on risk.

Although exclusive breast feeding is recommended in all countries for infants during the first 4–6 months of life, this is not always achievable, particularly amongst new mothers with type 1 diabetes (Hummel et al, 2014) whose infants are particularly at risk of developing the disease. Around one third of the study population had been exclusively breast fed until 3 months with no data on first feed type for less than 20% of the cohort.

TEDDY is a prospective cohort study, which follows 8676 children at increased risk of developing type 1 diabetes in the US, Germany, Finland and Sweden, by regular monitoring for islet cell autoimmunity and development of type 1 diabetes. ■

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