Latest news: FLASH-UK study, tirzepatide marketing authorisation, Dexcom G7 launch and GLP-1 RA shortages

Stay abreast of the latest news that could impact diabetes nursing.

GLP-1 RA shortages and how to manage them

The Primary Care Diabetes Society (PCDS) has published a statement on reported shortages of the GLP-1 receptor agonists Ozempic (subcutaneous semaglutide) and Trulicity (subcutaneous dulaglutide), proposing a strategy to ensure that, where supply is limited, people with diabetes can be safely switched to alternative agents within the GLP-1 RA class.

On 30 September, the Department of Health and Social Care issued medicine supply notifications for Ozempic and Trulicity. Although it has been stated that supplies of Ozempic 1 mg will be available for existing patients from the week commencing 17 October, the PCDS accepts the possibility that supply issues may persist up to or even beyond January 2023.

Eli Lilly & Co. have indicated they will maintain sufficient supply of Trulicity for existing patients, and that people with diabetes who are already taking Trulicity can be titrated up to higher doses.

The consensus advice states, first and foremost, that there should be no new initiations of Ozempic or Trulicity. For patients who are already taking Ozempic or Trulicity, and where supply issues persist or develop, guidance is offered on switching to alternative agents within the class.

Click here to read the statement.

Dual GIP/GLP-1 receptor agonist tirzepatide receives MHRA marketing authorisation

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorisation for tirzepatide, the new once-weekly glucose-dependent insulinotropic polypeptide–glucagon-like peptide-1 (GIP/GLP-1) receptor agonist.

Tirzepatide (brand name Mounjaro®; Eli Lilly & Co.) is authorised for the treatment of adults with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise:

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or
- in addition to other medicinal products for the treatment of diabetes.

The authorisation is based on data from the SURPASS phase 3 programme, which included five global clinical trials involving 6263 people with type 2 diabetes (4199 treated with tirzepatide). Efficacy was evaluated for tirzepatide 5 mg, 10 mg and 15 mg, used alone or in combination with other diabetes medications, including metformin, SGLT2 inhibitors, sulfonylureas and insulin glargine. Across all studies in the SURPASS programme, tirzepatide demonstrated statistically significant and clinically meaningful reductions in HbA_{1c} and body weight compared with both placebo and active comparators (the GLP-1 RA semaglutide, insulin glargine and insulin degludec).

In the modified intention-to-treat analyses at 40–52 weeks, HbA_{1c} reductions from baseline across the SURPASS programme averaged around 25 mmol/mol (2.3%) with the 15 mg dose, while average weight reductions at this dose typically exceeded 10 kg.

Tirzepatide is the first GIP/GLP-1 receptor agonist authorised for the treatment of adults with type 2 diabetes in Great Britain. It will be available in six doses (2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg and 15 mg) and will come in Lilly's auto-injector pen with a pre-attached, hidden needle that patients do not need to handle or see.

Dexcom G7 rtCGM device launched

Dexcom has announced the launch of the new G7 real-time continuous glucose monitoring (rtCGM) system for people with diabetes aged 2 years and older in the UK and Republic of Ireland from 4 October.

As with the previous G6 model, the G7 monitors interstitial glucose levels, sending readings automatically to a compatible display device, including smartphones, and remote monitoring and reporting capabilities allow data-sharing with family members and healthcare teams. In addition, the manufacturer reports the following changes:

- A 60% smaller, all-in-one sensor (shown below).
- A 30-minute warm-up time for new sensors, the fastest of any CGM device on the market.

- A 12-hour grace period to replace finished sensors, for a more seamless transition between sessions.
- A redesigned and simplified mobile app with Dexcom Clarity integration.
- Improved hypo- and hyperglycaemia alert settings.
- A redesigned optional receiver that is smaller with an easier-to-read display.
- Compatibility with Apple Watch (pending anticipated software release).

As with the previous G6 system, the G7 is indicated for wear on the back of the upper arm and abdomen for people aged 2 years and older, or the upper buttocks for those aged 2–6 years.

More information can be found here.

DUK study shows benefits of isCGM

Data from the Diabetes UK-funded FLASH-UK study, published in the *New England Journal of Medicine*, show the benefits of intermittently scanned continuous glucose monitoring (isCGM) with optional alarms in terms of glycaemic control in people with type 1 diabetes.

The open-label study randomised 156 people (mean age 44 years, mean diabetes duration 21 years) to isCGM (FreeStyle Libre 2) or to standard care with fingerprick blood glucose monitoring. At 24 weeks, mean HbA_{1c} fell from 72 to 63 mmol/mol in the intervention group, compared with a reduction from 69 to 67 mmol/mol in the control group (between-group difference 5.5 mmol/mol). The isCGM group were also 2.47 times more likely to achieve an HbA_{1c} ≤59 mmol/mol and 4.30 times more likely to reduce their HbA_{1c} by 11 mmol/mol or more. Time in range increased by 9%, or 130 minutes, per day compared with the control group.

Mean Diabetes Treatment Satisfaction Questionnaire scores were 7 points higher (out of a possible 36) in the isCGM arm; however, other participant-reported outcomes, including scores related to diabetes, depression, fear of injections/testing and eating behaviours, were not significantly different between the groups. The incidence of adverse events was low in both groups.

This study recruited participants with HbA_{1c} as high as 98 mmol/mol, and thus demonstrates the glycaemic benefits of isCGM in people with high HbA_{1c}, who would benefit the most from reducing their blood glucose levels in terms of the risk of micro- and macrovascular complications.

Click here to read the study in full. ■

Citation: Latest news: FLASH-UK study, tirzepatide marketing authorisation, Dexcom G7 launch and GLP-1 RA shortages. *Journal of Diabetes Nursing* **26**: JDN255