Introduction
The incidence of diabetes mellitus is rising with estimations of more than 346 million people worldwide affected. It is estimated that 193,944 people in the Republic of Ireland, or 5.6% of the population, have diabetes. All patients with Type 1 diabetes mellitus, and up to 50% of patients with Type 2 diabetes mellitus, require insulin treatment for the management of their condition. Many patients with Type 2 diabetes are also prescribed oral medication such as sulphonylureas.

Both insulin therapy and sulphonylurea medications have the potential for hypoglycaemia occurrence. Hypoglycaemia can have serious consequences if it occurs while driving. The majority of adult patients with diabetes mellitus are drivers.

Hypoglycaemia
Hypoglycaemia is a common acute complication in patients with diabetes. It is defined as a low blood glucose level of <3.9mmol/L. It is the most common diabetes short-term adverse event associated with insulin and sulphonylurea medications. The publication of the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) research trials in type 1 and type 2 diabetes mellitus demonstrated that good glycaemic control reduced the risk of long term diabetes complications. However as a result of tighter glycaemic control, the risk of hypoglycaemia is increased. This risk increases once insulin/sulphonylurea medication is commenced and with the duration of diabetes.

The brain depends on a constant supply of glucose for its activity because it is unable to store or synthesise glucose. Initial symptoms of hypoglycaemia include weakness, pallor and sweating, although symptoms can vary between individuals and hypoglycaemic episodes. Moderate to severe hypoglycaemic symptoms include difficulty concentrating, confusion and visual disturbances. This is associated with cognitive impairment that affects the person’s ability to self manage and function normally during a hypoglycaemic episode.

The inability to recognise symptoms and manage low blood glucose can have serious consequences for a person with diabetes. Hypoglycaemia unawareness is observed in 19.5% – 25% of adults with Type 1 diabetes and 8% of adults with Type 2 diabetes rising to 50% of patients after 20-30 years duration. It is more common in people with excessive determination to achieve strict glycaemic control. Strategies to regain hypoglycaemia awareness should be discussed at diabetes clinic reviews.

Safe driving guidelines
Drivers with diabetes should have an awareness of hypoglycaemia. Ideally they should plan their journeys before driving. Blood glucose meter and test strips should always be carried in the car with them. They are advised not to drive if their blood glucose level is <4.0mmol/L or if they feel hypoglycaemic symptoms. A snack should be taken if the blood glucose is <5.0mmol/L before driving. They should have a supply of fast acting carbohydrate within easy access in the vehicle. (It is important to ensure that family members or any other car users are aware that this is for their emergency use). They should carry personnel diabetes identification. They should take regular meals, snacks and rests on long journeys and ensure that they test their blood glucose every two hours while driving.
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Hypoglycaemia management while driving
Should the patient with diabetes experience hypoglycaemia while driving, they should:
• Stop the vehicle as soon as possible, pull over and park safely
• Switch off the engine, remove the keys from the ignition and move to the passenger seat
• Treat the hypoglycaemia with appropriate fast acting glucose such as 3-4 dextrose sweets or 100mls Lucozade or 150mls of non-diet sugary drink
• Retest blood glucose after 10 minutes
• Repeat these 2 steps if necessary until blood glucose is > 4.0mmol/l
• A carbohydrate snack or meal may be required to maintain blood glucose levels.

Patients should not start driving until 45 minutes after blood glucose has returned to normal as it takes this time duration for the brain to recover fully from hypoglycaemia.

Patient responsibilities
Patients should be advised that drivers in certain categories need to inform the National Driving Licence Service (NDLS) of his/her diabetes.

Group 1 Drivers: i.e. drivers of motorcycles, cars and tractors (with or without trailer).
• Patients with any form of diabetes treated with insulin;
• Patients on medication with potential for hypoglycaemia and who have had more than one episode of hypoglycaemia requiring the assistance of another person within the preceding 12 months
• Temporary insulin treatment if continues for more than 3 months
  1-3 year licence issued

Group 2 Drivers: i.e. drivers of trucks and buses (with or without trailer).
Any diabetes patient may apply for a Group 2 licence

• Must meet more stringent criteria
• Insulin treated (regular or temporary), or sulphonylureas
  1 year licence issued
The vehicles in Group 2 are regarded as higher-risk vehicles which require a higher standard of physical and mental fitness on the part of the driver.

Healthcare professional responsibilities
The Road Safety Authority Medical Fitness to Drive Guidelines for Group 1 and Group 2 drivers changed in 2014.10 According to this guideline, it is the responsibility of the health care professional:
• To assess the person’s medical fitness to drive based on the current ‘Slainte agus Tiomaint’ medical standards
• To advise the person regarding the impact of their medical condition on their ability to drive and recommend restrictions and ongoing monitoring as required
• To advise the person of their responsibility to report their condition to the Driving Licensing Authority if their long term illness may affect their ability to drive
• To treat, monitor and manage the person’s condition with ongoing consideration of their fitness to drive
• To report to the Driving Licensing Authority regarding a person’s fitness to drive in the exceptional circumstances where there is a risk to the public and the driver cannot or will not cease to drive.

Driving and diabetes audit
Prior to introduction of the new driving guidelines it was decided to conduct a regional audit to measure the level of knowledge that patients have regarding the new driving regulations and their knowledge of the management of hypoglycaemia if driving. This was to form a baseline assessment prior to developing a concise, user-friendly information leaflet around diabetes and driving.

A detailed data collection tool was designed and completed by 413 people with diabetes. 74% of people surveyed stated that they were aware of the driving guidelines, with 62% having informed the licensing authorities of their condition. When asked specifically about hypoglycaemia and driving the responses were surprisingly high with 77% of respondents admitting episodes.

Have you experienced a hypo event while driving (Graph 1)
For your patients with type 2 diabetes uncontrolled on metformin

**Experience that counts**

**THE ONLY SGLT2 inhibitor with efficacy and safety data over 4 years**

**LOWERS HbA1c**

with secondary benefit of weight loss

When FORXIGA is used with insulin or SU, a lower dose of insulin or SU may be considered to reduce the risk of hypoglycaemia. FORXIGA is not recommended for use with pioglitazone. *FORXIGA is not indicated for weight loss.

FORXIGA® 5mg & 10mg FILM-COATED TABLETS (dapagliflozin) ABRIDGED PRESCRIBING INFORMATION Consult Summary of Product Characteristics before prescribing.

**Presentation:** 5mg or 10mg dapagliflozin (as propanediol monohydrate) film-coated tablets. **Indications:** Adults 18 years and older: For patients with type 2 diabetes mellitus to improve glycaemic control: **Dosage:** Adults: 10mg once daily as monotherapy and add-on combination therapy with other drugs including insulin when these, together with diet and exercise, do not provide adequate glycaemic control and use of metformin is considered inappropriate due to intolerance, or in combination with other glucose lowering drugs including insulin when these, together with diet and exercise, do not provide adequate glycaemic control. **Doseage:** Adults: 10mg once daily as monotherapy and add-on combination therapy with other drugs including insulin. Forxiga can be taken at any time of day with or without food. Consider a lower dose of insulin or insulin secretagogue such as a sulphonylurea when used in combination with dapagliflozin to reduce the risk of hypoglycaemia. **Children and adolescents:** <18 years: Safety and efficacy not yet established. **Elderly:** ≥ 65 years: No dosage adjustment is recommended based on age. **Renal function and risk of volume depletion should be taken into account.** 75 years: Not recommended. **Moderate renal impairment:** No dosage adjustment. **Severe hepatic impairment:** Starting dose of 5mg is recommended, if well tolerated, dose may be increased to 10mg. **Contraindications:** Hypersensitivity to dapagliflozin, or excipients. **Warnings and precautions:** Not to be used in patients with type 1 diabetes mellitus or for diabetic ketoacidosis. Dapagliflozin is not recommended in patients concomitantly treated with pioglitazone and has not been studied with GLP-1 analogues. Use in patients with renal impairment: Not recommended in moderate to severe renal impairment (CrCl <30ml/min or eGFR <45ml/min/1.73m2). Renal function monitoring is recommended: prior to initiation of dapagliflozin and at least yearly thereafter, prior to initiation of concomitant medicinal products that may reduce renal function and periodically thereafter, for renal function approaching moderate renal impairment, at least 2 to 4 times per year. If renal function falls below CrCl <30ml/min or eGFR <60ml/min/1.73m2, treatment should be discontinued. Use in patients with hepatic impairment: Exposure is increased in patients with severe hepatic impairment. Use in patients at risk of volume depletion, hypotension and/or electrolyte imbalances: Dapagliflozin is associated with a modest decrease in blood pressure, which may be more pronounced in patients with very high blood glucose concentrations. Not recommended in patients receiving loop diuretics or who are volume depleted. Exercise caution in patients for whom a dapagliflozin-induced drop in blood pressure could pose a risk, such as patients with known cardiovascular disease, patients on anti-hypertensive therapy with a history of hypotension or elderly patients. Careful monitoring of volume status and electrolytes is recommended in conditions leading to volume depletion, such as acute gastrointestinal illness. In volume depleted patients temporary interruption of dapagliflozin is recommended until volume depletion is corrected. **Urinary tract infections:** Temporary interruption of dapagliflozin should be considered when treating pyelonephritis or urinary tract infection. Elderly patients: Elderly patients are more likely to have impaired renal function, be treated with medicines such as anti-hypertensives or diuretics, and be at a greater risk of volume depletion. **Cardiac failure:** Experience in NYHA class II is limited, and there is no experience in clinical studies with dapagliflozin in NYHA class III-IV. Caution in patients with elevated haematocrit. **Urine laboratory assessments:** Patients will test positive for glucose in the urine due to mechanism of action. Lactose: Not recommended in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, and when being used in combination with pioglitazone. **Drug interactions:** Diuretics: Dapagliflozin may add to the diuretic effect of thiazide and loop diuretics and may increase the risk of dehydration and hypotension. Consider a lower dose of insulin or insulin secretagogue in combination with dapagliflozin to reduce the risk of hypoglycaemia. Dapagliflozin has a low potential for other interactions with commonly used agents in patients with type 2 diabetes. **Pregnancy and lactation:** Do not use during pregnancy or breast-feeding. **Undesirable events:** Refer to SmPC for complete information on side effects. Very common (1/10): Hypoglycaemia (when used with SU or insulin). Common (1/100 to <1/10): Vulvovaginitis, balanitis and related genital infections, urinary tract infection, dizziness, back pain, dysuria, polyuria, haematocrit increased, creatinine renal clearance decreased, dyslipidaemia. **Local Category:** POM. **Marketing authorisation number:** EU/1/12/795/002 & EIIR/1/12/795/007 **Marketing Authorisation holder:** AstraZeneca AB, SE-151 85 Södertälje, Sweden. **Further product information available on request from:** Freephone 1800 800 899 or contact AstraZeneca UK Limited, Horizon Place, 60 Capability Green, Luton, Bedfordshire, LU1 3LU, United Kingdom. **Forxiga** is a trademark of the AstraZeneca group of companies. Date of API preparation: 10/2014.

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Those of concern are a small group of people who are experiencing recurrent severe hypoglycaemia or who have lost hypoglycaemic awareness.

Conclusion
In conclusion, studies show that people with diabetes are no less safe than any other group of the population.\(^1\) In a review of evidence for the European working group on diabetes mellitus and driving\(^2\) it was found that any differences in the risk of accidents were small compared with the differences in risk seen in the general population. Those of concern are a small group of people who are experiencing recurrent severe hypoglycaemia or who have lost hypoglycaemic awareness.\(^3\) It is the responsibility of all health care professionals to educate people with diabetes at risk of hypoglycaemia. It is equally the responsibility of all people with diabetes at risk of hypoglycaemia to drive safely and reduce the risk of accident to themselves and all road users.

References
1. WH0, 2011

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