Driving and hypoglycaemia: New European regulations

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Kilpatrick and colleagues (summarised alongside) have produced an interesting paper. It will fuel debate but whether or not it will influence how we manage diabetes and driving is more doubtful. Most of us will be very familiar with the Diabetes Control and Complications Trial (DCCT). Before the DCCT we had no real evidence that tight glucose control influenced the progression of complications of diabetes. The study robustly showed that tight glucose control reduced the risk of kidney, eye and nerve damage. Subsequently the same study has shown a smaller effect on reducing cardiovascular risk. The same group showed that this came at a price. There was a clear relationship between glucose control and hypoglycaemia risk. The lower the HbA_{1c} achieved the higher the risk of both minor and severe hypoglycaemia. Hypoglycaemia impacts on the lives of people with diabetes in many ways. One of the most obvious is the potential to lose your driving licence. Until 2010 the Driver and Vehicle Licensing Agency (DVLA) standard for people with diabetes required an awareness of impending hypoglycaemia. Towards the end of that year the standard was tightened to include a restriction based on frequency of severe hypoglycaemic episodes. Individuals who had experienced more than two episodes of severe hypoglycaemia within the past 12 months would have their licence withheld.

Kilpatrick and colleagues used the published frequency of severe hypoglycaemic episodes suffered by volunteers participating in the DCCT to calculate the number of people who could have potentially lost their ability to drive a car. The headline figure suggests that nearly half of those who were intensively treated may have lost their licence.

Of course this study is a hypothetical scenario based on historical data. There are many reasons why the current situation may be different. Of more interest perhaps would be the current data on the number of people who have had their licence withheld on the basis of the rule changes. It is certainly nothing like the suggested numbers quoted in the paper. Why there is such a difference is an interesting question. These changes were employed to improve road safety, but we are unlikely to get a clear answer about whether the changes have had a significant impact. As this is a EU directive, we would need Europe-wide data to show a difference. This is not being collected.

J CLIN ENDOCRINOL METAB

IDeg: Flexible routine is efficacious

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 The authors aimed to determine if a more flexible injection regimen could be achieved with insulin degludec (IDeg) without affecting efficacy or tolerability in people with T1D.

2 An open-label randomised control trial was conducted to compare the efficacy of IDeg forced flexible (Forced-Flex) once daily (OD) to IDeg or insulin glargine (IGlar) given OD at the same time for 26 weeks. Participants receiving IDeg were then switched to a free-flexible regimen (Flex-Free) for a further 26 weeks.

3 IDeg Forced-Flex was noninferior to IGlar in HbA_{1c} lowering activity and produced similar reductions in fasting plasma glucose. At week 26, nocturnal hypoglycaemia was reduced with IDeg Forced-Flex compared to IDeg (37%, P=0.003) and IGlar (40%, P=0.001).

4 The authors concluded that IDeg could be tolerated OD with varied injection times without compromising glycaemic control compared to IDeg or IGlar OD at the same time.

Mathieu C, Hollander P, Miranda-Palma B et al (2013) Efficacy and safety of insulin degludec in a flexible dosing regimen vs insulin glargine in patients with type 1 diabetes (BEGIN: Flex T1): A 26-week randomized, treat-to-target trial with a 26-week extension. *J Clin Endocrinol Metab* **98**: 1154–62

DIABETIC MEDICINE

Change in legislation: Impact on drivers with T1D

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 Severe hypoglycaemia presents a serious hazard to people with diabetes whilst driving. An estimated 27 hypoglycaemia-related events are reported to the Driver and Vehicle Licensing Agency (DVLA) every month in the UK.

2 The authors aimed to establish the effects of a recent change to the European Union driving regulations, which state that more then one episode of severe hypoglycaemia in a period of 12 months would result in the withdrawal of a driving licence.

3 A total of 1441 participants from the Diabetes Control and Complications Trial (DCCT) were included in the study. All participants were assumed to drive.

4 During a 12-month observation period, 439/1441 (30%) participants experienced more then one episode of hyperglycaemia, and would have lost their driver's licence.

5 Overall, 312/711(44%) intensively treated and 127/730 (17%) conventionally treated participants would have lost their licence during the trial. The probability of licence loss was found to increase with decreasing age, HbA_{1c} and longer T1D duration (P<0.001).

6 The authors concluded that more then one episode of hyperglycaemia was a frequent occurrence in participants from the DCCT, suggesting that it may be difficult for people with T1D to retain their drivers licence under the new legislation.

Kilpatrick ES, Rigby AS, Warren RE et al (2012) Implications of new European Union driving regulations on patients with Type 1 diabetes who participated in the Diabetes Control and Complications Trial. *Diabet Med.* 6 Dec [Epub ahead of print]

"The authors concluded that glycaemic control deteriorated in women with T1D after delivery, with body weight remaining above prepregnancy levels."

DIABETES CARE

Glycaemic control deteriorates after pregnancy in T1D

Readability	✓✓✓
Applicability to practice	✓✓✓
WOW! factor	✓✓

1 The majority of women with T1D achieve normoglycaemia during pregnancy. However, little is known about glycaemic control after delivery.

2 The authors aimed to examine postpartum glycaemic control and weight gain in 254 women with T1D. Participants that entered the diabetes care programme prior to conception were placed into the "pregnancy planning" group or the "unplanned" group if the pregnancy was not planned.

3 Within 6 months of delivery, HbA_{1c} had risen by 0.8% (8.7 mmol/mol; $P<0.0001$) compared with the third trimester of pregnancy. HbA_{1c} continued to deteriorate by a further 0.8% (8.7 mmol/mol) until the end of the observation period.

4 Body weight and BMI had increased by 4.4 kg and 2.5 kg/m^2 respectively ($P<0.0001$) compared to preconception. Weight (2.5 kg; $P=0.0079$) and BMI (0.9 kg/m^2; $P=0.0058$) remained high and did not return to prepregnancy baseline.

5 HbA_{1c} was worse in women from the "pregnancy planning" group 12 months after delivery ($n=117$) compared to preconception levels (7.1% [54 mmol/mol]) versus 6.5% [48 mmol/mol)]; $P=0.0018$). Women with unplanned pregnancies, however, had similar HbA_{1c} levels postpartum and preconception (7.3% [56 mmol/mol] versus 7.4% [57 mmol/mol]; $P=0.59$).

6 The authors concluded that glycaemic control deteriorated in women with T1D after delivery, with body weight remaining above prepregnancy levels. This suggests that these women may need additional care to achieve optimal diabetes control.

Cyganek K, Hebda-Szydlo A, Skupien J et al (2012) Postpregnancy glycemic control and weight changes in type 1 diabetic women. *Diabetes Care* 18 Dec [Epub ahead of print]

DIABETES RES CLIN PRACT

Insulin therapy and BMI in young people with T1D

Readability	✓
Applicability to practice	✓✓
WOW! factor	✓

1 Previous studies suggest that weight gain is often an outcome of improved glycaemic control in adults with T1D, but there is little evidence examining this association during youth.

2 The authors aimed to investigate the cross-sectional and longitudinal associations of BMI with glycaemic control in young people with T1D. A total of 320 participants from the US were followed for 2 years in a prospective interventional study that examined the effects of a behavioural intervention on diabetes management.

3 Baseline HbA_{1c} and BMI were unrelated. However, baseline HbA_{1c} was positively related to BMI change ($P=0.04$) and inversely correlated to HbA_{1c} change ($P=0.002$).

4 Baseline BMI was inversely associated with BMI change ($P=0.01$) and displayed no relationship with HbA_{1c} change. Multilevel regression revealed that BMI was inversely associated with HbA_{1c} (beta±SE=-0.11±0.02, $P<0.001$) and positively associated with insulin dose (0.23±0.07; $P=0.001$).

5 Baseline weight status was statistically related to baseline insulin dose ($P=0.048$) and Tanner stage ($P=0.001$). BMI was positively associated with pump regimen in the intervention group only (0.18±0.08, $P=0.02$).

6 The authors concluded that increased insulin treatment could lead to a higher BMI in young people with T1D, reflecting the importance of further investigation into minimising weight gain whilst achieving optimal glycaemic control.

Nansel TR, Lipsky LM, Iannotti RJ (2013) Cross-sectional and longitudinal relationships of body mass index with glycemic control in children and adolescents with type 1 diabetes mellitus. *Diabetes Res Clin Pract* 19 Jan [Epub ahead of print]

DIABETES CARE

LBGI predicts hypoglycaemia outcome in CSII

Readability	✓
Applicability to practice	✓✓
WOW! factor	✓

1 Although the HbA_{1c} lowering benefits of continuous subcutaneous insulin infusion (CSII) are well known, evidence regarding the predictors of reduced hypoglycaemic events when switching from multiple daily injections (MDIs) to CSII is scarce. The authors aimed to establish if glucose variability could predict hypoglycaemia outcome in people with T1D receiving CSII.

2 HbA_{1c}, hypoglycaemia and glucose variability were retrospectively reviewed in 50 participants with long-standing T1D. Blood glucose profiles were compared at baseline and after 6 months of CSII.

3 Baseline low blood glucose index (LBGI) was found to be an independent predictor of hypoglycaemia outcome in patients receiving CSII ($R^2= 0.195$; $P=0.0013$). An LBGI cut-off value of 3.34 was the best predictor of hypoglycaemia reduction, with a sensitivity and specificity of >70%.

4 Participants were divided into three groups sorted by increasing baseline LBGI, known as tertiles. A 23.3% decrease in hypoglycaemic events (60 mg/dL [3.3 mmol/L]) was observed in the third tertile (range 4.18–9.34) with HbA_{1c} remaining unchanged ($P<0.05$). The greatest reduction in HbA_{1c} (-0.99%, -10.81 mmol/L; $P=0.00001$), was observed in the first tertile (range 0.62–2.05), but this was associated with increasing hypoglycaemic events.

5 The authors concluded that baseline LBGI is predictive of hypoglycaemic outcome in people with T1D on CSII, with higher LBGI values correlating to a bigger reduction in hypoglycaemia.

Crenier L, Abou-Elias C, Corvilain B (2013) Glucose variability assessed by low blood glucose index is predictive of hypoglycemic events in patients with type 1 diabetes switched to pump therapy. *Diabetes Care* 12 Feb [Epub ahead of print]