

# Driving and diabetes: new licensing standards by European Union directive

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New changes to the standards for UK drivers with insulin-treated diabetes are now in place and subject to current implementation.<sup>1</sup> Essentially, two new standards of differing nature now apply. The first relates to ordinary drivers (known as Group 1), requiring consideration of severe hypoglycaemia during sleep as well as waking hours. The second is to consider entitlement for insulin-treated drivers to drive large vehicles (Group 2 drivers) subject to appropriate safeguards. The first is a minimum standard which required immediate implementation from September 2010 while the second, still subject to government ratification, commenced on 1 October 2011. Not surprisingly, these changes have resulted in significant impact from the media<sup>2</sup> and particularly for those people with diabetes treated by insulin to whom the new standards are most relevant. To date, of those whose personal driving licences have been revoked since September 2010 because of serious hypoglycaemia concerns, a minority (10%) have been consequent to episodes occurring during sleep.<sup>3</sup> For all so affected, this has proved a distressing outcome for which most were unprepared. In the second category, the Driver and Vehicle Licensing Agency (DVLA) is anticipating that many, currently of uncertain number, will seek the opportunity of obtaining an 'occupational' licence previously prohibited with insulin treatment.

## 'Tightening up' under EU law

Full details of these new standards specifically addressing issues of severe and recurrent hypoglycaemia as well as hypoglycaemia unawareness in the context of driving and crash risk can be accessed on the DVLA website.<sup>1</sup> Severe hypoglycaemia is defined as 'requiring the assistance of another person'. Recurrent hypoglycaemia is defined as 'a second severe episode during a period of 12 months'. Further clarification may be necessary as it is intended that this should be severe symptomatic hypoglycaemia and not simply biochemical which might be detected on, say, continuous overnight glucose monitoring, but where the clinical implications are much less certain. Similarly, administration of glucose by a spouse or partner to avoid worsening hypoglycaemia should not necessarily be interpreted as 'third party assistance'. Common sense should prevail. Furthermore, there are distinctions between the two standards – for Group 1 drivers two serious episodes of severe hypoglycaemia within a 12-month period, but only a single episode of such for Group 2 drivers, will debar. There is also a subtle distinction that Group 1 drivers shall not have impaired awareness of hypoglycaemia whereas for Group 2 drivers full awareness is required.

These changes to the minimum standards for diabetes in relation to driving derive from a consensus review<sup>4</sup> by officials and medical experts drawn from across

the European Union and submitted to the European Commission's Driving Licence Committee. Having identified clear discrepancies between member states in respect of diabetes evaluation and regulation in respect of driving, proposals for harmonisation of minimum medical standards throughout the European Economic Area have been set out in an updated Annex 111 to the European Directive (2006/126/EC) on driving licence standards for Vision, Diabetes and Epilepsy. The proposals were submitted to a period of consultation, now completed, with full implementation intended by 19 January 2013. However, where the UK currently falls below the minimum standard, immediate implementation has been required and is now currently operative.

## Hypoglycaemia and crash risk

Although an expert consensus report, the working group examined the existing evidence-based literature and the document is referenced in some detail. From published data it is evident that unrecognised hypoglycaemia is clearly a significant potential driving hazard and hypoglycaemia unawareness substantially increases the frequency of severe hypoglycaemia. Furthermore, recurrent severe hypoglycaemia, defined as requiring the assistance of another person, has been reported in separate studies as consistently and strongly related to crash risk while driving.<sup>5,6</sup> A history of severe hypoglycaemia, resulting in loss of consciousness, over the past two years has been linked to a doubling of crash accidents.<sup>7</sup> Neither the European report nor these population-based case control studies specifically address differences between episodes during waking hours and while asleep, but it is deemed that any recurrent severe hypoglycaemia under whatever circumstances remains strongly predictive of future crash risk. The report comments that those prone to recurrent severe hypoglycaemia represent a small subgroup of high risk individuals who may be identified from certain specific characteristics including unduly strict glycaemic control, later age at diagnosis, longer duration of diabetes and, in particular, impairment of hypoglycaemia awareness. Failure to recognise hypoglycaemia substantially increases the risk of incurring severe hypoglycaemia, and thereby represents a significant driving hazard.<sup>8</sup> Evidence supporting a vulnerable subgroup of drivers with type 1 diabetes experiencing difficulty in detecting hypoglycaemia has been reported recently under virtual reality driving simulator test conditions.<sup>9</sup>

## Ensuring fitness to drive and road safety

Exact figures for serious events experienced on the roads by drivers with diabetes are difficult to determine and reports of such have been conflicting. A high risk subgroup more likely to suffer motor vehicle crashes can

be identified,<sup>5,6</sup> but for the overall population with insulin-treated diabetes accident rates may be no different from those in the non-diabetic population.<sup>10</sup> Fatalities resulting from road traffic events due to medical or health related impairment are relatively small (<3% of all road crash deaths) and those related to hypoglycaemia in insulin-treated diabetes proportionally fewer. Approximately 3000 police reports are received annually by the DVLA of driving accidents where medical factors appear relevant, including blackouts of differing causation, confusion, visual impairment and insulin-treated diabetes.<sup>11</sup> Latest figures indicate police notification of *ca.* 27 incidents a month related to hypoglycaemia while driving in drivers with diabetes.<sup>12</sup> The introduction of these new driving standards has drawn attention to the clear and continued importance of assessing fitness to drive and road safety issues.

The working group report expressed concern regarding the apparent lack of implementation of the existing licensing medical criteria and the general lack of awareness of these criteria on the part of both the general public and health care professionals. Lack of knowledge concerning medical fitness to drive remains an educational issue of concern.<sup>13</sup> In recent issues of *Practical Diabetes*,<sup>14,15</sup> we have stressed the responsibilities of both public and professional groups, emphasised the importance of including within the annual review process an assessment of fitness to drive, and highlighted that the principles of safe driving on insulin may still not be fully understood or accepted by the drivers themselves.<sup>16</sup> The report concludes by stating that it is the responsibility of health care professionals 'to advise patients of the possible impact medical conditions and treatments could have on their driving capabilities' and that drivers 'should honestly assess their driving capabilities with regard to their medical condition and treatments, and act appropriately'.

Fitness to drive is now very much established on the agenda of diabetes management. For the individuals concerned much may be at stake. Group 1 drivers suffering recurrent severe hypoglycaemia while asleep are at risk of losing their licence. In contrast, insulin treatment may not necessarily preclude holding a Group 2 licence. Although differing clinical issues, both require an objective, fair assessment, based on 'equitable, evidence-based decision-making' as best possible.<sup>17</sup>

Health care professionals should discuss ways of minimising the risk of nocturnal hypoglycaemia and ensure that insulin regimens are appropriate. Assessing hypoglycaemia unawareness may be very difficult indeed

with the lack of current, clear-cut measures, and with new methodology much needed. Recognising this very complex difficulty, particularly with the new licensing consideration for Group 2 drivers, it is probable that a national network of experienced specialists trained in the assessment of hypoglycaemia unawareness will need to be put in place. A number of applications for Group 2 licensing by drivers on insulin has already been received.

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## Declaration of interests

Professor Ken Shaw is a current member of the Secretary of State's Honorary Medical Advisory Panel on Driving and Diabetes Mellitus.

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