# Diabetes and Driving in Europe

**A Report**
**of the**

**Second European Working Group on Diabetes and Driving,**
an advisory board to the Driving Licence Committee of the European Union

# DIABETES and DRIVING

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**Meetings of the Working Group (WG) "Diabetes and driving":**

- 24th June 2004
- 16th November 2004
- 15-16th February 2005
- 21st June 2005

**Conversion factor for blood glucose: 1 mmol/ = 18.18 mg/dl**

This document reflects the consensus of experts who gathered to discuss this topic. Consensus is generally defined as the majority opinion or general agreement of the group. In that vein, it should be noted that consensus does not mean that all of the participants unanimously agreed on all of the findings and recommendations.

Parts of this text are coming from publications of the American Diabetes Association, the Canadian Diabetes Association, the Monash University (Influence of Chronic Illness on Crash Involvement of Motor Vehicle Drivers (2004)).

# Introduction

The driving licences department of the Directorate General for Energy and Transport of the European Commission expressed its intention to advance the revision of Annex III to Directive 91/439/CEE, concerning minimum standards of physical and mental fitness for driving power-driven vehicles. To this end, a number of workgroups were formed: one of these addressed diabetes.

## Definition of diabetes

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycaemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels.

Type 1 diabetes:

Type 1 diabetes is a condition in which pancreatic beta cells are destroyed, resulting in a failure of the pancreas to produce insulin. This form of diabetes usually develops during childhood and adolescence, but adult onset may occur (American Diabetes Association, 2003). Type 1 diabetes is always treated by insulin therapy, delivered by pump or injection.

Type 2 diabetes:

Type 2 diabetes arises when the pancreas is unable to produce sufficient insulin to overcome insulin resistance. Insulin resistance means that the body cells are unable to use insulin effectively. Type 2 diabetes is a progressive disease because of destruction of the insulin producing cells in the pancreas. This type of diabetes is associated with older age although is increasingly being diagnosed in children and adolescents. Risk factors include genetic predisposition, and obesity and other lifestyle factors e.g physical inactivity. Type 2 diabetes represents around 90 percent of all cases of diabetes. Type 2 diabetes may be controlled by diet and exercise and/or oral medications and/or insulin.

More information on the definition and classification is available on
http://care.diabetesjournals.org/cgi/reprint/29/suppl_1/s43

More information on all aspects of diabetes can be found on eg
http://diabetes.niddk.nih.gov/dm/pubs/overview/ or
http://www.diabetes.ca/Section_About/FactsIndex.asp

## Prevalence of diabetes

The WHO estimates that the prevalence of diabetes is just over 175 million worldwide
In 2003, the prevalence of the disease in Western European countries (EURO A group which includes Belgium, Denmark, Finland, France, Germany, Netherlands, Norway, Sweden, UK and others) was estimated at 17.8 million or around 4.3 percent of this population.
Detailed values for the individual countries in Europe can be seen in this table.

| | | | Number of people with DM (000's) in the 20-79 age group | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Country | Population (20-79) (000's) | DM prevalence (%) | Rural | Urban | Male | Female | 20-39 | 40-59 | 60-79 | Total | Country |
| Albania | 1,966 | 3.8% | . | . | 34.9 | 40.1 | 4.0 | 27.2 | 43.7 | 75.0 | Albania |
| Andorra | 50 | 7.7% | . | . | 1.9 | 2.0 | 0.1 | 1.3 | 2.5 | 3.9 | Andorra |
| Austria | 5,991 | 9.6% | . | . | 258.5 | 317.5 | 38.8 | 172.7 | 364.5 | 576.0 | Austria |
| Azerbaijan Republic | 5,154 | 6.9% | 122.1 | 235.4 | 143.6 | 213.9 | 44.7 | 159.8 | 152.9 | 357.5 | Azerbaijan Republic |
| Belarus, Republic of | 7,336 | 6.9% | . | . | 309.1 | 374.3 | 63.4 | 242.3 | 377.7 | 683.4 | Belarus, Republic of |
| Belgium | 7,531 | 4.2% | . | . | 140.6 | 174.5 | 3.1 | 71.1 | 240.9 | 315.1 | Belgium |
| Bosnia and Herzegovina | 3,074 | 9.6% | . | . | 117.2 | 178.2 | 24.5 | 141.0 | 129.9 | 295.4 | Bosnia and Herzegovina |
| Bulgaria | 5,894 | 10.0% | 135.8 | 455.4 | 235.7 | 355.5 | 37.6 | 248.1 | 305.5 | 591.2 | Bulgaria |
| Croatia | 3,412 | 5.8% | . | . | 82.4 | 116.7 | 5.3 | 56.8 | 137.1 | 199.1 | Croatia |
| Cyprus | 541 | 5.1% | . | . | 12.3 | 15.4 | 0.9 | 9.4 | 17.5 | 27.7 | Cyprus |
| Czech Republic | 7,734 | 9.5% | . | . | 365.2 | 369.6 | 66.8 | 286.2 | 381.9 | 734.9 | Czech Republic |
| Denmark | 3,863 | 6.9% | . | . | 120.9 | 144.0 | 23.3 | 87.0 | 154.6 | 264.9 | Denmark |
| Estonia | 991 | 9.7% | . | . | 43.4 | 52.9 | 8.6 | 33.3 | 54.4 | 96.3 | Estonia |
| Finland | 3,775 | 7.2% | . | . | 130.3 | 143.2 | 10.3 | 56.3 | 207.0 | 273.5 | Finland |
| France | 42,546 | 6.2% | . | . | 1,306.3 | 1,347.3 | 175.0 | 1,045.3 | 1,433.3 | 2,653.6 | France |
| Georgia, Republic of | 3,681 | 9.0% | 102.8 | 229.5 | 129.0 | 203.4 | 25.6 | 134.7 | 172.1 | 332.4 | Georgia, Republic of |
| Germany | 61,895 | 10.2% | . | . | 2,879.3 | 3,415.0 | 374.0 | 1,752.7 | 4,167.6 | 6,294.3 | Germany |
| Greece | 8,069 | 6.1% | . | . | 217.0 | 276.0 | 12.9 | 129.0 | 351.0 | 493.0 | Greece |
| Hungary | 7,350 | 9.7% | . | . | 336.3 | 375.1 | 62.6 | 259.5 | 389.2 | 711.4 | Hungary |
| Iceland | 192 | 2.0% | . | . | 2.1 | 1.7 | 0.2 | 1.2 | 2.4 | 3.7 | Iceland |
| Ireland, Republic of | 2,674 | 3.4% | . | . | 43.7 | 46.2 | 6.0 | 34.4 | 49.4 | 89.8 | Ireland, Republic of |
| Israel | 3,959 | 7.1% | . | . | 140.9 | 140.7 | 36.8 | 102.7 | 142.1 | 281.6 | Israel |
| Italy | 43,925 | 6.6% | . | . | 1,400.2 | 1,479.9 | 185.7 | 1,009.4 | 1,684.9 | 2,880.1 | Italy |
| Kazakhstan | 10,235 | 5.5% | 147.3 | 411.6 | 305.2 | 253.8 | 39.1 | 288.8 | 231.1 | 558.9 | Kazakhstan |
| Kyrgyzstan | 2,896 | 4.3% | 57.7 | 67.1 | 71.4 | 53.5 | 9.1 | 62.1 | 53.6 | 124.8 | Kyrgyzstan |
| Latvia | 1,758 | 9.9% | . | . | 77.5 | 96.1 | 15.1 | 58.4 | 100.1 | 173.6 | Latvia |
| Lithuania | 2,648 | 9.4% | . | . | 114.7 | 134.2 | 24.6 | 84.8 | 139.5 | 248.9 | Lithuania |
| Luxembourg | 327 | 3.8% | . | . | 5.8 | 6.8 | 0.1 | 3.0 | 9.3 | 12.5 | Luxembourg |
| Macedonia | 1,428 | 4.9% | . | . | 30.9 | 39.0 | 2.5 | 23.2 | 44.2 | 69.9 | Macedonia |
| Malta | 280 | 9.2% | . | . | 10.6 | 15.3 | 0.3 | 9.0 | 16.5 | 25.8 | Malta |
| Moldova, Republic of | 2,915 | 9.3% | . | . | 117.2 | 124.6 | 26.6 | 97.8 | 117.3 | 241.8 | Moldova, Republic of |
| Monaco [a] | 23 | 6.1% | . | . | 0.7 | 0.7 | 0.1 | 0.6 | 0.8 | 1.4 | Monaco |
| Netherlands | 11,678 | 3.7% | . | . | 203.4 | 228.8 | 5.3 | 118.3 | 308.5 | 432.2 | Netherlands |
| Norway | 3,154 | 6.7% | . | . | 95.5 | 116.2 | 19.8 | 69.6 | 122.3 | 211.7 | Norway |
| Poland | 27,852 | 9.0% | . | . | 1,238.7 | 1,267.8 | 239.0 | 1,002.5 | 1,265.0 | 2,506.5 | Poland |
| Portugal | 7,471 | 7.8% | . | . | 278.5 | 305.9 | 14.9 | 170.9 | 398.7 | 584.5 | Portugal |
| Romania | 16,392 | 9.3% | . | . | 760.0 | 759.2 | 154.7 | 519.0 | 845.6 | 1,519.2 | Romania |
| Russian Federation | 105,244 | 9.2% | . | . | 4,417.7 | 5,275.9 | 899.4 | 3,637.5 | 5,156.7 | 9,693.6 | Russian Federation |
| San Marino [a] | 20 | 6.1% | . | . | 0.6 | 0.6 | 0.1 | 0.5 | 0.7 | 1.2 | San Marino |
| Serbia and Montenegro | 7,542 | 5.6% | . | . | 182.0 | 240.1 | 11.8 | 127.1 | 283.2 | 422.1 | Serbia and Montenegro |
| Slovakia | 3,903 | 8.7% | . | . | 167.5 | 171.3 | 35.9 | 135.6 | 167.2 | 338.7 | Slovakia |
| Slovenia | 1,511 | 9.6% | . | . | 72.2 | 73.1 | 13.1 | 53.5 | 78.6 | 145.2 | Slovenia |
| Spain | 30,329 | 9.9% | . | . | 1,209.7 | 1,794.6 | 838.4 | 973.2 | 1,192.6 | 3,004.3 | Spain |
| Sweden | 6,290 | 7.3% | . | . | 206.4 | 250.5 | 36.3 | 140.1 | 280.5 | 456.9 | Sweden |
| Switzerland | 5,310 | 9.5% | . | . | 235.0 | 270.0 | 35.3 | 166.6 | 303.1 | 504.9 | Switzerland |
| Tajikistan | 3,174 | 3.7% | 62.9 | 53.8 | 70.3 | 46.4 | 9.6 | 57.5 | 49.6 | 116.7 | Tajikistan |
| Turkey | 42,411 | 7.0% | 514.1 | 2,444.6 | 1,254.3 | 1,704.4 | 370.4 | 1,440.7 | 1,147.7 | 2,958.7 | Turkey |
| Turkmenistan | 2,648 | 4.0% | 42.5 | 62.5 | 61.7 | 43.3 | 9.7 | 55.7 | 39.6 | 105.0 | Turkmenistan |
| Ukraine | 35,625 | 9.7% | . | . | 1,552.3 | 1,901.1 | 302.2 | 1,154.7 | 1,996.6 | 3,453.4 | Ukraine |
| United Kingdom | 42,423 | 3.9% | . | . | 813.7 | 857.9 | 89.4 | 588.9 | 993.3 | 1,671.5 | United Kingdom |
| Uzbekistan | 14,144 | 4.0% | 244.0 | 316.5 | 333.0 | 227.5 | 48.7 | 287.7 | 224.1 | 560.5 | Uzbekistan |
| Total | 621,235 | 7.8% | 1,429.3 | 4,276.5 | 22,336.9 | 26,041.5 | 4,461.8 | 17,388.4 | 26,528.2 | 48,378.2 | Grand Total |

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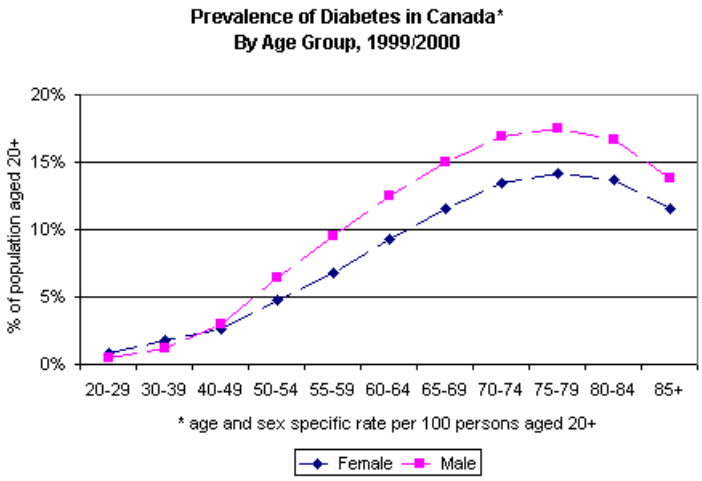
Source: Diabetes Atlas, International Diabetes Federation.

The prevalence of Type 2 diabetes reaches epidemic values in the older age (> 60) group (see figure and table).




source: http://www.phac-aspc.gc.ca/ccdpc-cpcmc/ndss-snsd/english/diabetes_data/index_e.html

The prevalence of diabetes is increasing, due to several factors: the increasing of age of the population, the increase in obesity, and physical inactivity. Furthermore, because of a more aggressive treatment of cardiovascular risk factors, diabetic patients live longer.

More information about the prevalence of diabetes can be found on the "diabetes e-atlas" from the IDF (International Diabetes Federation): http://www.eatlas.idf.org/

## Complications of diabetes

Acute hypoglycaemia:

This refers to *low* blood glucose concentrations (usual below 50-60mg/dl(3.0mmol/l). A hypoglycaemic event may result when there is "an imbalance between carbohydrate intake, administered exogenous or augmented endogenous (drug therapy) insulin". The manifestations of the reaction vary widely between individuals and within individuals across time and can impact on visual functions, cognitive functions and general orientation. This may influence the ability of the person to drive safely.
More info: see infra in this report

Acute hyperglycaemia:

This refers to *high* blood glucose concentration, which most commonly is associated with uncontrolled diabetes. Severe hyperglycaemia may lead to biochemical imbalances that can cause acute life-threatening events such as ketoacidosis or hyperosmolar (nonketotic) coma. Hyperglycaemia may also result in visual impairment, disorientation and decreased mental processing capacity, which may in turn affect driving performance.
More info on: http://care.diabetesjournals.org/cgi/reprint/27/suppl_1/s94

*Chronic hyperglycaemia can lead to the late diabetes complications such as retinopathy (eyes), nephropathy (kidneys), neuropathy (nerves) and cardiovascular disease. Recent studies (DCCT, UKPDS) proved the crucial role of good glycaemic control in the prevention*

*of these diabetic complications. Other factors, such as smoking, hypertension, and lipids can play an enhancing role in the development of these complications.*

Diabetic retinopathy (DR)

Refers to eye disease resulting from damage to small blood vessels in the retina. DR is the leading cause of blindness and visual impairment in adults. DR is strongly associated with time since onset of diabetes and level of blood glucose control. It is common amongst those with Type 1 diabetes and it is estimated that after about 20 years post-onset, almost all those with Type 1 diabetes will have DR. It is also estimated that about 21 percent of those with Type 2 diabetes have retinopathy on diagnosis of their condition and most will develop DR eventually. Studies have found that after 15 years of diabetes, approximately 2 percent of people become blind, while about 10 percent develop severe visual handicap. Other visual conditions such as glaucoma and cataract may be more common in people with diabetes than in those without the disease.
More info on: http://care.diabetesjournals.org/cgi/reprint/27/suppl_1/s84

Cardiovascular disease, stroke and high blood pressure

Diabetes is frequently associated with high blood pressure and high blood cholesterol and triglycerides (metabolic syndrome), which increase the risk of heart disease and stroke. Recent studies in Australia have shown that people with diabetes are two to five times more likely to have heart disease or stroke than those without diabetes. In addition, 73 percent of adults with diabetes have high blood pressure (BP ≥ 130/80) or are treated for hypertension. About 70-80% of people with type 2 diabetes will die from cardiovascular disease (50-60% from coronary artery disease).

Nephropathy

Nephropathy or kidney disease is associated with both types of diabetes.
Nephropathy affects 10-21 percent of people with diabetes. Good blood glucose control and control of blood pressure is important in prevention of nephropathy. The condition is progressive and takes several years to develop. Eventually the entire filtration system may break down, leading to end-stage renal disease (ESRD) or kidney failure, requiring kidney transplant or dialysis for survival.
More info on: http://care.diabetesjournals.org/cgi/reprint/27/suppl_1/s79

Neuropathy or peripheral nerve disease

This is the most common complication of diabetes, affecting up to 50 percent of people with both types of diabetes. The condition may result in sensory loss and damage to the limbs. 'Diabetic Foot' is an example of a peripheral neuropathy, characterised by chronic or recurring diabetic foot ulcers. Peripheral vascular disease and peripheral neuropathy can lead to ulceration, weakness and amputation, which may have negative effects for some drivers.
More info on:
http://care.diabetesjournals.org/cgi/reprint/28/4/956?ijkey=433c8b53a5a14b78301554321bb1b48576d610e0

## Newer, lower goals for BG: DCCT, UKPDS

The DCCT (Diabetes Control and Complication Study) is a clinical study conducted in people with type 1 diabetes from 1983 to 1993 by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in the USA and Canada. The study showed that keeping blood glucose levels as close to normal as possible slows the onset and progression of eye, kidney, nerve diseases and cardiovascular disease caused by diabetes. It was published in 1993.
More info on: http://diabetes.niddk.nih.gov/dm/pubs/control/

Analogous results were found in type 2 diabetes with the UKPDS (UK Prospective Diabetes Study) conducted in the United Kingdom. It was published in 1998.
More info on: http://www.dtu.ox.ac.uk/index.html?maindoc=/ukpds/

Both studies had an enormous impact on the way that people with diabetes are treated in the last 10 years. People with diabetes try to bring their blood glucose down as close as possible to within the normal range. Oral hypoglycaemic drugs and insulin are used in a more intensive way. This has consequences on the risk for hypoglycaemia. This is discussed later on in this report.

## Newer tools to monitor disease and treatment: self blood glucose monitoring.

Self-monitoring of blood glucose (SMBG) is an important component of modern therapy for diabetes mellitus. SMBG has been recommended for people with diabetes. Their health care professionals are advised to encourage SMBG in their patients in order to achieve a specific level of glycaemic control and to prevent hypoglycaemia.
The goal of SMBG is to collect detailed information about blood glucose levels at many time points to enable maintenance of a more constant glucose level by more precise regimens. It can be used to aid in the adjustment of treatment in response to blood glucose values and to help individuals adjust their dietary intake, physical activity, and insulin doses to improve glycaemic control on a day-to-day basis.

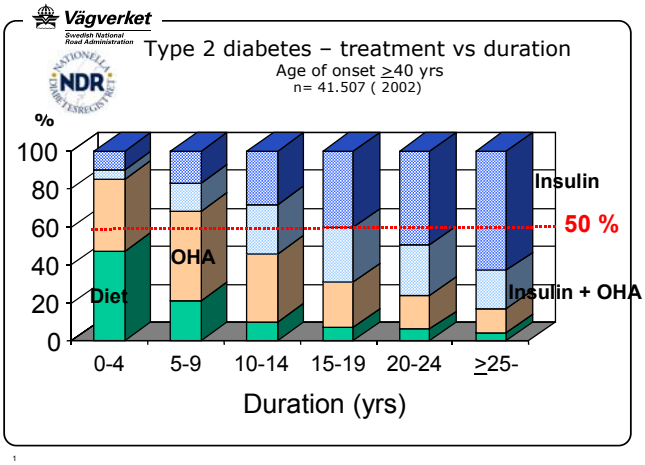
SMBG can aid in diabetes control by:

- facilitating the development of an individualized blood glucose profile, which can then guide health care professionals in treatment planning for the individual
- giving people with diabetes and their families the ability to make appropriate day-to-day treatment choices in diet and physical activity as well as in insulin or other hypoglycaemic agents;
- improving patients' recognition of hypoglycaemia or severe hyperglycaemia; and
- enhancing patient education and patient empowerment regarding the effects of lifestyle and pharmaceutical intervention on glycaemic control.

SBGM is the prerequisite to obtain a safe and adequate level of glucose control.
It plays an important role in detecting hypoglycaemia and is crucial for safe driving (see infra).

## More people with T2DM are treated with insulin

The UKPDS resulted in a more assertive treatment of Type 2 diabetes: during the normal progression of the disease, a progressive insulin deficiency develops. By this, more and more people will require an insulin treatment, in order to obtain satisfactory glycaemic control, as illustrated by this table. After some years, the majority of most of the patients with Type 2 diabetes need insulin therapy to maintain optimal control.



# DIABETES AND DRIVING

## Some general remarks

- Public safety (crash prevention) is the primary goal, but individual mobility rights should not be violated if there is no special risk for public safety

- A person with diabetes is an individual. There is a lot of heterogeneity in the group of diabetics (type of treatment, level of stabilisation, presence of complications, duration of the disease, active personal involvement with the disease, level of diabetes education, frequency of hypoglycaemia, etc.…)
  Ideally, these should be taken into account when assessing fitness to drive.

- In the evaluation of the driving ability, there should be equal attention paid to the preventive measures that the patient can take (eg level of diabetes education and diabetes control, frequency of self blood glucose monitoring, etc) as to the medical condition per se.

- More emphasis should be given to the implementation of the rules.
  The more the rules are restrictive and difficult in their implementation (eg administratively complex), the less they will be followed. This problem of compliance to the regulations (with frequent under reporting in many Member States) is not only mentioned in this WG, but is a problem noted for a number of medical conditions.

## Is "diabetes and driving" a relevant problem in our present society?

Diabetes and driving is a very relevant problem in our society:

- The disease is very frequent (see introduction) and is in the older age group epidemic (25% and more incidence).

- The majority of people with diabetes will be treated with drugs (oral hypoglycaemic drugs or insulin) that eventually can provoke hypoglycaemia, resulting in temporary adverse effects on functional abilities (slower reaction time, impaired coordination, etc) and in some cases to loss of consciousness.

- Some diabetes complications can interfere with driving ability:
  - Visual impairment by diabetic retinopathy
  - Physical impairment by neuropathy with loss of sensation or muscle weakness or by amputation

## History

*Annex III of Directive 91/439/EEC on driving licences.*

The Council Directive 91/439/EEC on driving licences, called the 'Second Directive' on Driving licences, entered into force on 1 July 1996. In very general terms, the main issues of the Second Directive are as follows: the harmonisation of licence categories (though the introduction of subcategories is not mandatory), the introduction of minimum ages as a prerequisite for the entitlement to drive vehicles, as well as a mandatory theory and practical examination. Furthermore, the Directive lays down the principle of mutual recognition of licences issued by a Member State and defines normal residence as a prerequisite for obtaining a licence. The Second Directive also contains detailed provisions on minimum health criteria and introduced a harmonised Community model driving licence. Additional provisions refer to the effect of cancellation, withdrawal and restriction of licences.

**The medical examination**

Different intervals as to medical examinations derive from provisions in Annex III of the Second Directive: its point 3 lays down that applicants for group 1 licences have to undergo a medical examination only in cases where substantial doubts with respect to the applicants' fitness to drive arises in the course of the application procedure. After a driving licence has been issued, no mandatory medical examination at all is prescribed for holders of group 1 licences.

For holders of group 2 licences, Annex III point 4 stipulates that they have to undergo a medical examination before the first issue of such a licence. Thereafter, the Directive foresees the imposition of periodic examinations without specifying regular intervals.

DIABETES MELLITUS

*Group 1:*
10. Driving licences may be issued to, or renewed for, applicants or drivers suffering from diabetes mellitus, subject to authorized medical opinion and regular medical check-ups appropriate to each case.

*Group 2:*
10.1. Only in very exceptional cases may driving licences be issued to, or renewed for, applicants or drivers in this group suffering from diabetes mellitus and requiring insulin treatment, and then only where duly justified by authorized medical opinion and subject to regular medical checkups.

## Problems with Annex III of Directive 91/439/EEC!

The second Directive has already reached a certain degree of harmonisation.
Nonetheless, some aspects have not been harmonised yet and the Directive leaves room for manoeuvre for Member states. Thus, considerable practical and legal differences persist in the above-mentioned fields in the licensing systems of the various Member states.
This was summarised in 2003 for the EU by Daniel Vandenberghe in a discussion note "The medical examination for driving licence applicants/holders in the European Union"

Therefore, the WG looked in more detail into the regulations concerning Driving and Diabetes in some selected Member States (see table). They found clear discrepancies in the way diabetes was evaluated and in the regulations in these member states. There is a need to move further towards harmonisation.

# Diabetes and Driving – regulations in selected states

| Country<br>source of information | Driver Group | Type 2<br>diet alone | Type 2<br>diet + tablets | Type 1/2<br>insulin-treated | single hypoglycaemic episodes | instable, risk of hypoglycaemia | end organ effects |
|---|---|---|---|---|---|---|---|
| **EU**<br>Annex III<br>Council Directive 91/439/EEC | **1** | subject to authorised medical opinion and regular appropriate check-ups | | | not explicitly mentioned | | |
| | **2** | subject to authorised medical opinion and regular appropriate check-ups | | very exceptional cases<br>authorised med. opin.<br>regular med. check-ups | | | |
| **Belgium**<br>Presentation of Paul van Crombrugge | **1** | *diet, metformin, glitazones:*<br>certification of GP<br>regular follow-up<br>compliance<br>limitation 5 / 3 years | | *other OHD, insulin:*<br>certification of specialist<br>regular follow-up<br>compliance, education<br>limitation 3 / 5 years | not explicitly mentioned | refusal/revocation | "no significant complications" |
| | **2** | *diet, metformin, glitazones:*<br>eval. by occupational physician<br>after advice by specialist<br>regular medical follow-up<br>compliance<br>limitation 3 years | | *other OHD, insulin:*<br>exceptional cases<br>eval. by occupational physician<br>after advice by specialist<br>regular medical follow-up<br>compliance, education, self-monitoring, good traffic perf.<br>limitation 3 years | | | |
| **Denmark**<br>Trafikministeriets bekendtgørelse om kørekort 2000<br>Trafikministeriets cirkulære 2000 | **1** | certification of GP<br>limitation 5 years<br>appropriate review | certification of GP<br>limitation 5 years<br>no hypo in last 2 years | certif. of medic. officer<br>limitation 2 years<br>no hypo in last 2 years | 2 years after hypo:<br>certification of medical officer | refusal/revocation | not explicitly mentioned |
| | **2** | certification of GP<br>limitation 5 years<br>appropriate review | certification of medical officer<br>limitation 2 years | very except. cases<br>certif. of public health department | 2 years after hypo:<br>certification of medical officer | | |
| **Germany**<br>"Begutachtungs-Leitlinien zur Kraftfahrereignung"<br>BASt 2000 | **1** | no restriction if satisfactory control and awareness of hypo | | | driving ban until satisfactory control | refusal/revocation | dependent on degree, vision tests recommended |
| | **2** | exceptional cases<br>no hypo for 3 month<br>3 yearly review GP | | very except. cases<br>certific. of specialist<br>2 yearly review | | | |

# Diabetes and Driving – regulations in selected states

| Country<br>source of information | Driver Group | Type 2<br>diet alone | Type 2<br>diet + tablets | Type 1/2<br>insulin-treated | single<br>hypoglycaemic episodes | instable, risk of hypoglycaemia | end organ effects |
|---|---|---|---|---|---|---|---|
| **Great Britain**<br>For medical practitioners "At a glance"<br>DVLA 9-2004 | **1** | not notifiable if no complications | licence till 70 if no complications | 1,2 or 3 year licence<br>awareness of hypo<br>visual standards | driving ban until satisfactory control<br>certification of GP | driving ban until satisfactory control<br>certification of GP | dependent on degree |
| | **2** | not notifiable if no complications | licencing if no complications<br>possibly short period licence | exceptional cases<br>1 yearly review | refusal/revocation recommended | refusal/revocation recommended | |
| **Spain**<br>Annex IV. National Regulation for drivers (Royal Decree-law 772/97 modified by Royal Decree-law 1598/04) | **1** | No restriction.<br>It is not allowed DM with severe metabolic problems that required hospital attendance. | Conditional licence with medical (GP) certificate* mandatory | Specialized report* is mandatory. Renewal every 4 years. | Not explicitly mentioned | no repeated hypoglycaemic episodes | In accord to "Spanish medical rules for drivers", (see legal reference): visual, neurological and renal sections. |
| | **2** | | Specialized report* is mandatory. Renewal every 3 years. | Specialized report* is mandatory. Renewal every year. | | | |
| | | *(*Note: all medical reports need to have references about: treatment control, hypoglycaemia control and adequate diabetological education)* | | | | | |
| **The Netherlands**<br>Regeling eisen 2000 | **1** | no restriction if satisfactory control and free of complications<br>limitation 5 years | | no restriction if satisf. control, free of complic.<br>limitation 5 years | not explicitly mentioned | refusal/revocation | depend. on degree<br>eye examination recomm. after 20 years of diabetes |
| | **2** | | | exceptional cases<br>certif. of specialist<br>satisfactory control<br>free of complications<br>self-monit., compliance<br>limitation 3 years | | | |
| **Australia**<br>"Assessing fitness to drive"<br>Australian Transport Council 2003 | **1** | no restriction<br>not notifiable<br>GP review recomm. | not notifiable<br>5 yearly review | conditional licence<br>certification of GP<br>2 yearly review<br>awareness of hypo | driving ban 6 weeks<br>control of specialist<br>crash: notification | refusal/revocation | depend. on degree<br>conditional licence<br>certification of GP |
| | **2** | no restriction<br>not notifiable<br>GP review recomm. | conditional licence<br>certific. of specialist<br>1 yearly review<br>high compliance<br>agents with min. risk<br>awareness of hypo | conditional licence<br>certific. of specialist<br>1 yearly review<br>high compliance<br>agents with min. risk<br>awareness of hypo | driving ban, duration according to opinion of specialist<br>crash: notification | | depend. on degree<br>conditional licence<br>certific. of specialist |

The WG outlined some difficulties in the present situation:

- a statement mentioning “only in exceptional cases” is not only too vague and ambiguous (what is exceptional: 1% ? 1/1000?; of people with diabetes; of commercial drivers; of applicants?), but also doesn’t guarantee safety. We should define the criteria and process to select people with diabetes with a safe driving profile, instead of stating the frequency that this can be allowed.

- In the past, too much emphasis has been put on general selection criteria. Although some obvious criteria can be used to try to foresee the risk of crashes, guidelines about how the medical condition will be treated and monitored by the patient is of (at least) equal importance for a safe implementation of the rules. In diabetes, the patient himself plays a major role in the treatment and the monitoring of his disease. Accurate and frequent self blood glucose monitoring and optimal diabetes education are of major importance for a stabilised diabetes regulation.

- Criteria that are seen as too rigid may result in a situation where the diabetic and his doctor fail to report the medical condition. Such criteria may also deter patients from seeking optimal assessment and treatment. This generates an unsafe situation.

- Physicians are often unaware of the guidelines and criteria used to evaluate the driving fitness of people with certain medical conditions. The proper implementation of these rules with clear guidelines is of major importance. Also, the support of the relevant medical associations would assist in implementation.

- The way the medical regulations are brought into practice is very heterogeneous between the member states: notification by the patient (with or without authorisation from general practitioner or specialist), medical evaluation by own general practitioner/specialist or other general practitioner/specialist, medical evaluation by specialised drivers licensing agency, etc.

- The assessment criteria for group 2 (commercial driving) can not be extrapolated from the data for group 1. These group 2 drivers have longer driving times and drive longer annual distances. The severity of accidents and number of fatalities in group 2 is worse than for group 1. Moreover, a lot of these drivers have to adhere to a strict working time frame. Some of these are also involved in the loading and unloading of their cargo: this has a clear influence on their risk of hypoglycaemia.

- A more difficult situation is the transport of people: such drivers have a specific responsibility for the safety of these passengers. In a situation of incipient hypoglycaemia, it is psychologically more difficult for the driver to stop, check his BG, and eat something (and wait for 20-30 minutes), than for a driver of goods.

- A special situation is driving emergency vehicles: each time-delay (eg by hypoglycaemia) could have a major influence on the outcome of the victim(s) of the emergency (accident, fire, etc).

# HYPOGLYCAEMIA IN DIABETES

Unrecognised hypoglycaemia represents a significant driving hazard. Therefore, some aspects of hypoglycaemia are discussed here in more detail. This topic was recently reviewed by Cryer (2002 and 2003) and Zammit (2005)

## Introduction

The brain primarily uses glucose as its source of energy. When blood glucose falls under 3.3 mmol/l, symptoms of neuroglycopenia and cognitive impairment develops, potentially interfering with driving ability. However, adrenergic symptoms often start at higher glucose values, giving the patient time to react to these warnings and to eat some food containing carbohydrates to correct the BG value. The problem is that not all patients have symptoms of low blood glucose (silent hypoglycaemia). Therefore, patients are dependent on recognition of hypoglycaemic symptoms or self-monitoring of blood glucose to detect hypoglycaemia. As many patients lose their warning signs or do not perform frequent monitoring of blood glucose, the chance of recognising episodes during daily life is not optimal. Unrecognised hypoglycaemia may be corrected by chance, by a planned meal, by dissipation of the insulin effect, or by counter-regulatory mobilisation of glucose from the liver, or may progress to severe hypoglycaemia with cognitive impairment and need for assistance from a third party. About 70-80% of all hypoglycaemic episodes(blood glucose <3.0 mmol/l ) are not accompanied by symptoms. Silent hypoglycaemia is an underestimated problem especially in Type 1 patients.

## Frequency in T1DM

Hypoglycaemia is the most common side effect of insulin treatment. Asymptomatic plasma glucoses lower than 60mg/dl are frequent: as many of 10% of the BG readings of a patients attempting to obtain good glycaemic control will fall in this range. Mild symptomatic hypoglycaemia will happen on an average of 2 times a week, and will often be corrected by the patients themselves.

More problematic are the severe hypoglycaemia's, where often somebody else (family, colleague at work, nurse or physician) have to intervene with treatment. This happens approximately to at least one third of patients one or more times a year. The risk of severe hypoglycaemia is skewed and a subgroup of patients experience most of the severe hypoglycaemic episodes per year. Risk factors for severe hypoglycaemia are impaired hypoglycaemic awareness, C-peptide negative (no endogenous insulin secretion and therefore no glucagon response to hypoglycaemia), strict hypoglycaemic control and long duration of diabetes.

## Frequency in T2DM

The frequency of hypoglycaemia is substantially lower in type 2 diabetes. The risk of severe hypoglycaemia in diet treated Type 2 diabetes is nil.
Some oral antidiabetic drugs (eg alfa-glucosidase inhibitors, metformin, thiazolidinediones) give no or a very low risk for hypoglycaemia.

Other oral drugs (eg sulfonylureas and glinides) can induce hypoglycaemia, but at a much lower rate than insulin.

The frequency of hypoglycaemia in insulin treated type 2 diabetes depends on the duration of the diabetes. The frequency is lower than for type 1 diabetes in the beginning. Once they lose their ability to secrete insulin after some years, the frequency for severe hypoglycaemia becomes similar in type 2 and type 1 diabetes when matched for disease duration. As in Type 1 patients, a subgroup of insulin treated Type 2 patients will also experience most of the severe hypoglycaemic episodes per year.

Clinical risk factors for hypoglycaemia:

1. Insulin (or oral hypoglycaemic drugs) doses are excessive, ill-timed, or of the wrong type.
2. Glucose delivery is decreased: eg after missed meals.
3. Endogenous glucose production is decreased: eg after alcohol ingestion.
4. Glucose utilization is increased: eg during exercise.
5. Sensitivity to insulin is increased eg late after exercise, after weight loss, with increased fitness, or improved glycaemic control, or during treatment with an insulin sensitizer.
6. Insulin clearance is decreased, eg with progressive renal failure.

## Treatment

Most episodes of hypoglycaemia can be effectively self-treated by ingestion of 20g glucose or carbohydrate in the form of glucose tablets, a soft drink, juice, a sweet or a meal. Sometimes, this has to be repeated after 15–20 min if symptoms have not improved or the monitored blood glucose remains low.
The glycaemic response to oral glucose is transient. Therefore the ingestion of a snack or meal is advisable within 2 hours. Parenteral treatment (intravenous glucose or subcutaneous glucagons) is only needed in the exceptional situation where the diabetic is unable or unwilling to take food orally.

## Hypoglycaemia unawareness

Some diabetics experience a loss of the warning (largely reduced sympathetic neural(adrenergic and cholinergic) actions) symptoms or an impaired perception of or reaction to the early warning symptoms of hypoglycaemia. The early warning symptoms such as anxiety, palpitations, hunger, sweating or tremor normally occur when the blood glucose is about 55-60mg (3.0mmol/l). The patients with unawareness do not realise that the plasma blood glucose level is decreasing below the threshold for neuroglucopenia (about 2.5mmol/l) and do not correct the blood glucose by food intake. This is called hypoglycaemia unawareness. By this, such patients have a 10 times higher frequency of severe hypoglycaemia. This situation can be induced by frequent hypoglycaemia's or chronic hypoglycaemia by itself and a vicious circle of recurrent hypoglycaemia is created. After a hypoglycaemic episode the patients will display attenuated symptoms and counter-regulation for 24-48 hours. Note that by meticulous avoidance of hypoglycaemia for 2-3 weeks, hypoglycaemia unawareness and the reduced counter-regulatory response are reversible, especially in patients with less than 10 years duration of diabetes. After 20-30 years duration of diabetes at least 40% of the patients display hypoglycaemia unawareness. The explanation of the unawareness after many years duration of diabetes is unknown.

Hypoglycaemia unawareness is observed in at least 25% of Type 1 diabetics and 10 % of

Type 2 diabetics. After 20-30 years duration of diabetes more than 50% of the patients will display hypoglycaemic unawareness.

Three quarter of people experiencing severe hypoglycaemia during the last year, experienced only 1 such an event; one quarter (those with hypoglycaemic unawareness) have more than 1 event a year and were responsible for about 60% of all hypoglycaemic events. This small subgroup (about 3 % of the patients with T1DM or long standing T2DM) has a very high risk for recurrent severe unrecognised hypoglycaemia, and are therefore at risk if driving.

## Severe hypoglycaemia requiring emergency medical services intervention.

In the group with Type 1 diabetes, only 1 in 10 of those experiencing severe hypoglycaemia required emergency service treatment compared with 1 in 3 of the group with type 2 diabetes. About 7 % of type 1 and or type 2 diabetics, and 1% of sulfonylurea treated patients needed emergency treatment in the past 12 months. Risk factors were older age, a history of previous hypoglycaemia, longer duration of diabetes, higher HbA1c, and socio economic deprivation..

## Influence of hypoglycaemia on driving performance.

The effect of hypoglycaemia on driving performance and on the drivers awareness of their driving impairment was studied by the group of Cox (1993).

These studies showed that starting at moderate BG (2.6 +/- 0.28 mmol/l), there was an impairment of driving capacity. About 44% of these diabetics did not react on these driving decrements and indicated they would drive in these circumstances.
See infra.

## Prevention

A well-informed person with the ability and willingness to take charge of his or her diabetes is key to successful glycaemic control, including the prevention of hypoglycaemia.
Therefore, patient education and empowerment, frequent self-monitoring of BG, flexible insulin and other drug regimens , individualised glycaemic goals, and ongoing professional guidance are crucial factors in the prevention of hypoglycaemia.
However, Cox et al (2003) reported that one half of the Type 1 diabetic drivers and three quarters of the Type 2 diabetic drivers had never discussed hypoglycaemia and driving with their physician.
Graveling et al (2004) reported on a questionnaire in the UK. About 87% of patients reported keeping carbohydrates in their vehicle. About 60 % never tested blood glucose before driving and 38% never carried a blood glucose meter when driving. Most of the participants of the questionnaire would stop driving to treat a hypoglycaemia, but only 14% would wait longer than 30 minutes to drive again.

Educational points for diabetes and driving.

The following items are important for each driver with diabetes, treated with insulin or oral hypoglycaemic drugs:

- understand the interaction between food-insulin-activity
- have rapid absorbable carbohydrate available in the car and have a BG meter available in the car to measure BG before and during long trips
- inject insulin at regular times
- do not skip meals
- anticipate any abnormal physical activities (eg loading/unloading a car)
- do not drive between injection and meal
- if HYPOGLYCAEMIA OCCURS: stop as soon as possible, take carbohydrates
  wait 15-30 min before driving again

## Research and future directions:

New insulin analogs have insulin profiles that allow better adaptation of the insulin treatment to the life style of the person with diabetes. Clinical studies show lower frequencies of hypoglycaemia with these new treatment modalities.

Also for the oral hypoglycaemic drugs, clinical research is going on to study differences in the hypoglycaemic potential of new drugs eg glinides, GLP-1 analogues and DPP-IV inhibitors.

Today, non-invasive continuous glucose monitoring gives warnings to the patient if BG is lowering too fast or if a low threshold value is reached, allowing the patient to treat the tendency to hypoglycaemia in time. This could be of particularly value for the diabetic driver of group 2 (professional driver) and for the patients with hypoglycaemia unawareness. The first clinical studies with such non-invasive continuous glucose monitoring devices are under way.

Therefore, the WG stresses the necessity to follow this research closely, in order to adapt the regulations and guidelines quickly in this rapidly changing field.

## In summary:

Hypoglycaemia is a frequent event in diabetes, especially in insulin treated patients. Some of these hypo's are recognised in an early stage and can be easily treated by eating some food with carbohydrates. Proper patient education, the availability of a blood glucose meter and carbohydrates are essential in this regard.
A subgroup of patients lose their ability to recognise the early signs of hypoglycaemia: this is called "hypoglycaemia unawareness". Their risk for severe hypoglycaemia is at least 10 times higher than that of diabetics without this hypoglycaemic unawareness. This makes these persons unfit to drive. Frequent severe hypoglycaemia or self blood glucose monitoring showing frequent low values (more than 15% below 70mg/dl or 3.5 mmol/l) are alarm signals of hypoglycaemia unawareness. Once recognised, this situation can be treated in the majority

of patients: avoidance of all hypo's during 2 or 3 weeks (allowing a slightly higher glucose target than usual) gives a return of the awareness, especially in patients with less than 10-20 years duration of diabetes.

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# RISK OF CRASHES IN VARIOUS CATEGORIES. REVIEW OF THE LITERATURE

For this report, we started from the recent literature search mentioned in an exhaustive review commissioned by the Swedish National Road Administration, and performed by the Monash University (Accident Research Centre) in Clayton, Australia:
www.monash.edu.au/muarc//reports/muarc213.pdf

Moreover, we performed our own literature search in PubMed using the search terms "diabetes driving", "diabetes crash", "diabetes car accident". All articles in the English language, and published in accessible journals were collected. Articles not cited in the Monash survey were added to this text and to the references.

## Introduction

There are some inconsistencies in the road safety outcome studies, with considerable heterogeneity of study protocols. This is a general remark for all medical conditions, not just for diabetes.

- Which eligibility criteria were used (eg some high risk patients were eliminated in advance; was there a focus on problem cases; were people with certain diabetes complications allowed in the studies?, etc)
- What type of Diabetes Mellitus (T1DM, T2DM)?
  Duration of DM?
  Treatment (insulin, oral hypoglycaemic drugs, diet only)?
- What was the distribution of other risk factors (gender, age, urban situation, etc)
- What was the unit of evaluation (year, distance travelled?)
- What was measured (crashes, hospital admissions, violations)
- Which crashes were evaluated (all, injurious, fault, fatal?)
- There was often a problem of underreporting
- How recent was the study (the present traffic situation is far more complex than 10-20 years ago, the present treatment modalities provoke more frequent hypoglycaemic events than 10-20 years ago.

In evaluating the crash risk of people with a medical condition, we should realise that the total risk of someone is not only influenced by the any increased risk from the condition, but also by the reduction in risk associated with self-regulation and adaptive behaviour.

Driving performance studies (with a simulator) have the disadvantage of being artificial, and are on an individual basis. They are less predictive for the future driving performance for people with diabetes than for those who have a functional orthopaedic disability or a visual problem.

## GROUP 1

We will summarise the studies mentioned in the report of the Monash University (Accident Research Centre): www.monash.edu.au/muarc//reports/muarc213.pdf See summary of most important studies in table 16 on p161 of this document (= p178 in Acrobat Reader), taken over in Annex 1 of this document.
We also include the studies from our own literature search.

Crashes

Vernon et al (2002) found that drivers with diabetes on restricted licenses had a not significant elevation of their crash risk (RR 1.38; 95% CI 0.75-2.54), while drivers with diabetes without license restrictions had a significant elevation (RR 1.3; 95% CI 1.23-1.38). In their discussion, they propose some possible interpretations (and biases) in their findings. Hansotia and Broste (1991) found a slightly higher risk for crashes in diabetics (1.32; p=0.01).

Koepsell et al (1994) studied the rate of injury crashes in older drivers and found a significant elevation in diabetics in general (OR 2.6; CI 1.4-4.7). In subgroup analysis, they found a significant difference in insulin treated diabetics, but not in OHA (oral hypoglycaemic agents) treated or diet treated people. A diabetes duration of more than 5 year (OR 3.9) and a co-existing coronary heart disease (OR 8.0) were also linked at a higher risk for crashes. Staplin et al (1999) studied also an older population, and did find a slightly increased risk for diabetics (OR 1.34).

McGwin et al studied also an older population (> 65 y) by self report (telephone interview). They didn't find a significant association for at-fault crashes and diabetes. They didn't find an association between diabetic retinopathy and at-fault crashes. However, prior crash involvement influenced clearly the relationship between diabetes and at-fault crashes.
The study of Salzberg and Moffat (1998) is difficult to interpret due to the very limited number of diabetics (27) and a lot of methodological problems.

Eadington and Frier (1998) did find a lower crash rate in people with diabetes. Of these crashes, 16% were attributed to a hypoglycaemic event. This study showed also that self-reporting of their medical condition was not done by a third of the study group. Interestingly, the majority that ceased driving did so on a voluntary base.

Songer et al (1988) did find a slightly higher crash rate (also after adjustment for distance travelled) in diabetics, but these differences were not significant. Sub analysis showed a higher crash risk in women with diabetes. Only 6 % from the crashes were attributed to hypoglycaemic events.

Stevens (1989) did find a similar crash rate in diabetics and non-diabetics, even if expressed by kilometres driven or by driving time/ year. About 29% declared a hypoglycaemic event while driving in the previous year. There was a relation between the number of hypoglycaemic reactions while driving and the total number of crashes in the previous five year period.

Songer (2002) studied a group of type 1 diabetics, some with medical complications (retinopathy, neuropathy, kidney disease, heart disease, hypoglycaemic unawareness). Crash

frequency was not related to glycaemic control, use of insulin treatment, hypoglycaemia unawareness, and neuropathy. Crashes were associated with younger age, miles driven, and severe (not mild!) hypoglycaemia.

Cox et al (2001) compared self reported crash rates of persons with T1DM and T2DM with those of their spouses. The crash rate of drivers with T1DM was twice of that of their spouse. For T2DM, there was a slight non-significant elevation, even it they were treated with insulin. Songer (1998) described some results from the DCCT trial concerning accident histories. There was no clear difference between the intensively treated group and the less intensively treated control group. However, the determinant factor appeared to be a history of severe hypoglycaemia (resulting in a loss of consciousness) over the past 2 years: these individuals had a doubling of their risk for a crash accident.

Violations, citations

Vernon et al (2002) didn't find a significant difference in the rate of citations for diabetics compared with persons without a medical condition.
Salzberg and Moffat (1998) came to the same findings
Hansotia and Broste (1991) didn't find a difference either.

Treatment modalities

Mc Gwin et al (1999) didn't find a significant effect of treatment modalities (insulin, OHA, diet) on at fault crash risk.

In contrast, Koepsell et al (1994) found significantly higher crash rates amongst insulin treated (OR 3.1) and OHA treated (OR 5.8) drivers. However, these authors used medical records instead of crash reports what could induce a bias.

Jude et al (1998) studied the binocular visual acuity immediately after pupil dilatation (an examination that should be done at least annually in all diabetics). They found a significant reduction of this visual acuity, especially under condition of glare. A practical conclusion of their work is that people with diabetes should be advised not to drive for at least 2 hours after pupillary dilatation.

Driving performance

The effect of hypoglycaemia on driving performance and on the drivers awareness of their driving impairment was studied by the group of Cox (1993).

These studies showed that starting at moderate hypoglycaemia (BG 2.6 +/- 0.28 mmol/l), there was an impairment of driving capacity. About 44% of these diabetics did not react on these driving decrements and indicated they would drive in these circumstances.
It is not clear how these findings can be translated to the actual driving risk of such patients.

Instructions and information for people with diabetes

Cox et al (2003) reported that one half of the type 1 diabetic drivers and three quarters of the type 2 diabetic drivers had never discussed hypoglycaemia and driving with their physician.

Graveling et al (2004) reported in a UK study that 32 % already had experienced hypoglycaemia while driving, and 13% did so during the last year. About 87% reported keeping carbohydrates in their vehicle. About 60 % never tested blood glucose before driving and 38% never carried a blood glucose meter when driving. Most of the participants of the questionnaire would stop driving to treat a hypoglycaemia, but only 14% would wait longer than 30 minutes to drive again.

IN SUMMARY FOR GROUP 1:

The results of the studies of crash risk and diabetes are conflicting: some show a slightly higher risk, some no difference, and some a slightly lower risk. The differences are small, compared with the differences in crash risk that we see in the general population (eg influence of gender or age: see fig 1), and seems therefore acceptable.

There is no clear relationship with the type of diabetes (T1DM or T2DM), or with the treatment modality (insulin, oral hypoglycaemic agents).

Recent severe hypoglycaemia or hypoglycaemic unawareness or past crashes seems to be predictive for future crashes.

It is obvious that some major diabetes complications are relevant for the driving capacity of people with diabetes: eg diminished visual acuity in serious diabetes retinopathy. In these cases, the same impairment on driving ability can be expected as by non-diabetics with similar problems.

Health care professionals should be encouraged to discuss driving and diabetes with their patients during consultation. People with diabetes should be educated about the influence of their disease and their treatment (with special reference to hypoglycaemia) on their driving capacity.

Health care professionals (physicians and diabetes nurses) should have access to clear, accessible (eg on the internet) guidelines about diabetes and driving, and should be trained in giving patient education on this topic.

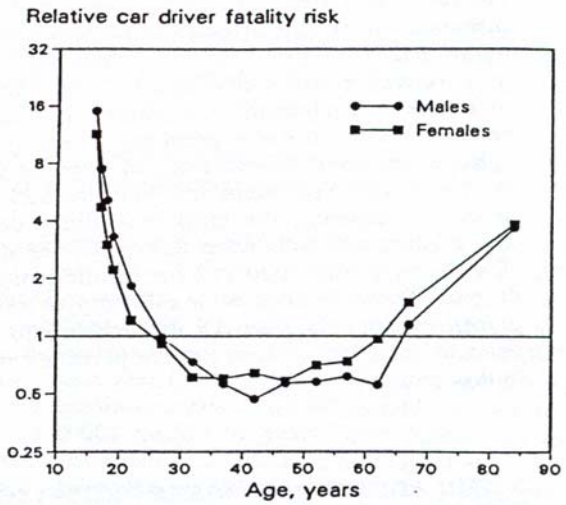


Fig. 1. Car driver fatalities per unit distance of travel relative to the average for all drivers, as indicated by the horizontal line at unity.
Figure 1 from: L. Evans, M. C. Frick, and R. C. Schwing, "Is It Safer to Fly or Drive," *Risk Analysis* 10, 239–246 (1990).

## GROUP 2

In many countries, a driving licence for group 2 was (until recently) not granted for people with diabetes. Therefore, the data on road safety in this group 2 are sparse.

Songer T et al (1993) and Lave et al (1993) from the same Pittsburgh group conducted a (hypothetical) risk analysis to evaluate the impact of licensing diabetics (insulin treated and non-insulin treated) for commercial vehicles on the number of crashes in the USA, and they put this risk into perspective to other risk factors such as allowing young persons to drive a truck, etc. They conclude that the additional risk from insulin-using CMV (commercial motor vehicle) drivers was within the present range of acceptable risks. They stress that hypoglycaemic unawareness and a history of severe hypoglycaemia are strong risk factors, and excluding these drivers could reduce the risk of accidents considerably.

In the FHWA Waiver Program Risk Assessment, the FHWA in the USA evaluated the crash risk of drivers with diabetes that received grandfather rights in the Waiver program (1993-1996).

This was a group who met strict qualifications, no history of diabetic complications or recent severe hypoglycaemic events, and with clear stringent guidelines concerning the frequency of self blood glucose monitoring, and the actions to take when BG became too low. The FHWA found an accident rate of 2,309 accidents per million vehicles miles travelled (VMT) for diabetics compared with a national accident rate of 2,605 per million VMT.

Another FHWA study in 1998 evaluated insulin treated drivers of CMV's, driving under intrastate programs or under grandfathered interstate programs. They found an accident rate of 1,950 per million VMT. There was some discussion concerning the comparison group to use: CMV operators (1,444) or national accident rate (2,272), so that a firm conclusion couldn't be drawn.

Laberge-Nadeau et al (2000) reported on the results of truck-permit holders in Quebec, Canada during 1987-1990. For articulated trucks (AT), they found no significant difference between diabetics and a healthy group. For single unit trucks (ST), they did find an increased crash risk of 1.68 compared with a healthy group. They speculate that several factors can play a role in the discrepancy between these findings: perhaps that ST drivers work in a more stressful environment, and spend more time in handling materials than AT drivers; perhaps that for the selection of AT drivers, higher medical standards were used than for ST drivers, etc. In these data, a self-selection effect (the more severely affected individuals restrict their driving even if they have a permit) or the "healthy worker effect" (only the less affected individuals with this disease apply for a permit) cannot be excluded.

Since 2005, exemption applications can be asked for individuals with diabetes in the USA, and this under very strict criteria: at least 3 years of safe driving experience with the disease (eg intrastate), no more than 1 severe hypoglycaemia during the last 5 years and at least 1 year stabilisation since the last severe hypoglycaemia, no significant diabetes complications, meet the current vision standards, perform at least a BG measurement every 2 to 4 hours, regular evaluation by an endocrinologist, etc. (details on http://dmses.dot.gov/docimages/pdf88/253696_web.pdf ). There are, as yet, no study results available for this group of exemptions.

IN SUMMARY FOR GROUP 2:

Only limited data are available for this group, exclusively from the USA and Canada (not from Europe).

These data suggest an acceptable accident risk on condition that there are clear requirements of the absence of hypoglycaemic unawareness or severe hypoglycaemia, and with stringent guidelines on the frequency of self blood glucose monitoring and on the treatment of BG's under 5.5 mmol/l and above 22 mmol/l.

**Table 16 Summary of studies of risk associated with diabetes mellitus**

| Study: Author/date | Methods | Outcome Measure of Risk | Crash Risk/Main Findings |
|---|---|---|---|
| Vernon et al., 2002 | Pop/case-control;<br>Cases (with diab, thyr, parathyr; pituit; other metabolic conditions)<br>n=10,105<br>(Restricted and unrestricted licence holders)<br>Control (without medical conditions) n= 20,210 | (i) All Crash<br>(ii) At-fault crash (iii) Citations<br><br>Rates per 10,000 lic days | For low impairment cases (unrestricted):<br>RR: 1.30 (1.23-1.38) * (p < .05), all crashes<br>RR: 1.46 (1.36-1.58)* (p < .05, at-fault crash<br>RR: 1.02 (0.98-1.07) NS, citations |
| | | | Higher impairment cases (restrictions):<br>RR: 1.38 (0.75-2.54) all crash<br>RR: 1.77 (0.87-3.61) at-fault crash<br>RR: 1.39 (0.92-2.09) citations |
| Koepsell et al., 1994 | Case-control;<br>n=234 (65yrs+) injury crashes<br>n=446 no injury crashes; | Police-reported injury crashes requiring medical care | OR: 2.6 (1.4-4.7)* for diab<br>OR: 5.8 (1.2-28.7)* for insulin-treated<br>OR: 3.1 (0.9-11.0) for OHA treated<br>OR: 0.9 (0.4-2.4) for diet only<br>OR: 3.9 (1.7-8.7)* for >5yr diag<br>OR: 1.4 (0.5-3.7) for ≤ 5 yr diag<br>OR: 8.0 (1.7-37.7)* for diab & CHD vs neither diab nor CHD |
| Salzberg et al., 1998 | Case-control;<br>Cases<br>n=27 with diabetes; passed Washington state special exam in 1994<br>Controls<br>n= 449 drivers not in special exam program in 1994; age, gender, city of residence matched | (i) Crashes per 100 drivers per year<br>(ii) Violations per 100 drivers per year | Pre–exam crash rate: Case:Control 6.4:3.8<br>Post exam crash rate: Case:Control 1.1:1.2<br><br>Pre-exam violations: Case:Control 8.5:7.5<br>Post-exam violations: Case:Control 2.3:2.3 |
| Staplin et al., (1999) | Cases n=363 with diabetes aged 68-89 years.<br>Controls | | OR 1.34<br>Females OR: 2.13 |
| Hansotia & Broste 1991 | Pop/retrospective cohort study<br>Cases n= 484 drivers with diabetes (approx 10% type 1)<br>Controls n=30,420 drivers | (i) mishap ratios all crashes and viol (MR)<br>(ii) MR for moving violations<br>(iii) MR for injury crashes<br>(iv) MR for property damage crashes | MR: 1.32 (1.06-1.63)* (p=0.01)<br>MR Moving Viol: 1.14 (0.92-1.39) * (p=0.23)<br>MR Injury Crash: 1.57 (1.04-2.29)* p < 0.05<br>MR Property Damage Crash:1.24 (0.95-1.59) |

| Study: Author/date | Methods | Outcome Measure of Risk | Crash Risk/Main Findings |
|---|---|---|---|
| McGwin et al., 1999; 2000 | Pop/rdmzd, case-control;<br>Cases n=198 at-fault crash involved drivers (65+yrs)<br>Controls (i) n=198 not at-fault crash-involved (ii) n=454 non-crash involved drivers | (i) At-fault crash in previous year<br>(ii) not-at-fault crash | **For diabetes vs (i) at-fault crash involved controls:**<br>Adj OR: 0.7 (0.4-1.3)<br>**For diabetes vs (ii) not at-fault crash involved controls:)**<br>Adj OR: 1.1 (0.7-1.9)<br>**For diabetes vs prior crash involved**<br>Adj OR for diab 2.5* (0.9-7.2)<br>Treatment modalities and at-fault crashes:<br>**For OHA**<br>Adj OR: 1.3 (0.7-2.6) NS<br>**For Insulin**<br>Adj OR: 1.3 (0.6-2.9) NS<br><br>Complicating Conditions<br>**Diab Retinopathy**<br>OR: 1.3 (0.3-5.2)NS<br>**Diab Neuropathy**<br>OR: 2.2 (0.4-11.2)NS |
| Eadington, & Frier, 1989. | Cases<br>n=166 IDDM<br>Controls<br>N=(general population statistics, DOT, London, 1986) | Crashes in previous 8 years expressed as rates per million miles driven | Number crashes per million miles driven:<br>Cases: 5.4<br>Females: 6.3<br>Males: 4.4<br>Controls: l0<br><br>Males with/without hypoglycemia:<br>hypogl > non-hypogl, $p < 0.01$ |
| Songer et al 1988 | Cases<br>n=158 IDDM<br>Controls<br>n=158 non-diabetic siblings | Crashes per 100 drivers/1,000,000 miles driven | Adj OR for diab:<br>0.99 (0.28-3.50)<br>Adj OR for female cases:controls:<br>5.73 (1.04-31.6)* ($p < .05$) |
| Stevens et al. 1989 | Cases<br>n=596 insulin-treated diabetics<br>Controls<br>n= 476 non-diabetics | (i) Rates of crashes; and<br>(ii) Driving convictions in past 5 years | Crash rates for cases and controls: (23.2% vs 24.8%), $\chi^2=0.25$, p=0.62. |
| Songer, 2002 | Cases<br>n=428 IDDM | Crashes in previous year | Severe hypogl:<br>Unadj OR 2.34*(1.13-4.83)* (p=.05) |

| Study: Author/date | Methods | Outcome Measure of Risk | Crash Risk/Main Findings |
|---|---|---|---|
| | Controls N/A | | Hypogl w/o warning:<br>Unadj OR 3.62 (1.64-7.98)* ($p < .05$) |
| Cox et al, 2001 | Cases<br>n=25 Type 1 diabetes<br>n=25 Type 2 diabetes<br>Controls<br>Spouses without diabetes<br>Total n=1036 | Crashes in previous 2 years | Type 1 diabetes twice no. crashes as spouses* (p=0.001)<br>Type 2 diabetes not diff to spouses |

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# Concluding remarks and comments

This is a summary of the concluding remarks (in italic) of the WG with some comments.

*General banner: Responsibilities*

The WG has concerns regarding the current lack of implementation of the existing driver licensing medical criteria. It would appear that the majority of the general public and health care professionals are not aware of these criteria.

The WG suggested that there should be more emphasis on the responsibilities of licensing authorities, health care professionals and drivers. These responsibilities should be included as a general statement in the new directives and budgets should be dedicated to an information campaign.
Of course, this is applicable not only to diabetes, but to each relevant medical condition.

1. *Licensing authorities:*
   *should provide information to both drivers and health care professionals*

It would appear that most drivers are not familiar with the legal issues concerning driving and the criteria used to evaluate the driving abilities of people with certain medical conditions.
Several methods to provide information were proposed: leaflets, websites and advertisements via magazines, newspapers, TV and radio.
The importance of the support of the relevant medical associations was recognised.

The health care professionals often appear unaware of the legal issues concerning driving and the criteria used to evaluate the driving abilities of people with relevant medical conditions.
Clear guidelines concerning this matter (preferably on the web) would be very helpful. Good examples of these are in existence from Canada, New Zealand, and Australia:
Canada: http://www.diabetes.ca/section_advocacy/adv_CPG_driving.asp and http://www.diabetes.ca/Files/DrivingGuidelines.pdf
New Zealand: http://www.ltsa.govt.nz/licensing/docs/ltsa-medical-aspects.pdf
Australia: http://www.austroads.com.au/upload_files/docs/AFTD%202003-F_A-WEBREV1.pdf
Authorities in each member state should finance such initiatives, as these are crucial to implementation of the proposed criteria.

2. *Health care professionals:*
   *should advise patients of the possible impact medical conditions and treatments could have on their driving capabilities*

Many patients have never discussed the influence of hypoglycaemia on their driving abilities with their physicians (see literature review).
It is recognised that health care professionals have to cover numerous aspects of diabetes care and its complications during the short consultation period. Driving may not always be considered a priority topic at this time and may be omitted from discussions.
More attention should be given to the training and continuous education of health care professionals to the importance of this.

3. *Drivers:*
   *should honestly assess their driving capabilities with regard to their medical condition and treatments, and act appropriately.*

Drivers with a medical condition are often resistant to declare this to the authorities, because they fear that in doing so this will be an automatic ban to driving. This belief is often due to a lack of information and to misconception, and plays a major role in under reporting of relevant medical conditions.

*General banner for diabetes mellitus*

*The primary concern for drivers with diabetes mellitus treated with medication is hypoglycaemia. This is generally not a problem with lifestyle and diet-controlled diabetes.*

Unrecognised hypoglycaemia is the most relevant driving hazard for drivers with diabetes.
Hypoglycaemia is generally not a problem if the diabetes is treated by lifestyle and dietary measures alone. This is also the case when treated with certain oral drugs such as metformin, alfa-glucosidase inhibitors, glitazones, GLP-1 analogues or DPP-IV inhibitors, because these do not provoke severe hypoglycaemia when used as monotherapy or in combinations with other drugs in this category.

Treatment with other oral medication such as sulphonylureas and glinides may provoke hypoglycaemia, similar to that seen with insulin treatment, also in combination with the aforementioned drugs.

People with hypoglycaemic unawareness are at particular risk of developing sudden unrecognised hypoglycaemia (see higher).

*In assessment of all applicants/drivers, consideration should be given to the presence of any diabetic complications such as retinopathy, neuropathy, nephropathy, foot problems and cardiovascular complications.*

A minority of people with diabetes will develop diabetic complications that could interfere with their ability to drive safely. The most frequent example is severe diabetic retinopathy, with diminished visual acuity.

The workgroup proposes that the same criteria for assessing these complications should be used as for non-diabetics (eg see the visual criteria).

*Group 1*
*Driving licences may be issued to, or renewed for, applicants or drivers who have diabetes mellitus. When treated with medication, they should be subject to authorised medical opinion and regular medical review, appropriate to each case, but at no greater than a 5-year interval.*

Diabetes per se is not a bar to the holding of a driving entitlement. A person with diabetes, stabilised and without relevant diabetes complications or recurrent hypoglycaemia events can be considered for Group 1 entitlement (see literature review).

The stability of the diabetes, and development of complications may change with time. Therefore, the WG proposes regular medical licensing review at no greater than 5 year intervals. The members of the WG on Diabetes and Driving were of the opinion that the final assessment of driving ability should preferentially be done by an independent doctor, not by the treating physician. Of course, both patient and treating physician can give relevant information for this assessment.

*Driving licences shall be withdrawn (revoked) from drivers who have recurrent severe hypoglycaemia and/or impaired awareness of hypoglycaemia.*

A sporadic severe hypoglycaemic event can never be anticipated or excluded with certainty, but has no significant influence on the overall crash risk of an individual.
However, recurrent severe hypoglycaemia is usually a sign of impaired hypoglycaemic awareness. The literature shows a much higher (9 fold) risk for hypoglycaemic events in this subgroup. These persons should not drive, and should seek medical advice. Often, hypoglycaemia awareness may be regained after appropriate adjustment of treatment.

*Understanding of the risk of hypoglycaemia and adequate control of the condition should be demonstrated by the driver with diabetes.*

Good diabetes education of the patient on how they should treat and monitor their own condition is of major importance for safe driving. In diabetes, the patient plays a major role in the treatment and the monitoring of the condition. Proper self blood glucose monitoring and optimal diabetes education are of major importance for stable diabetes control.

*Group 2*

The words “Only in very exceptional cases” should be omitted in the present sentence about Group 2 licensing in Annex III (Only in very exceptional cases may driving licenses be issued to, or renewed for, applicants or drivers in this group suffering from, etc).

Such a statement is too vague and ambiguous (what is exceptional: 1% ? 1/1000?; of people with diabetes; of commercial drivers; of applicants?), but also doesn’t guarantee safety. We should define the criteria and process to select people with diabetes with a safe driving profile, instead of stating the frequency that this can be allowed.

The WG proposes the following:

*Consideration may be given to the issuing/renewal of Group 2 licences to drivers with diabetes mellitus, taking into account the nature of the treatment and the type and use of the vehicle.*

Several aspects would be taken into account when evaluating the current status of the medical condition: eg type of diabetes treatment, stability of the diabetes, frequency of self blood glucose monitoring, hypoglycaemia’s in the past, diabetes complications, duration of diabetes, etc.
It was noted that in some Member States it is the Occupational Physician that evaluates the patient for eligibility for Group 2 licensing.

*Such licences should be issued subject to authorised medical opinion and to regular medical review, undertaken at no greater than a 3-year review.*

This regular 3 year review should be mandatory, but this can be more frequent if required by the authorities, the overviewing physician or the patient.

*Driving licences shall not be issued to, or will be withdrawn (revoked) from, drivers who have recurrent severe hypoglycaemia and/or impaired awareness of hypoglycaemia.*

Recurrent severe hypoglycaemia and/or impaired awareness of hypoglycaemia is not compatible with safe driving.

*The applicant/driver must demonstrate understanding of the risk of hypoglycaemia and show adequate control of the condition by blood glucose monitoring at least twice daily and at times relevant to driving. The requirement for glucose monitoring may be modified for a treatment which has a low risk of hypoglycaemia.*

For the importance of proper diabetes education: see remarks on group 1.
The WG felt that regular blood glucose monitoring to detect low blood glucose is a prerequisite to safe driving. Studies undertaken in the USA in Group 2 drivers (see literature review) were done in the context of regular self blood glucose monitoring with clear guidelines regarding procedures to be followed in the presence of low blood glucose values. The WG realises the economic consequences for the patient, but stresses that this is one of the most important safety measures to undertake. They recommend the use of memory glucosemeters (these are readily available), so that the measurements can be assessed by the treating physician and by the authorities if indicated.

*A severe hypoglycaemic event during waking hours should result in reassessment of the licensing status.*

The WG stated that each severe hypoglycaemic event during waking hours should be reported, even if this happened unrelated to driving. The driver should understand that this will not automatically result in license withdrawal, but the cause and circumstances of the hypoglycaemic event would be evaluated. Appropriate adjustment of the diabetes treatment would have to be undertaken to reduce the risk of recurrence before reassessment of the driving status and possible license reinstatement could be undertaken.

*D licences should not be issued to drivers with insulin-treated diabetes mellitus. Consideration may be given to renewal/issue of licences for drivers with type 2 diabetes, who require treatment with once-daily insulin and oral medications.*

The WG felt that there are some situations where risk of developing a severe hypoglycaemic event is unacceptable. One of these situations is bus driving. Such drivers have a specific responsibility for the safety of their passengers. Moreover, in a situation of incipient hypoglycaemia, it is psychologically and physically more difficult for the driver to stop, check his BG, eat something (and wait for 20-30 minutes), than for a driver of goods.
Insulin treated drivers should not be issued a D license. An exception could be considered for drivers with type 2 diabetes on oral medication, who require in the evolution of their disease the addition of one insulin injection a day, because most of these persons will have a relatively low

risk of hypoglycaemia. Of course, all the prerequisites for group 2 formulated earlier stay in place.
The WG did not discuss the situation of small buses (eg D1) as a consideration separate from full category D.

*EMERGENCY VEHICLES*

*Drivers with insulin treated diabetes mellitus should not drive emergency vehicles.*

Another situation where any severe hypoglycaemia is also unacceptable is the driving of emergency vehicles. Each time-delay (eg by hypoglycaemia) can have major influence on the outcome of the victim(s) of the emergency (accident, fire, etc). Furthermore, because of the "stress" involved during the driving of emergency vehicles it may mask the symptoms of hypoglycaemia.

Therefore, the WG stated that drivers with insulin-treated diabetes mellitus should not drive emergency vehicles.

*TAXI LICENSING*

*It was noted that different situation/rules exist in the Member States*
*Group 2 licensing standards should apply to Taxi licensing.*

The WG realised that different situations/rules exist in the Member States concerning taxi licensing: sometimes this is done by the license authorities, sometimes by local authorities.
The Group 2 standards should apply.

The same problem exists for licensing requirements for the transportation of people if this is organised and run by the employer: again there are huge differences between Member States.

**Suggestions for the future:**

- The WG felt that there was a need for continuation of the WG of experts, to evaluate new studies and new treatment strategies. New treatment strategies currently under development could have a major impact on the safety of driving in the future (eg new continuous blood glucose monitoring devices with alarms are under investigation and could play a major role in the future to detect risk of hypoglycaemia).
  This WG should establish and maintain contact with other bodies outside the EU that are dealing with similar concerns: the USA, Australia and Canada have developed protocols for Group 2 drivers with diabetes. Modern communication techniques should enable useful exchange of information without undue expense.

- As stated, it was preferred that the criteria should appear in guidelines rather than in the law. The law cannot provide more than a framework of minimum criteria. However, the EU could play an important role in constructing a website with suggestions for the practical guidelines and forms for the implementation of the law. The expertise of "centres of excellence" (be it research centres, clinical centres or driver licensing agencies) on these matters could be disseminated by this way. Moreover, this could lead to a better harmonisation of the specific criteria and guidelines in each Member State.

- Such a WG should make suggestions for a research study to undertake a prospective evaluation in the EU of the safety performance of drivers with diabetes doing non commercial driving (comparing with drivers without diabetes). The reason for this sharing of data is that the number of persons with diabetes in Group 2 is in most countries too limited to draw any conclusion. Of course, such co-operation is only possible between countries with directly analogous procedures regarding diabetes and driving.

July 2006,
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