

Setting occupational standards for insulin-treated diabetes at sea, on land and in the air

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Abstract

Diabetes, particularly treatment with insulin, has proved a longstanding and frustrating barrier to employment in certain occupations where public safety has been deemed to be potentially at risk. Historically, health and safety issues within the work environment have dictated employment policy, precluding people with diabetes who would otherwise be entirely capable of undertaking required responsible and skilled activities. Such considerations have been especially evident for professional occupations involving both commercial and public transport on land, by sea and in the air. This situation is changing. With the combination of individualised diabetes management and implementation of the Disability Discrimination Act, it is no longer appropriate to apply a 'blanket ban' restriction to employment irrespective of circumstances.

The UK Maritime and Coastguard Agency (MCA), the Driving and Vehicle Licensing Agency (DVLA) and the Civil Aviation Authority (CAA) have each accepted the principle that insulin-treated diabetes should no longer be an absolute contraindication to occupational employment, but to be potentially permissible subject to strict, robust individual assessment. Each transport agency has established regulatory standards and operational protocols appropriate for their respective domains with a prime emphasis on minimising hypoglycaemia risk. Ensuring public safety remains paramount, but, with these protocol surveillance and assessment processes in place, it has proved possible for individuals with insulin-treated diabetes to achieve fitness certification and gain employment previously excluded to them. Over the last few years, despite having diabetes and being treated with insulin, many merchant seafarers, drivers of heavy goods vehicles and commercial airline pilots have successfully achieved fitness accreditation to work safely and reliably within these special occupational situations. Copyright © 2015 John Wiley & Sons.

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Key words

Disability Discrimination Act; insulin-treated diabetes; hypoglycaemia; blood glucose monitoring; maritime; driving; aviation; public safety

Introduction

As any person with diabetes will be well aware, the issue of employment and perceived occupational risk has been a longstanding controversy but one that now engages a more liberal attitude. Not that long ago, treatment with insulin would be regarded by many employers as potentially compromising to safety and effectiveness at work. Many people with diabetes found that they were prevented from obtaining gainful employment for which they were otherwise entirely suited. Reversing this situation has been a long and challenging process, involving determination and a championing of the way forward. As modern treatment and management of diabetes have advanced in so many ways with a crucial emphasis on personalised care, so it has become inappropriate to simply apply a 'blanket ban' irrespective of individual circumstances

and capabilities. The Disability Discrimination Act of 1995, and more recent amendments, finally legislated that it was no longer lawful to discriminate against a person because of their condition, and this applies to insulin-treated diabetes.

However, the Disability Discrimination Act does recognise that some occupations may present particular hazard by the nature of the specific employment, and advises that, under these circumstances, a person's fitness to work should be medically assessed at individual level. For example, emergency 'blue light' services of police, fire and ambulance can now be considered within this regulatory framework subject to such individual assessment and review process. The UK armed forces remain exempt from the Equality Act and hence recruitment into the military services for those with diabetes is largely restricted. A

similar policy is currently adopted for railway workers with diabetes.¹ Nonetheless, there are now many diverse occupational scenarios where more progressive considerations can now be applied. Among these, situations involving responsibility for travelling by sea, driving on the roads and flying in the air can all be reviewed in this context. Advised regulatory standards for each of these three modes of transport are now in place.

Sea

Navigating the sea has the longest recorded history of occupational-related disease and disability. The ravages of long-distance sailing over the centuries have been well documented but, by the late 18th century, pioneering guidance on 'the most effectual means of preserving the health of seamen in the Royal Navy' was becoming available.² The need to assess the health and fitness of those whose employment was based at sea was recognised by the Merchant Shipping Act of 1867, making provision for medical examiners based in ports to undertake inspection of seamen and to issue medical certification as to fitness or otherwise for duties at sea. Scurvy, dysentery and venereal disease were more prominent conditions at that time, but familiarity with diabetes itself was then unknown.

Present-day merchant shipping legislation requires that it is the duty of the seafarer to report any medical condition, now specifically including diabetes, and the laws of most maritime countries, under the Maritime Labour Convention,³ require that all seafarers must carry a valid medical certificate. Medical practitioners performing examinations are expected to have a clear understanding of the special demands of seafaring life, knowing that their professional judgement may be critical to the lives of others.

Dependent on the considered medical risk, a seafarer may be certified fully fit or unfit for undertaking duties at sea, or may be qualified by either temporary unfitness or restricted from certain activities such as lone watchkeeping or working at heights on vessels.

Working may be restricted to near coastal waters on vessels that

Restricted category fitness for UK near-coastal duties with no lone watchkeeping

- Conditional on informing master/responsible officer of insulin use
- Regular recording of blood glucose levels
- No significant adverse history of hypoglycaemia
- Annual specialist assessment and individual risk assessment
- Only fit for work in worldwide waters, but without lone watchkeeping duties, if on vessel with ship's doctor

Box 1. The UK's Maritime and Coastguard Agency's standards, which mirror international maritime guidelines for insulin-treated diabetes

return to port daily for off-duty periods. Fitness for work on a worldwide basis without lone watchkeeping duties may be possible provided a ship's doctor is on board.

Current guidelines

The current international *Guidelines on the Medical Examinations of Seafarers*³ on insulin-treated diabetes emphasise the need for stable, well-controlled blood glucose control and the need for 'full awareness of impending hypoglycaemia, with no reported or observed significant hypoglycaemic episodes within the last year'. Treatment with sulphonylureas or glinides may be subject to restriction dependent on medical review. For example, starting insulin treatment renders a period of temporary unfitness until stabilised, and then may be restricted to near-coastal duties without solo watchkeeping. Regular specialist surveillance is mandatory. Poorly-controlled diabetes, adverse hypoglycaemia experience or 'impairing' complications of diabetes will render unfitness, possibly on a permanent basis.

Present-day responsibility in the UK for standards of health and fitness for those in commercial occupation at sea rests with the Maritime and Coastguard Agency (MCA), covering a range of vessel types from tankers and container ships to cruise liners, passenger ferries and commercial yachts. Medical assessments are undertaken from a register of approved doctors who must take into account whether any identified medical condition could either be aggravated by working at sea or represent an unacceptable risk to others or the safety of the ship.

The *Approved Doctor's Manual: seafarer medical examinations* manual⁴ gives guidance on the current medical standards for diabetes (ADG 4),

specifically to avoid the risk of sudden incapacitation from hypoglycaemia. Evidence is cited that 'failures in the control of diabetes have led to medical emergencies at sea, some fatal, and some instances where there has been a failure of disclosure of diabetes'. A track record of good glycaemic control is taken as a favourable indicator in assessing risk. In particular, regular self-monitoring of blood glucose levels for those on insulin is considered essential.

The MCA UK standards (Box 1), mirroring international guidelines, generally advise, for well-controlled insulin-treated diabetes, a restricted category of fitness for near-coastal duties with no lone watchkeeping. It is conditional that the master/responsible officer is informed of insulin use and an individual risk assessment prior to embarkation is recommended. Despite the need for this measure of restriction and surveillance, MCA guidance has endeavoured to be more understanding and flexible with the needs of employees treated with insulin, including better determination of time periods of duty and ways of adapting to keep the person at work.

Land

Driving on the roads in the UK is governed by many legal powers, including driver competence and personal responsibilities (licensing, highway code regulations, motor insurance) as well as vehicle safety. Medical health is also subject to consideration by legal regulatory framework with recognised responsibilities for both drivers and health care professionals who give expert advice to their patients. A comprehensive reference publication on 'Fitness to Drive', by a former Chief Medical Officer at the Department of Transport,⁵ provides useful guidance on assessment

of various health-related medical conditions including diabetes. Risk with diabetes is considered in respect of physical impairment due to complications of diabetes and, in particular, the risk of cognitive impairment and incapacitation from hypoglycaemia, adversely affecting driving performance – reduced reaction time, inappropriate speeding and braking, lack of attention, increased likelihood of crash, and ultimately potential tragedy. Although assessment of hypoglycaemia risk is the predominant consideration, poor visual acuity consequent to advanced retinopathy, severe peripheral neuropathy or serious cardiovascular disease may also determine a decision of being unfit to drive safely.

With the current drive to mitigate risk of long-term diabetes complications by optimising blood glucose control, the risk of hypoglycaemia increases, with evidence that tighter glycaemic control may be associated with an increased risk of motor vehicle crash.⁶ In contrast, others have found that the overall annual accident rate between non-diabetic and diabetic populations is no different, and conclude that those insulin-treated as a group do not pose an increased risk to road safety.⁷ However, confidential questionnaire enquiries would suggest that many insulin-treated drivers (13% in one survey⁸) have experienced symptomatic hypoglycaemia at some time while driving. As a consequence, diabetes has been deemed by law to be ‘a prospective disability’ and, except for diet-controlled diabetes, to be declared to the licensing authority (DVLA⁹).

Ordinary driving licences (Group 1) are currently period-restricted (up to three years) for insulin-treated drivers, and prior to the EU Directive of 2010, vocational (Group 2) licences were refused for those on insulin.

The recent changes in licensing policy for both of these driver groups have received much attention and certainly some controversy. More recently, focus has been directed to the potential hypoglycaemia risk of insulin secretagogues (sulphonylureas and glinides), particularly with the advent of newer oral glucose-lowering agents less

likely to cause hypoglycaemia (thiazolidinediones and DPP4 inhibitors). One observational study reported comparable rates of severe hypoglycaemia in type 2 diabetes treated with either sulphonylureas or insulin in the short term (less than two years), but nonetheless still much less frequently than with type 1 diabetes.¹⁰ The DVLA now requires Group 2 drivers to notify treatment with sulphonylureas or glinides, whereas Group 1 drivers do not currently need to notify the DVLA. Both groups are advised to understand the principles of safe driving to avoid hypoglycaemia, including blood glucose testing ‘at times relevant to driving’.

New licensing standards

Following a report from the *European Working Group on Diabetes and Driving*,¹¹ an EU Directive was issued with new licensing standards to be adopted by all participant European states, including the UK. These changes will now be familiar to most:

- *Group 1 drivers* (from 2010): ‘no more than one episode of severe hypoglycaemia (defined as requiring third-party assistance and including nocturnal/while asleep episodes [this latter restriction is still under appeal]) within the preceding 12 month period and continued ability to detect onset of hypoglycaemia’.
- *Group 2 drivers* (buses and lorries): the new opportunity for a licence to be issued for insulin-treated drivers provided ‘no episode of severe hypoglycaemia has occurred in the previous 12 months and that full hypoglycaemia awareness remains intact’.

The fitness assessment of Group 2 drivers treated on insulin has been made a three-step process with initial driver submission/self-declaration followed by requested report from the individual’s personal diabetes advisor (usually the general practitioner). If this medical report raises concerns as to fitness to drive, the application does not proceed, but, if it is supportive in principle, then a further assessment by an independent diabetes consultant specialist is undertaken.

Not surprisingly, the stricter criteria for Group 1 insulin-treated

drivers were seen with some concern, and with fears that many might find their licence fitness compromised as a result of the new regulations. Latest data available from the DVLA indicate that, of the total number of Group 1 licence applications for people with diabetes treated by insulin, only a relatively small proportion (<1%) have had their licence either refused or revoked in any one year. In 2014 (January–December), of a total of over 112 000 applications that were processed by the DVLA, 0.6% of individuals had loss of licence due to recurrent severe attacks of hypoglycaemia and 0.3% as a result of lost warning signs of hypoglycaemia. With the even stricter criteria for Group 2 drivers on insulin, many for the first time have been declared fit to hold an occupational licence, but with the three-step assessment process the standard is necessarily tighter – 34% of applicants at initial medical review and a further 15% at independent assessor stage not meeting the required standard of fitness.

Consequences of hypoglycaemia

The consequences of hypoglycaemia while driving can be extremely serious and, sadly, tragic cases are too often recorded. When deemed a consequence of negligence, a fatal accident can be interpreted in court as recklessness sufficient to lead to custodial sentencing. Moreover, it is possible for the law to be interpreted as driving under the influence of a drug, namely insulin – again leading to charge of dangerous driving with lack of due care and attention. If the attendant clinician has knowledge that more than one episode of severe hypoglycaemia has occurred within a 12-month period or that significant hypoglycaemia unawareness is evident, it should be understood that present General Medical Council (GMC) guidelines indicate that it is the clinician’s responsibility to first inform the individual concerned of their statutory requirement to notify the DVLA of their situation. If this advice is not heeded, the clinician, under GMC direction, is obliged to inform the DVLA directly. As public safety is the prime consideration, consent for

disclosure from the individual concerned is not required.

Guidance on the principles of safe driving on insulin

To minimise risk of hypoglycaemia at the wheel, the DVLA has issued guidance on 'principles of safe driving on insulin', which should be part of every given educational opportunity. Although these principles are not actually enshrined in current EU or UK legislation, a failure to have observed due diligence in the event of an untoward accident can be seen as a failure to take personal responsibility for one's diabetes, for which a signed undertaking is part of the self-declaration licence submission. A failure to test and record can, therefore, be interpreted as negligent (Box 2). The principles for safe driving define appropriate blood glucose testing within 2 hour intervals, when and what to eat and when not to drive, specifically when the blood glucose is <4mmol/L or for 45 minutes after an episode of hypoglycaemia has occurred. Clearly, blood glucose monitoring is essential to maintaining adherence to the requirements of safe driving on insulin, and also with other glucose-lowering agents with potential hypoglycaemia risk. Those responsible for prescribing blood glucose strips should be aware that monitoring is needed for driving safety and should be sufficiently supplied for this purpose, and not restricted for overall glycaemic control.

The vast majority of drivers on insulin are entirely conscientious concerning their responsibilities, and willful disregard is exceptional. However, despite widespread publicity of these essential principles of safe driving on insulin, it is remarkable how many surveys continue to show poor awareness, limited understanding, suboptimal adherence and general reluctance to accept the common-sense guidance provided.¹² A plethora of recent questionnaire surveys has been either published or presented at recent professional conferences, all indicating similar observations.^{13–15} Drivers' knowledge of the basic principles still seems remarkably deficient, and difficult to fully understand given the substantial interest in the topic, and

Blood glucose testing on insulin

'Drivers should test at times relevant* to driving and not doing so would be consistent with not having a clear understanding of diabetes and the precautions necessary for safe driving'

DVLA Diabetes Advisory Panel, October 2014

* 'No more than 2 hours before the start of the first journey and every 2 hours while driving'

Box 2. The DVLA's Advisory Panel's guidance. A failure to test and record blood glucose levels can be interpreted as negligent

presumed dissemination of such by health care professionals.

Why is blood glucose measurement so difficult for drivers to undertake?¹⁶ This situation may reflect everyday practical realities, but the matter may still be an educational issue that needs constant reminder and better ways of encouraging positive behavioural change. It is of some concern to note a significant reduction in the reporting of severe hypoglycaemia by people with type 1 diabetes, apparent since the introduction of the new EU legislation, suggesting a concealment of episodes to avoid risk of licence withdrawal.¹⁷ Medical incapacitation at the wheel is a relatively minor proportion of total crash causation on the roads, but mitigating the risk of hypoglycaemia-related traffic accidents (currently about 45 UK police notifications to the DVLA per month) continues to be shared responsibility between driver and health care professional. It should be noted that, in the event of a driving licence having been revoked due to disabling hypoglycaemia, current DVLA policy requires subsequent review of clinical status and of driving fitness to be undertaken only by a consultant specialist in diabetes.

Air

Until recently, insulin-treated diabetes has been regarded as an absolute restriction in terms of medical fitness to fly an aircraft. But with a number of new developments – improved insulin management regimens, structured surveillance and monitoring protocols, and more appropriately determined individualised diabetes care – this limitation has been subject to review by a few aviation authorities responsible for ensuring flight safety. Furthermore,

following the changes in European driving regulations for insulin-treated diabetes (ITDM), it has been recognised that parallel principles for aviation may be similarly applied.

In 2012, a *position paper on behalf of the European Society of Aerospace Medicine* observed that the civil aviation authorities of Australia, Canada and USA were permitting pilots on 'a case by case basis and under strict conditions' to fly while treated with insulin, including at least 15 Canadian insulin-treated commercial pilots flying 'under intensive aeromedical control'.^{18,19}

The UK Civil Aviation Authority (CAA), aware that Air Canada commercial ITDM pilots had been flying without incident within UK airspace, developed their own protocol to review aeromedical certification of ITDM pilots, followed by submission to the European Aviation Safety Agency (EASA).

Specific issues

While identifying common principles across all means of transport – sea, land and air – certain specific issues related to aviation do arise: for example, long-distance flights, requiring scheduled periods of duty and rest, as well as the impact on diabetes management of changing time zones. However, these should be effectively accommodated with modern diabetes therapeutic regimens, and should not be seen as an absolute barrier. Knowing that significant numbers of pilots with insulin-treated diabetes were concerned to move the issue forward, the UK CAA took up the initiative by establishing a prospective plan of individual assessment and protocol guidance, under the direction of a specialist diabetes consultancy panel led by the CAA Medical Officer, Dr Stuart Mitchell.

Medical assessment of pilots

The medical assessment of pilots is based on agreed standards of recognised diabetes management, glycaemic control and the presence or otherwise of complications of diabetes. Potential hypoglycaemia risk is carefully scrutinised and any preceding episode of severe hypoglycaemia or significant impairment of hypoglycaemia awareness will be considered as rendering medically unfit. Review assessments at six-monthly intervals require a recent separate and supportive report from the individual's consultant diabetes specialist and other essential data such as the annual retinal screening report.

The UK CAA medical surveillance routinely includes standard optometry and cardiac screening, and, where appropriate, specialist ophthalmological and cardiological assessments may be undertaken. Although the HbA_{1c} level is noted, particular attention is placed on serial blood glucose measurement, of variability and stability, with surveillance requirements including inspection of operational glucose data recorded in the pilot's flying/duty log book. (Figure 1 shows an example of log book entries.)

The operational protocol

The operational protocol is based on regular capillary blood glucose monitoring to tight standard, with measurement at defined intervals, specifically before reporting and commencing flight duties, at 1 hour intervals during flight, and within 30 minutes of anticipated landing time. The protocol states where an unacceptable glucose reading before duty renders the pilot as unfit to fly on the day concerned, and indicates when appropriate in-flight corrective actions, such as supplementary short-acting carbohydrate, should be taken. Glucose levels measured by the pilot are shown on meter display to the co-pilot, who has been made aware of the circumstances and who confirms that the test has been done. Results are entered into the pilot's data log book return.

At present, only conventional capillary glucose monitoring is specified, with interstitial glucose measurement (continuous glucose

Date and Time:	Flight Phase:			Reading (MMol ⁻¹):	X-Check		Symptoms:	Comments:
	Pre-flight	In-flight	Post-flight		One Check	Two		
ZB 729713				6.6	✓		NIL	
13.01 04 Oct	X			5.7	✓	✓	NIL	
15.53 04 Oct			X	1.0	✓	✓	NIL	
16.39 04 Oct			X	8.1	✓	✓	NIL	Post-swack.
17.06 04 Oct			X	8.2	✓	✓	NIL	
18.18 04 Oct		X		6.7	✓	✓	NIL	
19.05 04 Oct			X	6.8	✓	✓	NIL	
20.09 04 Oct			X	6.8	✓	✓	NIL	
ZB 729713				6.8				
13.52 05 Oct	X			4.8			NIL	CORRECTIVE ACTION - SWACK
14.14 05 Oct	X			5.3	✓		NIL	Post-correction
15.25 05 Oct			X	8.9	✓	✓	NIL	
16.19 05 Oct			X	8.0	✓	✓	NIL	

Figure 1. Example of entries made in the pilot's flying/duty blood glucose log book

monitoring, flash glucose monitoring) considered not yet sufficiently validated for this special circumstance at altitude.

The situation to date

The UK CAA initiative has attracted considerable interest – from individual pilots with insulin-treated diabetes, from other European states, and from the European regulatory body: EASA. As yet, there is no unanimous consensus in Europe and certification has been limited to pilots flying aircraft registered in the UK only. The UK protocol has been considered as robust by the EASA, but wider implementation has been presently withheld until more positive experience has been gained from the UK initiative. Presently, just over 50 pilots, most with type 1 diabetes, have been assessed, the majority (84%) being certificated as medically fit to fly. All have been on modern flexible insulin regimens, mostly MDI and some on insulin pumps. Most have now been assessed several times, evaluating flying experience and with monitoring data during operational procedure being available for critical inspection. The results to date have been encouraging, all pilots so far proving highly motivated and disciplined. In-flight protocol testing has proved compliant and effective, and reassuringly no indication of adverse hypoglycaemia risk has been observed.

In terms of European status, the project is currently under ongoing review – still a research exercise, but with reasonable optimism of eventual accepted policy agreement.

'Would you fly with a pilot on insulin?'

This question was raised in a *Lancet* commentary published on-line.²⁰ Reviewing the available evidence and the safety processes put in place, the authors conclude that they 'will confidently fly with an insulin-treated pilot who has stable glycaemic control, has no substantial disease complications, and is compliant with self-measurement of pre-flight and in-flight blood glucose.' Not all have been persuaded by the initiative,²¹ but, overall, present consensus does recognise that it is the correct direction to take, subject to meticulous monitoring of progress and to rigorous evaluation.

Summary

Only a few years ago, accepted advice in respect of persons whose diabetes is treated with insulin was that work should not be undertaken where sudden onset of hypoglycaemia might pose a risk to themselves or others in potentially hazardous situations. For that reason 'it was not permitted to drive large goods (LGVs) or public service vehicles (PSVs), to fly aeroplanes, drive trains or continue as seafarers'.²² However, within a relatively short subsequent timescale, a significant change in attitude and altered risk assessment – driven by individual determination and underpinned by the Disability Discrimination Act – have led to a more flexible and liberal approach to the employment of individuals with insulin-treated diabetes in certain risk occupations.

In the three domains of sea, land and air, insulin treatment in itself is

Key points

- The Disability Discrimination Act has opened opportunities of employment in professional occupations previously precluded because of diabetes
- Despite stricter EU standards on diabetes and driving, revocation of personal licence (Group 1) has occurred in <1% of drivers with insulin-treated diabetes, but the principles of safe driving on insulin are still poorly understood and insufficiently implemented
- The UK Civil Aviation Authority has taken the initiative of commercial airline pilots with insulin-treated diabetes and accredited medical fitness to fly, subject to individual assessment and adherence to operational protocol
- Blood glucose monitoring is fundamental to surveillance requirements, ensuring public and passenger safety at sea, on land and in the air

no longer an absolute contraindication for those who seek to work within these special circumstances. Structured protocols and strict professional monitoring processes have been put in place, eliminating unreasonable occupational discrimination while ensuring that the safety of others is fully regarded.

Declaration of interests and acknowledgements

Prof Ken Shaw has served as Consultant Advisor (Diabetes) to the UK Maritime and Coastguard Agency (2004–2015), to the Secretary of State for Transport's DVLA Medical Panel (2005–2015), and to the Medical Safety Regulation Group, Civil Aviation Authority (2010–2015).

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(DVLA), and Drs Stuart Mitchell and Sally Evans (CAA), all of whom are most gratefully acknowledged.

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