

## **APPENDIX D**

### **The Medical Panel's Responses to the Screening and Monitoring Issues**

**Response of**

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**REPORT TO THE FEDERAL HIGHWAY ADMINISTRATION'S  
MEDICAL PANEL ON INSULIN -TREATED  
DIABETES MELLITUS**

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## **Introduction**

The Federal ruling providing for the blanket prohibition of individuals with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles in interstate commerce was handed down almost thirty years ago. This ruling reflected the concern that such individuals might pose an increased and unacceptable safety risk stemming primarily from cognitive and other performance decrements induced by hypoglycemia. Viewed almost thirty years later, this decision seems justified and appropriate due primarily to the uncertainties that existed regarding the true dimensions of the risk posed by such individuals. The medical literature of the day certainly did not provide clear guidance to decision-makers. The blanket ban ruling was supported by several organizations, including in 1977, the American Diabetes Association (ADA).

Since then understanding of the factors that contribute to road safety both in the general population as well as in ITDM individuals has expanded. Studies reported during the past three decades have provided fresh and novel insights regarding the epidemiology of motor vehicle accidents involving individuals with ITDM. In addition they have provided more precise estimates of the risk that might be reasonably expected to accompany rule changes, how such potential risks might best be managed as well as the likely practical impact of such changes. The safety records, now available, of ITDM individuals granted intrastate commercial motor vehicle licenses by the DOT of several states has proven both illuminating and reassuring.

The results of basic and clinical research conducted since 1970 have led to a dramatic increase in knowledge regarding diabetes mellitus. This in turn has greatly enhanced our ability to accurately evaluate and effectively manage individuals with the disease. Such advances include, but are not limited to, the development and refinement of precise methods for assessing metabolic control, the provision of new and exciting disease management strategies, better understanding of the causes of complications and insight into both the mechanisms of hypoglycemia and hypoglycemia unawareness and how they may be prevented. Not unexpectedly, the clinical benefits flowing from these advances has added to the rising chorus of criticism of the blanket ban on ITDM commercial vehicle drivers (1).

Accumulated information regarding the favorable risk profile of ITDM commercial motor vehicle drivers combined with an enhanced ability to effectively manage this disease emphasizes the correctness of lifting the blanket ban on interstate commercial driving. It can then be replaced by a provision that evaluates each CMV license applicant on a case by case basis to determine their suitability based upon strict and rigidly enforced initial assessment and ongoing monitoring.

Data regarding risk assessment, combined with the accumulated favorable experience of individual states and advances in disease management has prompted the ADA to reverse its 1977 decision in support a blanket ban on ITDM drivers. The FAA has also adopted a more enlightened approach regarding licensing of private ITDM pilots who have been documented to be in compliance with established standards (2). The Federal Highway Administration Waiver Program for ITDM commercial motor vehicle was introduced in 1992. Under its provisions, drivers who met certain preset criteria were licensed to operate CMVs. This program was prompted in part by the growing evidence pointing to acceptable risk (3). The provisions of the waiver program, which included a plan to prospectively study the performance of these drivers, was abandoned, however, following a decision of the U.S. Court of Appeals (DC) citing a lack of empirical support regarding safety data. The issue is again being addressed under the provisions of The Transportation Equity Act for the 21st Century (TEA 21). Under this act the Secretary of Transportation has been directed to determine if a practical and cost-effective program can be developed which allows some individuals with ITDM to operate commercial motor vehicles. The continued blanket denial of CMV licenses to individuals with ITDM appears to fly in the face of the great bulk of evidence that supports a rule change. The failure, in this modern era of medical care, to deny a case by case review of ITDM applicants for CMV licenses would seem to be at odds with the Americans with Disabilities Act of 1990 which emphasizes that vocational opportunities not be unnecessarily deprived by virtue of disability.

### **Traffic Accidents Rates Involving ITDM Drivers**

In 1965, a retrospective study conducted in California pointed to a 78% higher accident rate and a 39% increase in rates of traffic violations among drivers with diabetes mellitus (4). Another study in the late 1960s suggested a trend towards increased traffic accidents and violations in this group which however did not reach significance (5). Contrasted with these reports was a 1967 study pointing to a 23.5% reduction in traffic violations and a 35% reduction in accident rates among diabetic drivers compared to non-diabetic controls (6). In a 1973 study of medically restricted drivers, no difference in the accident rates of 108 patients with ITDM compared to 1.6 million healthy controls could be identified (7). The results of these studies need to be viewed with some caution due to methodological problems, including the fact that no clear distinction was made between insulin-dependent and non insulin-dependent diabetic drivers.

In a more recent study a trend towards increased accident rates among ITDM drivers was noted which however only reached significance among female drivers (8). Continuing concern that ITDM individuals experienced higher accident rates was not supported by other findings of several studies reported in the late 1980s (9,10,11). Analysis of both accident frequency and severity conducted between 1995 and 1997 by the Federal Highway Administration (FHWA 1999-personal communication) provides further evidence of the overall safety of ITDM commercial motor vehicle drivers. In this report, relatively small increases in crude accident rates and severity in ITDM individuals compared to controls did not reach significance when the data was subjected to a statistical model that adjusted for confounding variables. Not unexpectedly perhaps this study, which attempted to salvage data from the terminated Waiver Program, might also be criticized on methodological grounds. While not having the power that the original study likely would have provided, it does nevertheless provide valuable guidance.

## **Risk Assessment and Management**

Further insight into the potential risks that might result from licensing persons with ITDM to drive trucks was provided in a 1993 report. (12). This study, supported by the FHWA and the National Science Foundation, estimated that 1420 insulin using persons would likely seek CMV licenses in the event that the blanket ban was ended. This included 500 type I and 920 insulin requiring type II patients. The model included estimates of the annual incidence of mild and severe hypoglycemia, the frequency with which this might be expected to occur while driving, and estimating the risks of accidents during such episodes. The conclusions using this model were that 42 extra crashes might be expected to occur annually which would be equally divided among the type I and type II drivers. Obviously the estimate of hypoglycemia incidence was based upon projections which in turn reflected the level of understanding regarding the mechanisms and prevention of hypoglycemia that prevailed almost a decade ago. Current treatment strategies might well be expected to further reduce the incidence of severe hypoglycemia and consequently overall risk.

Risk management analysis, conducted by the same group of investigators led them to conclude that the additional risks likely to result from granting CMV licenses to ITDM are indeed well within the range currently acceptable to society (13). In particular the risks compare favorably with those posed by different vehicle types, driver age and experience as well as adverse highway conditions. The results of another study of traffic accident risk involving large numbers of drivers, including those with epilepsy and diabetes, has also provided guidance (14). While a modest increase in accident rate was observed in ITDM individuals, the attendant risk was felt to fall far short of that which would justify the imposition of regulatory restrictions.

It seems worthy of note that the incidence of accidents on interstate highways is less than half that of other highways (13). It may be reasonable to expect that the shift of travel itineraries to the interstate highway system by ITDM drivers currently engaged in intrastate commerce on demonstrably more hazardous roads might have the effect of lowering overall national accident incidence.

### Hypoglycemia and Hypoglycemia Unawareness

Brain function is dependent upon a continuous and adequate supply of glucose delivered by the circulation. Unlike most other tissues, the brain is incapable of either using alternative fuels or of storing glycogen for its metabolic needs. Hypoglycemia deprives the brain of its fuel source that if not reversed, leads to deterioration of higher cerebral function resulting in cognitive impairment, seizures, coma (and ultimately even death). These symptoms are manifestations of so-called neuroglycopenia. Warnings of such impending events are usually preceded by so called adrenergic symptoms that include sweating, tremor, palpitations and hunger. Oral treatment with absorbable glucose preparations rapidly reverses such symptoms and thereby prevents progression to severe hypoglycemia. This may be defined as hypoglycemia that results in impaired consciousness or cognitive function and requires the assistance of others to treat.

Older studies point to high rates of hypoglycemia among insulin-treated patients while they are driving (44,45). Despite this, the number of additional crashes that result from mild insulin reactions has proven small particularly among insulin treated type II drivers (12). This may be explained by the occurrence of early warning adrenergic symptoms which allows mildly hypoglycemic drivers sufficient time to pull over and consume rapidly absorbable glucose thereby preventing progression to more advanced neuroglycopenic stages. Some ITDM individuals however have little or no warning of impending severe hypoglycemia, a condition referred to as hypoglycemia unawareness. The importance of recognizing and treating early warning symptoms is emphasized by studies pointing to cognitive impairment and driving skill decrements in individuals with more advanced stages of hypoglycemia (18,44).

Awareness of hypoglycemia and the ability to counteract it requires the complex interaction of both the central and autonomic nervous systems combined with normal functioning of counter-regulatory hormones including epinephrine and glucagon which act to rapidly increase blood glucose levels (19,20,21). Predisposing factors leading to hypoglycemia have been identified, as have approaches that limit their frequency and severity (22,23,24). The results of the Diabetes Control and Complications Trial (DCCT)



pointed to dramatic decreases in frequency of chronic diabetes related complications among tightly controlled diabetics (25). However, tight diabetes control was accompanied by a tripling in the frequency of hypoglycemia. This worrisome finding triggered further research aimed at identifying the mechanisms of hypoglycemia unawareness and how it might be prevented and treated. These new and ongoing research efforts have shed new light on this important phenomenon (22,26,27). It appears that patients with tightly controlled diabetes maintain normal rates of brain glucose uptake from the circulation despite systemic hypoglycemia (27). This provides only short benefit and is ultimately maladaptive as the maintenance of normal brain metabolism dampens down the protective responses mediated by the glucose raising effects of counter regulatory hormones. Modern management of diabetes therefore aims to maintain good metabolic control, reflected in hemoglobin A1C levels of less than 7% (nondiabetic less than 6%) while meticulously avoiding hypoglycemia because of its potential of further blunting awareness (26). Hypoglycemia unawareness should it occur may be reversed through the avoidance of subsequent hypoglycemia (22,26,29,30).

There is recent evidence that the threshold for release of the contra insulin hormones, epinephrine and norepinephrine as well as ACTH and cortisol, occurs at higher plasma glucose levels in NIDDM compared to IDDM patients (31). This suggests that the risk of progression of hypoglycemia among type II patients is considerably less. This is of relevance as two-thirds of ITDM driver applicants would likely have type II disease (12)

Strategies whereby hypoglycemia may be avoided have been the subject of a recent comprehensive review (22). These include avoidance of nocturnal hypoglycemia by measures that include the use of bedtime intermediate insulin, combined with rapid-acting lyspro insulin administered at the start of meals or through the use of newer delivery systems and dosage schedules. Clearly these measures will only be successful if patients are appropriately instructed in the nuances of their use and show both the aptitude and the willingness to apply them. This requires sound and effective educational methods combined with the ability to objectively assess the impact of such efforts on the patient.

### Newer Diabetes Management Tools

The management of diabetes was revolutionized by the emergence of tests that permitted assessment of overall metabolic control (32) and by the availability of accurate, relatively inexpensive glucometers that provide patients the opportunity for self-monitoring blood glucose levels (SMBG). Newer glucometers equipped with memory and the capability for downloading via modem also provide enhanced opportunities for effective diabetes management.

A particularly exciting and promising development of late has been the development of new glucose sensing methodologies that do not require frequent finger sticks. One such device called the GlucoWatch biographer extracts interstitial fluid through the skin by reverse iontophoresis, the glucose content of which is then measured electrochemically. Excellent correlation of glucose levels by this technique with those determined by conventional methods has recently been reported (33). This device which is currently undergoing fast track approval by the FDA is likely to become available within a year and will permit non-invasive assessment of glucose determinations every fifteen minutes for a period of twelve hours at which point re-calibration of the sensor is required. This, however, will reduce the frequency of blood glucose determinations to a maximum of twice daily. The expected cost of the sensor (\$300) as well as the cost of the disposable auto-sensor pads (\$4.00 daily) compares favorably with the cost of current technology. The reduced need for blood testing by fingerstick is likely to enhance compliance and it would appear that such a device will have particular application among pilots, operators of hazardous equipment as well as commercial motor vehicle drivers and others in whom avoidance of hypoglycemia is particularly desirable.

The opportunities that these technologies and treatments provide to the well-motivated and disciplined patient to pursue a normal life and career are great. They lend further support to the ADA policy statement on employment, recently re-articulated (34), which states that "any person with diabetes whether insulin-dependent or non-insulin dependent should be eligible for any employment for which he or she is otherwise qualified".

## Medical Screening

Patients with diabetes have an increased risk of complications affecting the eyes, kidneys, nerves and cardiovascular system. The presence of such complications may seriously impair functional abilities including the safe operation of commercial motor vehicles. Most often a detailed medical history and physical examination can detect the presence of such complications and are therefore an essential component of a screening program (35,36).

The presence of peripheral and particularly autonomic neuropathy may seriously impair driving ability and may be detected clinically using guidelines established by the specialty organization (37). The finding of autonomic nerve dysfunction to a degree that results in postural hypotension and syncope should result in denial of a CMV license. The standard of care, that requires a baseline electrocardiogram (36), should probably be supplemented in ITDM commercial vehicle drivers by non-invasive stress testing of coronary artery status. This seems justified by the higher prevalence of silent myocardial ischemia reported in most studies of coronary artery disease in diabetic patients (38). This requirement should certainly apply to ITDM individuals whose duration of disease exceeds 10 years or who have co-existent risk factors for atherogenesis.

Current requirements for visual acuity (greater than 20/40 in each eye either corrected or uncorrected) apply equally to both diabetic and nondiabetic drivers seeking CMV license. Ophthalmologic assessment should also include a dilated pupil fundus examination and, when appropriate, assessment of color perception. Assessment of renal function should also be included in the manner outlined in the standards of care (36).

Screening history should attempt to determine the frequency and severity of hypoglycemia as well as the ability of the patient to perceive hypoglycemic symptoms. If hypoglycemic unawareness is present, licensure should be denied. Re-evaluation may be considered if, after a six to twelve month period of meticulous control, the patient has regained the ability to perceive early warning adrenergic symptoms. Recurrent severe hypoglycemia despite optimal treatment and patient education is reason for denial. Mild hypoglycemic symptoms occurring infrequently (2 or less/month) should not trigger

denial assuming the patient self treats appropriately. All ITDM drivers should be required to carry with them a source of rapidly absorbable glucose that is stored in an accessible location.

Assessment of metabolic control is achieved by determining hemoglobin A1C levels supplemented by the review of SMBG test results stored in the glucometer memory. It would be expected that patients test glucose levels four times daily. These criteria, while strict, can be achieved through effective patient education and often through avoidance of known risk factors for hypoglycemia (23).

Blood glucose awareness training (BGAT) (39) should also be recommended for CMV license applicants. The efficacy of such training and the use of a low blood glucose index have been confirmed in recent reports (40,24). They have not, however, as yet been applied to larger populations of ITDM individuals.

Initial screening should also include assessment of the individual's overall understanding of their disease, evidence of mastery of the techniques of accurate SMBG testing and insulin dose adjustment. Demonstrated familiarity with the FHWA rules regarding ITDM drivers should also be a requirement for CMV licensure. It is to be expected that ITDM individuals who engage in interstate commerce would be considered eligible for licensure by the FHWA provided that they have a clean driving record over the preceding three years, have no other disqualifying physical conditions and have demonstrated both the willingness and ability to control their disease over that period of time.

Expectations regarding the physicians performing the screening would be that they have up to date knowledge regarding diabetes evaluation and management including the ability to detect complications at an early stage. The relatively small number of ITDM individuals expected to apply for a license should Federal regulations change (12) makes assessment by an endocrinologist a practical as well as desirable option. The DOT in turn would be expected to maintain a registry of endocrinologists who have received a copy of the standards and have demonstrated familiarity with their content.

Assessment for the presence of co-morbidity, which might impair driving performance, should also be sought at the time of the initial evaluation. Somnolence while driving has been documented among long haul truck drivers (41) and is closely

linked to either inadequate quantity or poor quality of sleep. Sleep apnea (SA) has a higher prevalence rate among diabetics likely reflecting an increase in body mass index known to be a risk factor for both conditions (42). Inquiry into the possibility of daytime somnolence should be sought in ITDM vehicle operators with increased body mass index and pursued when appropriate with overnight oximetry or polysomnography.

A rule that would require diabetic drivers be accompanied by another individual seems over-restrictive particularly if the individual has fulfilled all other criteria for CMV licensure. The expense associated with such a ruling would likely be prohibitive and prove difficult to enforce.

### **Monitoring Protocol**

Specific treatment goals for blood glucose and hemoglobin A1C levels outlined in the ADA Standards (36) should also apply to ITDM commercial vehicle drivers. As noted earlier, the results of the DCCT reported in 1993 focused attention on the question of whether hypoglycemia is the price that must be paid for more intensive metabolic control. The results of several studies reported since then have served to further define the mechanisms of both hypoglycemia (27) and hypoglycemia unawareness (26). It is apparent that hypoglycemia induces unawareness of early warning adrenergic symptoms. This has led to the introduction of more novel treatment regimens using newer insulin products that have more favorable pharmacokinetic profiles as well as newer insulin delivery systems. These have convincingly shown that the goals of good metabolic control and hypoglycemia prevention are not mutually exclusive (22,26,40). It would be unnecessary and indeed unacceptable therefore to advise or encourage CMV drivers to aim for higher Hgb A1C levels in order to lessen the risks of hypoglycemia. Whether such levels of care can be achieved and sustained in ITDM individuals engaged in interstate commerce has not been determined. There is every reason to believe, however, that it indeed can be. It is reasonable to expect that it may be for several reasons. It is to be expected for example that strict monitoring provisions will likely discourage individuals lacking the ability or motivation to achieve good diabetes management from applying for a CMV license. Modest elevation of the Hgb A1C should not place

licensure at risk. Values of Hgb A1C that consistently exceed 9% should serve as a red flag for the FHWA medical examiner and should prompt more detailed review and intensified education.

Documentation of good control over a one year period should be followed by quarterly evaluations to include a limited and focused history and physical examination, review of SMBG results, as well as hemoglobin A1C values. While this is somewhat more frequent than called for in the standards, this would appear to be justified for such individuals. Specific expectations should include checking blood glucose levels the hour before commencing a journey and then at least every four hours while driving. Such a strategy would also permit documentation of compliance with the guidelines regarding frequency of glucose testing while engaging in interstate driving. This would include, for example, downloading of stored SMBG results. This would permit screening for compliance with guidelines regarding frequency and timing of SMBG determinations.

A more detailed annual examination that follows the format provided for in the standards for initial examination (36) also seems appropriate. Support for this is provided by the experience gained during the waiver program when it was found necessary to revoke licenses because of the emergence of chronic diabetic complications detected at the time of follow up examinations.

The monitoring program will also be expected to include ongoing patient education consistent with the National Standard for Diabetes Health Management. These educational programs are likely to be more effective if taught by Certified Diabetes Educators (36). Booster educational sessions among individuals undergoing BGAT training has been shown to result in lower rates of both hypoglycemia and auto accidents (43).

Guidance regarding the need for additional testing should be made on the basis of results of monitoring examinations and recommended laboratory tests. This information would be formally reported to the FHWA and would supplement information on driving performance that the agency would have on the CMV licensees.

## Conclusions

Remarkable advances in both the evaluation and management of patients with ITDM combined with favorable estimates of the risk such individuals might pose makes the blanket ban on interstate commercial driving both redundant and unnecessary. It should not, however, be simply replaced by blanket approval but rather by case by case assessment of ITDM individuals applying for CMV licensure. The strict nature of the recommended medical criteria will likely have the effect of identifying individuals who have clearly demonstrated superior skill and motivation in managing their disease and in so doing removing any undue risk to either themselves or other road users. Continued denial of CMV licenses to such individuals would seem discriminatory and certainly not in keeping with the letter or the spirit of the Americans with Disabilities Act. The recommendation included in this report would assure fair treatment of ITDM commercial vehicle operators while protecting the public good.

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