B. Chantelau, et al. (Chantelau 1990) surveyed the accident and moving violation experience of 241 insulin-treated patients in Germany over a two-year period of time. Accidents in this report were defined as road crashes that came to the attention of the German police (producing injuries or more than 3000 DM in damage) and thus excluded minor collisions.

Ten accidents in the report were definitely related to hypoglycemia. Another six were suspected, but could not be substantiated. The estimated incidence of hypoglycemia-related car crashes was about 3 per 100 insulin-treated drivers per year. Based upon this data, the number of hypoglycemia-related road accidents for the insulin-using cohort would be expected to amount to at least 43 per year.

$$\text{E (accidents)} = \text{incidence of hypoglycemia-related car crashes} * \text{number of drivers}$$

IDDM: E (accidents) = 3/100 drivers * 500 drivers = 15

Insulin-using NIDDM: E (accidents) = 3/100 drivers * 920 drivers = 28

C. The third alternative approach considers the number of accidents expected from the perspective of the number of hypoglycemia-related accidents per unit of exposure (miles driven). Data have become available on the rate of hypoglycemia-related accidents per mile driven from three studies. One is of insulin-treated patients in Germany (Chantelau 1990, personal communication), the second from a study of insulin-treated diabetics in Scotland (Eadington 1989, personal communication), and the third from a study that we have done in Pittsburgh (Songer 1988). All three reports were characterized by small sample sixes and mileage (kilometer) data provided by the participants. A summary of the crash rates per mileage driven from these reports is presented below.

Study	N[1]	time period	hypoglycemia related accidents	total miles driven in the study	hypoglycemia related accidents per 10^6 miles
Chantelau	241	2 years	10	~ 5,693,450	1.76
Eadington	166	8 years	9	~ 10,465,920	0.90
Songer	127	1 year	2	1,501,648	1.30

1 sample size

All three studies provide roughly similar estimates of the expected number of hypoglycemia-related accidents per 1,000,000 miles driven. The rate of such incidents, on average, is suggested to be near 1.32 accidents per 10 miles driven. The number of accidents expected **were** calculated as below. The total among both IDDM and insulin-taking NIDDM drivers amounts to 85 per year.

E (accidents) = rate of hypoglycemia related accidents per mile driven * mean number of miles driven * number of drivers

	IDDM	insulin-using NIDDM
Rate of h oglycemia-related accidents per 10miles driven	1.32	1.32
Average number of miles driven by a CMV operator per year'	45,000	45,000
Number of diabetic drivers expected	500	920
Number of accidents due to hypoglycemia	30	55

Summary : The number of accidents related to the occurrence of hypoglycemia range in these estimates from 42 to 191. Under normal conditions, the expected number of accidents among the 1420 diabetic drivers would be about 11 (assuming an accident rate of .785 percent per person per year in the CMV population). It would appear that the risk for hypoglycemia-related accidents is at least 3.5 times higher than that expected in the general CMV-driving population.

However, these estimates reflect the number of accidents expected if all insulin-using drivers, who were otherwise medically qualified to drive, were licensed to operate CMVs. No consideration is given to the impact of disqualifying factors related to diabetes (other than complications).

Identification of the risk factors for hypoglycemia may allow a licensing agency to **screen** for drivers at high risk for hypoglycemia-related road crashes.

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1 FHWA estimates

4. The Role of Risk Factors for Hypoglycemia in Licensing Recommendations

The accident estimates presented so far have considered the experience of diabetic drivers from the perspective of what might occur if there were no regulations (direct or indirect) regarding the risk for hypoglycemia. This estimated experience may not mirror the case in reality, as evaluation guidelines specific to diabetes and hypoglycemia are under consideration for all future applicants. These guidelines would presumably further reduce the likelihood of hypoglycemia occurring while driving. In this part of the report, we will examine what role risk factors for hypoglycemia may play as screening tools for reducing hypoglycemia-related accidents.

Risk factors of importance suggested by the literature include a history of severe hypoglycemia, hypoglycemia unawareness, diabetes treatment regimes, the type of diabetes, strenuous activity and missed meals. The relationships of the amount of insulin used, age, and duration of diabetes to the frequency of hypoglycemia, respectively, are inconsistent.

The general picture that emerges on hypoglycemia indicates that the strongest and most consistent determinant of risk for severe hypoglycemia is a history of previous severe episodes. Patients with severe hypoglycemia tend to report more previous episodes than those without severe reactions. The loss of awareness to the symptoms of hypoglycemia is another powerful risk factor for the development of severe reactions. Diabetics without warning symptoms of hypoglycemia are more likely to suffer severe reactions than those with warning symptoms.

Evaluation of the treatment-related variables suggests that the risk for hypoglycemia is much higher for individuals undertaking intensive management of their blood glucose levels. Persons trying to achieve physiologically normal blood glucose levels have more episodes of hypoglycemia than those whose approach to blood glucose control is not as strict. Moreover, persons with a history of severe reactions who are put into strict diabetes control regimes appear to be the most likely to develop future hypoglycemic episodes.

Quite separately, it has been noted that differences in the frequency of severe hypoglycemia exist by the type of diabetes present. Insulin-dependent diabetics have an increased propensity for severe reactions than insulin-using NIDDM cases. This relationship, however, may be due to differences in the treatment regimes, hypoglycemia unawareness, and history of reactions between individuals with the two types of diabetes. There is still a great deal more to learn about the interrelationship between these and the other risk factors for hypoglycemia.

This includes the contributions of exercise and missed meals to hypoglycemia as well. Plenty of evidence demonstrates that both can, and do, contribute to the risk for hypoglycemia. What remains elusive, however, is the extent to which these factors might actually affect the rate of hypoglycemic reactions in the free-living diabetes population, let alone a CMV licensed population.

The focus throughout this section will be on the risk factors for severe hypoglycemia and their possible contribution towards the reduction of hypoglycemia-related road accidents. Since the majority of road accidents related to hypoglycemia are probably those resulting from severe

reactions and the number of predicted accidents from mild hypoglycemia was quite low it is likely that regulation of the elements related to severe hypoglycemia would bring about the largest influence on road accidents.

Prior Episodes of Severe Hypoglycemia : The factor that could potentially be the most useful for regulation is that of a history of severe hypoglycemia. Patients with severe hypoglycemia have a significantly higher number of previous severe episodes than do control subjects (Bergada 1989, DCCT 1987). One approach to screening may be to exclude from licensure any person who has had one or more severe reactions during a defined period of time, such as one year, two years, or five years. The impact of this action upon accidents can be fairly easily identified, as a number of studies have reported data on the frequency of severe reactions (Table 5).

Table 5

Percent of Diabetes Population with Severe Hypoglycemic Reactions

Study	Percent with Severe Reactions	Time Period
Ward, 1990	17	one year
Hepburn, 1990	31	one year
Bergada, 1989	7	one year
DCCT, 1987	10	one year
EDC study, 1986	11	one year
Casparie, 1985	7	one year
Muhlhauser, 1985	15	18 months
Goldgewicht, 1983	26	one year
Basdevant, 1982	30	one year
Potter, 1982	9	one year
Goldstein, 1981	4	18 months

As shown, these data are quite varied. Examination of the studies in more detail suggests that a number of reasons may explain the differences seen. These include variations between the studies in the way severe hypoglycemia was defined, in the ages of the patients studied, in the representativeness of the cohorts. and in the treatment regimes used[1].

[1] the DCCT data presented are those for the standard treatment group

One obvious reason for variation suggested by the review is the definition of severe hypoglycemia used in the studies. Potter, et al. defined severe hypoglycemia as reactions that required hospitalization. Muhlhauser, et al. defined severe hypoglycemia as episodes characterized by a loss of consciousness. The vast majority of studies, however, defined severe hypoglycemia as those reactions that needed external assistance (help from another person), some of which did not require hospitalization or lead to a loss of consciousness.

The largest reason for the variation was probably due to differences between the cohorts under study themselves. The average age of the patients studied, for example, differs throughout the reports listed. Two studies (Goldstein 1981, Bergada 1989) evaluated adolescents with IDDM. Both found relatively low rates of severe hypoglycemia. Adolescents and young adults may be less likely to have severe episodes since there has been little time for the impairment of hypoglycemia awareness to ensue.

The representation of patients studied could also contribute to the differences seen. Responses of individuals identified from medical locales, such as diabetes clinics, may be biased since the diabetics attended these facilities in order to seek health care. Insulin-treated diabetics who do not have severe reactions may have less reason to seek health care. Indeed, data from the EDC study indicate that persons visiting a doctor within the last year had a higher frequency of severe reactions than those who did not see a doctor (0.31 episodes&r vs. 0.22).

Five of the studies (Bergada, DCCT, Muhlhauser, Goldgewicht, Goldstein) focused entirely upon insulin-dependent diabetics. The remainder, exempting Casparie, were primarily composed of IDDM patients. Thus, the data reported are likely to reflect the experience of Type I diabetics rather than insulin-using Type II patients. Casparie provides the only data on the percentage with severe reactions by type of diabetes. In that report, 8.5 percent of the IDDM and 4.5 percent of the insulin-treated NIDDM patients had one or more severe episodes of hypoglycemia.

The average percentage of the cohorts studied with one or more reactions a year is approximately 15 percent. Given the likely over-representation of reactions identified from clinic populations, the under-representation of reactions defined by hospitalization, and the 11 percent figure suggested by the EDC study, this 15 percent figure is probably a good approximation of that expected for the IDDM population.

The rate for the insulin-treated NIDDM population is more subject to debate as only one report to date has provided information on its possible impact. An approximated measure for NIDDM drivers can be determined by applying the ratio of severe hypoglycemia among insulin-treated NIDDM and IDDM patients from this report to the best estimate of the frequency of severe hypoglycemia in IDDM subjects without complications (4.5/8.5 = x/15). The percentage of the insulin-treated NIDDM population with one or more episodes of severe hypoglycemia then would be close to 8 percent.

If the insulin-using applicants for CMV [illegible] were screened on the oasis of the presence of severe hypoglycemia within the last year and were eliminated from

consideration if such a history was demonstrated, then the number of IDDM drivers expected to be licensed might be reduced by about 15 percent and the number of insulin-treated NIDDM drivers might be reduced by approximately 8 percent. The extent of this reduction depends upon the degree of any self-selection by ITDM drivers themselves, and the ability of medical records to identify those with previous episodes of severe hypoglycemia.

The second, and more important, point relevant to this discussion is that the majority of severe episodes of hypoglycemia reported in the literature are accounted for by a minority of the population, many of whom have a history of severe reactions. It could be expected that the number of episodes of severe hypoglycemia present among those diabetics qualified to drive (after screening for a history of severe reactions) would be significantly reduced.

This notion is shown quite clearly in the data available from the EDC study. When all diabetics without complications were considered, the number of severe reactions was approximately 0.31 per person per year. If the 15 percent with one or more severe episodes of hypoglycemia within the last year are excluded, the number of severe reactions expected falls to 0.16 per person per year (Table 6).

Table 6

Number of Severe Episodes of Hypoglycemia (per person per year)
in the EDC Study Before and After a Screening for
a History of Severe Reactions in the Last Year

Before			After		
n	Frequency	Rate	n	Frequency	Rate
0	1/day	0.31	0	1/day	0.16
0	1-2/week		0	1-2/week	
3	1-2/month		0	1-2/month	
154	< 1-2/month		102	< 1-2/month	
209	never had one		209	never had one	

Using the before and after screening difference in the number of severe episodes of hypoglycemia from above, an approximated rate may be determined for the insulin-treated NIDDM drivers)0.16/0.31 = x/0.18). On this basis, we estimate that the expected number of severe reactions among insulin-treated NIDDM drivers after screening would be close to 0.09 reactions/person&ear.

The number of accidents due to severe hypoglycemia expected among drivers without a history of severe reactions within the last year is calculated to be 20?year. This represents approximately 50 percent fewer accidents due to severe hypoglycemia than that shown before. The reduction is mainly due to the substantially lower number of severe reactions expected, rather than a lower number of qualified drivers.

	IDDM	Insulin-using NIDDM
Number of severe reactions expected per person per year	0.160	0.093
Number of severe reactions expected while driving/person/year	0.032	0.019
Likelihood of severe reaction resulting in an accident	~0.67	~0.67
Number of diabetic drivers'	425	846
Number of accidents expected	9	11

It is important to point out that the estimates shown above are independent of the influence of the other risk factors for severe hypoglycemia. At present, there are limited data available on the interactive associations between the risk factors for hypoglycemia. In the report by Hepburn and colleagues, about 56 percent of the cohort with severe reactions in the last year had hypoglycemia unawareness. There is no information on the extent of such interactions that might explain the number of severe reactions expected among those remaining diabetics still eligible to drive, or the likelihood that severe reactions might result in an accident.

Hypoglycemia **Unawareness** : The loss of awareness to the early warning signs of hypoglycemia is another strong element in the development of severe hypoglycemia. Data from Scotland (Hepburn 1990) suggest that there is a clear relationship between unawareness and severe reactions. Ninety-one percent of patients in the study with a total absence of awareness to hypoglycemia had one or more severe reactions within the last year. This compares to 69 percent of the patients with a partial awareness to hypoglycemia and 18 percent of the patients with a normal awareness. As such, another approach to licensing regulation may be to exclude from licensure any person with partial or complete loss of warning symptoms to hypoglycemia. Much debate remains over whether hypoglycemia unawareness can be easily or accurately identified on a large scale through a medical examination or controlled testing.

Two reports (Hepburn 1990, Ward 1990) have placed the prevalence of hypoglycemia unawareness (defined as impaired or total absence of symptoms) at 23 to 50 percent of the insulin-treated population. Both studies used patient-reported information on the presence or absence of symptoms during hypoglycemia. The Hepburn data were also

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1 number of driven without complications multiplied **by 0.85 and 0.92** repectively

followed up with clinical tests on acute insulin-induced hypoglycemia in 23 subjects. These tests appeared to confirm the self-reported assessments.

Both studies also were based upon insulin-treated patients who attended diabetes clinics. Their findings may not represent the experience of the insulin-treated population. Additionally, it is likely that some of the respondents included in the reports had diabetes complications and would be ineligible for CMV licensure. Since the duration of diabetes is a risk factor for the development of both complications and hypoglycemia unawareness, it is conceivable that hypoglycemia unawareness may be more prevalent among individuals with complications. Thus, it is not clear if the frequency of hypoglycemia unawareness in the general diabetes population would be similar to that for the diabetes population expected to qualify to drive CMV.

Forsaking the impact that this limitation may present, we will assume that the prevalence of hypoglycemia unawareness in the insulin-treated population qualified to drive will be close to the estimate of Hepburn and colleagues roughly 25 percent. More studies are needed to confirm this figure.

As discussed earlier, the findings of three reports (Hepburn 1990, Bergada 1989, Duncan 1990) suggest that nearly 67 percent of all severe reactions have no early warning signals. If the insulin-using applicants for CMV licenses were screened and disqualified on the basis of the presence of hypoglycemia unawareness, then the number of severe hypoglycemia expected in the remaining drivers might be about 67 percent lower than that seen if there were no regulations at all.

What might such a regulation mean with regard to the likelihood of severe reactions leading on to road accidents? The disqualification of drivers with hypoglycemia unawareness might suggest that all future episodes of severe hypoglycemia would have warning symptoms. As mentioned, warning symptoms could potentially provide sufficient time for an individual to stop driving. A great deal of uncertainty, however, remains over how this early warning system would actually relate to the prevention of accidents. Severe hypoglycemia may still be hazardous, even with the presence of warning symptoms, if the operator is unable to park the vehicle or is unwilling to pay attention to the warning signs.

The only data available on the likelihood of hypoglycemia leading to accident are the data from Scotland on diabetic automobile drivers mentioned earlier. In this study (Eadington 1989), approximately 3.3 percent of the hypoglycemic episodes that occurred while driving resulted in an accident. Both mild and severe reactions are included in the figure, although the authors believe that the majority of accidents probably followed episodes of severe hypoglycemia while driving.

Much mention has been made of the fact that driving a CMV is very different from driving a private automobile. A CMV operator must often perform many different types of driving in heavier vehicles and in all types of weather conditions. It is also common for CMV drivers to spend long hours on the road and be expected to help in loading and unloading the vehicle. An estimate for the likelihood of hypoglycemia while driving leading to accident may be quite different for a CMV operator.

Given this circumstance and the limited data on the likelihood of severe hypoglycemia leading to road crashes, estimates of the number of accidents expected if a regulation existed regarding hypoglycemia unawareness were determined over a range of possible values (Table 7). The number of accidents expected due to severe hypoglycemia, if screening for the loss of hypoglycemia awareness were implemented, are shown below

	IDDM	Insulin-using NIDDM
Number of severe reactions expected per person per year	0.102	0.059
Number of severe reactions expected while driving/person/year	0.021	0.012
Likelihood of severe reaction resulting in an accident	0.033	0.033
Number of diabetic drivers	375	690
Number of accidents expected	0.3	0.3

Table 7

Number of Accidents Expected if a Screening Program Based on Hypoglycemia Unawareness Were Implemented by Type of Diabetes and Likelihood of Severe Hypoglycemia Causing an Accident

Chance of Severe Reaction Leading to Accident	IDDM	Insulin-using NIDDM
0.033	0.26	0.27
0.066	0.52	0.55
0.100	0.79	0.83
0.280	2.21	2.32
0.560	4.41	4.64
0.670	5.28	5.55

2 the breakdown of the prevalence of hypoglycemia unawareness and the percentage of severe reactions without warning symptoms by type of diabetes are not known. The accident estimates, then, assume that the impact of both conditions will be similar between the two classifications.

3 rate for complication-free applicants multiplied by 0.33

4 number of driven without complications multiplied by 0.75

These figures are substantially lower than those expected if there was no regulation at all. Again, the reduction is mainly due to the lower number of severe reactions expected with regulation. This might suggest that many hypoglycemia-related accidents could be reduced through a process focusing on hypoglycemia unawareness. There is not, however, an easy test to accurately detect individuals with unawareness to hypoglycemia. As such, the history of severe hypoglycemia may be a far better indicator for regulatory purposes. The report by Hepburn, et al. found that 75 percent of the respondents with hypoglycemia unawareness had a history of severe reactions as well.

Treatment Factors : Diabetes is characterized by abnormally high concentrations of blood glucose. In the short-term, this can lead to ketoacidosis and coma if left untreated. In the long-term, hyperglycemia is associated with an increased risk for diabetic complications, including retinopathy, nephropathy, and macrovascular disease. These complications contribute to an eightfold to tenfold increase in risk for death among individuals with IDDM (Dorman 1984).

The primary goal of medical therapy for individuals with diabetes is to achieve blood glucose control. Strict metabolic control means getting the blood glucose values to a near normal (physiologically) level. Treatment regimes have been designed to reduce blood glucose values both in the short-term and long-term so that the consequences of diabetes may be postponed or foregone.

The greatest difficulty with regards to diabetes treatment and CMV operation is that efforts to improve blood glucose control to levels that approximate those seen in the non-diabetic population appear to greatly increase the risk for hypoglycemia. Several studies suggest that diabetics trying to achieve normal blood glucose values have more episodes of severe hypoglycemia than those whose approach to blood glucose control is not as strict. In the EDC study, insulin-dependent diabetics with near normal control of blood glucose (HBA_1 values < 9.0) had a higher rate of severe hypoglycemia than those with less strict control of blood glucose (HBA_1 values > 9.0) (0.54 reactions/person/year vs. 0.25). Metabolic control which achieves normal glycemia may actually increase the risk for road accidents.

Self-monitoring of blood glucose values is now an Important component of diabetes treatment. The wide availability of home blood glucose monitors and testing strips allows an individual to accurately follow his or her blood sugar levels and take the action needed to maintain metabolic control. Blood glucose monitoring has been suggested as a special item of interest with regards to CMV driving because it may reduce the risk for hypoglycemia.

There is little evidence to indicate that self-monitoring of blood glucose can prevent severe hypoglycemia. Data from the EDC study demonstrate that diabetics who tested their blood glucose levels once a day or more had a higher rate of severe hypoglycemia than those who tested less frequently (0.36 reactions/person/year vs. 0.18). This finding is probably due to the increased reliance upon blood glucose testing among individuals trying to achieve normal glycemia. Self-monitoring of blood glucose, however, may be quite useful for CMV drivers in that it can make them aware that they are in, or might be entering into, a hypoglycemic reaction. This early awareness could avert an accident.

The regulatory approach to treatment factors in diabetes may be different from that seen for hypoglycemia unawareness and the history of severe hypoglycemia. Both of these strong risk factors for severe reactions are more or less permanent states. They are not going to disappear to any great extent. Treatment factors, however, can be easily changed or implemented and monitored by the physician treating the diabetic patient. A treatment regime that is discovered to increase the chance for severe hypoglycemia, for example, can be changed to one that places the individual at a lower risk level. Aptitude in SBGM may also be required of all applicants.

The extent to which treatment-related variables may be related to road accidents is not known and is difficult to estimate given the lack of data on the prevalence of their use in the free-living diabetes population. This is particularly true for the insulin-using Type II diabetics, where representative data on variables describing treatment and metabolic control are hard to find.

Type of **Diabetes** : Differences in the risk for severe hypoglycemia appear to exist by the type of diabetes. The evidence to date indicate that individuals with IDDM have more severe reactions than those with insulin-treated NIDDM. However, there remains a great deal more to learn about this association. It is entirely possible that the difference observed could be due to differences in hypoglycemia unawareness or treatment regimes between the groups. Because of this limitation, licensing regulations based upon the type of diabetes that an individual is diagnosed with would appear to be premature.

Exercise and Missed Meals : Exercise and missed meals are also risk factors for hypoglycemia to the extent that they affect the balance between injected insulin and carbohydrate intake and absorption. The probability that strenuous activity or missed meals will lead to hypoglycemia, however, is not known. Evidence from several studies has linked these elements to the development of severe hypoglycemia.

Bergada, et al. found that exercise was the probable cause for about 36 percent of the severe reactions that occurred among their patients. Missed or delayed meals were probable contributors to 32 percent of the severe episodes. Similarly, Ward and colleagues reported that approximately 33 percent and 20 percent of the severe reactions recorded were due to unplanned exercise and missed meals, respectively. A review of 100 insulin-treated diabetics who collapsed at the wheel of a motor vehicle because of hypoglycemia found that a missed meal was the cause in 31 percent of the drivers, and unusual effort was the cause among 14 percent (Taylor 1985). Twenty-seven percent of the collapses were unexplained.

The extent to which exercise and missed meals would contribute to the risk for severe hypoglycemia in diabetic CMV drivers is also not known. It is a well-known fact that unplanned exercise and delayed or missed meals are a part of life when driving a CMV. This could mean that the chance for hypoglycemia may be increased for diabetic CMV operators. It is also possible that SBMG and an appropriate treatment regime could negate its occurrence. Given the data limitations present, it is not reasonable to estimate the number of road accidents that may be attributed to strenuous activity or missed meals.

Summary : A number of risk factors for the development of severe hypoglycemia have been identified in the diabetes literature to date, including, but not limited to, the history of severe reactions, hypoglycemia unawareness, treatment regimes, the type of diabetes, strenuous activity, and delayed or missed meals. Licensing regulations designed to reduce the risk for hypoglycemia-related accidents may focus upon these risk elements in an attempt to screen out those at high risk for severe hypoglycemia.

The evidence to date suggests that a history of severe hypoglycemia is one of the most consistent and perhaps most identifiable determinants toward predicting future hypoglycemic episodes. A screening program focusing upon this risk factor is suggested to reduce the number of hypoglycemia-related accidents by about 50 percent. The ability to accurately identify individuals with previous episodes is under debate. Some feel that medical records and daily blood glucose logs will provide the evidence needed. Others feel that ITDM drivers may try to conceal their previous hypoglycemia history.

Hypoglycemia unawareness is also a strong risk factor for severe hypoglycemia and a regulatory program regarding it is suggested to reduce the number and **risk** for accidents from severe hypoglycemia by a considerable amount. Implementation of a regulatory process regarding hypoglycemia unawareness, however, may be hindered by the uncertainty with which these high-risk individuals could be distinguished in a medical examination.

Data regarding the potential impact of treatment regimes, exercise, and missed meals on hypoglycemia-related accidents are not yet available. The implication of IDDM as a ridk factor for hypoglycemia requires further study as well.

5. Sensitivitv Analysis

Insulin-treated diabetics presently are unable to operate CMV on an mterstate basis. This restriction in employment opportunity is one of a number of factors that have led to the unavailability of data concerning hypoglycemia and CMV operation. Estimates of the risk associated with licensing insulin-treated diabetics, therefore, have relied upon a number of assumptions which have some degree of uncertainty.

The assumptions of importance used in this analysis include, **but are not limited to,** estimates on:

a. The number of persons with diabetes
b. The number of diabetics using insulin
c. The number of diabetics with IDDM
d. The proportion of insulin-using diabetics applying for licensure
e. The frequency of hypoglycemic reactions
f. The distribution of hypoglycemic reactions
g. The summarization of data on the general diabetes population to the CMV truck driving population
h. The likelihood of hypoglycemia while driving leading to accident

Additional reasons for the uncertainty in the estimates provided include the reliance upon data from studies that used different definitions for the same term, the reliance upon data from studies that surveyed populations of different characteristics, the small sample sizes present in some reports, and the inability of some reports to distinguish IDDM patients from NIDDM patients.

Sensitivity analysis considers the impact that variation in the assumptions used may have on the number of accidents expected. We present first an evaluation of the hypoglycemia while driving data, where there is additional evidence to suggest that a significant variation may be likely. An assessment of how variations would affect the remaining assumptions follows thereafter.

Number of Hypoglycemic Episodes While Driving: Earlier, it was estimated that the number of hypoglycemic episodes while driving total about 5.7 per year for IDDM drivers and 3.2 per year for NIDDM drivers. Both mild and severe reactions were included in the estimates. These figures were also calculated on the assumption that the rate of hypoglycemia would be evenly distributed over the hours of the day and the days of the year. A number of reports imply that hypoglycemic events are not evenly distributed throughout the day, but occur more frequently during the morning hours. The frequency of hypoglycemia while driving may be overstated. Indeed, data from two reports suggest that the number of hypoglycemic episodes that occur while driving, as estimated, may be too high. Eadington and colleagues (1989, personal comm.) found an overall rate of approximately 0.20 episodes/person/year in their study of diabetic automobile drivers. Stevens, et al. (1989) suggested a rate of at least 0.76 episodes. Both figures are substantially lower than that predicted from before. They encompass both IDDM and NIDDM drivers, and mild and severe reactions. On the basis of these

reports, it might be assumed that the number of hypoglycemic episodes expected while driving would be close to 0.50 per person per year. The total number of accidents related to all episodes of hypoglycemia would, therefore, be 23/year. This is an 88 percent reduction from the estimate provided earlier.

	All Insulin-usine Drivers
Number of hypoglycemic reactions expected while driving per person per year	0.500
Risk of hypoglycemia ending up in accident	0.033
Number of diabetic drivers	1,420
Number of accidents expected	23

Assessment of Additional Assumptions : Table 8 indicates how variation in the assumptions listed would affect the estimate of the number of hypoglycemia-related accidents. At present there are few credible data to suggest the extent to which variation would affect these assumptions.

Table 8

Estimated Change in Hypoglycemia-Related Accidents When Variation in Assumptions is Considered

	Value Used Previously	Possible Range	Percent change in Expected Number of Accidents
Number of persons with diabetes	6.6 million	± 10%	± 10%
Percent of diabetics aged 20 to 64 using insulin	28%	**20 to 35%**	± **27%**
Number of persons with IDDM	385,040	± 10%	± 5%
Number of persons expected to be licensed	**1,420**	1000-3000	**-29%, + 112%**
IDDM Number of severe hypoglycemic episodes/person/year	0.31	0.12 to **0.50**	**-28%, +32%**
Percent with a history of sever hypoglycemia	15%	**8 to 25%**	+ 13%, -15%'
NIDDM Number of severe hypoglycemic episodes/person/year	0.18	**0.05 to 0.25**	**-38%, +21%**
Percent with a history of severe hypoglycemia	8%	**5** to 15%	+ ll%, -17%'

'change in number of accidents expected after screening

6. Views of States Regarding Licensing of Insulin_Using Drivers

While social and discriminatory factors are likely to contribute to a lower number of insulin-using diabetics applying for CMV licensure, it should also be pointed out that not all eligible individuals would be expected to apply immediately if the laws were changed today. It is likely that the majority of drivers who would apply first off would be those diabetics who are currently permitted to operate CMVs on an intrastate basis.

We have completed a survey of the 50 states regarding the current state regulations governing intrastate operation of CMV by insulin-using diabetics. Thirty-eight states allow insulin-treated drivers to operate CMV, although 25 place special requirements or conditions on their licensure. Only nine states forbid insulin-users from applying for a CMV license. Three states have not responded to the survey.

The overall impression from the survey is that there is enormous variability between the states on this issue. Some place absolutely no restrictions on licensure for persons with diabetes, while others have a complete ban. Outside of Michigan, where only 12 insulin-treated drivers have been licensed in the last six years, no state that allows insulin-using diabetics to drive CMV had any information on the number who were licensed.

Another source of applicants will likely be those CMV drivers who develop insulin-requiring diabetes after a number of years of experience as an interstate truck driver. Crude estimates of the incidence of NIDDM by age (Everhart 1985) suggest that 5295 new cases of insulin-requiring diabetes will develop per year among the 5.5 million licensed non-diabetic CMV operators. Twenty-five percent of these may be ineligible to drive because of diabetes complications.

Age	Number of CMV drivers'	Incidence rate	Percent using insulin	Percent with complication	Total
25-44	~ 3,740,000	20.2	46%	25%	2606
45-54	! 935,ooo	43.9	22 %	25%	677
55-64	~ 825,000	58.5	19 %	25 %	688

Many other diabetics who might have been prevented from driving trucks originally by legal circumstances are probably working in other jobs and would not elect to change occupations straightaway. These data and the experience of Michigan and Quebec suggest that a considerable number of years may be needed for the insulin-using population to attain a licensing proportion similar to that of the non-diabetic population (3.8 percent), if it would attain this rate at all.

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1 assuming that the distribution of CMV drivers is similar to the age distribution of US general population

2 rate per 10,000 persons

The second major point to come out of the data from the states is that the risk for hypoglycemia-related accidents is accepted by the majority as worthy of a licensing program. Thirty-eight states (comprising 66 percent of the US population) permit insulin-treated diabetic drivers to operate CMV within their state borders. It is probable that some of these intrastate diabetic drivers have been involved in road accidents due to hypoglycemia.

Our consideration of the number of hypoglycemia-related accidents that might be expected to occur if insulin-treated diabetics were licensed to operate CMVs in interstate commerce has, to this point, assumed that these incidents would be accidents over and above that already observed in the non-diabetic population (i.e. additional new accidents). However, the data from the states suggest that a number of the accidents might not be new incidents.

Assuming that approximately 66 percent of the insulin-treated population in the United States are already eligible to drive CMV, and assuming that the accidents occurring would be evenly dispersed throughout the drivers licensed from the 50 states under a new interstate licensing program, it may be likely that 66 percent of the interstate hypoglycemia-related accidents expected to occur are events that would have happened anyway. Until now they would have been recorded on the intrastate level rather than the interstate level. This would suggest that onlv 34 percent of the hvooelvcemia-related accidents would he new incidents

7. Conclusions

Diabetes mellitus is a prevalent chronic health condition in the U.S. today. The medical issue of most importance regarding insulin-treated diabetes and motor vehicle operation is the development of hypoglycemia while driving. If not treated promptly, hypoglycemia can lead to alteration in judgement and perception, and possibly the loss of consciousness.

At present, insulin-treated diabetics are unable to operate CMVs on an interstate basis because it is thought that they are at a higher risk for road accidents. This restriction and the lack of data on hypoglycemia and accidents from the 38 states which do permit insulin users to drive CMV render it difficult to quantify what their risk might be.

The major findings of this risk assessment are:

1. There are approximately 968,000 insulin-treated diabetics from 20 to 64 years of age in the U.S. population. Figures from Michigan and Quebec, where both allow ITDMs to drive CMV, suggest that about 1,420 drivers might be expected to become licensed.

2. If insulin-treated drivers were allowed to be licensed without any restrictions, our best estimate is that the risk for hypoglycemia-related accidents would be nearly 4 times greater than the accident risk associated with non-diabetic CMV drivers (Table 9).

3. Regulations concerning previous episodes of severe hypoglycemia have been suggested to reduce this risk by one-half. Eligible insulin-treated drivers, after the implementation of such a regulation, are estimated to have a hypoglycemia-related accident risk of two times that seen for accidents overall in the non-diabetic CMV population (Table 9).

4. Some degree of uncertainty surrounds the risk estimates for insulin-treated diabetic drivers. The data available suggest that the risk ratio of hypoglycemia-related accidents to overall accidents among non-diabetic CMV drivers ranges from 0.25 to 4.d.

5. The absolute number of hypoglycemia-related accidents expected if 1,420 drivers were licensed range from 23 to 191 (with 42 as the best estimate) before any licensing restrictions are applied (Table 9).

6. A survey of individual states suggests that nearly two-thirds of the hypoglycemia-related accidents expected to occur in interstate commerce are incidents that would have occurred anyway, except that they would have been recorded on the intrastate level rather than the interstate level.

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1 Variation in the number of hypoglycemic episodes expected to occur while driving suggest that a lower estimate (0.50 episodes/person/year) would lead to 88% fewer accidents (Alternative A: 4.09 episodes vs. 0.50, Table 9). Applying this reduction to the accident estimate generated after screening (n=20) suggests that the Number of accidents expected may approximate 2.4 (2.4/10 = 0.24).

Alternative C based upon the number of accidents observed per Id miles driven in three reports of diabetic automobile drivers suggests a risk ratio of 7.6 if drivers were not regulated. Rules implemented regarding a previous history of severe hypoglycemia might reduce this risk ratio by half.

7. The hypoglycemia accident risk for insulin-treated CMV drivers is suggested to be lower than the overall accident risk for passenger car drivers, but higher than the illness-related accident risk for car drivers (Table 10).

8. The risk for IDDM drivers appears to be larger than that for insulin-treated NIDDM drivers (Table 11).

This discussion has necessarily focused upon the risk for hypoglycemia-related accidents among insulin-treated drivers. The number of accidents expected from causes other than hypoglycemia are not known. If we assume that the accident risk for the diabetic population for causes other than hypoglycemia will be similar to that seen for non-diabetic drivers, the total accident rate for insulin-using CMV drivers would be about three times higher than that for the non-diabetic drivers.

The overall accident risk of diabetic automobile drivers, however, has been reported to be similar to or. no more than two times higher than that observed for non-diabetic drivers. One recent study (Hansotia 1991) found that the accident rate of diabetic drivers was approximately 30 percent higher than the rate for drivers without diabetes. Hansotia and Broste also found that diabetic drivers had fewer alcohol-related violations than the non-diabetic population. Other studies have implied this connection as well. While confined to automobile drivers, these findings might suggest that the number of hypoglycemia-related accidents and/or the number of accidents from other causes are lower than predicted for drivers with diabetes. The extrapolation from automobile to truck drivers may not be precise. Table 12 provides estimates of the accident risk from factors other than hypoglycemia for insulin-using drivers.

Table 9

Comparison of Number of Hypoglycemia-Related Accidents to Those Expected in the General CMV Driving Population

	Insulin-using Population	Non-diabetic Population	Risk Ratio
NO SCREENING (N=1420 DRIVERS)			
Number of accidents (mild & severe)	42	11	3.82
Alternative A: (4.09 reactions while driving)	191	11	17.40
Alternative A: (0.50 reactions while driving)	23	11	2.10
Alternative B:	43	11	3.91
Alternative C:	85	11	7.70
SCREENING FOR A HISTORY OF SEVERE HYPOGLYCEMIA (N=1271 drivers[1])			
Number of accidents (mild & severe)	20	10	2.00

Table 10

Accident Risk Per Person Among Various Categories of Drivers

Diabetic CMV drivers with no restrictions	0.030
Diabetic CMV drivers with screening for a history of severe hypoglycemia	0.016
Non-diabetic CMV drivers	0.008
Fatal CMV accident in non-diabetic drivers	0.00072
Passenger car drivers	0.12203
Illness-related accidents in car drivers	0.0002

1 **Assuming that this number of driven would be without a history of severe hypoglycemia**

Karlson1978

National **Safety Council. 1985**

Table 11

Comparison of Number of Accidents by Type of Diabetes[1]

	IDDM	NIDDM
NO SCREENING	500 Drivers	920 Drivers
Number of hypoglycemia-related accidents	20	22
Number of accidents expected in CMV population	4	7
Risk Ratio:	**5.0**	**3.1**
WITH SCREENING FOR A HISTORY OF SEVERE HYPOGLYCEMIA	425 Drivers	846 Drivers
Number of hypoglycemia-related accidents	9	11
Number of accidents expected in CMV population	3.3	6.6
Risk Ratio:	**2.7**	**1.7**

Table 12

Accident Risk From Factors Other Than Hypoglycemia

Hypoglycemia accident risk	Overall Accident Risk				
	1.0	1.3	2.0	3.0	4.0
0.25	0.75	1.05	1.75	2.75	3.75
0.50	0.50	0.80	1.50	2.50	3.50
2.00	-	0.30	1.00	2.00	3.00
3.00	-				
4.00	4.0200	3.00	0	1.000	2.00 1.00 0

Grattan 1968, Doege 1988

1 Assuming that 67% of severe hypoglycemic reactions while driving result in accident

2 compared to accident rate of the general population

SUPPLEMENT

At this time our best estimate is that approximately 1,420 insulin-using drivers would be expected to be licensed to operate CMVs on an interstate basis over 3 to 6 years. This estimate is based upon the information available from Michigan and the province of Quebec where both have recently instituted new regulations concerning insulin-using CMV operators. The drivers who fulfilled the licensing criteria in these regions represented, on average, about 0.001 percent of the population of driving age, This is in contrast to the experience with non-diabetic CMV operators in the United States who represent about 3.8 percent of the U.S. population of driving age.

You **cannot** say for sure what will happen after six years. The number could stay the same as in the first six years or it may increase. A look at the number of non-diabetic CMV drivers who will develop diabetes suggests that it might increase. But again there are other factors involved such as the medical qualifications of these drivers (other than their risk for hypoglycemia), the "acceptability" of the regulation by employers and insurers, and the attitudes of the general public towards the risk presented by insulin-treated CMV drivers.

Medical, social, and discriminatory factors are likely to contribute to a lower number of insulin-using diabetics applying for CMV licensure. The presence of visual, renal, and cardiovascular disorders in persons with diabetes is not uncommon and it follows that a sizable proportion of the insulin-using population (about 39 percent of those with IDDM, and 2.5 percent of those with NIDDM) will not be able to satisfv the medical criteria for licensing, independent of diabetes.

It should also be pointed out that not all eligible individuals would be expected to apply immediately if the laws were changed today. Social factors, such as discouragement by physicians, employers, and family, may lead eligible applicants to seek other occupations. Discriminatory policies against insulin-treated applicants may also be implemented by some employers.

It is likely that the majority of drivers who would apply would be those diabetics currently permitted to operate CMVs on an intrastate basis. Subsequently, most new applicants will likely be those CMV drivers who develop insulin-required diabetes after a number of years of experience as an interstate truck driver. Crude estimates of the incidence of NIDDM by age (Everhart 1985) suggest that there might be 5,295 new cases of insulin-requiring diabetes per year among the 5.5 million licensed non-diabetic CMV operators.

It is estimated that 25 percent of these would be ineligible to drive because of diabetes complications. That leaves approximately 3,900 individuals who might be eligible to apply for a license. It is impossible to say at this time, however, what number of these would be licensed. That number will ultimately depend upon the licensing criteria (operating conditions and medical examination) decided upon, the extent to which the 3,900 drivers would be able to the criteria, and the degree of acceptance of insulin-treated drivers by employers. Remember also that this figure is based upon crude data on the incidence of NIDDM by age.