2. Frequency of Hypoglycemic Reactions

The central issue relating to motor vehicle accidents among drivers with diabetes is the role that their disease, specifically hypoglycemia, plays in their propensity for accidents. As mentioned, there have been a number of case reports linking hypoglycemia to truck accidents. There are no data, however, concerning the frequency in which hypoglycemia results in accidents while operating large commercial vehicles. In order to estimate this rate it is important to understand the relative frequency in which hypoglycemia will be occurring overall and while driving. Distinction is also made by the severity of the reaction, mild or severe.

Overall

Very few data are available on the frequency of hypoglycemia in the diabetes population. A number of stipulations are present in the studies that have been completed as well. These limitations are likely to include the selective nature of the populations examined and the under-reporting of hypoglycemic episodes by the patients themselves.

Most of the studies conducted have been based upon selected groups of diabetic patients, some of whom were seeking to maintain tight control of their blood glucose levels, and others who were identified from specific hospitals, clinics, or age groups. The DCCT has shown that the rate of hypoglycemia is markedly higher for patients trying to achieve tight control of blood glucose levels in comparison to those who are not (DCCT 1987). Groups identified from hospitals and clinics are usually not representative of the diabetic population. The characteristics of persons seeking care are often different from those who do not seek health care. The **data available then** may **be** overestimates of the true frequency. On the other hand the number of episodes reported by patients on surveys are likely to be underestimated.

The frequencyof mild hypoglycemia in the diabetes population is largely unknown. The complexity of juggling insulin dosages with carbohydrate intake, exercise, and the affairs of daily living ensures that nearly everyone using insulin is likely to experience mild hypoglycemia at some point in their lives. Data from two surveys (Ward 1990 EDC study) suggest that more than 95 percent of the IDDM population have had a mild reaction. The frequency with which it occurs, however, is rather difficult to quantify, as there is no standard definition of a mild reaction. In addition all of the definitions that have been used in free-living situations have weaknesses.'

Defining mild hypoglycemia as occurring every time that the blood glucose value drops below a certain level, say 50mg/dl, will unfairly characterize the experience of individuals who can function normally at any level above 35mg/dl. Basing the definition of mild hypoglycemia upon the presence of symptoms, such as sweating shakiness, and forceful heartbeat, will exclude those individuals who do not experience symptoms.

Two French reports (Goldgewight 1983 and Basdevant 1982) have estimated the frequency of mild hypoglycemic episodes to be roughly one reaction per week per patient. A New Zealand study (Ward 1990) reported that 73 percent of the clinic patients surveyed had at least one mild reaction per month.

Estimates of the frequency of severe hypoglycemia are more common. One reason for this may be that severe reactions provide a more rigid endpoint for investigation than do mild reactions. Severe hypoglycemia is also likely to occur less frequently than mild hypoglycemia.

Although there is no standard definition for severe hypoglycemia applied in the literature, severe reactions are commonly defined as episodes that (1.) require the intervention of another person; (2.) result in loss of consciousness; or (3.) require hospitalization. Table 1 presents a summary of the findings to date. The populations and definitions used between the studies were quite variable.

Table 1

Incidence of Severe Hypoglycemia in
Insulin-Treated Diabetic Patients
(Number of reactions per person per year)

Study	IDDM	NIDDM
Bergada, 1989	0.07	
DCCT, 1987 -regular therapy -intensive therapy	0.17 0.54	
Hiss, 1986	1.70	1.30
Casparie, 1985	0.12	0.05
Mulhauser, 1985	0.19	
White, 1983	1.20	
Potter, 1982	0.14	
Mecklenburg, 1982	0.12	

On the basis of these data, two previous reports (FHWA 1989, FAA 1986) concluded that the number of expected mild hypoglycemic events for the average person with diabetes in one year would be 50, and the number of severe hypoglycemic events would be around 0.25 per year. Neither considered differences in frequency by the type of diabetes.

We have subsequently been able to obtain information on the occurrence of hypoglycemic reactions from two large population-based studies; the Epidemiology of Diabetes Complications study (based in Pittsburgh) and the Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR). Because both studies were based upon fairly representative samples of the free-living diabetes population, their estimates are likely to be less biased than those reported previously. Estimates of the frequency of hypoglycemia, though, were based upon patient recall in both studies.

The Pittsburgh data reflect the experience of insulin-dependent diabetics without chronic complications. As discussed earlier, persons with complications, specifically proliferative retinopathy, nephropathy, CVD, and amputation, will not otherwise be able to drive trucks because of their medical condition. However, there was no large difference observed in the frequency of hypoglycemia between individuals with complications and those without them in the EDC cohort.

Mild reactions in the EDC study were defined as reactions characterized by the presence of early symptoms, but episodes that did not result in a loss of consciousness. Severe reactions were defined as reactions characterized by the loss of consciousness. Both definitions are subject to the limitations pointed out above. This definition of severe reactions, for example, is less encompassing than one which measures all episodes that require the intervention of another person.

The Wisconsin data reflect the overall frequency of hypoglycemia and are stratified by the age at diagnosis of diabetes. The majority, if not all, of the persons diagnosed under age 30 will have IDDM. Most of the individuals diagnosed after age 30 will have NIDDM, but use insulin to manage their blood sugar levels.

The frequency of hypoglycemia as reported in these studies is shown below:

EDC data: (1985-87)

Frequency of Mild reactions (characterized by symptoms)

n	Frequency	Conversion Factor	Total Number of Reactions	Rate/Person Per Year
10	1 per day	365	3650	
63	1-2 per week	52	3276	
113	1-2 per month	12	1356	24.1
159	< 1-2 per month	2	318	
11	never had one	0	0	

Frequency of severe reactions (characterized by loss of consciousness)

n	Frequency	Conversion Factor	Total Number of Reactions	Rate/Person Per Year
0	1 per day	365	0	
0	1-2 per week	52	0	
3	1-2 per month	12	36	0.31
154	< 1-2 per month	0.5	77	
209	never had one	0	0	

WESDR data: (1980-82)

Frequency of hypoglycemia in insulin-taking diabetics diagnosed under age 30

n	Freauencv	Conversion Factor	Total Number of Reactions	Rate/Person Per Year
35	1 per day	365	15775	
298	1-2 per week	52	15,496	
254	1-2 per month	12	3,048	32.6
346	< 1-2 per month	2	692	
49	never had one	0	0	

Frequency of hypoglycemia in insulin-taking diabetics diagnosed over age 30

n	Frequency	Conversion Factor	Total Number of Reactions	Rate/Person Per Year
14	1 per day	365	5,110	
76	l-2 per week	52	3,952	
105	l-2 per month	12	1,260	16.5
256	< l-2 per month	2	512	
207	never had one	0	0	

There are three major conclusions to consider from these data. First, the manner in which the frequency of hypoglycemia was assessed in both surveys was open-ended. Respondents indicating a rate of hypoglycemic reactions of less than 1 to 2 per month could include those with one reaction everv three months. one reaction every year

one reaction every four years, and so on. Calculation of an average rate of occurrence for the whole population depends upon the value selected to represent the experience of this category of people. The influence that this has upon the overall rate of hypoglycemia is described below.

Second, these data confirm the findings of other reports (Casparie 1985, Bergada 1989, Ward 1990) that severe hypoglycemia is a relatively rare event. Fifty-seven (57) percent of the IDDM respondents in the EDC study reported never having a hypoglycemic episode that ended in the loss of consciousness.

Third, the WESDR data suggest that the frequency of hypoglycemia is much lower for the insulin-using Type II diabetics than the insulin-dependent Type I diabetics. Two other reports support this finding (Casparie 1985, Hiss 1986). The vast majority (70 percent) of the Wisconsin NIDDM cohort also had fewer than one reaction a month.

How does the selection of a value to represent the hypoglycemic experience of individuals with less than 1 to 2 episodes per month affect the overall rate of hypoglycemic occurrence in these populations? Table 2 presents the overall rate of hypoglycemia in the EDC and WESDR populations expected by the interval with which hypoglycemic episodes might occur for respondents in this category.

Table 2

Differences in the Overall Rate of Hypoglycemia Expected by the Interval Between Reactions Among Diabetics With < l-2 Reactions a Month

	Frequency of Reactions if < l-2 Per Month	Expected Rate of Hypoglycemic Episodes Per Person Per Year
EDC data mild reactions	One episode every 2 months	25.9
	6 months	24.1
	1 year	23.7
	2 years	23.5
	4 years	23.2
EDC data severe reactions	One episode every 2 months	2.62
	6 months	0.94
	1 year	0.52
	2 years	0.31
	4 years	0.20

WESDR data age at diagnosis less than 30	One episode every 2 months 6 months 1 year 2 years 4 years	34.0 32.6 32.2 32.1 32.0
WESDR data age at diagnosis greater than 30	One episode every 2 months 6 months 1 year 2 years 4 years	18.0 16.5 16.1 15.9 158

Which value is likely to represent the average interval between reactions for respondents answering the open-ended category? Previous reports suggest that the probability of a miid reaction is quite high. It is likely, however, that the traits of persons with one or more reactions a month are very different from those with fewer reactions. Without any data to document the distribution of reactions among individuals reporting fewer than one episode a month, we assume that the frequency of events will be evenly spread throughout the year. The average interval for this category would be 6 months (one reaction every 6 months).

The frequency of severe reactions, on the other hand, is much lower than that for mild episodes. It is likely that the distribution of reactions among individuals reporting less than one severe episode a month would be spread out over longer periods of time. As severe reactions appear to be rare events, it is probable that the distribution of severe episodes would reflect a poisson distribution. We, therefore, assume that the averaee interval between reactions for this category would be 2 years.

The WESDR data measure the overall frequency of hypoglycemia (mild and severe reactions combined). As mild hypoglycemia occurs much more frequently than severe hypoglycemia, we assume that the average interval between reactions (for those with less than one reaction a month) will be 6 months.

On the basis of the data available, best estimates for the average expected frequency of hypoglycemia in the insulin-using diabetes population are as follows:

Mild Episodes IDDM population: 28 episodes/person&earl
insulin-using NIDDM population: 16 episodes/person/yea?

Severe Episodes IDDM population: 0.31 episodes/person/yea2
insulin-using NIDDM population: 0.18 episodes/person/year

'While Driving

The rate with which hy[illegible] commercial motor vehicles was calculated from the following equation:

$$\text{Frequency} = E(\text{Frequ}) \times \text{average number of hours driven by CMV operators} \times \frac{1}{\text{number of hours in a year}}$$

Two basic assumptions underpin this equation. One, that the hypoglycemic experience of insulin-using CMV operators will be identical to the experience of the general (complication-free) insulin-using diabetes population. This may or may not be the case, depending upon the extent to which the factors underlying the development of hypoglycemia differ between the groups. For example, the physical activity and stress related to operating CMVs as an occupation may increase the chance for hypoglycemia. There are, however, no data available to evaluate this issue. The second assumption is that the occurrence of hypoglycemia w-ill be evenly distributed over the hours of the day and the days of the year.

Estimates of the average time spent driving CMVs center around the assumption that a commercial driver spends approximately 20 percent of his or her time in a year driving trucks (about 1760 hours per year)(FHWA estimates).

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1 The average of the EDC and WESDR (onset under age 30) data

2 WESDR data (onset > **age 30)**

3 EDC data

4 Calculated by considering the % difference in the frequency of mild hypoglycemia between IDDM **and** NIDDM populations (@ 75% higher for the IDDM cohort), and the difference in the rate of severe hypoglycemia in 2 earlier reports (Casparie 1985, Hiss 1986) in reference to the 0.31 figure for the average rate of severe reactions in the IDDM cohort

5 Frequency of hypoglycemia while driving

6 Expected frequency of hypoglycemia overall

Thus, the expected number of hypoglycemic reactions while driving per driver per year are estimated to be:

Mild hypoglycemia	IDDM operators:	5.6 episodes
	insulin-using NIDDM operators:	3.2 episodes
Severe hypoglycemia	IDDM operators:	0.060 episodes
	insulin-using NIDDM operators:	0.036 episodes

3. Relationship of Hypoglycemia to CMV Road Accidents

The extent to which hypoglycemia, while driving, results in an accident is, by far, the largest unknown in the issue of diabetes and CMV operation. There are very few data available on the relationship of hypoglycemia and accidents in automobile drivers, let alone CMV operators. Additionally, it is often difficult to prove that hypoglycemia caused an accident (Taylor 1985). Determination of the blood glucose levels at the time of an incident is fraught with difficulty.

The process that determines whether or not hypoglycemia, while driving, leads to a road accident is likely to be multifactorial. Elements of importance include the severity of hypoglycemia (mild or severe), the recognition of warning signs for hypoglycemia (yes/no) and the driving conditions present when hypoglycemia occurs (the ability to pug the vehicle off the road).

The symptomatology of mild and severe reactions suggests that the risk for accidents from mild hypoglycemia is lower than that for severe hypoglycemia. Although there may be elements of alteration of judgement present during a mild reaction, individuals suffering such an episode still have a state of control over their response. Indeed, the first symptoms of hypoglycemia (sweating, anxiety, forceful heartbeat, and light-headedness) provide a clear sign to most diabetics to take corrective action (FAA 1986). Severe reactions, on the other hand, are commonly defined by the loss of control over the situation by the diabetic. The grave danger is that they may occur without warning in some individuals.

What is the role of warning signs for hypoglycemia in relationship to motor vehicle accidents? A hypoglycemic reaction is not necessarily dangerous for CMV operation if there are premonitory symptoms to which an individual can react. Warning signs (the first symptoms of hypoglycemia) may provide sufficient time for the diabetic to pull the vehicle off the road and stop driving. On the other side, the inability to recognize the early symptoms of hypoglycemia ('hypoglycemia unawareness') has been associated with an increased risk for severe hypoglycemia (Hepburn 1990). Drivers with such a loss of hypoglycemia awareness are at a definite risk of sudden collapse at the wheel of a vehicle.

A study of 302 insulin-treated patients attending a clinic in Scotland found that 75 percent of the group had normal symptomatic awareness to hypoglycemia (Hepburn 1990). Sixteen percent had impaired awareness and 7 percent had a total absence of symptomatic response.' Similarly, a study in New Zealand reported that 5 percent of the clinic patients surveyed had no warning of hypoglycemia on a regular basis (Ward 1990). Roughly 48 percent had symptoms before every episode.

Common risk factors for hypoglycemia unawareness include the duration of diabetes and the presence of autonomic neuropathy. Insulin-treated individuals with a total loss of hypoglycemia awareness tend to have diabetes of a longer duration (Baldimos 1959, Hepburn 1990). The absence of autonomic functioning in patients with autonomic neuropathy has been associated with hypoglycemia unawareness as well (Cryer 1986). Autonomic responses are generally the first indication of the development of hypoglycemia.

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1 Two percent reported that they never had hypoglycemia

The driving conditions' present at the time in which hypoglycemia occurs are also likely to influence the frequency of an accident. The availability of an emergency stopping area may enable a diabetic driver with suffcient warning to park the CMV and treat the hypoglycemic reaction. Traffic levels and weather conditions may influence the ability to stop driving as well.

Uncertainty remains, however, over how the severity of reaction, the recognition of warning symptoms, and the driving conditions present at the time of reaction translate into the probability for a hypoglycemia-related road accident. In the only data available, Eadington and Frier (Eadington 1989, personal comm.) found that nine out of approximately 272 (3.3 percent) occurrences of hypoglycemia while driving went on to result in an accident. These data were largely based upon diabetic automobile drivers. As the tasks involved in operating CMVs as an occupation differ from those of ordinary private automobiles, the rate in which hypoglycemia leads to road accidents for CMV drivers may differ. Exact representation of this difference depends upon the extent to which influences, such as physical activity and job-related stress from deadlines, affect the development of hypoglycemia.

Because of the lack of information on this vital point, the discussion of the number of accidents expected from the licensing of diabetic drivers for CMV operation will be presented from many different viewpoints. We begin, first, with an analysis of the number of accidents expected from both mild and severe reactions. A discussion of the number of accidents expected from hypoglycemia, overall, follows and is based upon not only the summation of accidents expected from part one, but the evaluation of three alternative methods as well.

Number of Accidents Expected From Mild Hypoglycemia : Mild hypoglycemia is commonly characterized by the symptoms presented earlier. Mild reactions may also entail impairment in cognitive and physical performance. It is thought that the greatest hazard of mild hypoglycemia in relation to driving would be its presence at the time of a critical phase of driving (FAA 1986). This may include the need for quick decisions to avert an accident.

These descriptive traits are simular to those of anvers sunenng from fatigue. Because of absence of data relating mild reactions to accident causation, an assumption has been made (FHWA 1989) that inferences on the role of mild hypoglycemia can be drawn from studies of fatigue and road crashes. The risk of an accident due to mild hypoglycemia might be suggested to be 1.5 to 3 times higher than that seen under normal driving conditions.

Because of the uncertainty involved in this inference, we have calculated the number of accidents from mild hypoglycemia over a range of accident risks.. All are based, additionally, on the assumptions that the average duration of a reaction will be 15 minutes (FAA 1986) and that driving will continue during that time. This may clearly not be the case if the driver recognizes the reaction and has appropriate conditions in which to park until the reaction is over. These estimates represent what might happen if the driver intervened while continuing to drive.

The number of accidemts expected from mild hypoglycemia are calculated from the formula below. Table 3 presents the expected number of accidents due to mild reactions over a range of accident risks.

E (accidents) = number of mild reactions per person/year while driving * average time of reaction * diabetic accident rate * number of drivers

	IDDM	Insulin-usine **NIDDM**
Number of mild reactions expected while driving/person/year	5.6	3.2
Average time of reaction (in hours)	**0.25**	0.25
Average time spent driving with mild hypoglycemia per year	1.40	0.80
Non-diabetic accident rate/driver/y?	0.00785	0.00785
Non-diabetic accident rate/driver/hr	0.0000045	0.0000045
Increased chance of accident due to hypoglycemia	3	3
Hypoglycemia accident rate/driver/h?	0.0000135	0.0000135
Hypoglycemia accidents/driver/j@	0.0000189	0.0000108
Number of diabetic drivers	500	920
Number of accidents expected'	**0.009**	0.010

1 Diabetic accident rate per driver per hour driven
2 number of reactions * average time of reaction
3 FHWA estimates
4 (0.00785 accidents per year/1760 hours driven per year
5 Non-diabetic accident rate per hour * 3
6 Hypoglycemia accident rate * time spent driving with hypoglycemia
7 Hypoglycemia accidents per driver * number of drivers

Table 3

Number of Accidents Expected by Type of Diabetes and
by Chance of Accident due to Mild Hypoglycemia

Chance of Accident Due to Hypoglycemia in Relationship to Normal Rates	IDDM	Insulin-using NIDDM
similar	0.003	0.003
1.5 times higher	0.005	0.005
2.0 times higher	0.006	0.007
3.0 times higher	0.009	0.010
5.0 times higher	0.016	0.017
10.0 times higher	0.032	0.033

Quite clearly, the number of accidents expected from mild hypoglycemia in the CMV licensed diabetes population is very low when the risk of mild reactions leading to accidents is calculated in this manner.

Number of Accidents Expected From Severe Hypoglycemia - Again, estimates of the number of accidents related to severe hypoglycemia are difficult to compute because of the absence of data defining the connection between severe reactions and accidents. Although there are no data relating severe reactions to accident causation, studies of hypoglycemia unawareness and severe hypoglycemia provide some evidence of what this risk might be. The presence of warning symptoms to the development of hypoglycemia may signal the **CMV** operator to pull the vehicle off the road. Such an action may not have an impact upon stopping the severe reaction, but it would likely avert an accident due to the loss of self-control.

One recent report (Hepburn 1990) found a strong association between hypoglycemia unawareness and severe hypoglycemia. Patients without warning signs for hypoglycemia had more severe reactions than those with warning signs. Of the severe episodes that were reported, nearly 44 percent were preceded by symptoms. Two other studies (Bergada 1989, Duncan 1990) found that 28 percent of the severe reactions reported had warning symptoms. These three reports suggest that on average, 33 percent of all severe reactions may not go on to a road accidents.

A great deal of uncertainty remains, however. Severe reactions may still be hazardous, even with warning symptoms, if the operator is unable or unwilling to park the vehicle. The extent to which this might occur is unknown. To overcome the reservations over severe reactions and accidents, a range of values on the potential relationship of **severe** hypoglycemia and road accidents is presented.

Estimates of the number of accidents expected, due to severe hypoglycemia, are based upon the following equation. The number of accidents expected, on average, assuming that 67 percent of severe reactions will result in an accident, amount to 42/year.

E (accidents) = number of severe rxns per person/year while driving * likelihood of severe rxns leading to accident * number of drivers

	IDDM	Insulin-using NIDDM
Number of severe reactions expected while driving/person/year	0.06	0.036
Likelihood of severe reaction ending up in an accident	0.67	0.67
Number of diabetic drivers	500	920
Number of accidents expected	20	22

Table 4 presents the expected number of accidents due to severe hypoglycemia while driving over a range of possible accident probabilities.

Table 4

Number of Accidents Expected by Type of Diabetes and Likelihood of Severe Hypoglycemia Causing an Accident

Chance of Severe Reaction Leading to Accident	IDDM	Insulin-usine NIDDM
0.10	3	3
0.28	8	9
0.56	17	19
0.67	20	22
0.72	22	24
0.80	24	26

The number of predicted accidents due to severe hypoglycemia is larger than that for mild hypoglycemia. This is due primarily to the methodology used in estimating the accidents. It was assumed that mild reactions would affect CMV operation in a minimal way. Drivers would be at heightened risk during mild episodes, particularly if another driving hazard were present, but every episode would not necessarily have a high chance to lead to an accident. The assumptions about severe hypoglycemia were completely different. Because of the seriousness of the loss of consciousness while driving or the need for help from another person, it was assumed that every severe episode had a significant chance of leading to an accident. Both points, however, are difficult to verify.

Number of Accidents Expected Fmm Hypoglycemia Overall : Taking the sum of the best estimates from the previous sections, we find the expected number of CMV accidents due to hypoglycemia would be about 42 per year. The issue of hypoglycemia and traffic accidents can be approached from a number of alternative perspectives as well. New data on hypoglycemia and road accidents are available from three recent studies of diabetes and automobile driving. Although the experience related to commercial vehicles may be quite different, these data provide additional evidence towards the impact of hypoglycemia on road accidents. Three alternative methods of estimating the number of CMV road accidents related to hypoglycemia follow.

A. In an eight-year follow-up study of 250 insulin-treated patients attending a diabetes clinic in Scotland, Eadington and Frier (Eadington 1989, personal comm.) found that nine out of @ 272 hypoglycemic episodes went on to result in a road accident. Most episodes were mild and self-treated. The probability of hypoglycemia while driving causing an accident, then, is approximately 3.3 percent. Using this data and the following equation, it was estimated that about 191 accidents would be expected from hypoglycemia in the insulin-using CMV cohort.

E (accidents) = number of reactions per person/year while driving * likelihood of hypoglycemia leading to accident * number of drivers

	IDDM	Insulin-usine NIDDM
Number of hypoglycemic rxns expected while driving/person/year	5.66	3.24
Likelihood of hypoglycemia ending up in an accident	0.033	0.033
Number of diabetic drivers	500	920
Number of accidents expected	93	98

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 poke (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.

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

$$\text{IDDM: E (accidents)} = 3/100 \text{ drivers} * 500 \text{ drivers} = 15$$

$$\text{Insulin-using NIDDM: E (accidents)} = 3/100 \text{ drivers} * 920 \text{ drivers} = 28$$

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.

[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 apphcants. 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. Insuhn-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 he majority of road accidents related to hypoglycemia are probably those resulting from severe

3. Relationship of Hypoglycemia to CMV Road Accidents

The extent to which hypoglycemia, while driving, results in an accident is, by far, the largest unknown in the issue of diabetes and CMV operation. There are very few data available on the relationship of hypoglycemia and accidents in automobile drivers, let alone CMV operators. Additionally, it is often difficult to prove that hypoglycemia caused an accident (Taylor 1985). Determination of the blood glucose levels at the time of an incident is fraught with difficulty.

The process that determines whether or not hypoglycemia, while driving, leads to a road accident is likely to be multifactorial. Elements of importance include the severity of hypoglycemia (mild or severe), the recognition of warning signs for hypoglycemia (yes/no) and the driving conditions present when hypoglycemia occurs (the ability to pull the vehicle off the road).

The symptomatology of mild and severe reactions suggests that the risk for accidents from mild hypoglycemia is lower than that for severe hypoglycemia. Although there may be elements of alteration of judgement present during a mild reaction, individuals suffering such an episode still have a state of control over their response. Indeed, the first symptoms of hypoglycemia (sweating, anxiety, forceful heartbeat, and light-headedness) provide a clear sign to most diabetics to take corrective action (FAA 1986). Severe reactions, on the other hand, are commonly defined by the loss of control over the situation by the diabetic. The grave danger is that they may occur without warning in some individuals.

What is the role of warning signs for hypoglycemia in relationship to motor vehicle accidents? A hypoglycemic reaction is not necessarily dangerous for CMV operation if there are premonitory symptoms to which an individual can react. Warning signs (the first symptoms of hypoglycemia) may provide sufficient time for the diabetic to pull the vehicle off the road and stop driving. On the other side, the inability to recognize the early symptoms of hypoglycemia ('hypoglycemia unawareness') has been associated with an increased risk for severe hypoglycemia (Hepburn 1990). Drivers with such a loss of hypoglycemia awareness are at a definite risk of sudden collapse at the wheel of a vehicle.

A study of 302 insulin-treated patients attending a clinic in Scotland found that 75 percent of the group had normal symptomatic awareness to hypoglycemia (Hepburn 1990). Sixteen percent had impaired awareness and 7 percent had a total absence of symptomatic response.[1] Similarly, a study in New Zealand reported that 5 percent of the clinic patients surveyed had no warning of hypoglycemia on a regular basis (Ward 1990). Roughly 48 percent had symptoms before every episode.

Common risk factors for hypoglycemia unawareness include the duration of diabetes and the presence of autonomic neuropathy. Insulin-treated individuals with a total loss of hypoglycemia awareness tend to have diabetes of a longer duration (Baldimos 1959, Hepburn 1990). The absence of autonomic functioning in patients with autonomic neuropathy has been associated with hypoglycemia unawareness as well (Cryer 1986). Autonomic responses are generally the first indication of the development of hypoglycemia.

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1 Two percent reported that they never had hypoglycemia

The driving conditions present at the time in which hypoglycemia occurs are also likely to influence the frequency of an accident. The availability of an emergency stopping area may enable a diabetic driver with sufficient warning to park the CMV and treat the hypoglycemic reaction. Traffic levels and weather conditions may influence the ability to stop driving as well.

Uncertainty remains, however, over how the severity of reaction, the recognition of warning symptoms, and the driving conditions present at the time of reaction translate into the probability for a hypoglycemia-related road accident. In the only data available, Eadington and Frier (Eadington 1989, personal comm.) found that nine out of approximately 272 (3.3 percent) occurrences of hypoglycemia while driving went on to result in an accident. These data were largely based upon diabetic automobile drivers. As the tasks involved in operating CMVs as an occupation differ from those of ordinary private automobiles, the rate in which hypoglycemia leads to road accidents for CMV drivers may differ. Exact representation of this difference depends upon the extent to which influences, such as physical activity and job-related stress from deadlines, affect the development of hypoglycemia.

Because of the lack of information on this vital point, the discussion of the number of accidents expected from the licensing of diabetic drivers for CMV operation will be presented from many different viewpoints. We begin, first, with an analysis of the number of accidents expected from both mild and severe reactions. A discussion of the number of accidents expected from hypoglycemia, overall, follows and is based upon not only the summation of accidents expected from part one, but the evaluation of three alternative methods as well.

Number of Accidents Expected From Mild Hypoglycemia : Mild hypoglycemia is commonly characterized by the symptoms presented earlier. Mild reactions may also entail impairment in cognitive and physical performance. It is thought that the greatest hazard of mild hypoglycemia in relation to driving would be its presence at the time of a critical phase of driving (FAA 1986). This may include the need for quick decisions to avert an accident.

These descriptive traits are similar to those of drivers suffering from fatigue. Because of absence of data relating mild reactions to accident causation, an assumption has been made (FHWA 1989) that inferences on the role of mild hypoglycemia can be drawn from studies of fatigue and road crashes. The risk of an accident due to mild hypoglycemia might be suggested to be 1.5 to 3 times higher than that seen under normal driving conditions.

Because of the uncertainty involved in this inference, we have calculated the number of accidents from mild hypoglycemia over a range of accident risks.. All are based, additionally, on the assumptions that the average duration of a reaction will be 15 minutes (FAA 1986) and that driving will continue during that time. This may clearly not be the case if the driver recognizes the reaction and has appropriate conditions in which to park until the reaction is over. These estimates represent what might happen if the driver intervened while continuing to drive.

The number of accidents expected from mild hypoglycemia are calculated from the formula below. Table 3 presents the expected number of accidents due to mild reactions over a range of accident risks.

E (accidents) = number of mild rxns per person/year while driving * average time of reaction * diabetic accident rate[1] * number of drivers

	IDDM	Insulin-using NIDDM
Number of mild reactions expected while driving/person/year	5.6	3.2
Average time of reaction (in hours)	0.25	0.25
Average time spent driving with mild hypoglycemia per year[2]	1.40	0.80
Non-diabetic accident rate/driver/yr[3]	0.00785	0.00785
Non-diabetic accident rate/driver/hr[4]	0.0000045	0.0000045
Increased chance of accident due to hypoglycemia	3	3
Hypoglycemia accident rate/driver/hr[5]	0.0000135	0.0000135
Hypoglycemia accidents/driver/yr[6]	0.0000189	0.0000108
Number of diabetic drivers	500	920
Number of accidents expected[7]	0.009	0.010

1 Diabetic accident rate per driver per hour driven

2 number of reactions * average time of reaction

3 FHWA estimates

4 (0.00785 accidents per year/1760 hours driven per year

5 Non-diabetic accident rate per hour * 3

6 Hypoglycemia accident rate * time spent driving with hypoglycemia

7 Hypoglycemia accidents per driver * number of drivers

Table 3

Number of Accidents Expected by Type of Diabetes and by Chance of Accident due to Mild Hypoglycemia

Chance of Accident Due to Hypoglycemia in Relationship to Normal Rates	IDDM	Insulin-using NIDDM
similar	**0.003**	**0.003**
1.5 times higher	0.005	0.005
2.0 times higher	0.006	**0.007**
3.0 times higher	0.009	0.010
5.0 times higher	0.016	0.017
10.0 times higher	**0.032**	**0.033**

Quite clearly, the number of accidents expected from mild hypoglycemia in the CMV licensed diabetes population is very low when the risk of mild reactions leading to accidents is calculated in this manner.

Number of Accidents Expected **From** Severe **Hypoglycemia** : Again, estimates of the number of accidents related to severe hypoglycemia are difficult to compute because of the absence of data defining the connection between severe reactions and accidents. Although there are no data relating severe reactions to accident causation, studies of hypoglycemia unawareness and severe hypoglycemia provide some evidence of what this risk might be. The presence of warning symptoms to the development of hypoglycemia may signal the CMV operator to pull the vehicle off the road. Such an action may not have an impact upon stopping the severe reaction, but it would likely avert an accident due to the loss of self-control.

One recent report (Hepburn 1990) found a strong association between hypoglycemia unawareness and severe hypoglycemia. Patients without warning signs for hypoglycemia had more severe reactions than those with warning signs. Of the severe episodes that were reported, nearly 44 percent were preceded by symptoms. Two other studies (Bergada 1989, Duncan 1990) found that 28 percent of the severe reactions reported had warning symptoms. These three reports suggest that on average, 33 percent of all severe reactions may not go on to a road accidents.

A great deal of uncertainty remains, however. Severe reactions may still be hazardous, even with warning symptoms, if the operator is unable or unwilling to park the vehicle. The extent to which this might occur is unknown. To overcome the reservations over severe reactions and accidents, a range of values on the potential relationship of severe hypoglycemia and road accidents is presented.

Estimates of the number of accidents expected, due to severe hypoglycemia, are based upon the following equation. The number of accidents expected, on average, assuming that 67 percent of severe reactions will result in an accident, amount to 42/year.

E (accidents) = number of severe rxns per person/year while driving • likelihood of severe rxns leading to accident * number of drivers

	IDDM	Insulin-using NIDDM
Number of severe reactions expected while driving/person/year	0.06	0.036
Likelihood of severe reaction ending up in an accident	0.67	0.67
Number of diabetic drivers	500	920
Number of accidents expected	20	22

Table 4 presents the expected number of accidents due to severe hypoglycemia while driving over a range of possible accident probabilities.

Table 4

Number of Accidents Expected by Type of Diabetes and Likelihood of Severe Hypoglycemia Causing an Accident

Chance of Severe Reaction Leading to Accident	IDDM	Insulin-using NIDDM
0.10	3	3
0.28	8	9
0.56	17	19
0.67	20	22
0.72	22	24
0.80	24	26

The number of predicted accidents due to severe hypoglycemia is much larger than that for mild hypoglycemia. This is due primarily to the methodology used in estimating the accidents. It was assumed that mild reactions would affect CMV operation in a minimal way. Drivers would be at heightened risk during mild episodes, particularly if another driving hazard were present, but every episode would not necessarily have a high chance to lead to an accident. The assumptions about severe hypoglycemia were completely different. Because of the seriousness of the loss of consciousness while driving or the need for help from another person, it was assumed that every severe episode had a significant chance of leading to an accident. Both points, however, are difficult to verify.

Number of Accidents Expected From Hypoglycemia Overall: Taking the sum of the best estimates from the previous sections, we find the expected number of CMV accidents due to hypoglycemia would be about 42 per year. The issue of hypoglycemia and traffic accidents can be approached from a number of alternative perspectives as well. New data on hypoglycemia and road accidents are available from three recent studies of diabetes and automobile driving. Although the experience related to commercial vehicles may be quite different, these data provide additional evidence towards the impact of hypoglycemia on road accidents. Three alternative methods of estimating the number of CMV road accidents related to hypoglycemia follow.

A In an eight-year follow-up study of 250 insulin-treated patients attending a diabetes clinic in Scotland, Eadington and Frier (Eadington 1989, personal comm.) found that nine out of @ 272 hypoglycemic episodes went on to result in a road accident. Most episodes were mild and self-treated. The probability of hypoglycemia while driving causing an accident, then, is approximately 3.3 percent. Using this data and the following equation, it was estimated that about 191 accidents would be expected from hypoglycemia in the insulin-using CMV cohort.

E (accidents) = number of reactions per person/year * while driving likelihood of hypoglycemia leading * to accident number of drivers

	IDDM	Insulin-usine NJDDM
Number of hypoglycemic rxns expected while driving/person/year	5.66	3.24
Likelihood of hypoglycemia ending up in an accident	0.033	0.033
Number of diabetic drivers	500	920
Number of accidents expected	93	98