Epilepsy and Driving in Europe

A report
of the

Second European Working Group on Epilepsy and Driving,

an advisory board to the Driving Licence Committee of the European Union.

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The SEWGED had meetings on 5th May 2004; 20th October 2004; 19th and 20th January 2005 and 2nd and 3rd March 2005.

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1. Introduction

The cumulative incidence of epilepsy is at least 4% of the population. The prevalence of active epilepsy in the adult population is 4 to 10 in 1000 people (Hauser *et al*. 1996; Goodridge *et al*. 1983). For the European union we assumed a value of 6 in 1000. Of these patients, a substantial number hold a drivers licence (Sonnen 1995). In general, driving is experienced as one of the top concerns of people with epilepsy, as is noticeable in the daily practice of any neurologist. In surveys, driving is listed as a first or second concern by people with epilepsy, after the wish to be seizure-free (Gilliam *et al*. 1997; Taylor *et al*. 2001; Fisher *et al*. 2000). On the other hand, driving while having active epilepsy clearly poses an increased risk, (Krauss *et al*. 1999; Berg *et al*. 2000) while drivers with epilepsy who are in compliance with driving restrictions and with medication intake pose no excess danger (Krauss 1999). This makes the topic of "epilepsy and driving" of importance to neurologists and the regulators of driver licensing alike.

HISTORICAL BACKGROUND

In the European Union, the regulations about driver licensing used to differ greatly among member states. (Fisher et al 1994) With the support of the European government, this led to the formation of European workshops on driving licence regulations in May 1995 and March 1996 organised by the International League against Epilepsy (ILAE) and the International Bureau for Epilepsy (IBE)(Sonnen 1995 and 1997). The recommendations of these workshops were not reflected in an official European guideline or in European law. In these recommendations, as well as in an American consensus statement, control or remission of seizures, measured as the "seizure-free interval" is the main determinant in the assessment of the ability to drive (Sonnen 1997, Krumholz 1994) and it will be the subject of a large part of this report.

Table 1

European Council Directive 91/439/EEC of 29 July 1991 on driving licences *Official Journal L 237 , 24/08/1991*	
Group I	**Group II**
A licence may be issued or renewed subject to an examination by a competent medical authority and to regular medical check-ups. The authority shall decide on the state of the epilepsy or other disturbances of consciousness, its clinical form and progress (no seizure in the last two years, for example), the treatment received and the results thereof.	Driving licences shall not be issued to or renewed for applicants or drivers suffering or liable to suffer from epileptic seizures or other sudden disturbances of the state of consciousness.

European member states have to stay within a Council directive: they can be more restrictive, but not more liberal. (table 1: see references. Group 1 refers to categories A: motorbike and B: car. Group 2 refers to categories C: lorry and D: bus. – for a full explanation see European commission transport internet site)
After the 1995 / 1996 workshops, national legislation was adapted to an important degree in several European countries, but remained unchanged in others. This situation led to a renewed call for harmonisation and the installation of several medical advisory boards like the working group on epilepsy and driving.
The purpose of this report is to give an overview of current knowledge of the subject of epilepsy and driving and to give regulations for implementation in European law.
It has to be stressed that rigorous scientific proof is not always sufficiently available for the decisions that have to be taken with regard to epilepsy and driving. In such cases, the best available evidence and reasonable estimates are used.
The recommendations of the 1996 European working group stated: rules must be as liberal as possible, simple and clear (Sonnen 1997).
They should also be based on calculated risk.

A PRACTICAL PROBLEM: THE QUESTION OF COMPLIANCE

In a period that the Belgian law required a 2-year period of seizure-freedom, even after a first epileptic seizure, a group of neurologists estimated that 70% of their epilepsy patients that were not allowed to drive still did so. (Schmedding 1996) Berg et al (Berg *et al.*2000), asking a group of epilepsy- patients that were included in an epilepsy-operation programme and found that one third of them drove regularly, despite having frequent seizures. Many patients do not report their seizures to their doctor (Dalrymple J 2000), especially in countries with compulsory notification. There are reasons to think that by making the law more liberal, more people will adhere to it. (Sonnen 1997; Krumholz 1991)

More liberal rules may persuade people with seizures to undergo an assessment and stick to the rules for several reasons:
-they may accept the rules as reasonable
-they have the perspective of getting their licence back
-they feel relieved of the responsibility and the uneasiness of doing something that may endanger other people, including their relatives.
-they can drive legally and have an insurance
Shorter seizure-free periods will also increase the reporting of seizures to their physician.

One needs to realise that there is a relationship between the social expectation or need to drive and the number of people with active epilepsy that drive illegally. This has been shown in the study of Berg (Berg et al 2000): seasonal or irregular employment increases the chance of driving illegally (as does being male, young and having a licence). There is likely an inverse relationship with the availability of public transport. The number of experienced seizures is also likely to influence compliance with the rules.
Compliance can only be increased if we can give an explanation of the risk-increase in terms that are understandable and convincing for the patient.

2. The search for a criterion

THE IMPACT OF EPILEPSY ON ROAD SAFETY

What is the impact of epilepsy on road safety? To establish this, several approaches are possible: a comparison of accident rates while applying different rules; a look at accident statistics or a calculation of risks based on a risk theory.

1 The effect of regulations on accident rates

One of them is a comparison of accident rates while comparing the effect of different medical criteria, applied in different places or different periods. In a recent study, the rate of seizure-related crashes in one American State did not significantly increase after the necessary seizure-free interval required after having had multiple seizures was reduced from 12 to 3 months (Drazkowski *et al*. 2003). Seizure-related crashes constituted 31% of all motor vehicle crashes due to medical causes in the same period.

2 Statistical studies

Another approach is to try and look at statistics about the possible impact of epilepsy on road safety.

If one looks at the increase of risk for the population at large, epilepsy-related accidents constitute a small minority:
-Only one hospital admission after a traffic accident in 250 has an associated medical factor. Of these, 37% was caused by epilepsy in the study by Taylor *et al*. (1995). This amounts to one in 675 hospital admissions, or 0.15% of serious accidents.
-Epilepsy-related accidents constitute an estimated 0.25% of all traffic accidents according to Parsonage. (Parsonage 1992). This is 1 in 400 accidents.
Only 11% of all accidents among individuals identified with epilepsy are reported as due to seizures. (Krumholz A *et al.* 1991)
First seizures (unavoidable) constitute on average 15% (Sonnen 1995) of seizure-related accidents.
In the Australian guidelines it is stated that epilepsy caused only 9 to 19 traffic accidents in 1991,being 0.025-0.053% of all traffic accidents in that year (Austroads), which is a factor 10 lower. These were medical causes collected via police reports, probably under-reported (Black 1996).
A population based study in the USA gave a number of 86 deaths per annum (total number per annum is 44,027; population about 275 million), which is 0.2% of all traffic deaths; 4.2% of deaths associated with medical conditions (Sheth SG 2004: see table 2)

Table 2 Causes leading to traffic deaths in the USA 1995-1997

	Number	Percentage
Seizures	86	0.2%
Diabetes	144	0.3%
Cardiac and hypertensive disorders	1800	4.1%
Young drivers	10,579	24%
Alcohol	13,434	31%
Others	17841	40.4%
Total deaths	43,884	100%

An European data bank (table 3) gives data about traffic accidents for the year 2001: 1,248,896 road accidents and 38,828 deaths. This is 31.2 fatalities per 1000 road accidents involving personal injury. In addition, 18% of all accidents are considered serious. (European internet site) These are figures about all traffic accidents. Cars seem to have a somewhat smaller death ratio: 22 per 1000 car accidents. The contribution of epilepsy to these figures is not known.

Table 3 http://europa.eu.int/comm/energy-transport-safety/

		Europe 2001	Europe 2000
A	Road accidents, involving personal injury	1,248,896	1,295,600
B	Per 1000 population		3.4 (1.4-5.2)
C	Victims		
D	Slightly injured		
E	Seriously injured	159.9 per 1000 of A	
F	Road fatalities	31.2 per 1000 of A	40,812 (31.5 per 1000 of A)
G	Serious + fatalities in %	201.1 per 10000 of A	
H	Fatalities in car accidents	22.0 per 1000	

NOTE
In recent studies the accident rate for people with epilepsy does not seem exclusively attributable to seizures. In the RESt-1 Group European cohort study (Van den Broek M and Beghi E 2004) accidents were investigated by type and circumstances. The risks for street accidents (many of them traffic accidents) were 5% at 12 months and 7% at 24 months (controls 2% and 4%; $p<0.001$) After exclusion of seizure- related events these figures decreased to 4% and 6% ($p<0.05$). Part of this increased risk might be due to the effect of medication. This increase in risk is not easily quantifiable and subject to individual assessment. In the following, we will deal with the risk increase due to seizures while driving.

SO THE NUMBERS ARE LOW, BUT ARE THEY INCREASED IN PEOPLE WITH EPILEPSY?

Two questions remain.
Is the number of accidents increased in people with epilepsy?
Do seizure-related accidents caused by persons with epilepsy more often lead to serious injury?

For a detailed discussion see Annex 4

CONCLUSION

The highest accident rate ratio found in overviews are 1.4 for serious accidents and 1.84 for all accidents in people with epilepsy compared to the general population. We will mainly look at serious or fatal accidents in this report and will use an accident rate ratio of 1.8 (!)for our risk calculations: a maximum estimate.

3 Risk assessment: theory

A driver can either have a (sudden) incapacity while at the wheel, as is the case in epilepsy, or an impairment, (meant as a permanent be it sometimes temporary disability) for instance visual disturbance, cognitive or motor deficit. Impairment in people with epilepsy is no different from impairment in other neurological disease and should be assessed accordingly. This is not the subject of this report. In the following we will only deal with incapacity.

TWO KINDS OF RISK

There are two kinds of risk involved in the assessment.

1 **A = Attributable risk**.

This is the increase in risk for the population, because there is a group of drivers that has an increased risk of an accident. The magnitude of the risk depends on the number of people in the group and the risk increase per individual in this group.
The formula that gives the relationship between the individual risk increase "R" and the risk for the population is:

$$A = P(R-1) \qquad \text{formula (1)}$$

Where A = risk increase for the population
P = the proportion of the population that has the increased risk under consideration
R = The relative risk is a ratio of risks: that of the group with the characteristic under consideration (epilepsy) compared to the group without this characteristic. (Ref: Spencer MB 2001) The "normal" population also has a risk of an accident. So the relative risk is a risk increase.
Assuming a prevalence of epilepsy in the adult population of 0.6% and assuming that 50% of people with epilepsy have a valid driving licence (this is a realistic value - see ANNEX 4) then (**P**) is 0.30 %

A quantitative approach to risk assessment as far as a sudden incapacity by a seizure is concerned requires a decision about the maximum acceptable accident rate for a person with epilepsy, on top of the risk for the population.
If no increase in overall risk is acceptable, any increase in risk because of epilepsy would have to be counterbalanced by a diminished risk elsewhere, be it a medical or a non- medical risk. In this report we advise to accept a small increase in risk for the population.

We propose to accept: **A** = 1% (The same percentage that was proposed by Sonnen in 1996: see ANNEX4)
Then the individual risk ratio of an accident **R** can be 4.3 (times, compared to someone without epilepsy)

If the percentage of people with epilepsy that drove would rise to a theoretical maximum of 70% (the percentage that will become seizure-free) (P) will become 0.42 and the corresponding R will be: 3.4.

Conclusion: the relative risk can be between 3 and 4.3 when we accept that A can be 1%

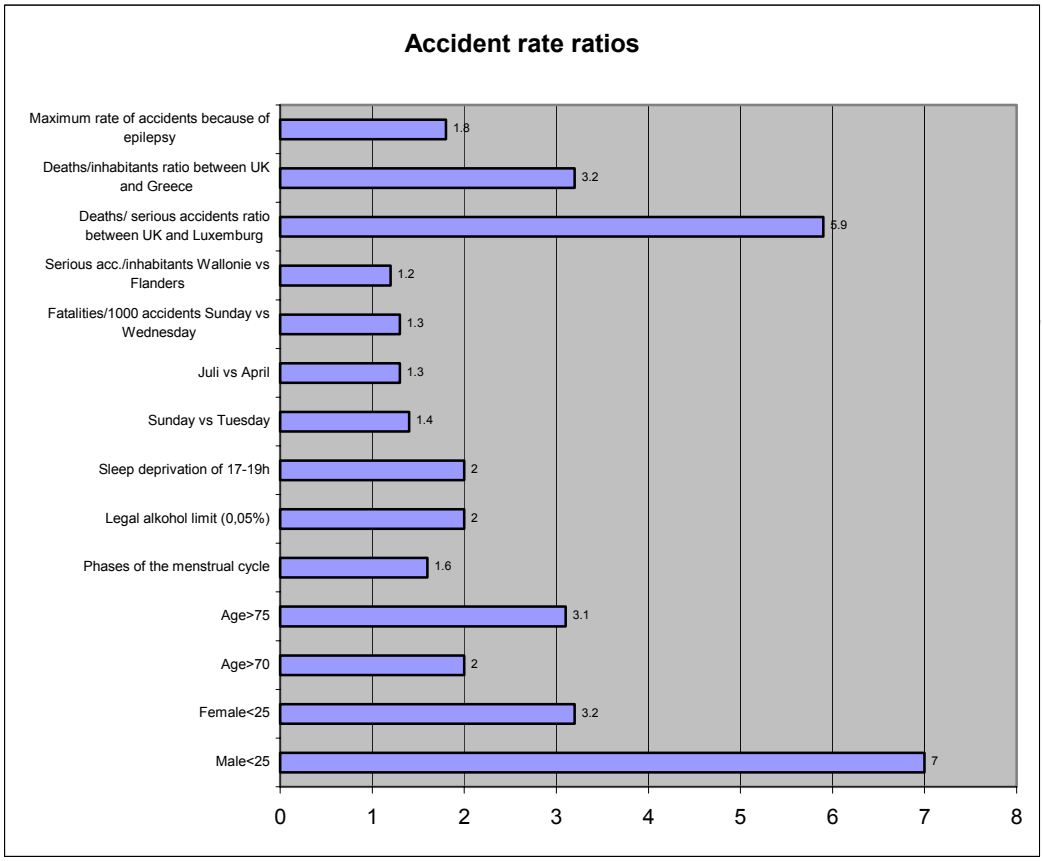
2 R = Relative risk

This is the risk of the group with the characteristic under consideration (epilepsy) compared to the group without this characteristic. (Ref: Spencer MB 2001)
To make a choice about which relative risk can be acceptable to us we have to look at other risks that occur in the general population.

An acceptable risk for the individual patient: comparison to other risks

The number of alcohol-related accidents is 30 times higher than that of epilepsy-related accidents. (Egli *et al.* 1977)
In the USA mortality study (Sheth 2004) this was 156 times! (not in the figure, but patients refer to it!)

Figure 1 Variability of unavoidable factors in the population



Data from the website of the Belgian Traffic Bureau (BIVV) and the "IMMORTAL" project, a study funded by the EU 2004

A number of common or unavoidable situations are mentioned in figure 1. The highest estimated risk for a driver with epilepsy is lower than most of these: 1.84.

Figure 1 shows some unavoidable variables that occur in the general population. These refer in part to Belgium, in part to Europe. The fact that young males or elderly people have got an increased accident rate is accepted as unavoidable and, in the elderly are due to an altered physical (and/or mental) functioning. It seems only fair to accept an increase in accident rate ratio for people with epilepsy that is comparable to these ratios, especially in view of the fact that the social consequences of not being able to drive for these people are often very important (loss of job, social contacts, disclosure of the epilepsy etc.).

Conclusion:

An acceptable individual accident rate ratio could be 3 to 6

Remark:

It seems more acceptable for the patient to base regulations on the "R", rather than on the "A" type of risk. It would also be easier to defend, so it might lead to better compliance with the rules.
At the same time, it is more fair: if we define "A" for a certain disease or for all medical causes, a disease that is prevalent like epilepsy or diabetes would have a resulting low "R"-value. Considering the small contribution of medical causes to accident statistics, the ultimate effect for the population will be low anyway, but the consequences for the patients are often important.

THE MEASURING STANDARD: THE "COSY" AND THE CHANCE OF CAUSING AN ACCIDENT

In the quantification of risk several factors have to be taken into account.

The additional risk that a driver with epilepsy runs (in comparison to those without epilepsy) so the risk of having an accident is mainly determined by four factors.

1. -the COSY (**C**hance of an **O**ccurrence of a **S**eizure in the next **Y**ear).
2. -the exposure to risk: the time spent behind the wheel
3. -the percentage of seizures behind the wheel that will lead to an accident.
4. -the likely outcome of an accident.

The likely outcome of an accident. This is generally measured in terms of serious injuries or fatalities. Less data seem to exist about material damage or danger for the environment. Statistics give the following numbers.
To stay at the safe side (ANNEX 4), we will assume that of all accidents there is:
21% chance of a serious accident
3% chance of a fatality (included in 21%)
0.6% of the population has epilepsy
60% of people with epilepsy have a driving licence.
All these values are "negative" estimates.

Time spent behind the wheel

Assuming that the chance of a seizure is equally spread over 24 hours, the chance of a seizure behind the wheel is a function of the time spent behind the wheel. (Note: according to Janz (1969), 50% of seizures occur during the 8 hours of sleep, which would lower the percentage during the “driving hours”!)
It is estimated that an average European with a driving licence spends 4% of his lifetime behind the wheel (60 minutes per day: this includes weekends, holidays etc). This means that only one in 24 seizures will occur behind the wheel. This number is in accordance with a Dutch figure that states that a driver drives an average number of 17.000 km per year. Taylor (1995) found a smaller total number of kilometres in Britain: about 10.000km (6000 miles). For Belgium, this figure was 15.000 km per year in 2001 (BIVV internet site). For group 2 we adopted a factor 5: on average these people drive 20% of their time (ANNEX 3).

The percentage of seizures that leads to an accident

An average of 5 studies shows that about half the seizures behind the wheel results in an accident (Sonnen 1995). Including the study of Berg *et al*. (2000) in this calculation the figure becomes 55,7%. This last study was done in a group of patients with refractory complex partial seizures which drove illegally and almost certainly overestimates the percentage for the epileptic population at large, seeing that most of the accidents are produced by patients with complex partial seizures (Krämer in Sonnen 1995).
In the following we will assume an accident rate of 60% per seizure behind the wheel (instead of 50%) for group 1; 80% for group 2.

The relation between the individual risk increase "R"and the COSY

If:
r = COSY (in %)/ 100
COSY means: the Chance of an Occurrence of a Seizure in the next Year, so the expected per annum seizure rate. This is often expressed as a percentage. Here it will be expressed as a ratio:
R = individual risk ratio compared to someone who does not fulfil the criterion (has no epilepsy)
F = the present fatal casualty rate per driver per year (in fact statistics give per car) It is estimated less than 1 in 7000 drivers (Annex 4)
D = proportion of time spent at the wheel. For group 1 this is 4.2% (one hour) or 0.042
X = probability of a seizure at the wheel leading to a fatality. The probability of a seizure at the wheel leading to an accident is 0.6 The chance of 3% of having a fatality can be multiplied with this factor: X is 0.6 x 0.03 = 0.018
The relation between **R** and **r** is given by formula (2)

r=(R-1).F/(DX) formula (2)

If for **group 1**:
F=0.00014; D=0.042 X= 0.018Then:
DX is 0.00076 F/DX is: 0.183
And:
r=(R-1). 0.183

For r = 0.02	R = 1.11	For r = 0.37:	R = 3.
For r = 0.10	R = 1.55	For r = 0.40	R = 3.2
For r = 0.20	R = 2.1	For r = 0.60:	R = 4.2

(Ref: Spencer MB 2001)

Conclusion

This implies that even in the worst case scenario if we accept an R = 3, as a value for the individual risk increase, the COSY can be as high as 37% while the risk for the population remains under 1. If one takes 20% COSY as the limit, R = 2.1 and A < 0.5%.in the worst case. As argued above, we do not advocate this last choice.

RECOMMENDATION 1

It is recommended that risk assessment shall be based on the risk for the individual ("R": relative risk) rather than on the risk for the population. For group 1, a relative risk of about 3 is acceptable. This implies that a COSY between 20% and 40% is acceptable.

THE CALCULATION OF INCREASED RISK FOR GROUP 2

There are two sets of criteria for medical assessment. Group 1 refers to non-commercial driving (cars and motor bikes) and group 2 to commercial (professional) driving (buses and HGVs). The medical assessment for group 2 in some countries (e.g. Belgium) is also applicable to the transport of people in a broader sense, e.g.: if this is organised and run by the employer.

The European workshop of 1996 accepted an arbitrary factor of 5 for the severity of an accident if caused by a heavy-goods vehicle compared to a private car (Sonnen in: Commission on Epilepsy, Risks and Insurance of the IBE 1994). A professional driver typically spends up to 8 hours per working day behind the wheel, which is 20% of his lifetime - about six times as long as car drivers.

From these approximations, it was taken that the maximum COSY for group 2 would have to be 30 times less. This resulted in an acceptable chance of a seizure in the next year of 2% (60% as a COSY for group 1 divided by 30 is 2% COSY for group 2).
This same percentage is used in the American consensus statement and in the official Australian Guidelines (AAN *et al*.1994; Austroads Incorporated 2003).
The European workgroup recognised the differences in risk for the respective categories of vehicles for which a group 2 assessment is required, but “for the sake of simplicity” the same rate for all was put forward.

Sonnen in his report (Sonnen 1997) calculated the risk for the different vehicles. He attributed factors of severity for 4 items:

1. driving time
2. toll of accidents
3. seizure/accident ratio
4. passenger transport.

We tried to find European statistics to base these factors on. For an extensive account, see ANNEX 3

Comparison of risk ratios: group 2 vehicles compared to cars.

Elsewhere we have argued that a certain risk is acceptable for drivers of cars. Here we have tried to establish how much more severe we have to be in the assessment of group 2 drivers. To that end, we tried to determine an overall factor of severity compared to car drivers. Because of the paucity of statistical data for Europe the approach can only be very approximative. We used global data from the literature and conclude that the overall factor 20 that Sonnen applied cannot be corrected on the basis of statistical data. For driving time and Toll of an accident see Annex 3. The seizure / accident ratio is 60% for group 1; 80% for group 2: a factor 1.33 more.

Table 4: Factors of increased risk for some vehicles compared to cars

	Bus	HGV
Driving time	5	5
Toll of accidents	3	3
Seizure / accident ratio	1.33	1.33
Overall risk factor	20	20

Conclusion

The overall factor 20 applies to buses and HGV´s. So we have no reason to change the 2% rule. Some other vehicles that, in some countries, drive under group 2 conditions do not need to be assessed as severely. (e.g. taxis) In countries where the transport of people organised by the employer in a car is assessed according to the criteria of group 2 the assessment should take account of the number of people transported and an arbitrary safety factor (3-5?).

Motorbikes should be assessed more severely than cars, because of a greater danger for the driver, or at least should the patient be informed about this. The danger to the driver is 2 to 3 times increased compared to a car.

RECOMMENDATION 2:

If we accept 40% or even 33% for group 1, the 2% rule (COSY should be <2%) can still apply for group 2. Car driving used for professional purposes carries in general a lower risk, as does taxi driving and the like. The COSY can be accordingly higher.

AN ESTIMATION OF THE RISK FOR THE POPULATION

Epilepsy and the current rules

If people with epilepsy adhere to the rules, the risk for the general public seems low. The above data from the literature give only rough approximations. Here we will attempt to estimate the impact of epilepsy on traffic statistics.

We propose to accept a ratio of 2 to 3 times. The most important groups however will have a risk increase no greater than R = 2 (see the next chapter). Fatal accidents were 3 % of all accidents in 2001. If this last number was increased up to 2 times it would become 6% for people with epilepsy. The number of injury accidents per year is about 3.4 per 1000 inhabitants, so 3,400 per 1 million population (this figure pertains to all accidents, not just vehicle or car accident!). Of these 63% are car accidents this is 2,142 per million. If 0.6% of the population has epilepsy and 70% of patients qualify for a drivers licence, 0.42% of the driving population could have epilepsy. These people would produce a proportional number of fatalities: 9. If we accept an accident rate ratio of 2, they will produce 18 fatalities.

So for car accidents the extra number of fatalities because of epilepsy is about 9 fatalities of a total of 3,400 per million !

CONCLUSION

The risk for the population is acceptable if people comply to the rules.

The first seizure

How many people in the population have a first seizure

Jallon (Jallon 2001) lists studies in western countries and concludes that there is a mean incidence per year of 70 / 100.000 Hauser finds 61 per 100,000 person-years for first unprovoked seizures (and 44 / 100,000 for epilepsy: Hauser 1996) A Swedish study finds an incidence of first seizures of 56/100,000/year between ages 17 to 60. Above age 65 the incidence was 139/100,000/year (men 166, women 116) (Forsgren 1996)
We will take 70 / 100,000 for our calculations. Of these, only 53% actually have a licence in Europe, but we will presume that 100% has a licence: 700 per million population.

What would happen if these people would all continue to drive their car till the second seizure (and then all stop driving)?

The number that recurs within a year is the average total recurrence (49%) times the percentage that has a second seizure in the first year (68%) (see below) = 33.32%. In 6 months this would be (53%) 25.97% and in 3 months (32%) 15.68%.
NOTE: for more explanation about these figures see page the next chapter: first seizure.

So of 700 people per 1,000,000 the number that will recur is 110 in the first 3 months, 182 in 6 months and 233 in the first year. In the long run 49% of 700 will recur: 343 people.
These people have a chance of an accident of (60% times 1/24) 2.5%. So 6 people will produce an accident in the first year, 9 in total.
Of the total number of accidents, 21% will produce a severely injured person including about 3% fatalities (so about 1 in 7 serious accidents leads to a fatality).
If we accept that the chance of having a serious accident or a fatality in people with epilepsy is twice that of the population (in most situations it will be less) these figures would be 42% and 6% respectively, but the increase is 21% and 3%. So 0.53% (21% x 2.5%) of people with a second epileptic seizure will have a serious accident because of this seizure: 1.8 people per 1 million population, of which 0.26 fatalities. In the first 6 months the number is 1.. In the first year it is 1.2 per million.

If these 700 people would all be allowed to continue driving (without restraint in time period) and if they all stop driving after the next (second) seizure this would cost 1.8 serious accidents per million population and 1 fatality per 4 million population.

What is the gain of not letting them drive for 6 months?

In the unlikely situation that these 700 people will stop driving for 6 months we save 1.7 serious injuries and 0.2 lives. So nearly half of the serious accidents will occur after the safety period and will not be avoidable.
Are we willing to pay the costs in terms of social and economic discrimination and harm? One of these 1.7 serious accidents will be a driver, 0.6 is a member of the public or a passenger.

What is the gain of not letting them drive for 3 months?

In the first 3 months, 1 serious accident (including 0.1 death) (of a total of 3.26) will occur as a consequence of a seizure at the wheel. The difference with 6 months is 0.7 serious accidents and 0.1 life.

These might be avoidable but many people will not be compliant to the rules, so the effect will be less, but the social consequence will be more: more people will drive illegally and possibly without insurance.

CONCLUSION

Here especially, the effect on the level of the population is small. The social and economic consequences are bound to be high in this group that has not (yet) adjusted to their new status. The difference between 3 months or 6 months driving ban for first-seizure patients is 0.7 serious accidents and 0.1 life per million population.

THE DRIVING RISK OF ALTERNATIVE TRANSPORT

Table 5: Data from the Netherlands suggest that driving a car is one of the least dangerous forms of road use.

The Netherlands 2001:victims per 1 billion driving kilometres per vehicle type		
	Victims	Ratio / car
Car (driver)	4.57	1.00
Car (passenger)	3.22	0.70
Moped	86.68	18.97
Light moped ("snorfiets")	116.8	25.55
Bicycle	15.76	3.45
Pedestrian	33.21	7.27

If people cannot drive their car, they very often have to use another means of traffic, like a moped, that, in some countries, does not require a drivers licence. These are all 3-25 times more dangerous per kilometre driven. What to advise them?

RECOMMENDATION 3:

The dangers for the population are low if people continue driving in a car after a first seizure and the effect on the population level of not letting them drive may not outweigh the socio-economic disadvantages. The increased risk is often acceptable to the patient. The alternatives of car driving: are often more dangerous for the patient. This is a group that has not accepted (yet) their disease and resulting incapacity. Compliance is bound to be low. After a neurological workup, restricted driving without passengers might be a solution for a prognostically favourable group.

3 When does a patient reach this risk-threshold: The influence of the seizure-free interval in different situations.

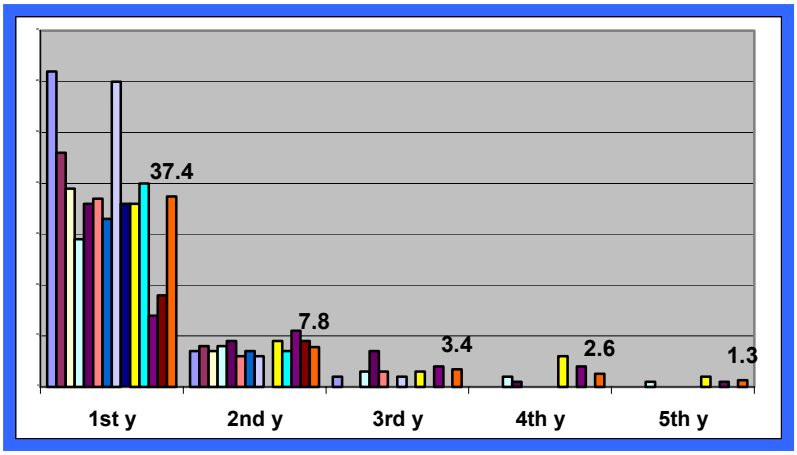
It is general experience that with an increase in the duration of the seizure-free interval, the chance of recurrence decreases. How this chance changes over time is of critical importance in the determination of the required seizure-free intervals in different situations. In the following, we try to describe two relevant parameters for the different situations:

1. The total chance of a recurrence.
2. The course of this chance over time

FIRST UNPROVOKED EPILEPTIC SEIZURE

The first question is to determine what would be the recurrence rate after a first seizure. For this reason we collected 13 studies that gave data about the recurrence in the first one-to-five years after the event and we arranged them according to the percentage of patients treated in the study. (Elwes *et al.* 1985; Stroink *et al.* 1998; FIRST 1993; Shinnar *et al.* 2000; Shinnar *et al.* 1996; Hopkins *et al.* 1988; Hart *et al.* 1990; Sander *et al.* 1990; Van Donselaar *et al.* 1991; Hirtz *et al.* 1984; Camfield *et al.* 1989; Annegers *et al.* 1986; Camfield *et al.* 1985; Hauser *et al.* 1990) One study was split into a treated and an untreated group and processed as if they were two different studies (FIRST 1993). This gave an impression of the overall recurrence rate, which was on average 46,2%. Weighting the average made little difference. Many neurologists do not treat patients after a first seizure, so the more important percentage is the average recurrence of the three studies (Elwes *et al.* R 1985; Stroink *et al.* 1998; FIRST 1993) in which patients were not treated, which was 55,5%. Out of the seven studies in which no more than 15% of the patients were treated, the average recurrence rate was 49%. In contrast, of the two studies with at least 80% treated patients, recurrence rate was 33,1%. These figures are in keeping with the observation that the recurrence rate in treated patients is roughly 50% lower in accordance with the findings of the FIRST study.

Fig 2: Five-year recurrence rate by percentage of treated patients



Legend of fig 2

Elwes 1985	0
Stroink 1998	0
FIRST 1993 untreated	0
Shinnar 2000 / 96	14
Hopkins 1998	15
NGPSE 1990	15
Van Donselaar 1991	15
Hirtz 1984 non-provoked	27
Camfield 1989	30
Annegers 1986	61
Camfield 1985	68
Hauser 1990 / 82	80
FIRST 1993 treated	80
Average % recurrence	

From this, a reasonable estimate of the recurrence rate after a first seizure in untreated patients would be 55%, in treated patients 33%.
In the meta-analysis of Berg *et al.* (1991), the average percentage recurrence risk in carefully selected studies was 42% in 2 years (treated and untreated patients). In an overview of the literature, Beghi *et al.* (1997) finds a range of 25-52% with an average of 38% in 2 years. Assuming a 87% recurrence in the first 2 years these averages imply about 49% and 44% of total recurrence risk respectively

Table 6: Average total recurrence after a first seizure

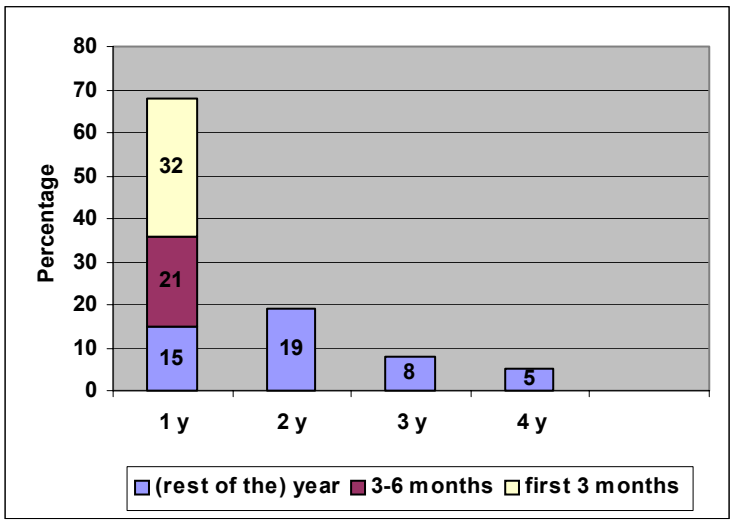
Author	Percentage
Beghi	44%
Berg	49%
Our compilation	46%
No treatment (3 studies)	55%
Treated (2 studies)	33%

The second question is the behaviour of the a priori recurrence rate over time *in the group where there were recurrences*. We found eight studies with a follow-up of longer than 2 years (in: Berg *et al* 1991; and: Hart *et al.* 1990; Sander *et al.* 1990) and two studies providing data about recurrences in the first 3 months and 6 months after a first seizure (leaving the Hirtz study out, because it provides data about very young children)(FIRST 1993; Annegers *et al.* 1986). Berg *et al.* (1991) in their meta-analysis calculated the percentage recurrence risk as a percentage of the total risk after 4 years in the studies that provided data over a longer period and found an average of 87%. We recalculated these data with the addition of later studies (Hart *et al.* 1990; Shinnar *et al.* 2000; Hui *et al.* 2000) and found a very similar number: 86,5% after 2 years. A recurrence risk in the 3rd, 4th and 5th year after a first seizure can be estimated from their data: respectively 8%, 5% and 4%.

What happens in the first year?

All studies gave data about the recurrence rate in the first 2 years. For that reason, the calculations of the data from the two studies that provided percentages about 3 and 6 months after the first seizure were recalculated assuming a fixed recurrence-percentage of 87% after 2 years. The percentage recurrence after 3 months was 32%; after 6 months 53% and after one year 68%. These percentages are put together to get an approximate curve of recurrence over time (Figure 3). Seeing that in Hauser's study the percentage recurrence in the first 3 months is 44% and 41%, the likelihood is that figure 3 is a conservative estimate.

Figure 3: When does recurrence take place if it occurs?



What happens after five years?

There are few data about the recurrence risk after 5 years. These seem to suggest a yearly recurrence of approximately 2% (Boulloche *et al.* 1989; Hauser *et al.* 1990 and Shinnar *et al.* 2000). Confidence intervals for these data are not published but will increase when follow-up is longer, because of decreasing sample size.
Annegers *et al.* (1986) state that the recurrence risk fell after 4 years of seizure-freedom to <5% in the fifth year. He mentions 7 recurrences among 117 subjects who were seizure free for >5 years (6%) without stating the time period

in which these recurrences occurred. Hauser (Hauser A in Jallon 2003) states: “Relapse was about 1% per year for the first 10 year after fulfilling remission criteria…” (5 years remission with or without medication)

THE FIRST PRESUMED IDIOPATHIC SEIZURE

An exceptionally low total recurrence risk was found by Van Donselaar *et al.* (1992) after a first unprovoked seizure "presumed idiopathic" (10% in the first year C.I. 2-18%; 12% in the first 2 years C.I. 3-21%). Here, "idiopathic" means without any apparent cause: normal neurological examination; normal CT scan; no abnormalities on a standard EEG and an EEG after (partial) sleep deprivation. This is not the same as "cryptogenic" according to the definitions of Engel, who defines cryptogenic as "probably symptomatic, but no aetiology has been defined" (Engel 2001). Similar percentages for the "idiopathic" group have been published by Berg, Hauser and Annegers (Berg *et al.* 1991; Hauser *et al.1990;* Annegers *et al.* 1986) (after 2 years respectively 24% [C.I. 19-29%], 21% and 22%) For the calculations below (Figure 4), we used 25% total risk over 4 years (about 22% in the first 2 years).

THE FIRST PROVOKED EPILEPTIC SEIZURE

What do we call "provoked"? If the seizure has a recognisable causative factor that is avoidable.
For many provoked seizures the recurrence risk is not known.
In some situations, like seizures provoked by medication or some metabolic diseases that might be cured and will not recur, driving ability might be considered sooner.
In others, like sleep deprivation or alcohol, a personal judgement is indispensable.
Certain brain disease, like serious cerebral trauma and bacterial or viral cerebritis, give a high chance of later seizures. In these situations, a prophylactic driving ban might be indicated, especially in Group 2.

EPILEPSY: MULTIPLE SEIZURES

Hauser *et al.* (1998) give data of the total recurrence after 2 or 3 seizures. After 2 seizures, 73% relapsed in an observation period of 4 years; after 3 seizures, 76% in an observation period of 3 years. Out of the patients that have a relapse, most - about 60% - will do so in the first 6 months (Table 7). In the table recurrence risk is given as a percentage of the total recurrence over the observation period, so the above-mentioned 73% and 76% would be expressed as 100% in this table.

Table 7

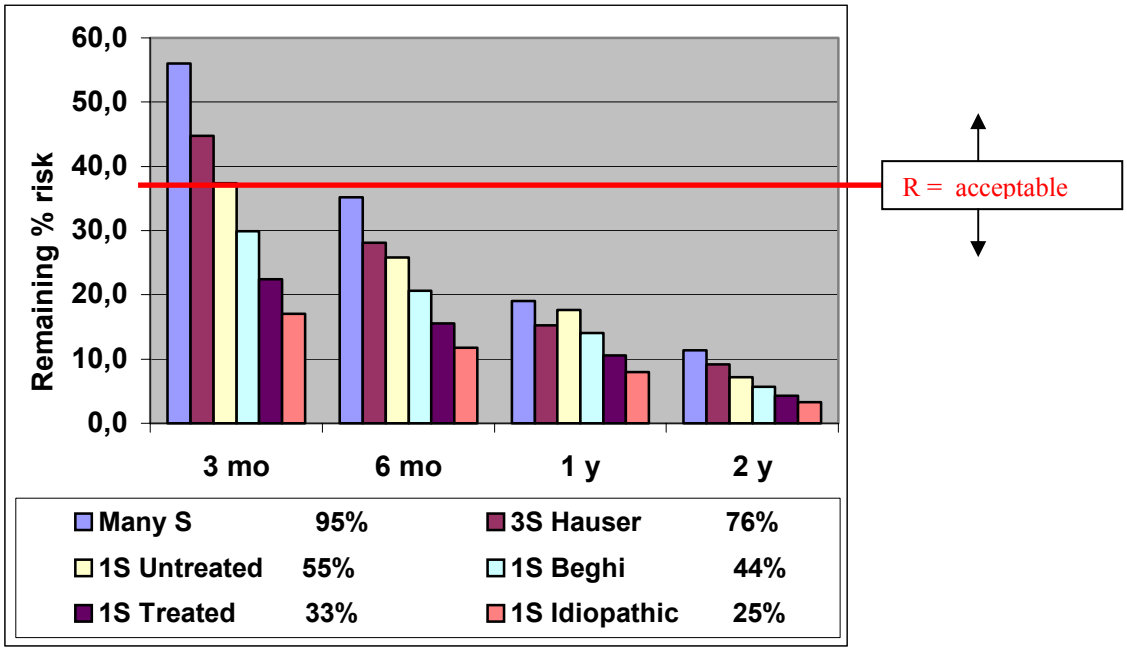
Recurrence risk as a percentage of the total recurrence over the observation period			
	After a number of seizures		
	1	2	3 or more
After the first 3 months	32	44%	41%
At 6 months	56	56%	63%
At 12 months	68	78%	80%
At 24 months	87	83,5%	88%

THE REMAINING RISK OF RECURRENCE AFTER A GIVEN SEIZURE-FREE PERIOD.

The product of these two figures, namely a) the total chance of recurrence in a certain situation and b) the percentage that relapses in a given period, gives an estimate of the remaining risk of a seizure after having attained a certain seizure-free period. In Figure 4, the result of such a calculation is shown for different situations: assuming 95% recurrence risk after several seizures (and applying the recurrence curve that was found after 3 seizures: Table 4); for Hauser´s data after 3 seizures; and for four situations after a first seizure: an untreated group, a treated group, the average found by Berg, and an "idiopathic" group. For these four first seizure groups, the data from the recurrence curve as shown above (Figure 3) are used. The recurrence curves for more than one seizure are somewhat steeper than the one after the first seizure. From Figure 4, one could deduce that an acceptable risk level (e.g. the 40% mentioned above as a worse case scenario) after one seizure is reached at 3 months and after more seizures at 6 months. Critics will point to the fact that the data have not been reproduced and that the confidence intervals are unknown. It seems, however, likely that we will have to live with these uncertainties in the foreseeable future. Decisions will have to be made on available evidence even if the evidence is not ideally suited.
It might be worth noting that 39 of 51 states of the USA regulations require seizure-free periods of 6 months or less, or have flexible restrictions in the case of epilepsy (Krauss G *et al.* 2001; Krauss G 2002).

An interesting study is the one of Krauss (Krauss et al 1999) They compared 50 patients with a seizure-related accident with 50 patients without an accident and found that the period of seizure freedom has a strong influence on the chance of an accident. If everybody had kept a seizure-free period of 12 months, 93% of the accidents would have been avoided. This percentage was 85% for a seizure-free period of 6 months. For 3 months it was not significant.

Figure 4: Remaining percentage recurrence risk (RRR) for six different situations at 4 seizure-free intervals (S = seizures)



A POSSIBLE CONSEQUENCE: LIMITED LICENCE

If one accepts the concept that the risk is linked to time spent behind the wheel, restricting the time or distance driven will decrease the risk. This can be an important alternative for people who are responsible enough and who cannot reach their work by other means of transport or in similar situations. One population based study found that a restricted licensing program appears to provide a significant decrease in the rate of crashes and traffic violations (Marshall SC *et.al. 2002)* Krumholz (Krumholz 1991) comes to a similar conclusion: one could limit the driving to necessary trips (work, school, shopping).

RECOMMENDATION 4

It is recommended that for every driving assessment an estimate of the COSY of the relevant situation is determined according to the described principles. This result can be compared with the acceptable R as described in chapter 2.

4. Less quantifiable factors in assessing the ability to drive

The 1995 and 1996 European workshops recommended the period of seizure-freedom as the most important criterion for assessment of the ability to drive and the following is an attempt at quantification thereof. However it is by no means the only factor to take into consideration. Many of the other factors are not quantifiable, which makes a personal assessment indispensable.
However, care should be taken not to use factors that would not be considered in people without epilepsy!
A number of favourable and unfavourable modifiers are described in the literature:

UNFAVOURABLE FACTORS

Unfavourable factors for recurrence of seizures

- Non-compliance with medication or medical visits and /or lack of credibility
- Alcohol and/or drug abuse in the past 3 months
- Structural brain lesion
- Non-correctable brain functional or metabolic condition
- Periods of frequent seizures after seizure-free interval
- Severity of the seizure (e.g.: complex partial seizures)

Unfavourable factors because of impairments

Impairments should be assessed appropriately and in accordance with the national regulations. If in doubt about the ability to drive, a practical driving test or cognitive tests can be useful.

Unfavourable factors because of other variables

- Driving a motorcycle
- Transport of passengers If the carrying of passengers is forbidden for drivers in group 1, this can reduce injuries and fatalities)
- Driving considerable more hours at the wheel than the average number of hours taken for the calculations (1 hour for group 1; 5 hours for group 2)
- Young age (under 25)
- The nature of the driving task (transport of people; explosives; chemical substances)
- Other co-morbid conditions that have an increased risk (diabetes, cardiovascular, visual etc)
- Medication, especially multiple drugs

For the assessment of drivers in group 2, extra care is needed in drivers of buses and drivers that transport dangerous goods.
Motor cycle drivers are likely to have an accident with most seizures while driving (not just a 50% or 60% risk). Moreover there are 2 to 3 times as many seriously injured + fatalities per vehicle in motorcycles compared to cars. (Belgian data 2001: cars 12.7; motorbikes 33.0 per 10,000 vehicles). The ratio serious accidents/all accidents, is 15 for cars and 27 for motorbikes.(Belgium 2001: BIVV website) Here the risk increases accordingly.
The RESt-1 group found an increased relative risk for non-seizure related events of 1.4 in patients without seizures. (Beghi 2002) It was argued that this could be an effect of medication.

FAVOURABLE FACTORS

Favourable mitigating factors will decrease the chance of recurrence or the chance of an accident.

- Provoked seizures
- Seizures during medically directed medication changes
- Seizures that do not interfere with consciousness or motor control
- Established pattern of pure nocturnal seizures.

Could be added:

- Treatment of the first seizure

Treatment of the first seizure does on average improve the recurrence risk (FIRST study 1993), but only for the first 2 years.

For most of these favourable modifiers, specific articles are part of the medical criteria in some countries. They are discussed in the above chapter. Others that are mentioned in the American consensus statement (AAN *et al.* 1994) or

by Beaussart (1994) are not. Seizures after sleep deprivation are not considered avoidable in most instances. An exception could be seizures after excessive sleep deprivation. Prolonged and consistent auras are proven not to be safe enough (Krauss *et al*. 1999).

Drachman (Drachman 1999) gives a list of questions to which the physician should provide an answer:
1. The cause of the episode (type of disorder) suffered
2. The means by which the condition is controlled (including medications and dosages)
3. The degree of impairment or disability suffered during an episode (extent of the episode)
4. The probability of recurrence of the episode (including frequency of recurrence, degree of assurance that the event will not reoccur, and the basis of estimate of this probability)
5. The date of the most recent episode
6. Certification, to a reasonable degree of medical certainty, that the individual's medical condition and medication will not interfere with the safe operation of a motor vehicle

The epilepsy syndrome

Not enough available data. See G Kraemer in Sonnen 1997. According to a recent study (Carole), it is possible in a majority of patients to diagnose the epilepsy syndrome. This could have prognostic implications if it is confirmed.

EEG

First seizure. The EEG is part of the diagnosis of epilepsy and therefore a necessary investigation after the occurrence of a first seizure. It also has a prognostic significance, as will be discussed below, in the case of a first seizure without detectable cause and normal EEGs.
Epilepsy and the prediction of seizure-free episodes. Limited prognostic value in this situation.
Exclusively seizures in sleep. The EEG can be useful in the diagnosis of generalised versus partial epilepsy, which is a prognostic factor in the study of Park et al.(see below).
Provoked seizures. The occurrence of epileptic activity after the acute period is a logical argument against the diagnosis of "provoked seizure"
Stopping medication: here Berg (BERG A et al 1997) found 15 studies. The range in relative risk for an abnormal EEG just before discontinuing medication was 0.82 to 6.47 with a typical estimate of 1.45.
Suspicion of "subclinical" seizures - mainly in some primary generalised epilepsy syndromes. Testing with the aid of video-EEG monitoring is advisable in this situation to determine the influence of epileptiform discharges on consciousness and cognitive function.

Medication

In the study of Taylor no increased risk was found in people taking AED (Odds ratio: 0.97 CI: 0.87-1.07). (TAYLOR 1996)
In the RESt-1 Group European cohort study (Van den Broek M and Beghi E 2004) accidents were investigated by type and circumstances. After exclusion of seizure- related events the risks decreased to 4% and 6% ($p<0.05$) but remained higher than the controls (2% and 4%; $p<0.001$). Part of this increased risk might be due to the effect of medication. A recent Belgian review classified drugs in groups according to their possible influence on driving. More detailed data were not found. Phenobarbitone, Primidone and Hydantoine were classified in group 3 ("probably a serious negative influence is possible"); All the other antiepileptic drugs in class 2 (probably a light (Valproate) or moderate (Carbamazepine; benzodiazepines) negative influence is possible). For the newer antiepileptic drugs influence was uncertain because of lack of data. (THE TOXICOLOGICAL SOCIETY OF BELGIUM AND LUXEMBOURG "Invloed van geneesmiddelen op de rijvaardigheid" Literature-study for the Belgian Institute of Traffic Safety (BIVV) 1999. Ed: BIVV, Haachtsesteenweg 1405 Brussels 1130 Belgium. The study is available in French). In clinical practice the main concern is during the period of drug initiation. Cognitive side effects vary, but are generally less in the newer AEDs.
A different question is the use of AEDs as a treatment of the first seizure or in the treatment of epilepsy. See below.

Driving time

If we accept the calculations based on driving time, a licence that restricts the time behind the wheel seems a alternative that is worth contemplating in certain situations. See "Limited licence"

RECOMMENDATION 5

There are many factors at play in the ability to drive that cannot easily be quantified. An individual assessment by a neurologist is recommended for every patient that has had one or more seizures.

5. Legal issues

It is preferred that the criteria should appear in guidelines rather than in the law. The law cannot provide more than a framework of minimum criteria. Each person has to be assessed individually.

WHO SHOULD DO THE ASSESSMENT?

The members of the Advisory Committee on Epilepsy and Driving are of the opinion that the final assessment of driving ability should be done by an independent doctor, not by any treating physician. This is already the case for group 2 in some countries, because of the complexity of the problem and the specific knowledge required about the working task and environment. It is advisable that the final licensing decision for group 1 drivers should also be taken by an independent doctor.

THE QUESTION OF IMMUNITY

In the case of the doctor reporting to the authorities the doctor should be legally protected against claims of breaking medical confidence. He should also be legally protected against claims about the consequences of his assessment and his advice.
These positions are in agreement with a consensus statement of the American Academy of Neurology, the American Epilepsy Society and the Epilepsy Foundation of America (AAN *et al*. 1994). The Working Group recognises the obligation to inform the patient about an eventual driving prohibition but is of the opinion that this obligation should be part of medical deontology, not of the law.

THE LEGAL STATUS OF A STATISTICAL DECISION

Whether somebody will experience a seizure in the (near) future is not a yes-no decision, but a weighing of odds. If the law asks a doctor to decide if a patient is able to drive, this question ideally is to be translated into a percentage of chance that the patient has to experience a seizure in the defined period (month or year) following that decision. The chance of a seizure in the next year is estimated on the basis of statistical data. Given that chance, we can estimate the chance of a seizure behind the wheel and the chance of an accident in the next year.
It might be needed to give thought to the legal status of such a scientific decision.

LEGAL OBLIGATIONS

Should the licence holder or applicant inform the authorities of any relevant disease/change in his/her health?

This should be imposed by law, both while applying for a licence and in the case of any relevant change in health status of a holder of a licence.

Should the medical practitioner be legally bound to inform the authorities?

The treating physician should not be obliged to report the patient to the authorities. There was unanimous agreement with this statement. The literature abounds with articles that show that mandatory reporting does not work: it does not decrease the number of people with epilepsy that drive. It increases the non-reporting of seizures to the treating physician and interferes with treatment. It increases non-compliance with the regulations, illegal driving and driving without insurance. It is a very bad rule.
There could be however the possibility to report if the physician considers the situation exceptionally dangerous. The earlier European guideline states: "A doctor should only notify the authorities without permission of the patient in case of imminent danger to the public, where the patient refuses to inform the authorities".

SHOULD TAXI DRIVERS ETC. BE INCLUDED IN GROUP 2, AND IF SO, SHOULD THE RISK ASSESSMENT BE EQUALLY SEVERE?

The medical assessment for group 2 in some countries is also applicable to the transport of people in a broader sense, notably taxi drivers; rental services with driver; public transport; drivers for school transport; transport of people if this is organised and run by the employer. The decision to do so is a national competence. The reason to do so might be to give an additional assurance that the driver is fit to drive in the case of the transport of people (required risk), or might be because of a perceived increase in risk because of an increase in driving distance etc. (calculated risk). The difference between required risk and calculated risk for these groups reflects the additional "safety margin". Some quantification of risk for taxi drivers is attempted in this report.
It is clear, however, that the risk for these group 1 vehicles is by far not as high as for heavy goods vehicles or buses. These drivers should be assessed accordingly.

RECOMMENDATION 6

It is the responsibility, not of the doctor, but of the patient whether he drives or not and it is his duty to report to the authorities. This is inherent part of the proposals in this report and should be part of European and national law. Mandatory reporting by the physician is recognised as working against road safety because it discourages the declaration of symptoms by the patient.
The assessing physician should be legally protected as regards his advice about driving ability and if he reports or does not report the non-compliant patient to the authorities.

6. The medical criteria as recommended

GENERAL REMARK

The recommendations here proposed are meant to serve as a base for implementation in European law. The Working Group has taken the position that, in view of the different levels of scientific evidence, the recommendations are minimal medical criteria for safe driving. Sometimes it might be advisable to be more severe than the recommendations. In that case the opinion of the Working Group is expressed elsewhere in the report.

IMPAIRMENTS AND COMORBIDITIES

Impairments should be assessed appropriately and in accordance with the national regulations. Additional risk because of co-morbidities or other factors are subject to a personal assessment.

NOTIFICATION BY THE PATIENT

A person who has had an epileptic seizure should notify the authorities, not only when applying for a driving licence, but also when one or more epileptic seizures occur for the first time in a person who is already in the possession of a driving licence

DEFINITION OF EPILEPSY

For the purpose of these regulations epilepsy is defined as having had 2 or more epileptic seizures, less than 5 years apart.

GENERAL RULES

Drivers, assessed under group 1 with epilepsy should be under review till they have been seizure- free for at least 5 years.

For group 2 this period will be dependent on the clinical situation and will be longest for the person with a diagnosis of epilepsy, i.e. until 10 years freedom from seizures has been demonstrated without the aids of anti-epileptic drugs

A person who has an initial or isolated seizure or loss of consciousness should be advised not to drive

A specialist report is required, stating the period of driving prohibition and the requested follow-up

If the person has epilepsy, the criteria for an unconditional licence are not met. The patient should notify the Licensing Authority
It is extremely important that the patient's specific epilepsy syndrome and seizure type are identified so that an adequate evaluation of the person's driving safety can be undertaken (including the risk of further seizures) and the appropriate therapy instituted. This should be done by a neurologist.

GENERAL CONDITIONS FOR ALL GROUP 2 DRIVERS

For group 2 the criteria are more severe than for group 1. For that reason some general conditions have been put into place. These are:

GENERAL RECOMMENDATIONS FOR GROUP 2

The applicant should be without anti-epileptic medication for the required period of seizure freedom.

There has been an appropriate medical follow-up.

On extensive neurological investigation no relevant cerebral pathology has been established and there is no epileptiform activity on the EEG.

The subject can only be declared able to drive subject to neurological opinion.

The risk of having a seizure should be 2% per annum or less.

FIRST UNPROVOKED SEIZURE

For reasons mentioned above, 3-6 months of seizure-freedom will lower annual recurrence risk under 20%. If there are epileptiform discharges on the EEG, this makes 6 months mandatory. Treatment lowers the recurrence risk, be it only for the first 2 years (FIRST study 1993), but was left out of the criteria because it would induce unnecessary treatment of first seizures. Conditions described under "the first idiopathic unprovoked seizure" could lower the period of seizure freedom.
The period of 5 years seizure-freedom for group 2 seems acceptable (fig2), although confidence intervals are not known.

A note of caution
Three questions are of major importance

1. Is the event epileptic vs. non-epileptic?
2. Is the event a first epileptic seizure or a recurrence: in using statistics for recurrence after a first seizure it is presumed that it really was the first one. If more than one seizure has occurred other statistics apply that are less favourable. More than 50% of patients that first come to a neurologist will have had more than one seizure! One should specifically ask for the occurrence of isolated auras, absences and myoclonic jerks (Wolf P 1997).
3. Is the seizure provoked or unprovoked?

For each of these questions a number of anamnestic and hetero-anamnestic data should be collected.

RECOMMENDATION FOR GROUP 1

The applicant who has had a first unprovoked epileptic seizure can be declared able to drive after a period without seizures of six months, if there has been an appropriate medical assessment.

National authorities may allow drivers with recognised good prognostic indicators to drive sooner.

RECOMMENDATIONS FOR GROUP 2

The applicant who has had a first unprovoked epileptic seizure can be declared able to drive once 5 years freedom of further seizures has been achieved without the aid of anti-epileptic drugs, if there has been an appropriate neurological assessment

National authorities may allow drivers with recognised good prognostic indicators to drive sooner.

FIRST PROVOKED SEIZURE

While the above refers to unprovoked seizures, the situation after provoked seizures is much more complex because of the diversity of causes and of the prognosis. The provocation has to be *explanatory and avoidable* for a seizure to qualify for a different more lenient judgement. Metabolic and toxic disturbances, withdrawal of prescribed drugs, seizures provoked by medication, eclamptic seizures, stroke, trauma, intracranial surgery and infection can be considered in the latter case if the seizure occurred within 7 days. An EEG should be part of the neurological workup.

For group 2, some situations that are usually considered provoked seem to have a recurrence risk that is too high

Post-traumatic seizures

The recurrence risk after early post-traumatic seizures is 25-60% according to Jennett (Jennett 1975). Late seizures occur 50% - 60% in the first year; 85% in the first 2 years (Caveness 1979). After the first late seizure the recurrence risk is 86% in 2 years (Haltiner *et al.* 1997).
Cranial trauma is considered serious if one of the following characteristics is present.
In a population-based study (Annegers 1998) risk factors for late post traumatic seizures were: brain contusion, subdural haematoma; skull fracture; loss of consciousness or amnesia of more than one day and age above 65. The standardised incidence ratio was 1.5 after mild injury, 2.9 after moderate injury and 17.0 (CI12.3-23.6) after severe injury. According to the criteria of Jennett (Jennett 1995 and 1997) head injury is serious if there is an acute intracerebral haematoma, required surgery, compound depressed fracture or dural tear with more than 24 hours post-traumatic amnesia. The presence of one of these factors is a reason for assessment.

The driving authority should consider whether these patients require a practical driving assessment. Very often they have psychological or cognitive alterations, which are misjudged by themselves and their physician (Hawley 2001).

Seizures after cerebral infection

Sasic *et al.* (2002) found a total recurrence risk after "cerebritis" (meaning viral or bacterial encephalitis) of 57%. Yang (Yang SY 1993) investigated 140 cases with a brain abscess. In 28% there were epileptic seizures. Hauser *et al*.(1990) points out that after early seizures in this situation, the chance of recurrence remains high for 5 to 10 years! The article of Annegers and Hauser (Annegers 1988) is more specific and states an overall percentage of 6.8% over an observation period of 20 years. The highest increased incidence was found in the first 5 years. Specific risks of developing unprovoked seizures over 20 years were:

Viral encephalitis with early seizures	22%
Viral encephalitis without early seizures	10%
Bacterial meningitis with early seizures	13%
Bacterial meningitis without early seizures	2.4%
Aseptic meningitis (no different from population)	2.1%

These two causes (serious trauma and encephalitis) were excluded as acceptable provoking factors in the case of early seizures for drivers of group II in a Belgian consensus. Driving is consider under group 2 criteria after serious traumatic cerebral injury only if the following prerequisites have been fulfilled:
- no early seizures
- after individual assessment of the seriousness of the trauma
- after a seizure-free period of 2 years

For some other diseases high risk have been stated: arteriovenous malformation 30-45%; intracerebral haemorrhage 25% with a follow-up of 4.6 years (half of these occurred in the first 24 h); in another series 32%; subarachnoid haemorrhage 27.8% (Fisher 2001). Most of these figures are not usable as such to determine a COSY.

Other causes

Causes that are not considered sufficiently avoidable in general are: sleep deprivation unless exceptional and excessive; stress.

For alcohol and alcohol withdrawal seizures and seizures in association with the use of illicit drugs a controlled period of abstinence is needed. A seizure after a night of binge-drinking might be more avoidable than a withdrawal seizure, because the latter occurs in general in chronic alcoholics.

RECOMMENDATION FOR GROUP 1

The applicant that has had a provoked epileptic seizure because of a recognisable provoking factor that is unlikely to recur at the wheel can be declared able to drive on an individual basis, subject to neurological opinion.
NOTES:

1 The assessment should be if appropriate in accordance with other relevant sections of Annex III of the European directive . (e.g. in the case of alcohol or other co-morbidity)
2 For a guideline see: "Recommendation 1" page 10.

RECOMMENDATION FOR GROUP 2

As for group 1 and:

An EEG and an appropriate neurological assessment should be performed after the acute episode.

Someone with a structural intracerebral lesion who has increased risk of seizures should not be able to drive vehicles of group 2 until the epilepsy risk has fallen to 2% per annum or less.

PROPHYLACTIC BAN

As discussed above, certain disorders have a high risk of epileptic seizures, even if early seizures have not occurred. As to whether this situation exists for group 1 is debatable, but for group 2 some recurrence risks are clearly too high, even if these are given as total recurrence risk over a longer time period and the COSY is not exactly known.

RECOMMENDATION FOR GROUP 2

Certain disorders have an increased risk of seizures, even if seizures have not yet occurred. In such a situation an assessment should be done: the risk of having a seizure should be 2% per annum or less

SEIZURES OCCURING EXCLUSIVELY IN SLEEP

In some countries, where a person with exclusively seizures in sleep (which is not the same as nocturnal seizures) driving is only permitted during the day. There are to our knowledge no data in the literature to support this or are there any logical reasons. It was recommended that this phrase should be omitted. Some people get seizures at sleep onset. Does this ever occur when they are just drowsy? Some generalised activity increases in drowsiness. These patients are bound to have seizures as well.. Are there data about this? (a Medline search "seizures and drowsiness" in the last 25 years did not produce informative titles)
An older study found 2 recurrences in 34 patients who started with sleep seizures, but only in the first 2 years. (D´Alessandro 1983)
More recently, a difference in recurrence of awake seizures was found: secondary generalised epilepsy has a much higher 2 years recurrence risk than primary generalised. (Resp 26% CI^{99} - 46% and 5% CI^{99} -36%) For this last situation one year without awake seizures could be considered (Park 1998). It will often be difficult to discriminate primary from secondary generalised seizures in sleep, since it fully depends on observation by a third person, usually the bed partner. For that reason it might be prudent to allow driving after 2 years without awake seizures.

RECOMMENDATION FOR GROUP 1

The applicant or driver who has had seizures exclusively during sleep or seizures which have been demonstrated exclusively to affect neither consciousness nor cause any functional impairment can be declared fit to drive so long as this pattern has been established for a period which must not be less than the seizure free period required for epilepsy.

RECOMMENDATION FOR GROUP 2

Ban

SEIZURES WITHOUT INFLUENCE ON CONSCIOUSNESS OR ABILITY TO ACT AND WITHOUT (EVER) HAVING (HAD) ANY OTHER KIND OF SEIZURE

Some seizures are not considered to be of influence on driving ability, mainly some myoclonias and simple partial seizures. Evidence about the (non-) harmfulness of these is lacking. In the first European Committee, there was no consensus about this. In the experience of the authors this situation is rare.

RECOMMENDATION FOR GROUP 1

The applicant or driver who has had seizures exclusively during sleep or seizures which have been demonstrated exclusively to affect neither consciousness nor cause any functional impairment can be declared fit to drive so long as this pattern has been established for a period which must not be less than the seizure free period required for epilepsy.

RECOMMENDATION FOR GROUP 2

Ban

SPORADIC SEIZURES: OLIGO-EPILEPSY

Some people only have rare seizures. If this has been the case for some time, the calculated total recurrence risk is low (50% for an interval of 2 years; 33,3% for 3 years etc.) In accordance with the recommendation of the European workshop (Sonnen 1997) these cases could be assessed as a first seizure.

RECOMMENDATION FOR GROUP 1

If the period between the last seizure and penultimate seizure is more than 5 years, the last seizure may be considered in a similar fashion to a first unprovoked seizure for licensing purposes, subject to neurological opinion.

RECOMMENDATION FOR GROUP 2

Ban

CHILDHOOD SEIZURES

RECOMMENDATION FOR GROUP 1

See under epilepsy. No specific recommendations

SEIZURE-FREEDOM AFTER CURATIVE EPILEPSY SURGERY

A 1 year seizure-free period was accepted. This seems a safe period for all subgroups described in a recent review (Spencer 1996). The occurrence of acute postoperative seizures predicted a less favourable outcome in children and adolescents: 49% experienced seizures vs. 20% in the control group (Park K 2002). In a recent retrospective study (McIntosh A et al 2004) patients with two seizure-free postoperative years had a 74% (CI 66-81) probability of seizure-freedom by 10 postoperative years. For one seizure-free postoperative year this percentage was 70 (CI 62-77). The percentage of patients that remained seizure free declined sharply in the first 6 months, less so in the first one to two years, less still thereafter. For the large majority of the patients (the groups with Hippocampal sclerosis or a foreign tissue lesion) the sharp decline was limited to the first year. After two years the decline was in the order of 2 to 3% a year for these groups. This trend seems to last for the duration of follow-up: up to 20 years.
Due attention should be given to visual field testing after epilepsy surgery on the temporal lobe.

RECOMMENDATION FOR GROUP 1 AND 2

See under epilepsy no specific recommendations

UNDERLYING PROGRESSIVE DISEASE

RECOMMENDATION FOR GROUP 1 AND 2

See under epilepsy no specific recommendations

BREAK-THROUGH SEIZURES

RECOMMENDATION FOR GROUP 1 AND 2

See under epilepsy no specific recommendations

SEIZURES AFTER DECREASE OR CHANGE OF ANTI-EPILEPTIC MEDICATION

It was not deemed necessary to prohibit driving when the medication is stopped. Data from the MRC study (1991) suggest a 32% COSY on stopping treatment after a seizure-free period of at least 2 years (but in fact on average more than 3 years). Berg & Shinnar (1994) found 25% (C.I. 21-30%) COSY for the first year, an additional 4% for the second year. An American guideline finds total (!) weighed relapse rate in 9 studies in adults of 39,4% after a variable, but in general very long follow-up(Practice Parameter 1996) and the MRC study patients started with a COSY of 40%, which reduced to less than 20% in the second year after medication stop: important numbers for counselling. This last finding lead in the U.K. to the guideline that the patient should be given the advice not to drive during the period of medication reduction and for 6 months thereafter. The advice is to inform the patient about recurrence risk.
A 3 months driving ban on recurrence while stopping medication seemed reasonable. The COSY is 28% after 3 months without further recurrence in this situation, 21% after 6months and 20% after 12 months in the MRC study (Chadwick D in Sonnen 1996)

RECOMMENDATION FOR GROUP 1

Patients should be warned of the risk they run coming off medication, both of losing their driving licence and also of having a seizure, which could result in a road traffic accident. The patient may be advised not to drive from commencement of the period of withdrawal and thereafter for a period of 6 months after cessation of treatment
Seizures occurring during physician advised change or withdrawal of medication require 3 months off driving if the previously effective treatment is reinstated.

RECOMMENDATION FOR GROUP 2

Not applicable

EPILEPSY

RECOMMENDATION FOR GROUP 1

Drivers or applicants can be declared fit to drive after a 1-year period free of further seizures.

EXCEPTIONS.
If the period between the last seizure and penultimate seizure is more than 5 years, the last seizure may be considered in a similar fashion to a first unprovoked seizure for licensing purposes, subject to neurological opinion.
The applicant or driver who has had seizures exclusively during sleep or seizures which have been demonstrated exclusively to affect neither consciousness nor cause any functional impairment can be declared fit to drive so long as this pattern has been established for a period which must not be less than the seizure free period required for epilepsy.

RECOMMENDATION FOR GROUP 2

10 years freedom of further seizures has been achieved without the aid of anti-epileptic drugs.

National authorities may allow drivers with recognised good prognostic indicators to drive sooner.

OTHER LOSS OF CONSCIOUSNESS

Every loss of consciousness should be assessed according to the risk of recurrence while driving. If there is strong clinical suspicion of a seizure, the loss of consciousness should be treated as a seizure. The so-called seizure markers can be of help in the situation of unwitnessed loss of consciousness / loss of or altered awareness:
Unconsciousness for more than 5 minutes; amnesia greater than 5 minutes; injury; tongue biting; incontinence; remain conscious but with confused behaviour; headache post attack.

RECOMMENDATION FOR GROUP 1

The loss of consciousness should be assessed according to the risk of recurrence while driving. If there is strong clinical suspicion of a seizure, the loss of consciousness should be treated in a similar fashion as a first seizure.

RECOMMENDATION FOR GROUP 2

As for group 1, and:

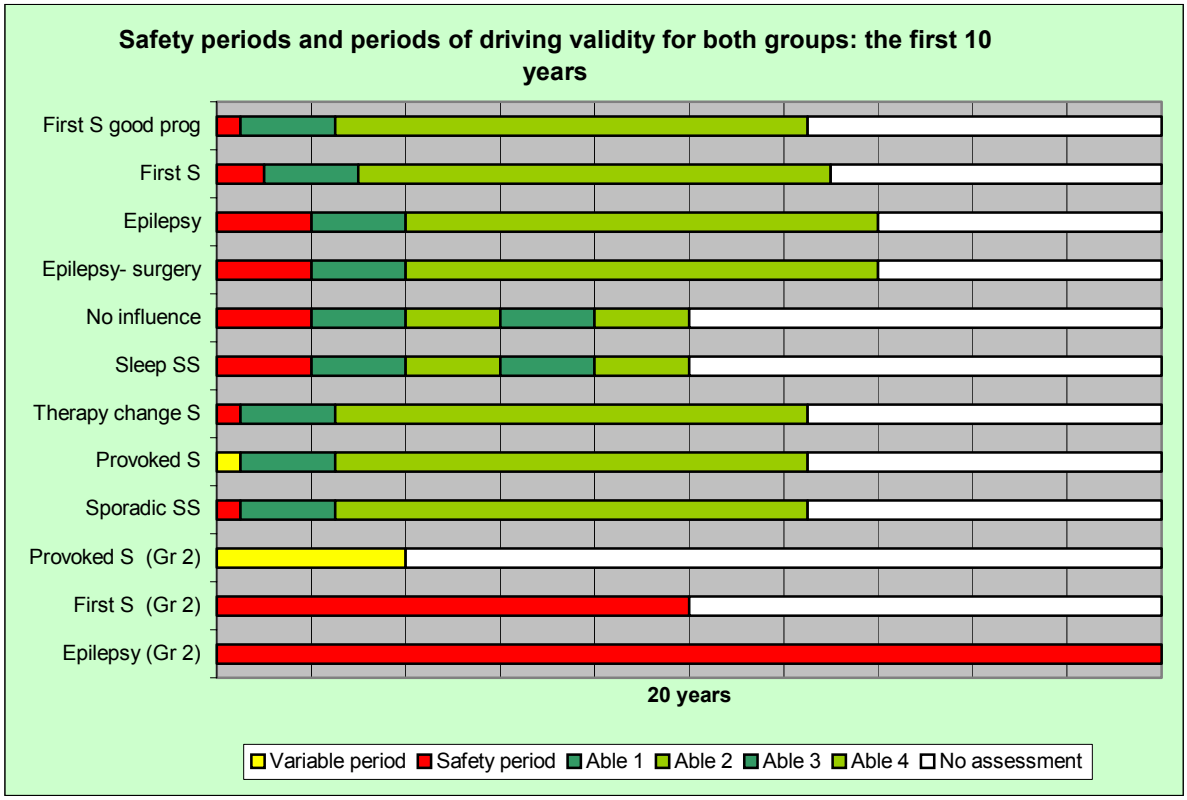
The risk of recurrence should be 2% per annum or less.

THE PERIOD OF DRIVING VALIDITY.

Group 1

It was decided that after the period of driving prohibition ("safety period"), the licence should be reviewed after one year, then 5 years. For seizures that do not influence driving ability or seizures that occur exclusively in sleep, the review will be annually for the first 5 years. After these periods no specific assessment for epilepsy was considered necessary.

Figure 5 Safety periods and periods of driving validity



Group 2

The applicant for group 2 will be regularly checked during the required periods of freedom. It is not recommended that there should be a regular check-up once he has received his drivers licence.

7. Overview of the regulations

Table 8 **Epilepsy: proposed guidelines for GROUP 1**	
General rules	
A person who has an initial or isolated seizure or loss of consciousness should be advised not to drive A specialist report is required, stating the period of driving prohibition and the requested follow-up	
Drivers, assessed under group 1 with epilepsy should be under licence review till they have been seizure- free for at least 5 years.	
If the person has epilepsy, the criteria for an unconditional licence are not met. The patient should notify the Licensing Authority	
It is extremely important that the patient's specific epilepsy syndrome and seizure type are identified so that an adequate evaluation of the person's driving safety can be undertaken (including the risk of further seizures) and the appropriate therapy instituted. This should be done by a neurologist.	
Clinical situations	**Advise**
Provoked epileptic seizure	The applicant that has had a provoked epileptic seizure because of a recognisable provoking factor that is unlikely to recur at the wheel can be declared able to drive on an individual basis, subject to neurological opinion. NOTE: The assessment should be, if appropriate, in accordance with other relevant sections of Annex III. (e.g. in the case of alcohol or other co-morbidity)
- First unprovoked seizure	The applicant who has had a first unprovoked epileptic seizure can be declared able to drive after a period without seizures of six months, if there has been an appropriate medical assessment National authorities may allow drivers with recognised good prognostic indicators to drive sooner.
Other loss of consciousness	The loss of consciousness should be assessed according to the risk of recurrence while driving.
- Epilepsy	Drivers or applicants can be declared fit to drive after a 1-year period free of further seizures.
Special situations	
- Sporadic seizures	If the period between the last seizure and penultimate seizure is more than 5 years, the last seizure may be considered in a similar fashion to a first unprovoked seizure for licensing purposes, subject to neurological opinion.
- Seizures without influence on consciousness or ability to act and without (ever) having (had) any other kind of seizure - Seizures exclusively during sleep	The applicant or driver who has had seizures exclusively during sleep or seizures which have been demonstrated exclusively to affect neither consciousness nor cause any functional impairment can be declared fit to drive so long as this pattern has been established for a period which must not be less than the seizure free period required for epilepsy.
- Seizures because of physician directed change or reduction of AE therapy	Patients should be warned of the risk they run coming off medication, both of loosing their driving licence and also of having a seizure, which could result in a road traffic accident. The patient may be advised not to drive from commencement of the period of withdrawal and thereafter for a period of 6 months after cessation of treatment Seizures occurring during physician advised change or withdrawal of medication require 3 months off driving if the previously effective treatment is reinstated.
- After curative epilepsy surgery	1 year of seizure- freedom

Table 9 **Proposed guidelines for GROUP 2**	
Clinical situation	**Advise**
General conditions for all Group 2 drivers	The applicant should be without anti-epileptic medication for the required period of seizure freedom; There has been a appropriate medical follow-up; On extensive neurological investigation no relevant cerebral pathology has been established and there is no epileptiform activity on the EEG. The subject can only be declared able to drive subject to neurological opinion. The risk of having a seizure should be 2% per annum or less.
- Provoked seizure, because of a recognisable and avoidable provoking factor	The applicant that has had a provoked epileptic seizure because of a recognisable provoking factor that is unlikely to recur at the wheel can be declared able to drive on an individual basis, subject to neurological opinion. An EEG and an appropriate neurological assessment should be performed after the acute episode. Someone with a structural intracerebral lesion who has increased risk of seizures should not be able to drive vehicles of group 2 until the epilepsy risk has fallen to at least 2% per annum. NOTE: The assessment should be if appropriate in accordance with other relevant sections of Annex III. (e.g. in the case of alcohol)
First unprovoked seizure	The applicant who has had a first unprovoked epileptic seizure can be declared able to drive once 5 years freedom of further seizures has been achieved without the aid of anti-epileptic drugs, if there has been an appropriate neurological assessment National authorities may allow drivers with recognised good prognostic indicators to drive sooner.
Other loss of consciousness	The loss of consciousness should be assessed according to the risk of recurrence while driving. The risk of recurrence should be 2% per annum or less.
Epilepsy	10 years freedom of further seizures has been achieved without the aid of anti-epileptic drugs. National authorities may allow drivers with recognised good prognostic indicators to drive sooner.
Special situations	Driving ban
Prophylactic ban	Certain disorders have an increased risk of seizures, even if seizures have not yet occurred. In such a situation an assessment should be done: the risk of having a seizure should be 2% per annum or less.

8. Other items discussed

GROUP 1

Does the syndrome or seizure type have influence on the policy after a first seizure?

There are no data that would indicate a different approach for different seizure types. The same holds true for epilepsy syndromes, at least as far as the short term prognosis is concerned.

Seizures while on a provisional licence and previously well controlled

"If the cause is not identified and the seizure did not cause an accident: 3 months of seizure-freedom"
Argument: this kind of (Australian) rule might greatly increase compliance!
Decision: the group decided not to make exceptions for this group.

Exclusively seizures on awakening

Exception for this group (driving only 1 hour after getting up) was considered impractical and impossible to control.

Newly established epilepsy

What could be the rationale to make a different regulation for newly established epilepsy as in the Australian criteria ?
The fact that it is often clear in the beginning of epilepsy if the patient is going to be refractory to treatment or not.
Patients with chronic epilepsy have seizure-free periods, but this occurs only in 20%. (Sander 1997)
In a prospective Scandinavian study 75% (C.I.: 65-83) of the patients who were seizure-free for 1 year remained so for the next 3 years. (Kuhl 1967). There was no definition of "epilepsy" in this study. One wonders how many patients were first seizure patients.
Another Scandinavian study 85% (C.I.:75-91) of the patients who remained seizure-free for 3 months did so in the first year.
In the Australian criteria a difference is made for patients that have not had more than 3 seizures in 10 years. Although intuitively acceptable, no support for this distinction was found in the literature. In the NGPSE study there was no difference in long term prognosis for patients that had had 2-3 or more than 10 seizures in the 6 months following the index seizure (Cockerell 1997).
Decision: the group decided not to make exceptions for this group.

Uncertainty of the diagnosis

Three studies give information about the certainty of the diagnosis after a first seizure. In less than 50% the physician is certain if the event was an epileptic seizure. The diagnosis remained in doubt in 30-50% even after 6 months! More seizures increase the diagnosis. In the study by Van Donselaar neurologists did not agree about the diagnosis in 16% of cases. This was reduced to 2% by the use of predefined criteria (Van Donselaar: " Reliability of the diagnosis of a first seizure "Neurology 1989;39:267).
Is uncertainty a reason to treat events that are possibly epilepsy the same as epileptic seizures? The UK criteria do just that for group 2. They give "seizure markers" - that, if present, increase the chance that the event was a seizure.
See: "loss of consciousness"

LIMITED LICENCE?

The existing list (for situations different from epilepsy):
-not during the night
-never alone
-not with passengers
-without trailer
-limited radius
-limited speed
-not on motorways
-without any alcohol
A limitation in time was considered, but it was thought impossible to control and therefore not practical to implement.

GROUP 2

First unprovoked seizure

Like Belgium
- 5 years of seizure- freedom plus general conditions
Doubt about the necessity to require the absence of anti-epileptic treatment is cast by the studies by the FIRST Group (Musicco M, Beghi E et al 1997): the effect of treatment seems to make a difference in recurrence risk only for the first two years! The requirement is based on the increased likelihood of seizures in the case of low compliance.

Prophylactic ban

Do we need a list of situations where, apart from the functional consequences of the underlying disease, the risk of the *de novo* seizures is increased to a level that group 2 driving should be advised against?
Sonnen 1997 page 117
Only for trauma there are sufficient data. For the other situations only overall risks are given. According to Doelman (in Sonnen 1997) brain abscess: best permanent ban.
Surgically treated AVM might also be a reason for an exclusion.

For the recommendations mentioning of the problem seems best. For guidelines a thorough study is needed.
Ideally, the collected data could have the following format.
Percentages of recurrence risk are given for a certain disorder for four different situations.

A list of disorders	As an initial sign	With early seizures	without early seizures	late seizures

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10 ANNEXES

ANNEX 1: The questions put to the working group

The request that was put to the working group was ("Terms of reference for all groups"):

1 Review the available evidence on the diagnosis, prognosis and treatment of the disease
2 Make rules on the best available evidence and rules that are "incontestable".
3 Identify any significant gaps in knowledge and define questions which might enable these gaps to be filled
4 Based on existing practices and viewpoints in Member States to formulate and propose recommendations to the Driving Licence Committee in order to adapt Annex III to Directive 91/439/EEC to scientific and technical progress

From a different source ("Communication from the Commission" of 4.8.2000 about Progressive harmonisation of Community driving licence law) comes the explicit request, also mentioned by Mr Valmain:

5 To harmonise (the validity periods of licences and) the periodicity of the medical examination, notably for cars and motorcycle drivers

This last question might refer to the periodic medical examinations for everybody, but the tenor of the article is to harmonise as much as possible also the "extra" medical examinations in patients because it will improve transparency and diminish legal uncertainty for people that go and live in another country.

First proposal was to change the Council Directive slightly, then make elaborate guidelines. Since guidelines cannot be law, this would have the disadvantage to still not have a regulation that would lead to harmonisation. The alternative we subsequently considered is, to propose a minimum set of criteria for the law and make a text with background information. This will have the advantage that the member states with liberal regulations do not need to change their existing laws.

ANNEX 2: Glossary of terms

A list of definitions can be found in the following articles. Below follow comments on the ones where the definition is not suited to the purpose of this report.

1 COMMISSION ON EPIDEMIOLOGY AND PROGNOSIS, ILAE Guidelines for Epidemiologic Studies on Epilepsy *Epilepsia* 1993;34(4):592-596
2 AAN, AES AND EFA Consensus statements, sample statutory provisions and model regulations regarding driver licensing and epilepsy. *Epilepsia* 1994;35:696-705
3 ENGEL J A proposed diagnostic scheme for people with epileptic seizures and with epilepsy: report of the ILAE task force on classification and terminology Epilepsia 2001;42(6):1-8

Epilepsy in remission with treatment
COMMENT: This definition is acceptable for group 1 if the seizure free period is 5 years, but not for group 2 where it should be 10 years
Epilepsy in remission without treatment
COMMENT: This definition is acceptable for group 1 if the seizure free period is 5 years, but not for group 2 where it should be 10 years

Provoked seizure (acute symptomatic seizure or situation-related seizures)
COMMENT: has to be avoidable!
COMMENT: Defined by a specific time period. See text.
Head injury
CNS infection
CNS tumour
Post intracranial surgery
Toxic
Withdrawal
Metabolic (related to systemic disturbances)

3 Additional terms from this text:

In sleep:	meaning while the patient is asleep, not just during the night. The physician should try to make the difference by anamnesis and hetero-anamnesis.
Seizure-free interval:	The period of time elapsed since the patient had his last occurrence of any type of seizure
COSY	An acronym: the Change of the Occurrence of a Seizure in the next Year
Total chance of a recurrence	used as cumulative incidence over a defined or sometimes undefined period.

ANNEX 3:The calculation of increased risk for group 2

Sonnen in his report (Sonnen 1997) calculated the risk for the different vehicles. He attributed factors of severity for 4 items and by multiplication of these factors he arrived at a total factor of increased risk of a certain vehicle compared to cars. There were factors attributed for:

1. driving time
2. toll of accidents
3. seizure/accident ratio
4. passenger transport.

Sonnen (Sonnen 1996) assumed a ratio of 30 between group 1 and group 2 in the severity of assessment. This did not always seem justified. For taxis and ambulances and lorries the risk seems considerably lower than for buses. Minibuses have an intermediate risk.

In some countries, like Belgium, transport of people organised by a company falls under group 2 assessment. This often involves a driver and one or two other people. This situation carries a calculated risk like a car, not like a bus! The only reason to be more severe is a (arbitrary) factor for extra-security because it is a professional risk to be a passenger of such a driver. Five times more severe than a car driver seems reasonable. Other factors do not apply in this situation.
We tried to find European (or national) statistics to base these factors on.

Driving time

For Belgium data are available.

The above mentioned risks are not the same for different vehicles. For some vehicles of interest data are shown in the table (Belgian data 2001: http://www.statbel.fgov.be/figures/d37_nl.asp).

Table: Driving distances and ratio of serious accidents compared to cars

Data for 2001, Belgium	Number of vehicles	km driven in 10^9 km	Km driven per vehicle	N of serious accidents	Serious accidents /10^9 km	Ratio of serious accidents / distance driven compared to cars
Motorcycles and mopeds >40km/h	293630	1.03	3508	1388	1347.57	17
Cars	4739850	76.98	16241	5999	77.93	1
Lorries	572636	13.19	23034	477	36.16	0.46
Buses	14676	0.67	45652	15	22.39	0.29

These Belgian data show an average driving time for lorries that is 1.5 times that of cars; for buses about 3 times. To stay at the safe side we could use 2 times for lorries and 4 times for buses. This is almost certainly an overestimation in view of the fact that the average speed goes up and thereby the average time at the wheel goes down by an increase of the distance driven, because it is likely that with an increase in distance, more kilometres will have been driven on motorways.
For the sake of uniformity we will use a factor 5 overall, a very safe value.
We did not find data for taxis. We asked taxi drivers and came to an average of 65,000 km/year. It seems that a factor 5, accounting for 80,000 km/year is safe. Taxi drivers often make long hours, but much of it is waiting for customers. In some countries or cities taxi drivers drive around all the time. Here the number of kilometres increases, but not necessarily the number of kilometres driven with customers!
The theoretical limit of driving time in the European Union is 9 hours per day for 6 days a week, which is 54 hours per week. Assuming 4 weeks of holiday, this is 48 x 54 = 2592 hours. One year is 8760 hours, so this is over 29% of the time, compared to 4.2% as an average for cars: 7 times as much. These values can only be reached for long distance (international?) transport, but even there it seems highly unlikely that they would be reached as an average. Remember: drivers of cars can drive for 12 or more hours a day too!

The higher ratio for motorcycles and mopeds (group 1) is due to the more exposed position of those drivers, but could be due to the effect of having less driving experience as well as to an influence of the young age of the drivers. This group consists of 3 subgroups: motorbikes >400cc; motorbikes <400cc and mopeds that can drive >40km/h. These subgroups contributed in 2001 to fatalities with ratios compared to cars of respectively 7.9; 1.4 and 4.0 (Belgian data: not corrected for distance driven).

Are there an increased number of serious accidents in group 2 vehicles? The factors " toll of accidents"

If anything, the opposite can be derived from the figures in the table about Belgian data above. As far as the ratio of serious accidents is concerned, the lesser ratio of accidents per vehicle for buses and lorries will in part be due to the effect that more experienced drivers produce less accidents. Since the total number of accidents is not given, we cannot calculate a ratio serious accidents per total number of accidents. Why would this be important?
If accidents that occur because of a seizure at the wheel are more serious than accidents with other causes and if we want to attribute a factor of severity, ideally we would want to know the severity of accidents that were caused by a seizure at the wheel for these different vehicle groups. Such data are not available. Neither are data available about a comparable situation: accidents caused by loss of consciousness at the wheel. The next best approximation is to know the "normal" severity per accident, for each vehicle group. This factor would be applicable over the time that

someone drives because the occurrence of a seizure is unpredictable. This is different from the normal situation, where the relative number of accidents tend to decrease with the time driven, because of the effect that more experienced drivers produce less accidents. So while in normal drivers the risk decreases with distance or time driven, in the case of possible seizures the chance increases, because it is a function of the time spent at the wheel. In a Canadian consensus conference (Canadian cardiovascular society 2003) truckers were found to be involved in 2% of accidents, but 6.2% of fatalities. From this, **a factor 3.6** for severity could be derived. It seems more realistic to use all serious accidents as a measure, not just fatalities. The European data on serious accidents have been based on different criteria in some of the member states. For that reason, we did not use them. For Europe, the same numbers can be found in the table.

Vehicle group	Fatalities / 100 accidents	Ratio compared to cars	Fatalities / serious accidents	Ratio compared to cars
Car	35	1.00	257	1
Bus	33	0.95	243	0.95
HGV	101	2.93	389	1.51
Lorry <3.5t	43	1.25	263	1.02

So the same factor that has been found in Canada (3.6) in European date is 2.93. This can be taken as an overall factor of severity of accidents produced by group 2 vehicles compared to cars.

A Dutch website (www.SWOV.nl slachtoffers) for traffic information states that per one billion vehicle kilometres a car produces 64 deaths outside the vehicle, a truck 114. This is a factor 1.8.

It seems an established fact that heavier vehicles protect their drivers (and passengers?) from the impact of an accident. This means that the relative risk shifts in the direction of the other road users. That should be taken into account with the assessment. It is shown in the data below about passenger transport. The factor "toll of accidents will not been taken into account separately.

The factor for passenger transport

Looking at the ratio of driver fatalities and passenger fatalities gives us an idea about how many passengers are present and the factor that should be attributed for passenger transport. The Belgian Assuralia website provides data:

Table: the factor passenger transport

Data for 2000, Belgium	Passenger fatalities / driver fatalities (99%C.I.) Belgium 2001	Ratio of the value compared to cars (99% C.I.)
Car	0.490 (0.48-0.50)	1
Light lorry	0.342 (0.31-0.37)	0.70 (0.64-0.75)
Lorry	0.266 (0.21-0.34)	0.54 (0.48-0.60)
Combination	0.092 (0.06-0.14)	0.19 (0.15-0.24)
Minibus	1.463 (1.30-1.70)	3.0 (2.70-3.34)
Bus, coach	4.017 (3.03-5.56)	8.20 (7.14-9.09)
Bicycle	0.011 (0.01-0.01)	0.02 (0.01-0.05)

Comparable and other European data for 2002 (others = passengers + outside the vehicle):

Killed	**Driver**	**Passenger**	**outside**	**Pass / driver**	**Ratio to car**	**Outside /driver**	**Ratio to car**	**Others/ driver**	**Ratio to car**
car or taxi	12.086	5806	7440	0,48	1,00	1,10	1,00	0,62	1,00
bus or coach	26	78	655	3,00	6,24	28,19	25,72	25,19	40,92
heavy goods vehicle	430	65	3192	0,15	0,31	7,57	6,91	7,42	12,06
lorry, under 3.5 tonnes	652	244	1713	0,37	0,78	3,00	2,74	2,63	4,27
unknown lorry	209	40	666	0,19	0,40	3,38	3,08	3,19	5,18

These last data seem to suggest that for every bus driver killed 6 times as many passengers are killed, and another 25 as many persons outside the bus! The ratios for HGVs are favourable for passengers, but 7 times as many others are killed per accident than in a car crash! These data seem to confirm the severity of bus accidents, mainly for people

on the road outside the bus. It is however not clear how to interpret these data, when the same risks do not show up in overall statistics that compare car an group 2 accidents!

How many seizures at the wheel in group 2 produce an accident?

Only one small study mentions a percentage of 70 (Sonnen 1997). Let us assume 80%. This is 1.33 times as much as the 60%, assumed for group 1 ("worst case scenario").

Comparison of risk ratios: group 2 vehicles compared to cars.

Elsewhere we will argue that a certain risk is acceptable for drivers of cars. Here we have tried to establish how much more severe we have to be in the assessment of group 2 drivers. To that end, we tried to determine an overall factor of severity compared to car drivers. Because of the paucity of statistical data for Europe the approach can only be very approximative. None of the presented data are exactly the kind of data we need. We used global data from the literature and conclude that none is higher than 3. This means that the overall factor of 20 still stands. The same factor was calculated in a consensus statement of Canadian cardiologists.

Table: Factors of increased risk for some vehicles compared to cars

	Bus	HGV
Driving time	5	5
Toll of accidents	4	4
Seizure / accident ratio	1.33	1.33
Overall risk factor	20	20

A conclusion

Motorbikes should be assessed more severely than a car, because of a greater danger for the driver, or at least should the patient be informed about this. The danger to the driver is 2 to 3 times increased compared to a car.
The 2% rule can still be applied for buses and HGVs. Some other vehicles that, in some countries, drive under group 2 conditions do not need to be assessed as severely. (e.g. taxis)
In countries where the transport of people organised by the employer is assessed according to the criteria of group 2 the assessment should take account of the number of people transported and an arbitrary safety factor (3-5?).

ANNEX 4: Other data used for calculations

THE PERCENTAGE OF THE POPULATION THAT HAS ACTIVE EPILEPSY

For our calculations we will take an average (among different age groups) of 6 / 1000 (Forsgren 1996; Jallon 2001)

THE PERCENTAGE OF THE POPULATION THAT HAS A FIRST SEIZURE PER YEAR

Jallon (Jallon 2001) lists studies in western countries and concludes that there is a mean incidence per year of 70 / 100.000 Hauser finds 61 per 100,000 person-years for first unprovoked seizures (and 44 / 100,000 for epilepsy: Hauser 1996) A Swedish study finds an incidence of first seizures of 56/100,000/year between ages 17 to 60. Above age 65 the incidence was 139/100,000/year (men 166, women 116) (Forsgren 1996)
We will take 70 / 100,000 for our calculations

THE PERCENTAGE OF PEOPLE WITH EPILEPSY THAT HOLDS A DRIVING LICENCE IN THE EUROPEAN UNION

In Finland the percentage of young people with epilepsy that drive is 69% versus 89% in the same age group of the general population (Ojala M 2001). In a USA study, the percentage of drivers with epilepsy that hold a licence was 57% (Krauss G 2001). Sonnen (Sonnen 1997) finds an average of 50%. The RESt-1 Group study (RESt-1 Group 2000) recently found an average of 50.3% in a group of 570 adult patients from six European countries compared with 75% in the control group (we excluded the Russian patients and controls).
The theoretical maximum of people with epilepsy that holds a drivers licence is the percentage of people that become seizure free: 70%.
The percentage of the general population that holds a drivers licence is 53% (200/375 million).

This makes the maximum percentage of people with epilepsy that has a licence at the time of writing: 53% * 70% = 37.1%
The theoretical maximum is: 70% times the theoretical maximum of the population. In most cases we have used 70%.

THE POPULATION OF EUROPE (15)

375 million inhabitants

IS THE NUMBER OF ACCIDENTS INCREASED IN PEOPLE WITH EPILEPSY?

The First European Working Group accepted an accident ratio of 1.33% in people with epilepsy compared to the general public, as a mean of 12 studies (median 1.25; range 0.5 to 2.56). The highest accident rate ratio is in a recent Danish study (Lings 2001): the number of epilepsy patients treated at the casualty department was seven times higher compared to a control group. The number of crashes was very low in this study, leading to great uncertainty in the found accident rate ratio (CI 2.18 to 26.13).
A recent Norwegian meta-analysis of 4 studies (including the Danish, but not including the U.K. study) found an accident rate ratio of 1.84 (C.I. 1.68 - 2.02) (Vaa T 2003). It is not clear if this figure reflects the risk in people with epilepsy that drove legally or not.
On the other hand, Berg and Engel (Berg A and Engel J 1999) mention three studies that demonstrated little or no increased risk of motor vehicle accidents for drivers with epilepsy who are, for the most part, compliant with local driving restrictions (Hansotia 1991; Gilason 1997; Taylor 1996)
In a recent UK study, 16,958 drivers with a previous history of epilepsy (but at least one year seizure-free) responded to a self-completion questionnaire and were compared to 8,888 non-epileptic drivers. (Taylor *et al*. 1996). No overall increase in risk of accidents for drivers with epilepsy who drove legally was found in this very large sample.

DO SEIZURE-RELATED ACCIDENTS CAUSED BY PERSONS WITH EPILEPSY MORE OFTEN LEAD TO SERIOUS INJURY?

There is uncertainty about this.
In the UK study the number of accidents was not increased in people with epilepsy with a valid driving licence, but there were twice the expected number of fatalities. These data were somewhat uncertain because of the methodology used (they could not calculate a relative risk, because there were no fatalities in the control group) (Taylor *et al*. 1996). The same UK study found an increase in the chance of a serious accident of 40%. (OR: 1.37 CI: 1.02-1.84)

Other studies only look at the overall chance of an accident. If this is increased, it seems likely that the number of serious accidents is increased proportionally.
Sonnen (1997) summarises four older studies and concludes that the question of increased severity is unsolved.

WHAT IS AN ACCEPTABLE RISK FOR THE POPULATION (ATTRIBUTABLE RISK)?

Every driver has a risk of an accident. With the concept of "acceptable risk" one means the additional risk on top of the risk of an accident taken by the general population of drivers.

Data from The Netherlands (Sonnen 1997) show a 10% average risk of an accident per year per person with a vehicle insurance. (Some minor accidents might not come to the attention of the assurance, but they are likely to be of no importance for safety) In the large UK study of Taylor *et al*. (1996) it was about 7%. Data from the literature vary between 5.7% and 12% with an average of 10% (Sonnen 1995).
Sonnen looked at the factors that contribute to this percentage, there are important variations, even for variables that can not be influenced at all. We already mentioned these factors above. (see: Figure 1)

The suggestion of the European workgroup was to take a 10% increase on top of the average of 10% accidents per year as an acceptable risk, which is an absolute increase of 1%. Clearly this is a very small increase in risk compared to the above-mentioned variables.

For group 1, a 10% increase of the average risk of an accident for the population was proposed. This population average is 10% per year, so **the resulting increase in risk is 1%** (10% x 10%).

WHAT IS THE LIKELY OUTCOME OF AN ACCIDENT

This is generally measured in terms of serious injuries or fatalities. Less data seem to exist about material damage or danger for the environment. Statistics give the following numbers.
In 2001 the chance to have a (serious or fatal) accident in Belgium was 12.65 per 10,000 cars. (cars, so per driver the number will be lower!)
This amounts to 145 accidents per million population in Belgium. The comparable European average is 111
If we apply this ratio to the above chance of a serious accident, we get: 111/145 x 12.65 = 9.67. So in Europe the chance to have a serious or fatal accident is less than 1 in 1000cars per year.
Statistics
The chance of a serious injury per accident is 17.7% for Europe in 2001 = 8.29 / 10,000 cars
The chance of a fatality per accident is 3% for Europe in 2001 = 1.38 / 10,000 cars = 1/7250 cars
Together: less than 21%; 1/7 is fatal
NOTE: in the statistics the percentages of 21% and 3% apply to all accidents. They are likely to be lower for cars (in one Belgian statistic 15% overall)(Ref: http://europa.eu.int/comm/transport/care/statistics/…

ANNEX 5: Recommendations for the future

STUDIES

Prospective study of the recurrence risk and the timing of recurrences in the first months to 2 years
Prospective study about the long-term recurrence-risk in seizure-free patients: 5 to 10 (20?) years of follow-up.
Meta-analysis of studies about both these situations.
European statistics about epilepsy (and other medical causes) and traffic accidents to underpin our decisions by better data about the dangers.
European data about the Percentage of people with epilepsy that hold a drivers licence.
An overview of the current knowledge on the recurrence risk of the different types of provoked seizures as a base for guidelines concerning driving ability.
An overview of disorders that might qualify for the installation of a prophylactic ban and the COSY thereof as a base for guidelines concerning driving ability.
Creation of an European registry of difficult problems in the assessment of people with epilepsy or seizures and discussion in this context.
Prospective study about the compliance with the rules once they are in place as well as for the occurrence of accidents and the severity thereof, for the respective clinical situations mentioned in the overview of the regulations and for both groups.

IMPLEMENTATION

Support consistency of the approach with other areas of medical risk assessment.
Sending of the Power Point slides to the members of the Working Group for presentations on the national level April 2005.
Presentation of the development of the arguments as described in this report on the International Congress on Epileptology in Paris, August/ Sept 2005.
Presentation of the document on the 7th European congress on Epileptology in Helsinki, Finland, 2-8 July 2006.
Submission of the document to Epilepsia, if possible to be published as an annex, as soon as the renewed Annex III is officially in place (2006).
Posting of the final version of the PP slide show and pdf document in downloadable version on the ILAE website as soon as the renewed Annex III is officially in place (2006).
Inform the National Leagues of the Member States as soon as the renewed Annex III is officially in place, so they can contact their governments for further advice on the national level (2006).