Limitations of risk analysis in the determination of medical factors in road vehicle accidents

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ABSTRACT – The purpose of risk analysis in the determination of medical factors in road vehicle accidents is to evaluate the risks that are associated with different strategies for accident reduction, so that the subsequent decision making process can be based on a best assessment of the likely benefits. However, it is vital to appreciate the limitations of such an approach, especially where the conclusions depend heavily on the accuracy of the assumptions made. In this paper the assumptions used in some recent analyses concerned with incapacitation, epilepsy, hypoglycaemia and psycho-active medication are explored, and the additional information required to reduce the uncertainty in the estimation of risk indicated. The conclusions from this analysis do not invalidate the use of risk assessment, but draw attention to its limitations and show how a sensitivity analysis can help to identify those areas where more precise information is needed before such an approach can be used confidently in a policy setting.

KEY WORDS: epilepsy, hypoglycaemia, incapacitation, psycho-active medication, risk analysis, road vehicle accidents, sensitivity analysis

As with many other aspects of human activity, transport, and especially road transport, is inevitably associated with an increased level of risk. While it may be impossible to eliminate all sources of risk, it is a natural ambition of a civilised society to ensure that they are reduced as much as is reasonably possible. However, the reduction of risk may not be cost free, and it is sometimes necessary to balance the desire for a safer environment against the financial and social consequences both to society and to the individual of the measures taken to reduce the risk. This would apply, for example, when a licence to drive is withdrawn from an individual or group of individuals on medical grounds. Such action is not aimed primarily at safeguarding the driver but is taken to protect passengers and other road users who may be placed at risk by a health-related decrement in the driver's performance. Thus, it raises particular questions concerning the degree of restriction on an individual which is appropriate to protect others. As such it has a political, as well as a scientific, dimension and any information on the nature and size of excess risk derived from investigations becomes the starting point for policy and regulatory decisions.

The purpose of any approach based on risk analysis is to evaluate the risks that are associated with different strategies for accident reduction, so that the subsequent decision-making process can be based on a best assessment of the likely benefits. This would serve to reassure those individuals whose mobility and livelihood are affected that decisions have not been taken on an arbitrary basis. However, it is vital that the limitations of such an approach are appreciated, especially where the conclusions depend heavily on the accuracy of the assumptions made. In this paper we explore the assumptions used in some recent analyses concerned with transport accident risk and indicate where additional information is required to reduce the uncertainty in the estimation of risk.

Assessment of risk

The assessment of risk in the case of vehicle drivers with known medical conditions requires information on several different factors. These include the duration of exposure to risk-creating situations ie time at the wheel, the probability and rate of the onset of acute incapacity or of acute/chronic impairment, the probability that a period of impairment or incapacity would lead to an accident and the likely outcome of an accident. These factors are not necessarily common to the individuals involved or to the medical conditions under consideration.

The overall frequency of accidents increases with time at the wheel and so the method of measuring the exposure is critical. In the case of road vehicles, the data are usually obtained using the distances travelled as the denominator, but these need to be converted to time at the wheel to be related to medical risk, as the probability of most forms of incapacity is expressed in relation to time intervals. Exposure may have important implications. It will differentiate between the private and vocational driver and take into account any consistent changes in driving frequency associated with a particular

medical condition or disability. Voluntary changes in driving habits may be the most important factor contributing to the lack of evidence that drivers with diabetes are at greater risk than the general population.[1] Further, the elderly may well be containing their overall accident risk by limiting the time spent driving. It is also necessary to estimate the time over which any impairment is likely to be of operational significance. In the case of cognitive and visual defects, the impairment is usually constantly present, whereas with diabetes and ischaemic heart disease impairment may occur only occasionally for a limited period of time or even on a single occasion.

It is then necessary to estimate the probability that a specific impairment will lead to an accident, but it is not easy to obtain accurate information on this issue. For a variety of reasons, mainly relating to multiple causal factors for accidents and the difficulties in identifying health-related risk factors retrospectively, it has been difficult to draw clear conclusions from accident data themselves. Thus, a retrospective study of drivers with epilepsy[2] showed that patients with controlled seizures posed a somewhat higher risk than the general public, but the authors were unable to demonstrate a direct relationship between seizures and accidents. For less severe conditions such as mild hypoglycaemia, it may be necessary to rely on observing the driver's performance either on the road or on a simulator.

Finally, the estimation of risk needs to be related to an outcome variable. An individual who suffers a seizure without prior warning is almost certain to suffer an accident unless the vehicle is stationary at the time. However, the consequences of such an accident will depend on many factors including the speed of the vehicle, the type of road and the density of traffic. For the assessment of risk, an estimate is required of the average outcome in terms of casualties and fatalities, and this is extremely difficult to obtain. This factor will also distinguish between the vocational (large vehicle) and the non-vocational (car) driver. For example, the complete loss of control in a heavy goods vehicle on a motorway is likely to lead to much more serious consequences for other road users than in a small car travelling along a country lane.

Assessments need to be related to specific medical issues, and so we have looked at recent analyses concerned with incapacitation arising from cardiovascular disease, epilepsy and hypoglycaemia and the impairment from ingestion of benzodiazepines.

Key Points

- **Risk analysis has gained wide appeal in the desire to provide data based on evidence that can link medical events to accident risk**
- **Examination of the parameters and the methodology used reveals many uncertainties, and casts doubt on the value of the uncritical application of the technique**
- **The approach used in the derivation of the 1% rule for sudden incapacitation in aircrew holds promise in its application to road transport**
- **In the case of epilepsy more information is needed on the consequence of an accident and the probability of a serious outcome**
- **The main issue with hypoglycaemia would appear to be the risk of lack of awareness, and more information on this issue would allow the risk to be based on a rule such as that used in epilepsy**
- **In the analysis of the effects of drugs on driving uncertainty would be reduced by more accurate information on the illness and the use of medication**

Incapacitation

The acceptable risk for sudden or subtle incapacitation is an important consideration in transportation safety. In the domain of air safety in the UK the risk that has been accepted is that a professional pilot will have no more than a 1% chance of an incapacitating event at any time during a twelve month period. The so-called 1% rule was first derived as a working hypothesis related to the cardiovascular event rate,[3] and approximates to the rate of cardiovascular mortality among UK men between 60 and 65-years-old.

The rule[4] is based on the assumption that the risk from medical incapacitation should not exceed 1% of the total risk of an accident or 10% of the risk associated with human error, as opposed to system malfunction. In this way medical incapacitation should cause a fatal accident no more than once in every thousand million flying hours. Taking into consideration the duration of the parts of the flight that could lead to an accident in the event of incapacitation and the presence of a co-pilot, it was argued that the incapacitation rate would be roughly equivalent to one in a 100 years.

There is a certain arbitrariness in some aspects of the derivation – particularly the assumptions concerning medical risk. Moreover, applying the same calculations to road safety could lead to different conclusions. Depending on the assumptions made and based on estimates of the risk associated with driver error,[5] the resulting number of fatalities in the United Kingdom could range from 35 to over 100 per year. Of course, many of the issues relating to accident risk due to sudden incapacitation are quite different for those who drive on the roads. A warning of an imminent collapse may be sufficient to enable a driver to pull off the road, but a sudden collapse of a driver on a motorway is likely to be more devastating than that for a pilot due to the presence of a co-pilot. Nevertheless, these calculations highlight the uncertainty of the risk of road accidents related to incapacitation, and this is compounded by individual variability in driving performance, independent of any medical disorder.

Epilepsy

For sufferers from epilepsy the critical issue with respect to driving is, again, the risk of sudden incapacitation. The threshold for risk recommended by the Medical Commission on Accident Prevention[6] for the non-vocational driver is a 20% probability of a seizure in the next year. The implications of this level of risk for

fatalities depends on information on the exposure to risk and the probability of an incident leading to a fatality. It could be assumed that an individual is at the wheel for 3% of the time and that there is one fatality per 10 accidents. In that case such a driver would carry a risk of causing an accident that is seven times greater than that of the average driver. This would imply an increase in the number of fatalities per year in the United kingdom of roughly 20.

However, this conclusion is extremely sensitive to the assumptions. For example, the proportion of time that these individuals will spend at the wheel is not known, and the frequency of fatalities arising from an accident is extremely difficult to determine, and could certainly range from one fatality in 20 accidents to one fatality in five accidents. If the optimistic assumptions are applied to a population at risk of one in 10 of those with epilepsy, the number of fatalities per year would be as low as five. On the other hand, if the pessimistic assumptions are applied to a population at risk of one in five of those with epilepsy, the expected fatalities per year would be almost 70. Clearly, further studies are required to determine the most appropriate assumptions.

For the vocational driver with epilepsy, the current recommended threshold is a 2% risk of a seizure in the next year. However, this reduction in the threshold compared with a car driver is likely to be more than offset by the increase in exposure and the more serious nature of the accidents that are likely to occur. As far as exposure is concerned, it may be reasonable to suppose that this could be five times as high as for the non-vocational driver. The accident rate for heavy goods vehicles is approximately twice that of cars.[7] Assuming that such accidents involve, on average, twice as many fatalities, the fatality rate may be four times that for with cars. The fatality risk associated with sudden incapacity in these drivers is therefore likely to be 20 times higher than for non-vocational drivers who carry the same medical risk. However, the reduction in the threshold from 20% to 2% reduces this resulting risk to approximately 40 fatalities per year if the same number of drivers are involved. Since many fewer drivers are likely to apply for a licence to drive a bus or a heavy goods vehicle, this number will be much reduced, perhaps to only four fatalities per year, if the ratio of such drivers to the overall number is 1:10. However, an analysis of the sensitivity of this conclusion to the assumptions would suggest that estimates between one and 20 are equally justifiable.

In these calculations, it has been assumed that the risk of a seizure is not subject to any variation or to any uncertainty. This is unlikely to be the case in practice since the licence to drive depends on the medical criteria used for the decision. Another consideration is the variability in seizure rates. In practice it is most unlikely that all individuals carry exactly the same risk factor of 20% or 2%. It is to be expected that many will carry a lower risk and so the accident risk would be less than currently estimated, though some individuals may be at higher risk. The implications of these considerations is that uncertainties in the assessment could easily account for accident rates that differ by a factor of 3 or 4, in addition to those concerned with seizure rate and distribution.

Hypoglycaemia

Hypoglycaemia, usually as a consequence of insulin treatment in diabetics, presents a similar issue to epilepsy, except that a hypoglycaemic event may be preceded by an awareness on the part of the individual that enables the driver to avoid an accident. Conversely, cognitive impairment associated with reduced glucose levels may impair judgement both in relation to the correct response to impending hypoglycaemia and in terms of general driving performance. Lack of knowledge of this factor increases the overall uncertainty concerning calculations of the risk of accidents. A major uncertainty is the risk of a severe reaction – defined as requiring the intervention of another person, resulting in the loss of consciousness or requiring hospitalisation. However, it is estimated that only about 33% of all severe reactions have some form of warning.[8] A wide variation in the risk of a severe reaction was also reported. This would translate to an uncertainty in the accident risk of a factor of 24. Even allowing that some of the studies with high rates may have used a broader definition of a severe reaction, it would be difficult to be confident that this uncertainty could be reduced by more than a third – to a factor of 8. The variability and the overall risk would be better controlled if a procedure such as the 20% rule for epilepsy could be applied to the risk of a sudden collapse through hypoglycaemia without prior warning.

The risk analysis for less severe reactions than sudden collapse depends on the event rate and consequent accident risk. A typical value for the event rate can be taken from the average of the rates assumed by Songer *et al*[8] for insulin dependent and non-insulin dependent diabetes. The proportion of time at risk is calculated from the event rate and the duration of an episode – assumed to be between 15 and 20 minutes. The parameter of greatest uncertainty is the accident risk factor that is likely to apply during a mild reaction. Until investigations can be carried out to establish the relationship between performance impairments associated with mild hypoglycaemia and accident risk this factor will remain uncertain. Calculations suggest, that given the best guess values for all the measures, the accident risk associated with mild hypoglycaemia (ie cognitive impairment without incapacity) is very small indeed – unlikely to be more than one additional fatality every 10 years in the UK.

Psycho-active medication

In a recent study[9] an increased total accident rate was found to relate to the prescription of benzodiazepines particularly when used as an anxiolytic – although this relationship became less strong with increasing age. The risk calculation can be based on the reported confidence interval for increased risk and the reported mean prescription rate. If it is assumed that the mean duration of the prescription is between one and four weeks, then the extrapolation to the UK population would imply an increased fatal accident rate of between one and 26 per annum. A similar rate was found for drivers under 45 years because the higher ratio was compensated by the smaller population and lower prescription rate.

Such calculations differ from those published.[9] These authors estimated that 110 fatal accidents per year in the UK could be prevented if users of anxiolytic benzodiazepines did not drive. This discrepancy probably arises because their estimate involved an extrapolation from a very small number (only three) of fatal accidents among the younger age group in the sample. Nevertheless, the paper raises the possible contribution of the existence and treatment of an affective disorder to road accidents, though, clearly, more information is needed to determine exactly the scope of the problem, and, therefore, whether this would be a significant policy issue.

Conclusion

Risk analysis has gained wide appeal in the desire to provide data based on evidence that can link medical events with accident risk. However, careful examination of the measured variables and the analysis methodology reveals many uncertainties, and casts doubt on the value of the uncritical application of this technique. Nevertheless, the approach used in the world of aviation concerning sudden incapacitation holds promise in its application to other situations. Such an approach has been used in an understanding of epilepsy and accidents and has led to the 2% rule for the annual risk for vocational drivers, and to the 20% rule for the annual risk for non-vocational drivers. However, in each case a more precise assessment of risk and, in the case of epilepsy, more information on the consequence of an accident and the probability of a serious outcome are needed to provide an accurate picture. The main issue with hypoglycaemia is the risk of lack of awareness on the part of the individual, and more information on this issue would allow the risk to be based on a rule such as that used in epilepsy. In the analysis of the effects of drugs on driving, uncertainty would be reduced by more accurate information on the appearance of the illness and the use of the medication.

In all these cases, absolute estimates of excess risk may require some heroic assumptions. However the simpler goal of stratification of risk ie the identification of sub-groups can form the basis for more rational decision taking. For instance, how soon after a seizure or cardiac event can a person return to driving and can any additional investigations, such as an exercise electrocardiogram, be used to discriminate between those with low and high risks of future incapacity from a cardiac event?

The conclusions from this review do not invalidate an approach based on risk assessment, but draw attention to its limitations and show how a sensitivity analysis can help to identify those areas where more precise information is needed before such an approach can be used confidently in a policy setting. Meanwhile, it is important in the move to evidence-based medicine that the expertise and experience of medical practitioners in the world of transportation, though inevitably subjective, remain a significant input to the decision making processes that identify potentially low and high risk situations.

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