# Task Force Report

# Driving and heart disease

# Prepared on behalf of the Task Force by M. C. Petch

# Introduction

This Task Force was proposed by the Board of the European Society of Cardiology in 1995. Dr M. C. Petch was suggested as Chairman in view of the United Kingdom's experience in road traffic safety and medical aspects of fitness to drive; he is currently Chairman of the U.K. Medical Advisory Panel on Cardiovascular Disease and Driving. Dr M. D. Joy was recruited because of his special experience in aviation safety. Other members of the Panel, such as Drs Jaussi, Halinen, Sandoe, Broustet and Luderitz, were easily identified from their interests and publications on the subject. Recruitment from other countries was generally via nomination from the national society. A full list of Task Force members is given in Appendix II

The Task Force has met formally on three occasions, in August 1996 and in May and August 1997. A particular issue confronting cardiologists during this period was the question of the implantable cardioverter defibrillator and this was the subject of a separate working group report under the Chairmanship of Professor B. Luderitz<sup>[1]</sup>. The recommendations of this working group have been incorporated into this Task Force report.

Much of the work was undertaken by correspondence, particularly the fact finding. The latter part of the work involved meetings and the authors are grateful to the European Society of Cardiology for financial support. Although the initial remit from the Board was to discuss solely those drivers of ordinary vehicles (Group 1), at the first meeting of the Task Force it was quickly realised that it would be necessary to revisit the proposals made by Professor Hugenholtz' committee which had not been widely circulated and implemented. (see page 1168).

# Medical aspects of fitness to drive

Driving is a universal activity in all developed nations. It has been estimated that ordinary drivers of private

**Key Words:** Driving, heart disease.

Task Force members are listed in Appendix II

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vehicles, depending upon age and occupation, may spend an average of 250 h a year at the wheel. For professional or vocational drivers the figure is many times higher.

In modern societies the motor car has become an essential part of daily living. People who live in rural communities rely upon the motor car for such things as getting to work, shopping, visiting. In all countries some regulation of driving activity is usual with insistence on a level of competence and medical fitness. To deny an individual an ordinary driving licence may seriously restrict their lifestyle and should not be undertaken lightly. Regulations therefore have to strike a balance between the liberty of the individual and the threat that that individual might pose to others by virtue of being a potential cause of a road traffic accident. Road traffic accidents are the commonest cause of death in young people and account for a significant minority of deaths each year in most developed countries, for example approximately 40 000 in the United States, 10 000 in Germany, and 4000 in the United Kingdom. There is, in addition, a substantial morbidity and a significant economic impact, both of which are very difficult to estimate.

In view of the foregoing, most developed countries have government departments or ministries devoted to transportation and these, together with departments of public health and interested medical practitioners, have accumulated a considerable body of knowledge on road safety and its medical aspects.

The available evidence suggests that the medical condition of a driver (with the exception of the effect of alcohol), is not an important factor in road accidents causing injury to other road users. Most road traffic accidents have a multi-factorial cause. Studies in the United Kingdom<sup>[2]</sup> and North America<sup>[3]</sup> have shown that approximately 95% of road traffic accidents involve human error, the other 5% being due to deficiencies in the vehicle or the road and/or environment. Legislation restricting the use of alcohol amongst drivers may have been responsible for the decline in road deaths, which have approximately halved over the past two decades in countries like Scandinavia, United Kingdom and Australia, where legislation has been introduced. Other factors known to be associated with an increased risk of road accidents includes young age (see Tables 1 and 2), fatigue, inappropriate speed and type of road, with

Table 1 Road accident deaths per 100 000 population: by age group: 1995\*

	Ages 0–15	Ages 16–20	Ages 21–24	Ages 25-64	Age 65+	All ages
United Kingdom	2.7	15.1	11:1	5.6	9.5	6.4
Great Britain	2.3	14.4	12.0	5.4	9.6	6.4
Austria	4.2	34.8	29.5	14.4	17.6	15.0
Belgium	4.8	25.7	30.2	14.4	14.8	14.3
Denmark	3.6	25.2	20.3	8.6	19.9	11.2
Finland	3.8	15.0	9.1	7.6	16.5	8.6
France	4.1	26.1	33.7	15.7	17.5	15.3
Germany	3.7	32.1	26.8	10.6	12.1	11.6
Former East Germany	5.9	56.6	48.0	17.7	15.0	18.9
Former West Germany	3.1	25.5	22.3	8.9	11.5	9.9
Greece	5.0	30.3	43.3	21.7	25.3	21.1
Irish Republic	3.3	16.3	32.2	10.5	16.2	12.1
Italy	3.0	21.0	19.5	10.9	17.4	12.3
Luxembourg	3.9	38.1	27.3	21.0	18.2	18.5
Netherlands	3.3	15.7	14.2	7.6	15.2	8.6
Portugal	9.2	48.1	53.0	28.5	30.8	28.8
Spain	3.7	21.0	25.2	15.6	14.3	14.7
Sweden	2.0	9.8	9.0	5.9	11.4	6.5
Hungary Iceland	4.2	16.6	21.3	17.5	18.8	15.6
Norway	2.7	17.2	14.8	5.2	11.5	7.0
Switzerland Turkey	3.8	16.9	21.9	8.4	16.0	9.9
Australia	3-6	22.8	20.4	9.7	17.4	10.9
Canada				10.5	15.2	11.1
Japan	2.3	18.5	14.0	7.9	22.0	10.1
New Zealand	7.4	32.4	36.5	14.9	13.4	16.2
USA	5.4	31.9	29.8	15.8	20.8	15.9

<sup>\*</sup>Figures in bold are for 1994.

motorways being the safest and small country roads the most dangerous. Numerous studies throughout the world have shown that driver incapacity as a result of spontaneous illness is a rare cause of serious road traffic accidents<sup>[4–10]</sup>.

Britain has a long record of research into the causes of road traffic accidents and the widely quoted publication of Grattan and Jeffcoate[4] in their study of 9390 accidents, indicated that 15 were caused by driver incapacity as a result of medical illness. These figures, which gave estimates of 1.5 per thousand for non-fatal, and 4 per thousand for fatal accidents are in keeping with studies elsewhere in Europe and North America. For example Herner et al. analysed all accidents due to sudden driver illness during 5 years in one region of Sweden and recorded 41 out of 44 255, an incidence approximating to 1 per thousand  $^{[6]}$ . More recently, Halinen and Jaussi  $^{[11]}$  found that sudden driver incapacity was the cause of 1.5% of all traffic deaths in Finland and 3.4% in the Canton of Vaud in Switzerland. Similar figures were obtained by Baker and Spritz in the United States<sup>[12]</sup>

The causes of road accidents involving collapse at the wheel are presented in Table 3. These data are

based on 2000 road accidents reported by the police in the United Kingdom to the Driver and Vehicle Licensing Centre in the United Kingdom. Epilepsy was the commonest cause of incapacity, in keeping with other studies<sup>[13]</sup>. Heart disease accounted for 8%. Unexplained blackouts accounted for 23% and some of these may have had a cardiovascular aetiology. Interestingly, 76% of accidents involving drivers with heart disease occurred in those who were already diagnosed; thus approximately one quarter were due to previously unrecognised heart disease<sup>[2]</sup>.

Most medical causes of road accidents occur in drivers who are already known to have pre-existing disease<sup>[2]</sup>. The relative infrequency of heart disease as a cause of road accidents may initially appear paradoxical in view of the prevalence of heart disease in men in middle life. To some extent this may be explained by the fact that drivers at highest risk of cardiovascular collapse, for example in the first month or so following myocardial infarction, are already advised not to drive. Nevertheless the paradox merits further consideration. (See following section.)

Road accident fatality rates are higher for large vehicles, as compared with cars; four times for buses and

Tables 1-3 provided by courtesy of Department of Transport, 2 Marsham Street, London SW18 3EB.

Table 2 Road user facilities, OECD Member States, 1995\*

	All road deaths	All road deaths per 100 000 pop	All road deaths per 10 000 motor vehicle	All road deaths per billion vehicle kilometres
United Kingdom	3765	6.4	1.4	8.7
Great Britain	3621	6.4	1.4	8.4
Austria	1210	15.0	2.5	18.6
Belgium	1449	14.3	2.7†	18.1
Denmark	582	11.2	$2 \cdot 6 \dagger$	13.6
Finland	441	8.6	1.9	10.5
France	8891	15.3	2.9	17.9
Germany	9454	11.6	1.9	15.7
Former East Germany	2928	18.9	3.6†	29.2
Former West Germany	6526	9.9	1.6†	13.0
Greece	2195	21.1	5.9†	
Irish Republic	437	12.1	3.5	13.7
Italy	7033	12.3		
Luxembourg	74	18.5	2.4†	
Netherlands	1334	8.6	1.8	12.4
Portugal	2710	28.8	3⋅8†	
Spain	5751	14.7	2.7	
Sweden	572	6.5	1.3	
Hungary Iceland	1589	15.6	5.8†	
Norway	305	7.0	1.3	10.6
Switzerland	692	9.9	1.6	11.3
Turkey				
Australia	1937	10.9	1.8	
Canada	3260	11.1		
Japan	12 670	10.1	1.5	18.4
New Zealand	581	16.2	2.5	
USA	41 798	15.9	2⋅2†	11.0

<sup>\*</sup>Figures in bold are for 1994.

coaches, and three times for trucks and lorries per mile travelled<sup>[2]</sup>. The consequences of an accident are greater because of the larger size and weight of the vehicle, and in the case of passenger carrying vehicles, because of the number of occupants of the vehicle. Furthermore, professional drivers spend more time at the wheel and do not find it easy to stop if they are feeling unwell because schedules have to be maintained and livelihood earned. Some vehicles carry dangerous cargoes which further exacerbates the potential hazard. For these reasons most countries, including all those of the European Union, distinguish between Ordinary (Group 1) and Vocational

Table 3 Causes of 2000 road accidents involving collapse at wheel, based on reports by the police to driver vehicle licensing agency

Epilepsy	38%
Blackouts	21%
Diabetes on insulin	18%
Heart condition	8%
Stroke	7%
Others	7%

(Group 2) driving in their guidance material (See 'The European dimension' below.)

# Cardiovascular disease and driving

All estimates of the prevalence of cardiovascular disease indicate that heart disease in particular is extremely common in developed countries. Another universal finding is the high case fatality rate<sup>[14]</sup> with approximately half of all heart attacks in the community resulting in death, which is often 'sudden'. Sudden cardiac death as a result of an arrhythmia is the most feared complication amongst drivers. Whilst death is, however, 'sudden' in epidemiological literature, it may not be instantaneous; there may be preceding symptoms. There is anecdotal evidence to indicate that a driver who suffers a fatal arrhythmia as a result of coronary heart disease may have time to pull over to the side of the road, where he/she may be found dead in the vehicle with the engine still running $^{[4,6,7]}$ . Conversely a benign arrhythmia, for example supraventricular tachycardia (SVT), may cause syncope, and hence driver incapacity, in up to one third

<sup>†</sup>Road users (except moped users) per 10 000 motor vehicles (except mopeds).

of patients, particularly at the onset of the tachycardia<sup>[15,16]</sup>. The likelihood of syncope in supraventricular tachycardia can be unpredictable because it is not related to the rate but rather to other factors, for example vasomotor, which may vary. The best predictor of syncope in SVT is thus a history of previous syncope; it appears to be abolished by curative treatment such as radiofrequency catheter ablation<sup>[16]</sup>. Transient AV block, sino-atrial disorder, and malignant vasovagal syncope may likewise cause sudden loss of consciousness, with loss of control of a vehicle, but may be followed by complete recovery. These cardiovascular disorders may well account for the unexplained blackouts which are the cause of road traffic accidents. Careful evaluation of drivers with a history of syncope is therefore very important.

Despite the foregoing considerations arrhythmia is the most likely cause of driver incapacity, and coronary heart disease is the most likely aetiology. There are, however, other less common cardiovascular conditions that may cause driver incapacity and which have to be taken into account, for example abdominal aortic aneursym. There is also overlap between cardiovascular and neurological disorders. Two areas are of particular concern. The first is the unexplained blackout as discussed above, the second is a cerebrovascular accident, either as a result of systemic embolism from the heart, or because of co-existing cerebral arterial disease. Heart disease and its effect on driving cannot be considered in isolation, other allied cardiovascular conditions, for example intermittent claudication, which may serve as markers for potential incapacity, must also be evaluated.

# The European dimension

A Council directive (80/1263/EEC) on 4 December 1980 proposed the establishment of a common European driving licence. A further directive of 29 July 1991 (91/439/EEC) formulated details and these have now been adopted.

Annex III (see Appendix I) of this directive describes the minimum standards of physical and mental fitness for driving a power driven vehicle. Two groups of drivers are defined. Group 1 comprises drivers of ordinary motor cycles, cars, and other small vehicles with or without a trailer (A, B, B+E, and sub-categories A<sub>1</sub> and B<sub>1</sub>). Group 2 includes drivers of vehicles over 3.5 metric tonnes (3500 k) or passenger carrying vehicles exceeding eight seats excluding the driver (C, C+E, D, D+E,  $C_1$ ,  $C_1+E_1$ ,  $D_1$ ,  $D_1+E$ ). Drivers of taxi cabs, small ambulances, and other vehicles form an intermediate category between the ordinary private driver, and the vocational driver. This group has an intermediate risk. On the one hand the number of hours spent behind the wheel is greater than the private driver and there is therefore a greater occupational exposure, on the other, the vehicles are not as large as those driven by Group 2 drivers, the

kinetic energies are smaller, and the consequences of incapacity are less. Most countries do not subject taxi drivers to Group 2 guidelines but there are exceptions, for example Denmark.

Higher standards are demanded of Group 2 drivers because of the higher accident fatality rates. Examination of the directive (see Annex III), however, reveals a lack of detail and precision. This is especially evident in Section 9.5 where no guidance is offered for professional drivers suffering from cardiovascular disease.

A European Community Concerted Action Performance Decrement Workshop, under the chairmanship of Professor Hugenholtz, met on three occasions in 1990 and 1991. A broad measure of agreement was achieved and cardiovascular standards for Group 2 drivers were defined. The existence of these and also the 1991 EEC Directive, enabled many nations to formulate guidelines, or to adapt existing ones. Thus in Britain, Ireland, Finland, Denmark, Germany and France, broadly similar guidelines have been adopted. There is, however, wide variation amongst other countries. A further difficulty is the enforcement of guidelines which range from having legal status in some countries such as the United Kingdom, to having little or no status and no means of enforcement in other countries (Table 4). The competent medical authority which determines fitness to drive also varies, as does the government department concerned with overseeing the driving licence.

In general, most European countries do not require a medical assessment for Group 1 drivers, although a declaration of fitness is required. All countries do, however, require a medical assessment for Group 2 drivers. If a doctor discovers a medical condition which may affect fitness to drive, then the doctor has an obligation to discuss this with the patient and advise him/her accordingly. If the driver rejects the advice then there is a dilemma, which is difficult to resolve. Most licensing authorities in Europe appear to by sympathetic to the doctor who does, under these special circumstances, divulge this information to the licensing authority. In the United Kingdom for example there is an Ombudsman who is empowered to adjudicate in such cases, and on the few occasions that an aggrieved driver has lodged a complaint, the Ombudsman has found in favour of the regulatory authority. There is, however, no universally agreed response; in Belgium it may be necessary to provide a written warning to the patient; in France such medical behaviour would be regarded as unacceptable. It is recognised throughout Europe that concealment of medical conditions that affect fitness to drivers may be common amongst Group 2 drivers, although most are responsible citizens and do support guidelines provided that they are not too stringent.

Not surprisingly, there is also wide variation in the road traffic accident statistics throughout the nations of Europe (Tables 1 and 2). These statistics can be expressed in several ways, but all tell the same story,

Table 4 Policy aspects Group 1 drivers (fitness declaration)

	Legislation	Authority (Ministry)	Family doctor	Other	Licence duration
Austria		Transport	_	+	
Belgium	_	Transport	_	_	Indefinite
Denmark	+	Health	+	?	Until 70 years
Finland	+	Transport	+	+	Until 70 years
France	+	Transport	_	+	Indefinite
Greece		•			
Germany	_	Transport & Health	_	Eye check	Indefinite
Ireland		Environment	?	?	10-3 years
Italy	+	Health	+	+	10–3 years
Netherlands	_	Health	_	_	Indefinite
Norway	+	Health	+		Until 70 years
Portugal					v
Spain	+	Interior	_	+	10- years
Switzerland	+	Interior	+		Until 70 years
UK	+	Transport	+	_	Until 70 years

<sup>- =</sup>no; +=yes; ?=varies; a gap indicates lack of data.

namely there is a four-fold difference between the safest nations, which include the United Kingdom, Sweden, and Norway, and the most dangerous nation, Portugal. The reason is not known.

Despite differences between the countries of Europe there is sufficient common ground in the approach to medical fitness and ability to drive for there to be agreed guidelines. The recommendations of this ESC Task Force for drivers with heart disease are presented in Table 5.

# Commentary on the guidelines

# General

Guidelines must be practical and enforceable. The Task force members were cognisant of the fact that elaborate guidelines would not be read, and too strict guidelines would be both unfair in view of the considerations outlined above, and unenforceable. All members were agreed that minimal restrictions were required for Group 1 drivers, but that certain drivers with heart disease at certain times should be advised not to drive. and that following a cardiac event some should be subject to specialist evaluation. In general, periods off driving following a cardiac event have become shorter because times for recovery following myocardial infarction, coronary bypass surgery etc. are quicker, and specialist evaluation can predict high risk groups who might be liable to collapse at the wheel.

The Task Force agreed that no screening need be undertaken for healthy asymptomatic individuals, and only in exceptional circumstances should cardiological abnormalities in such drivers be a cause for advising a period off driving.

In all guidelines of this nature there is a dilemma concerning the use of measurements to define acceptable standards. Estimates of such parameters as aortic valve

gradient, left ventricular ejection fraction, the degree of coronary arterial stenosis on angiography, aortic root diameter will always be subject to observer error. Minor adjustments of the measurement to ensure acceptability is a temptation that is too difficult to resist. Furthermore, an aggrieved driver who is advised not to resume driving would argue that he/she has been disadvantaged by a technical measurement which is only a few points adrift. Therefore the Task Force considered that it was important to emphasize that these guidelines should reflect a combination of clinical judgement by an accredited specialist, in addition to some individual technical measurements such as left ventricular ejection fraction, or exercise time on the treadmill.

In the estimation of coronary arterial stenoses, inter-observer error is well known, as is the tendency for underestimation of the severity of an angiographic stenosis, even by experienced observers. This can be particular problem in a stenosis affecting the left main coronary artery where overlapping vessels may make visualization difficult. The Task Force felt that there was no choice but to use percentage figures for angiographic stenoses, but wanted to emphasize that greater caution needed to be exercised when interpreting stenoses of the left main stem. It must be emphasized, however, that the figures 30% and 50% are not intended to be precise estimates of narrowing, but should rather be interpreted as those lesions which experienced angiographers judge to be 'significant'.

The Task Force recognised that a significant minority of collapses at the wheel would always occur in drivers who were previously asymptomatic. Any medical guidance, therefore, cannot totally prevent cardiovascular collapse as a cause of a road traffic accident. Coronary disease in particular has a long presymptomatic period and estimates of the prevalence of 'silent' but significant coronary arterial disease suggest that approximately one in three men with no history or signs of coronary disease will have a propensity for a sudden

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Diagnosis	Disqualifying criteria Group 1	Disqualifying criteria Group 2
Angina pectoris (stable or unstable)	Symptoms at rest or at the wheel; driving may be recommended once symptoms are controlled	Any history of and/or treatment for. If asymptomatic and requiring no anti-anginal medication (re-)licensing may be permitted subject to regular exercise evaluation. <sup>2</sup>
Myocardial infarction, CABG, PTCA	None, once clinical recovery has taken place, usually 4 weeks following MI or CABG, and one week following PTCA	Not permitted until at least 6 weeks has elapsed from the index event. If asymptomatic and requiring no anti-anginal medication (re-)licensing may be permitted subject to regular exercise evaluation. <sup>2</sup>
Peripheral vascular disease	None <sup>3</sup>	None, but associated coronary heart disease must be identified and evaluated (see above).
Hypertension	None <sup>3,4</sup>	If the blood pressure at rest consistently exceeds 180 systolic and/or 100 mmHg diastolic 4
Aortic aneurysm including Marfan syndrome	None <sup>3</sup>	from the following satisfactory repair and provided that there is no other discusalfying condition
Heart failure	Symptoms at rest or at the wheel. Driving may be permitted once symptoms are controlled	ansquantying condution. If asymptomatic (re-)licensing may be Any persisting symptoms. If asymptomatic (re-)licensing may be permitted provided that the LV ejection fraction is >0.40 on contrast angiography (or equivalent), there is no disqualifying arrhythmia (see helow) and the exercise requirements <sup>2</sup> can be satisfied.
Heart and/or lung transplantation (See Heart Failure)	Persisting symptoms.	
	If asymptomatic (re-)licensing may be permitted provided that the exercise <sup>2</sup> and arrhythmia requirements can be met	
Valve disease including valve surgery	$None^3$	Persisting symptoms.
Congenital heart disease	None <sup>3</sup>	If asymptomatic (re-)licensing may be permitted provided that there is no other disqualifying condition and no history of systemic embolism. Following cerebral or recurrent systemic embolism whilst receiving anti-coagulant treatment (re-)licensing is not permitted.  Any complex or severe disorder.
Hypertrophic cardiomyopathy	None <sup>3</sup>	Minor disorders and those which have been successfully corrected may be (re-)licensed provided that there is no other disqualifying condition Persisting symptoms.
		If asymptomatic (re-)licensing may be recommended for those with no family history of sudden cardiomyopathic death, no ventricular tachycardia on ambulatory electrocardiography and no hypotension on exercise testing.

(Continued) Table 5

Diagnosis	Disqualifying criteria Group 1	Disqualifying criteria Group 2
Arrhythmia (See Pacemaker, ICD)	Any disturbance of cardiac rhythm which is likely to cause disabling, symptoms, especially impairment of cerebral function	Driving will not permitted if the arrhythmia (i.e. non-sinus bradycardia, significant conduction defect, atrial flutter or fibrillation, narrow or broad complex tachycardia) has caused or is likely to cause disabling symptoms. Once the arrhythmia has been controlled (re-)licensing may be permitted provided that left ventricular ejection fraction is >0.40, ambulatory electrocardiography excludes ventricular tachycardia, and the exercise requirements <sup>2</sup> can be met.
Pacemaker implant Successful catheter ablation	Within one week	Any persistent symptoms. (Re-)licensing may be permitted after at least 6 weeks has elapsed, and provided that there is no other disqualifying condition.
ICD implant	Within 6 months if no arrhythmia recurrence and no disabling symptoms at time of ICD discharge. For drivers receiving 'prophylactic' ICD implant no restrictions are imposed	Permanent.
Syncope	Until cause identified and symptoms controlled	Requires specialist evaluation including a neurological review if appropriate. Following unexplained syncope, provocation testing and investigation for arrhythmia must be implemented. If the results are satisfactory (re-)licensing may be permitted after 3 months. Careful follow up is mandatory.

?NB In coronary heart disease angiography is not required for (re-)licensing purposes. If angiography has been undertaken (re-)licensing will not normally be permitted if the left ventricular ejection fraction is equal or <0.40 on contrast angiography, or if there is significant proximal, unrelieved coronary arterial stenosis (left main and proximal left anterior descending equal or >30%, or >50% elsewhere unless subtending a completed infarction). (See section commenting on the guidelines). Exercise evaluation shall be performed on a bicycle or treadmill. Drivers should be able to complete 3 stages of the Bruce protocol or equivalent (see Guidelines for Cardiac Exercise Testing. Eur Heart J (1993) 14, 969–988) safely, without anti-anginal medication for 48 h and should remain free from signs of cardiovascular dysfunction, such as angina pectoris, syncope, hypotension, ventricular tachycardia, and/or electrocardiographic ST segment shift (usually >2 mm horizontal or down-sloping) which accredited medical opinion interprets as being indicative of myocardial For Group 2 drivers licensing requires an annual declaration of fitness, with regular cardiological assessment, usually annually, exercise evaluation is likely to be necessary. ischaemia. In the presence of established coronary heart disease, exercise evaluation shall be required at regular interval, usually annually.

Provided that there is no other disqualifying condition. If drug treatment for any cardiovascular condition is required then any adverse effect which may affect driver performance will disqualify.

cardiac event by the time they reach the age of 60 years<sup>[17]</sup>. Angiography remains the gold standard in planning management strategies for patients with coronary heart disease, but there is very good evidence that clinical assessment, coupled where indicated with exercise testing, will provide equally good risk stratification<sup>[18–22]</sup>. Known powerful predictors of cardiovascular collapse include heart failure and poor left ventricular function, unstable cardiac syndromes due to coronary heart disease, and poor performance on exercise testing.

# Exercise testing

The Task Force considered carefully the nature of exercise test protocols and the level of acceptability. For most countries in Europe the standard treadmill test using the Bruce protocol should be adopted but other equivalent protocols are equally acceptable<sup>[19]</sup>. The choice of workload at the end of stage 3 of the Bruce protocol was supported by a number of studies. Bruce and Fisher studied 2373 men with clinically manifest coronary artery disease who had undergone exercise evaluation and follow-up for a mean of 61 months. Three hundred sudden cardiac incapacitations occurred. The annual incidence for such an event ranged from 0.084% per year in men aged under 38 years, increasing to 2.72% per year in men aged 64 years or older. The use of exercise electrocardiography enhanced the prediction to the extent that the highest risk group who could not achieve stage 3 of the Bruce protocol and were aged more than 64 years, had an annual risk of 21% per annum<sup>[18]</sup>. This report from the Seattle Heart Watch has been complemented by the Coronary Artery Surgical Study data. Wiener *et al.* studied 4083 medically treated patients with symptomatic coronary heart disease. They reviewed mortality at 4 years and found that the ST segment response and duration of exercise proved most important. They identified an extremely low risk group (32%) with an annual mortality of 1% or less, who could exercise into stage 3 of the Bruce protocol with less than 1 mm ST segment depression on the ECG (10 METS). In contrast, a high risk group (12%) comprised those who could only exercise to stage 1 of the Bruce protocol and who had ST segment depression of at least 1 mm. In this group, the annual mortality was 5% or more. The authors also confirmed the overriding prognostic importance of left ventricular function and the poor survival of patients with heart failure<sup>[20]</sup>.

These large studies reinforce earlier findings, for example by McNeer *et al.*, who found that patients who could exercise to stage 4 of the Bruce protocol with an adequate heart rate response had a 1 year survival of 99%, and a 4 year survival of 93%<sup>[21]</sup>. The Task Force favoured simplicity of the exercise time as the major determinant of acceptability, coupled with relevant clinical observations, such as absence of symptoms, ventricular tachyarrhythmias, hypotension and ST segment shift, rather than combing these into a prognostic score

which is more difficult to administer and interpret. Some delegates, for example those from Denmark, felt that the exercise criteria were too stringent and preferred to use the lower level of exercise, coupled with a prognostic score [22]. It should be pointed out that such prognostic scores have not been so well validated, although they may in future be adopted in some cases, for example if locomotor disability prevents the driver from achieving the required level of exercise.

The Task Force agreed that undue reliance should not be placed on estimates of ST segment depression alone because of the incidence of false-positive results, and because of the difficulties in interpretation in certain clinical situations, for example following coronary artery bypass grafting. Such difficulty in interpretation has also been highlighted by the description of syndrome X, for instance those patients with cardiac pain, reversible electrocardiographic or scintigraphic abnormalities, and normal coronary arteries. All authorities are, however, agreed that this group of patients has an excellent prognosis and that the exercise test provides good discrimination, symptoms can be misleading.

# **Arrhythmias**

The Task Force recognised that arrhythmias that had the potential to cause cardiovascular incapacity were generally malignant ventricular arrhythmias occurring in association with other cardiac disease, especially coronary heart disease. But apparently benign arrhythmias still have the potential to cause incapacity<sup>[23]</sup>. The words used to describe this incapacity presented the Task Force with some difficulty, although there was general agreement concerning the intention. Truly sudden incapacity, as in epilepsy, is unusual, but the phrase 'disabling symptoms, especially impairment of cerebral function, e.g. syncope or pre-syncope' was eventually agreed by the majority. This symptom is the most useful and widely recognised predictor of incapacity, being superior to other parameters of an arrhythmia, including those found on ambulatory electrocardiography, although this investigation is sometimes warranted, for example in the follow-up of Group 2 drivers.

A particular group of patients that has caused concern recently has been the driver with an implantable cardioverter defibrillator<sup>[1]</sup>. Early concerns that these devices might provoke a road traffic accident were based upon three theoretical considerations. First, the devices were implanted into patients at high risk of collapse, often those with coronary heart disease, previous cardiac arrest, and poor left ventricular function; second, device discharge or treatment was accompanied by involuntary movement and potential incapacitation; third, the reliability of the device was uncertain and false triggering, either from device and lead malfunction or from a relatively benign arrhythmia was judged probable. Observational studies have indicated that these devices

are generally safe, that involuntary movement is rare, and that false triggering is uncommon. Current experience indicates that patients with ICDs have approximately 50% chance of a discharge in the first year, and approximately 20% of patients will become syncopal. Lack of discharge in the first 6 months and the absence of syncope predicts a low risk of collapse at the wheel and this experience has been reinforced by published reports<sup>[24]</sup>. The guidelines proposed by the working group have therefore been incorporated into this Task Force report. The ICD is one example of changing practice and experience where revision of the guidelines may be required at a later date.

# **Syncope**

Another area of concern which may prompt re-examination of the guidelines at a later date is the evaluation of the patient with unexplained syncope<sup>[25]</sup>. Most syncopal attacks occur in young people and do not require medical attention, let alone further investigation. The precipitating events such as a hot environment, prolonged standing, pain, and fear, are well recognised, as are the sequence of symptoms and signs, such as nausea, light-headedness, pallor, bradycardia and hypotension, followed by rapid recovery on assuming a horizontal posture. This straightforward vasovagal syncope may be recurrent, but loss of consciousness is never abrupt and the victim does not present a hazard at the wheel.

In contrast, neurally mediated syncope in older patients may cause sudden loss of consciousness in incapacity. This 'malignant vasovagal syndrome' may be associated with carotid sinus hypersensitivity and may be reproduced by head-up tilt testing which is now in widespread use in the investigation of this disorder. On tilt-testing the immediate cause of the syncopal episode can be shown to be predominantly hypotension in some patients, bradycardia in others, or a combination of both in the majority. The problem from the regulatory point of view is that provocative testing in the investigation of syncope has a poor predictive value, and its usefulness in guiding therapy remains controversial. In everyday practice many adults have experienced a single syncopal episode with no recurrence. A survey of 66 cardiac electrophysiological centres which had treated more than 11 500 patients with syncope, indicated that 11% had treated at least one patient who had been involved in a motor vehicle accident. No respondent reported more than two such events<sup>[25]</sup>.

There is, however, overlap between neurally mediated syncope and epilepsy. Either may account for a single episode of unexplained loss of consciousness. The former is probably much more common. In either event some restriction is necessary for Group 2 drivers, pending the results of clinical assessment and further investigation. The time off driving is necessarily somewhat arbitrary, but 3 months generally permits time for assessment, the introduction of effective treatment, for

example pacemaking, and follow-up with repeat provocative testing. Most drivers will, however, never experience a recurrence and, as in other disorders which affect driver capability, reliance is best placed on clinical judgement by an experienced specialist.

# Other issues

The risk of incapacity at the wheel is small and difficult to quantify. The Task Force did not therefore adopt the mathematical approach as advocated by the Canadian Consensus Conference<sup>[26]</sup>. This approach has been shown to be satisfactory in the aviation industry where the '1% rule' has gained widespread acceptance [27]. The basis for this 'rule' is that society will accept a risk of incapacity in a pilot which is no greater than the average Northern European cardiovascular mortality, which happens to be 1% per year and which approximates to one death in 10<sup>6</sup> man hours. Pilots whose risk of a cardiovascular event exceeds this figure may not be certificated. The great merit of this approach is that it is objective, scientific, and easily understood 'if a potentially adverse judgement has to be made in an individual'. The approach is applicable in the aviation industry because the epidemiological data on cardiovascular events equates with pilot incapacity, and its consequences. The same does not apply on the road where cardiovascular death rarely seems to be the cause of an accident, whereas transient disturbances of consciousness, notably epilepsy, do and yet may be followed by complete recovery.

The deliberations of this Task Force of the European Society of Cardiology coincided with the preparation of a similar report concerning driving and arrhythmias which resulted in a medical/scientific statement from the American Heart Association and the North American Society of Pacing and Electrophysiology<sup>[25]</sup>. There is a broad measure of agreement on the important issues, for example the period of 6 months off driving following ICD implantation. This publication contains an excellent bibliography and detailed discussion of the issues relating to regulatory medicine. But it suffers from the disadvantage that arrhythmias are considered in isolation and not always in the context of the underlying heart disease. Hence the detailed recommendations have to be judged with this in mind and, for example, 6 months suspension of driving entitlement following an episode of ventricular fibrillation would not be applicable in Europe to a driver whose arrhythmias had occurred in the context of acute myocardial infarction, where subject to satisfactory clinical evaluation, absence of heart failure, and adequate performance on exercise testing, driving could be resumed much earlier.

# Conclusion

The Task Force endorsed previous recommendations by Hugenholtz, and by Joy and Broustet [28] that a common

cardiovascular standard for drivers be adopted by the European Union. It is hoped that these guidelines endorsed by the European Society of Cardiology will be disseminated to the member states through the national societies and individual cardiologists, who are in a position to influence Government ministries and departments

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# Appendix I

Annex III of Council Directive of 29 July 1991 on Driving Licences (91/439/EEC)

# ANNEX III

# MINIMUM STANDARDS OF PHYSICAL AND MENTAL FITNESS FOR DRIVING A POWER-DRIVEN VEHICLE

DEFINITIONS

- 1. For the purpose of this annex, drivers are classified in two groups:
- 1.1 Group 1

Drivers of vehicles of categories A, B and B+E and subcategory a1 and B1;

1.2 Group 2

Drivers of vehicles of categories C, C+E. D, D+E and of subcategory C1, C1+E, D1 and D1+E.

- 1.3 National legislation may provide for the provisions set out in this Annex for Group 2 drivers to apply to drivers of Category B vehicles using their driving licence for professional purposes (taxis, ambulances, etc.)
- 2. Similarly, applicants for a first driving licence or for the renewal of a driving licence are classified in the group to which they will belong once the licence has been issued or renewed.

# MEDICAL EXAMINATIONS

## 3. *Group 1*

Applicants shall be required to undergo a medical examination if it becomes apparent, when the necessary

formalities are being completed or during the test which they have to undergo prior to obtaining a driving licence, that they have one or more of the medical disabilities mentioned in this Annex.

#### 4. *Group 2*

Applicants shall undergo medical examination before a driving licence is first issued to them and thereafter drivers shall undergo such periodic examinations as may be prescribed by national legislation.

5. The standards set by Member States for the issue or any subsequent renewal of driving licences may be stricter than those set out in this Annex.

#### SIGHT

6. All applicants for a driving licence shall undergo an appropriate investigation to ensure that they have adequate visual acuity for driving power-driven vehicles. where there is reason to doubt that the applicant's vision is adequate, he shall be examined by a competent medical authority. At this examination attention shall be paid to the following in particular: visual acuity, field of vision, twilight vision and progressive eye diseases.

For the purpose of this Annex, intra-ocular lenses shall not be considered corrective lenses.

- 6.1 Applicants for a driving licence or for the renewal of such a licence shall have a binocular visual acuity, with corrective lenses if necessary, of at least 0.5 when using both eyes together. Driving licences shall not be issued or renewed if, during the medical examination, it is shown that the horizontal field of vision is less than 120°, apart from exceptional cases duly justified by a favourable medical opinion and a positive practical test, or that the person concerned suffers from any other eye condition that would compromise safe driving. When a progressive eye disease is detected or declared, driving licences may be issued or renewed subject to the applicant undergoing regular examination by a competent medical authority.
- 6.2 Applicants for a driving licence, or for the renewal of such a licence, who have total functional loss of vision in one eye or who use only one eye (e.g. in the case of diplopia) must have a visual acuity of at least 0.6 with corrective lenses if necessary. The competent medical authority must certify that this condition of monocular vision has existed sufficiently long to allow adaption and the field of vision in this eye is normal.

## Group 2

6.3 Applicants for a driving licence or for the renewal of such a licence must have a visual acuity, with corrective lenses if necessary, of at least 0.8 in the better eye and at least 0.5 in the worse eye. if corrective lenses are used to attain the values of 0.8 and 0.5, the uncorrective acuity in each eye must reach 0.05, or else the minimum acuity (0.8 and 0.5) must be achieved either by correction by means of glasses with a power not exceeding plus or minus four dioptres or with the aid of contact

lenses (uncorrective vision=0.05). The correction must be well tolerated. Driving licences shall not be issued to or renewed for applications or drivers without a normal binocular field of vision or suffering from diplopia.

#### HEARING

7. Driving licences may be issued to or renewed for applicants or drivers in Group 2 subject to the opinion of the competent medical authorities; particular account will be taken in medical examinations of the scope for compensation.

#### PERSONS WITH A LOCOMOTOR DISABILITY

8. Driving licences shall not be issued to or renewed for applicants or drivers suffering from complaints or abnormalities of the locomotor system which make it dangerous to drive a power-driven vehicle.

# Group 1

- 8.1 Driving licences subject to certain restrictions, if necessary, may be issued to physically handicapped applicants or drivers following the issuing of an opinion by a competent medical authority. This opinion must be based on a medical assessment of the complaint or abnormality in question and where necessary, on a practical test. It must also indicate what type of modification to the vehicle is required and whether the driver needs to be fitted with an orthopaedic device, insofar as the test of skills and behaviour demonstrates that with such a device during would not be dangerous.
- 8.2 Driving licences may be issued to or renewed for any applicant suffering from a progressive complaint on condition that the disabled person is regularly examined to check that the person is still capable of driving the vehicle completely safely.

Where the handicap is static, driving licences may be issued or renewed without the applicant being subject to regular medical examination.

# Group 2

8.3 The competent medical authority shall give due consideration to the additional risks and dangers involved in the driving of vehicles covered by the definition of this group.

#### CARDIOVASCULAR DISEASES

9. Any disease capable of exposing an applicant for a first licence or a driver applying for renewal to a sudden failure of the cardiovascular system such that there is a sudden impairment of the cerebral functions constitutes a danger to road safety.

# Group 1

9.1 Driving licences will not be issued to, or renewed for, applicants or drivers with serious arrhythmia.

9.2 Driving licences may be issued to, or renewed for, applicants or drivers wearing a pacemaker subject to authorized medical opinion and regular medical check-ups.

9.3 The question whether to issue or renew a licence for applicants or drivers suffering from abnormal arterial blood pressure shall be assessed with reference to the other results of the examination, any associated complications and the danger they might constitute for road safety.

9.4 Generally, a driving licence shall not be issued to or renewed to applicants or drivers suffering from angina during rest or emotion. The issuing or renewal of a driving licence to any applicant or driver having suffered myocardial infarction shall be subject to authorized medical opinion and, if necessary, regular medical check-ups.

# Group 2

9.5 The competent medical authority shall give due consideration to the additional risks and dangers involved in the driving of vehicles covered by the definition of this group.

#### DIABETES MELLITUS

10. Driving licences may be issued to, or renewed for, applicants or drivers suffering from diabetes mellitus, subject to authorized medical opinion and regular medical check-ups appropriate to each case.

#### Group 2

10.1 Only in very exceptional cases may driving licences be issued to, or renewed for, applicants or drivers in this group suffering from diabetes mellitus and requiring insulin treatment, and then only where duly justified by authorized medical opinion and subject to regular medical check-ups.

#### NEUROLOGICAL DISEASES

11. Driving licences shall not be issued to, or renewed for, applicants or drivers suffering from a serious neurological disease, unless the application is supported by authorized medical opinion.

Neurological disturbances associated with diseases or surgical intervention affecting the central or peripheral nervous system, which lead to sensory or motor deficiencies and affect balance and co-ordination, must accordingly be taken into account in relation to their functional effects and the risks of progression. In such cases, the issue or renewal of the licence may be subject to periodic assessment in the event of risk of deterioration.

12. Epileptic seizures or other sudden disturbances of the state of consciousness constitute a serious danger to road safety if they occur in a person driving a powerdriven vehicle.

#### Group 1

12.1 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.

# Group 2

12.2 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.

#### MENTAL DISORDERS

#### Group 1

13.1 Driving licences shall not be issued to, or renewed for, applicants or drivers who suffer from: severe mental disturbance, whether congenital or due to disease, trauma or neurological operations; severe mental retardation; severe behavioural problems due to ageing; or personality defects leading to seriously impaired judgement behaviour or adaptability unless their application is supported by authorized medical opinion and, if necessary, subject to regular medical check-ups.

## Group 2

13.2 The competent medical authority shall give due consideration to the additional risks and dangers involved in the driving of vehicles covered by the definition of this group.

#### ALCOHOL

14. Alcohol consumption constitutes a major danger to road safety. In view of the scale of the problem, the medical profession must be very vigilant.

#### Group 1

14.1 Driving licences shall not be issued to, or renewed for, applicants or drivers who are dependent on alcohol or unable to refrain from drinking and driving.

After a proven period of abstinence and subject to authorized medical opinion and regular medical checkups, driving licences may be issued, or renewed for applicants or drivers who have in the past been dependent on alcohol.

#### Group 2

14.2 The competent medical authority shall give due consideration to the additional risks and dangers involved in the driving of vehicles covered by the definition of this group.

#### DRUGS AND MEDICINAL PRODUCTS

15. Abuse. Driving licences shall not be issued to or renewed for applicants or drivers who are dependent on psychotropic substances or who are not dependent on such substances but regularly abuse them, whatever category of licence is requested.

# Regular use

#### Group 1

15.1 Driving licences shall not be issued to or renewed for applicants or drivers who regularly use psychotropic substances, in whatever form, which can hamper the

ability to drive safely where the quantities absorbed are such as to have an adverse effect on driving. This shall apply to all other medicinal products or combinations of medicinal products which affect the ability to drive.

# Group 2

15.2 The competent medical authority shall give due consideration to the additional risks and dangers involved in the driving of vehicles covered by the definitions of this group.

#### RENAL DISORDERS

# Group 1

16.1 Driving licences may be issued or renewed for applicants and drivers suffering from serious renal insufficiency subject to authorized medical opinion and regular medical check-ups.

# Group 2

16.2 Save in exceptional cases duly justified by authorized medical opinion and subject to regular medical check-ups, driving licences shall not be issued to or renewed for applicants or drivers suffering from serious and irreversible renal deficiency.

# MISCELLANEOUS PROVISIONS

#### Group 1

17.1 Subject to authorized medical opinion and, if necessary, regular check-ups, driving licences may be issued to or renewed for applicants or drivers who have had an organ transplant or an artificial implant which affects the ability to drive.

## Group 2

17.2 The competent medical authority shall give due consideration to the additional risks and dangers involved in the driving of vehicles covered by the definition of this group.

18. As a general rule, where applicants or drivers suffer from any disorder which is not mentioned in the preceding paragraph but is liable to be, or to result in, a functional incapacity affecting safety at the wheel, driving licences shall not be issued or renewed unless the application is supported by authorized medical opinion and, if necessary, subject to regular medical check-ups.

# Appendix II

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