

# Honorary Medical Advisory Panel Meetings

## MINUTES OF THE SECRETARY OF STATE FOR TRANSPORT'S HONORARY MEDICAL ADVISORY PANEL ON DRIVING AND DISORDERS OF THE CARDIOVASCULAR SYSTEM HELD ON WEDNESDAY 28TH SEPTEMBER 2005

<b>Present:</b>	Mr Dr H Swanton Dr M Anderson Dr J E Burns Dr M J Griffith Dr D R Holdright Dr A D Kelion Dr P M Schofield	(Chairman)
<b>Lay members:</b>	Mr P Tait Mr R Yates	
<b>Ex-Officio:</b>	Dr S Evans  Dr T Carter Dr H G Major Dr P Prasad Mrs A Rook Ms S Lloyd Dr C Jenkins	Civil Aviation Authority (observer)  Chief Medical Adviser, DfT Senior Medical Adviser, DVLA Medical Adviser, DVLA DMDG, DVLA DMDG, DVLA Panel Secretary, MA, DVLA

The Chairman welcomed Dr A Kelion to his first meeting.

### 1. Apologies for Absence

1.1. Apologies were received from Mr D Bastin, Dr D Smith, Professor A Bradbury, Dr D Mills and Dr Lily Read.

### 2. Minutes of the meeting held on 3 March 2005

2.1. The Minutes of the meeting held on 3 March 2005 were agreed.

### 3. Matters Arising not covered by the Agenda

#### (i) Item 4b Perfusion scan protocols and fees

There was further discussion about the need for DVLA to establish a protocol for both myocardial perfusion scans and stress echocardiography that are commissioned for licensing purposes. Members agreed that in order to maintain competence and expertise a minimum annual throughput of cases would be considered essential. A figure of 500 cases a year was suggested. It is likely that 20 or 30 centres in the UK met this criterion. However, in addition consideration had to be given to the geographical spread of the location of centres as well as to the quality of both the procedure and the reporting. DVLA will now survey all centres enquiring as to the availability of both myocardial perfusion scanning and echocardiography, and asking if they are able to carry out these procedures using the protocols recommended in:

(a) Procedure Guidelines for radionuclide myocardial perfusion imaging (Adopted by the British Cardiac Society, the British Nuclear Cardiology Society, and the British Nuclear Medicine Society) Nuclear Medicine Communications 2003;24:1105-1119

(b) Stress Echocardiography: Recommendations for Performance and Interpretation of Stress Echocardiography American Society of Echocardiography J Am Soc Echocardiogr 1998;11:97-104

DVLA would also enquire with respect to the availability of gated scanning, appropriate LVEF measurement etc, which stressors are used, and under what conditions. The results would be brought to the next meeting and a decision reached on how DVLA would proceed in its commissioning arrangements, including those of fee levels. It was further suggested that an expert in stress echocardiography should be invited to give a talk at a future Panel meeting.

**(ii) Item 5 Ankle Brachial Pressure Index**

In the absence of the relevant Panel member, the Panel was given a brief clarification of some of the mortality rates presented at the previous meeting.

It was advised that when ischaemic heart disease alone was analysed as the cause of death, the 10-year survival estimates by life table method for subjects were:

ABPI > 0.85 (i.e. considered free from peripheral arterial disease) 86%

ABPI 0.4-0.85 72%

ABPI < 0.4 53%

This trend was statistically significant at  $p < 0.01$ .

When cardiovascular disease in general was analysed as the cause of death, the 10-year survival estimates by life table method for subjects with

ABPI > 0.85 83%,

ABPI 0.4-0.85 63%

ABPI < 0.4 43%

This trend was statistically significant at  $p < 0.05$ .

Compared with subjects with ABPI > 0.85 (considered free from peripheral arterial disease), those with an ABPI 0.4-0.85 and < 0.4 had a relative risk (95% CI) for mortality of 2.02 (1.34, 3.02) and 3.35 (2.16, 5.20), respectively. These were statistically significant at  $p < 0.001$ .

For the 1984 US population, the standard mortality ratios (SMR) (95% CI) for ABPI > 0.85, 0.4-0.85 and < 0.4 compared to the US population were 1.14 (0.78, 1.61), 2.51 (2.06, 3.02) and 4.49 (3.52, 5.64), respectively.

The paper referenced was:

The Ratio of ankle and arm arterial pressure as an independent predictor of mortality McKenna et al, *Atherosclerosis* 1991;87:119-28

**(iii) Item 5.6**

The Panel had proposed a prospective research project examining the prognostic relevance of the ABPI compared to that of an Exercise test. It was agreed that it was a useful prognostic indicator. However it was only one of several such indicators. The Panel was also of the opinion that ABPI measurement is currently mainly carried out by vascular surgeons rather than by cardiologists.

It was important that the information about ABPI had been presented to the Panel, in order that DVLA was made aware of the significance of a severely reduced ABPI e.g. of <0.4 and the likely annual mortality rate represented by this figure, when reports came to DVLA which included an ABPI measurement.

After further discussion the Panel agreed that the face value of the ETT had a lot to commend it as an investigative procedure for licensing purposes. It was therefore felt inappropriate at this time to incorporate the measurement of ABPI as a routine investigation into cardiac fitness to drive. The Panel therefore agreed that there was not a pressing need, for licensing purposes, for further prospective research along the lines that had been suggested. It did not need to propose this topic to the DfT research arm at this time. In the absence of the relevant expert member of the Panel it was agreed that this decision could be reviewed at the next meeting if necessary.

**(iv) Item 7 Left Ventricular Assist Devices**

The Panel noted the paper:

Long term Use of a Left Ventricular Assist Device for End-Stage Heart Failure Eric A. Rose et al *NEJM* 2001; 345:1435-1443.

The Panel was reminded that following considerable discussion at the previous meeting, it had been agreed that a new entry would be included in the September 2005 (current) update of AAG. This allowed for the possibility of individual Panel consideration for re-instatement of Group 1 licensing entitlement 6 months after the insertion of the device. There was continuing concern about the high early mortality with these devices that was reported in this paper. However, in the information provided at the previous meeting, more modern devices had been noted to be likely to have a better survival rate than the larger and older devices reported in this particular paper. The Panel agreed that, pending any further comments from a cardiothoracic once a new member representing this area was appointed to the Panel, the current advice now given in AAG would stand.

**(v) Item 11 –Research - informative leaflet**

The Panel was told that there were some practical difficulties in implementing the proposal that an informative leaflet on the implications of lifestyle risk factors for future retention of a Group 2 licence should be enclosed with the issue of such a licence. The proposal could however be kept in mind for re-consideration in the future.

**4. Buerger's disease/thromboangiitis obliterans (TAO)**

4.1. The Panel considered the natural history of TAO. TAO is a rare condition which affects the medium and small arteries of the extremities. Large arteries are typically spared. Cardiac mortality is not increased. Systemic

manifestation involving the coronary arteries is said to be exceptional. However the Panel advised that the close association of TAO with smoking should prompt wider assessment to consider the need for ETT for Group 2 licence holders/applicants who declare Buerger's disease/TAO.

**5. Anticoagulation**

5.1. The Panel was asked to advise as to whether it may be appropriate to apply different clinical standards with respect to the requirement for, and the choice of, anticoagulation therapy, depending on the underlying condition. e.g. cardiac valve disease (and post valve graft), arrhythmia, cardiovascular disease.

5.2. The Panel noted that there was likely to be a growing number of drivers who were adults with congenital heart disease and had undergone surgical repair, on long-term anticoagulation. There was discussion around the absolute need for anticoagulation therapy in various situations and the attitudes of different clinicians towards this. It was felt that neither the decision to anticoagulate, nor the choice of appropriate anticoagulant, should be influenced by the desire to retain a group 2 licence.

5.3. In particular it was noted that after a TIA, advice might be given to take aspirin only. The Panel was reminded that because of the high risk of MI after a TIA, after a 1 year period off driving exercise testing was required before licensing could be reinstated.

5.4. After an embolic TIA with AF the risk of further embolus is high, reducing significantly with the use of Warfarin. This population is therefore at high risk. Warfarin was the anticoagulant of choice in this situation. If the driver did not wish to, or could not, take Warfarin for some reason it was suggested that it would be appropriate to ask the consultant's opinion with respect to the level of risk in an individual case so that the evidence of the appropriate management of risk factors, including the use of anticoagulation treatment, can be considered. The opinion of the Neurology Panel could also be usefully sought on this matter.

**5.5. The following amendment to be made to the AAG entry for arrhythmia**

	Group 1	Group 2
<b>ARRHYTHMIA</b> Sinoatrial disease Significant atrio-ventricular conduction defect Atrial flutter/fibrillation Narrow or broad complex tachycardia (See also following Sections - Pacemakers are considered separately) <b>NB: Transient Arrhythmias</b> occurring during acute coronary syndromes do not require assessment under this Section.	Driving must cease if the arrhythmia has caused or is likely to cause incapacity. Driving may be permitted when underlying cause has been identified and controlled for at least 4/52. DVLA need not be notified unless there are distracting/disabling symptoms. Disqualifies from driving if the arrhythmia has caused or is likely to cause incapacity.	Driving must cease if the arrhythmia has caused or is likely to cause incapacity. Driving may be permitted when the arrhythmia is controlled for at least 3/12, provided that the LV ejection fraction is satisfactory (i.e. LVEF is = or > 0.4), and there is no other disqualifying condition.

5.6. The Panel did not feel that a review of literature would be helpful in these circumstances but suggested that the Neurology Panel may also usefully consider the matter with respect to the risk factors associated with cerebrovascular disease. A joint meeting was suggested.

5.7. With respect to the risk factors associated with arrhythmias, the Panel was reminded that there had been a previous proposal submitted to DfT to hold a workshop on this. It was suggested that it may be helpful to revive this.

5.8 The following paper was tabled:

Anticoagulants in cardiovascular disease. John R and Swanton RH *British Journal of Hospital Medicine* 1990; **4: 207 – 214**

**6. Morbid obesity**

6.1. On occasion DVLA encounters a problem in undertaking cardiac investigations in a Group 2 driver, with a known cardiac history, because the weight of the driver precludes the use of either a treadmill or perfusion scanning. On occasion DVLA has had to refuse/revoke the entitlement on the grounds that cardiac fitness cannot be demonstrated.

6.2. The Panel was asked to advise if there is any other form of functional or prognostic assessment of cardiac fitness that could be used for these drivers/applicants, or whether morbid obesity (i.e. BMI >39) in itself should be considered of sufficiently high risk to be a bar to Group 2 driving. Morbid obesity is considered a serious chronic disease with co-morbidity with such conditions as diabetes, hypertension, heart disease, stroke, certain cancers, including breast and colon, depression, obstructive sleep apnoea and osteo-arthritis, several of which conditions have high relevance when assessing fitness to drive.

6.3. Doubt was expressed about the claim that there was an inability to carry out a scan because of weight. The weight limit for a scanning table was felt to be the same as for catheterisation, where the table could take weights of up to 160 Kg. Nevertheless it was noted that even if scanning could be carried out, misleading results could be produced. Careful interpretation of the results may be necessary.

6.4. Consideration is being given to including neck and waist measurements on the D4 medical examination form. The BMI can already be calculated from the height and weight. In an obese driver with known cardiac risk factors, a holistic view should be taken of the overall licensing risk, taking all factors into account, and including the risk of excessive day time somnolence as well as cardiac risk.

6.5. The Panel noted that the Civil Aviation Authority (CAA) has an upper BMI limit of 35 for initial Class I (Professional) medical certification. In addition seafarers may be required to lose weight if the BMI was >30. However there were other risk factors being considered for seafarers in these circumstances.

6.6. The Panel was advised that the Government had set up a Body to examine all aspects of obesity. In the meantime the Panel suggested that DVLA should commission a literature search on the risks associated with obesity.

6.7. The Panel advised that it was likely that a scan could be carried out in most cases but that where, rarely, fitness could not be demonstrated because of the inability of the equipment to accommodate the patient, a licence may need to be refused.

## 7. Report from IHD Workshop – 6-7 July 2005

### Item 11 Research - IHD Workshop

7.1. The meeting was advised that the report from the successful IHD workshop held on 11 July 2005 had not yet been finalised. It was anticipated that this would be available before the next meeting

7.2. Following the workshop the following matters were considered to have implications for DVLA current practice:

#### (i) Definition of risk

The workshop had agreed that the RISK definition referred to the risk per annum of ‘sudden severe disabling event’.

#### (ii) Variant angina/Prinzmetal’s

The Panel was asked to advise on the appropriate action to be taken in the presence of variant angina/Prinzmetal’s which was said to be due to coronary artery spasm rather than coronary artery disease. The Panel agreed that the pain from this cause should be regarded as disabling as pain from angina and should be treated in the same way for licensing purposes.

#### (iii) ETT post CABG

Following the proposal made at the workshop that ETT following CABG should be carried out no sooner than 3 months after the surgery, DVLA are carrying out a review of cases presented following notification of CABG. It is the current opinion that changing the time period requirement in this way will not have an adverse effect on case processing times.

	Group 1	Group 2
CABG	Driving must cease for at least 4/52. Driving may recommence thereafter provided there is no other disqualifying condition. DVLA need not be notified.	Disqualifies from driving for at least 3 months. Re/licensing may be permitted thereafter provided that the exercise test requirements can be met on a test carried out no sooner than 3 months post operatively and there is no other disqualifying condition. In addition the LVEF must be equal to or exceed 40%.

#### (iv) Stress echocardiography

The Panel confirmed that DVLA might request either perfusion scan or stress echocardiography where further functional investigation of cardiac fitness was needed, depending on local availability/quality. The criteria and protocols had been discussed earlier in Item 3(i).

#### (v) New algorithm

The Panel approved the new algorithm for cardiac investigation, which included the use of stress echocardiography

#### (vi) Value of angiographic evidence

The Panel confirmed that if unsolicited angiographic evidence is produced in support of a driver who cannot meet the exercise test requirements, any degree of stenotic lesion should lead to the request of a functional assessment

such as perfusion scan or stress echocardiography; which must be completed satisfactorily before the unsuccessful ETT can be disregarded. There no lower limit for an identified stenotic lesion which will allow this investigation to be avoided. If the outcome is still in doubt the advice of a Panel member should be sought.

**8. ICD standards for Group 1 drivers**

8.1. The Panel was asked to consider a proposed rewording of the sections of Chapter 2 of AAG addressing ICDs and prophylactic ICDs. The current wording had been felt by Panel members to be unclear. The wording was discussed at length and the agreed format is:

	Group 1	Group 2
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) implanted for ventricular arrhythmia which caused incapacity	<p>Patients should notify DVLA following initial ICD implantation and should not drive for:</p> <p>1) A period of 6 months after the first implant</p> <p>2) A further 6 months after any shock therapy and/or symptomatic antitachycardia pacing (see 3.a below).</p> <p>3) A period of 2 years if any therapy following device implantation has been accompanied by incapacity (whether caused by the device or arrhythmia).</p> <p>3.a) If therapy was delivered due to an inappropriate cause, i.e. atrial fibrillation or programming issues, then driving may resume 1 month after this has been completely controlled to the satisfaction of the cardiologist, <b>in which case DVLA will need to be notified.</b></p> <p>3b). If the incapacitating shock was appropriate (i.e. for sustained VT or VF) and new therapy has been introduced to prevent recurrence, driving may resume after 6 months in the absence of further symptomatic therapy.</p> <p><b>For 2 and 3 if the patient has been re-licensed prior to the event the DVLA should be notified.</b></p> <p>4) A period of 1 month off driving must occur following any revision of the electrodes or alteration of anti-arrhythmic drug treatment.</p> <p>5) A period of 1 week off driving is required after a defibrillator box change. Resumption of driving requires that;</p> <p>1) The device is subject to regular review with interrogation.</p> <p>2) There is no other</p>	Permanently bars

	disqualifying condition. Permanently bars	
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) implanted for ventricular arrhythmia which did not cause incapacity	If the patient presents with a non-disqualifying cardiac event, i.e. haemodynamically stable non-incapacitating ventricular tachycardia, the patient can drive after one month if all of the conditions below are met and DVLA need not be notified. 1) LVEF greater than 35% 2) No fast VT induced on electrophysiological study (RR <250 msec) 3) Any induced VT could be pace-terminated by the ICD twice, without acceleration, during the post implantation study. <b>If all these criteria cannot be met then these patients cannot drive for 6 months and DVLA needs to be notified. In addition, should the ICD subsequently deliver ATP and/or shock therapy (except during normal clinical testing) then the usual criteria apply and DVLA should be notified.</b>	Permanently bars
PROPHYLACTIC ICD IMPLANT	Asymptomatic individuals with high risk of significant arrhythmia: One month off driving and DVLA need not be notified. <b>However, should the ICD subsequently deliver ATP and/or shock therapy (except during normal clinical testing) then the usual criteria apply and DVLA should be notified.</b>	Permanently bars

With these changes, the section 'C' in the Annexe to chapter 2 can be removed.

## 9. Cases

### (i) Case 1/09/05

#### **The investigation required in the presence of RBBB**

#### **The investigation required with a history of heart failure**

#### **The investigation required post CABG**

The Panel discussed:

a) The problem with respect to the prognostic value of Exercise testing post CABG

The change to a minimum of 3 months post surgery has been agreed

b) Whether ETT should be carried out more frequently than every 3 years post CABG

It is not possible to ascertain accurately how many Group 2 licence holders have a further event within 3 years of having had an ETT post CABG, without notification to DVLA. A proportion of these will not reapply for licensing in any case. However it was suggested that post CABG the ETT should be repeated at shorter intervals than 3 years. No decision was made in the absence of supporting evidence about this.

c) The interpretation of ETT in the presence of RBBB

The Panel agreed that RBBB should be treated in the same way as LBBB – i.e. a gated scan with LVEF or a stress echo should be performed as first investigation, or if necessary if an ETT has been carried out and is equivocal because of previously unidentified LBBB/RBBB. However whilst it is advised that where there is known LBBB

exercising is not an appropriate stressor for the scan/echo, so that adenosine or dipyridamole MUST be used as the stressor, these restrictions on the stressor are not a necessity for RBBB.

d) The need to establish ventricular function where there is a history of heart failure or post CABG.

The Panel was of the opinion that the most important prognostic indicator in the presence of heart failure or any arrhythmia was the ventricular function and that this should always be ascertained where there was any history of heart failure and also post CABG.

The Panel advised that post CABG a successful functional assessment **and** evidence of a satisfactory LVEF should be obtained.

**(ii) Cases 2/9/05 and 3/9/05**

#### **ICDs**

These cases presented queries with respect to the interpretation of the advice about ICDs. This advice is now to be re-worded. (see 8.1)

**(iii) Cases 4/9/05 and 5/9/05**

#### **Variability of normal LVEF ranges in some centres**

The Panel discussed 2 cases from the same centre. Both had had myocardial perfusion scans. One of these appeared to have a satisfactory scan but in fact had not been adequately stressed. The LVEF in both cases was reported as <40% but considered by the centre to be acceptable. The Panel did not agree that there should be a variation in the acceptable level of LVEF depending on the centre doing the test. They referred to the papers:

(a) Prediction of myocardial infarction versus sudden death by gated myocardial perfusion SPECT: Risk stratification by the amount of stress induced ischaemia and the post stress ejection fraction Sharir et al *J Nucl Med* 2001;42:831-837

(b) Incremental prognostic value of post stress left ventricular ejection fraction and volume by gated myocardial perfusion SPECT Sharir et al *Circulation* 1999;100:1035-42

The Panel; advised that both cases should be refused. It was suggested that reports from this centre should be passed to a Panel member for opinion in the future.

**(iv) Case 1/12/04**

#### **Control of angina by the use of intrathecal morphine**

As no new reports had yet been received this case could not be discussed at this meeting

#### **10. Research update**

(i) The Panel had the opportunity to hear a preview of the findings of the review of the Risk of further Acute Vascular Events (RAVE) with particular emphasis on myocardial infarction and stroke. It was suggested that this report should also be made available in due course to the Neurology Panel.

(ii) The Panel proposed a number of additional questions that it would like answered in any future extension of the RAVE review project using more current data.

(iii) It was suggested that the value of holding an Arrhythmia workshop should be re-examined with the purpose of clarifying risk stratification. Specific questions that DVLA would wish to see answered should be composed to indicate the importance and relevance of this to driver licensing and submitted for consideration in order to help the DfT to prioritise this proposal in the 2006 submissions.

(iv) An ARIF literature search on the age related risks of obesity had been suggested during this meeting in response to a topic submitted.

(v) The Panel asked to review the list of previous research topics that had been proposed in past years to make sure that no important and relevant topic had been overlooked in the new format of the meetings.

(vi) The Panel agreed that Professor WJ McKenna should be invited to give a presentation on HOCM at the meeting on 8 March 2006, with the purpose of clarifying/refining the current advice given in AAG. His previous letter would be re-circulated to all Panel members.

#### **11. Dates of next meetings**

11.1. The date of the Spring 2006 meeting is Wednesday 8 March 2006.

The suggested date for the Autumn 2006 meeting is **Thursday 21st September 2006**

#### **12. Any Other Business**

12.1. There being no other business the meeting closed at 3.40pm

During the meeting the Panel considered the following papers:

1. The Ratio of ankle and arm arterial pressure as an independent predictor of mortality McKenna et al, *Atherosclerosis* 1991;87:119-28

2. Long term Use of a Left Ventricular Assist Device for End-Stage Heart Failure Eric A. Rose et al *NEJM* 2001; 345:1435-1443 Abstract

3. Abdominal aortic aneurysm Saklihasan et al *Lancet* 2004;365:1577-89

4. Incremental prognostic value of myocardial perfusion SPECT for the prediction of sudden death Hachamovitch et al *Circulation* 1998;97:535-543

5. Long term prognosis after normal exercise stress Tc-99 sestamibi SPECT study Elhendy et al J Nuc Card 2003;10: 261-6
6. Prediction of myocardial infarction versus sudden death by gated myocardial perfusion SPECT: Risk stratification by the amount of stress induced ischaemia and the post stress ejection fraction Sharir et al J Nucl Med 2001;42:831-837
7. Incremental prognostic value of post stress left ventricular ejection fraction and volume by gated myocardial perfusion SPECT Sharir et al Circulation 1999;100:1035-42
8. Standardised Myocardial segmentation and nomenclature for tomographic imaging of the heart AHA Circulation 2002;105:539-542
9. Determinants of risk and its temporal variation in patients with normal stress myocardial perfusion scans Hachamovitch et al J Am Coll Card 2003;41:1329-40
10. Procedure Guidelines for radionuclide myocardial perfusion imaging (Adopted by the British Cardiac Society, the British Nuclear Cardiology Society, and the British Nuclear Medicine Society) Nuclear Medicine Communications 2003;24:1105-1119
11. Clinical Competence Statement on Echocardiography – ACC/AHA Circulation 2003;107:1068-1089
12. Stress Echocardiography: Recommendations for Performance and Interpretation of Stress Echocardiography American Society of Echocardiography J Am Soc Echocardiogr 1998;11:97-104
13. Literature search on Prognostic Risk of Sudden Cardiac Related Events Based on Coronary Angiography Data ARIF June 2005