DRAFT

MINUTES OF THE MEETING OF THE SECRETARY OF STATE FOR TRANSPORT'S HONORARY MEDICAL ADVISORY PANEL ON DRIVING AND DISORDERS OF THE CARDIOVASCULAR SYSTEM

THURSDAY, 19 MARCH 2015

Present:

Dr M Griffith	Chairman
Dr A Kelion	
Dr L J Freeman	
Professor C Garratt	
Mr A Goodwin	
Mr M Gannon	
Dr R Henderson	
Dr D Fraser	

Ex-officio:

Dr S Mitchell	Civil Aviation Authority
Dr W Parry	Senior Medical Adviser, DVLA
Dr A Kumar	Panel Secretary, Medical Adviser, DVLA
Dr G Rees	Medical Adviser, DVLA
Dr M Y Dani	Medical Adviser, DVLA
Mrs J Leach	Medical Licensing Policy, DVLA

1. Apologies for absence

Apologies were received from Dr D Northridge, the Northern Ireland representative, Mr D Simpson, Dr T Keelan and Mr B Nimick.

2. Panel membership changes

The nominations for an expert in heart failure have been submitted to the Minister for approval.

Dr Kelion completes his 10-year period as a Cardiovascular Panel member at the end of March 2015. DVLA acknowledged and appreciated his valuable contribution to the Cardiovascular Panel and had sent a formal request to the Minister (with Dr Kelion's kind agreement) for an extension of his membership for a minimum period of one year (March 2016). Dr Kelion has received the ministerial approval letter and he has accepted the extension of his membership to March 2016.

DVLA would need to start the nomination process for a cardiologist with expertise in cardiac imaging to succeed Dr Kelion.

3. Chairman's remarks

There were no particular issues raised by the Chairman.

4. Minutes of the meeting of 18 September 2014

The minutes were accepted as accurate.

5. Matters arising from the minutes of 18 September 2014

Item 2: The European Union Cardiology Working Group proposals and UK Panel's opinion on certain issues (thoracic and abdominal aortic aneurysm, valvular heart disease)

Panel Secretary advised the Panel that following on from the issues discussed at the September 2014 meeting she has sent the relevant document and correspondence expressing UK Panel's view on these issues to the European Union Working Group. An e-mail correspondence from one of the members of the European Union Working Group mentions that the proposals were reasonable, however there has been no formal correspondence on these issues from the Working Group or the Driving Licence Committee. The Panel Secretary mentioned that it was important that

DVLA UK has expressed its views well in advance and hopefully will have the opportunity to vote accordingly in the future Driving Licence Committee meeting.

Item 5: Ventricular tachycardia: Group 1 and Group 2 licence standards

Panel had agreed in the September 2014 meeting that in addition to the current arrhythmia standards, cases of ventricular tachycardia need regular medical follow-up unless treated definitively by ablation, and this should be reflected in the 'At a Glance Guide to the Current Medical Standards of Fitness to Drive' section for arrhythmia standards.

The Medical Adviser group at DVLA wanted clarity regarding "the need for regular medical follow-up for ventricular tachycardia", in view of the fact that in the clinical situation all patients may not be necessarily followed-up regularly, and hence operationally may create difficulties in enforcing this advice. A lengthy discussion took place on this issue.

Conclusion:

Panel maintained its view that regular medical review (not necessarily follow-up) by a registered medical practitioner is important if ventricular tachycardia has not been treated definitively by ablation. This advice to the licence holder/applicant may need to be reinforced at the time of the issue of licence (either in the licence issue letter or as part of a declaration form just as for pacemaker/ICD). Although Panel did not feel a definite time limit could be advised regarding the frequency of this medical review, in the case of a Group 2 licence at least a 3-year review by DVLA would be acceptable. DVLA will need to decide how best to deal with this operationally.

Discussion points:

Panel appreciated the issues of variability in the pattern of medical follow-up/review of patients with ventricular tachycardia. In a number of cases patients may be discharged from specialist care to the care of their general practitioner, hence Panel's advice was that this review could be by a registered medical practitioner and not necessarily by a specialist in each case.

Panel Chairman's view was that at the DVLA in general, operationally there should be a system to make the licence holder/applicant aware of their legal responsibility and consequences if they do not declare a medical condition or do not comply with the advice given at the time of issue of the licence (for example, the need for a regular medical review). Panel agreed with the following suggestions: The licence issue letter in such cases of ventricular tachycardia should mention the advice for regular medical review with a registered medical practitioner (GP or cardiologist) OR to introduce a declaration form such as the pacemaker/ICD declaration form. DM Policy representative, Mrs Leach queried the consequences if a licence holder/applicant does not sign the pacemaker/ICD declaration form. Panel Secretary advised that if the above declaration forms were not signed, a licence would not be issued or be revoked.

6. DVLA's ETT protocol for Group 2 licence: Discontinuation of anti-anginal medication prior to exercise testing

The current DVLA ETT protocol for Group 2 licence assessment requires individuals to stop all their anti-anginal medication 48 hours before the exercise tolerance test (the anti-anginal medication refers to the use of Nitrates, betablockers, calcium channel blockers, Nicorandil, Ivabradine and Ranolazine prescribed for anti-anginal purposes). It also mentions that when any of the above drugs are being prescribed purely for the control of hypertension or an arrhythmia, then discontinuation prior to exercise testing is not required. The majority of cases which the DVLA refers for exercise tolerance tests have a background history of ischaemic heart disease and a significant number of cases do have

associated history of hypertension and/or arrhythmia in some cases. Panel agreed that in actual practice in very few cases the anti-anginal medication is prescribed purely for control of hypertension and/or arrhythmia. Whilst primarily prescribed for anti-anginal benefit, in individuals with associated hypertension/arrhythmia, the medication would also provide anti-hypertensive/anti-arrhythmic benefit. Hence, as per protocol when these medication(s) are stopped 48 hours before the test, in some cases the exercise test cannot be undertaken or completed to 9 minutes due to very high blood pressure or uncontrolled arrhythmia before or during the test. Currently, there are a number of ways these cases are being dealt with, in some cases the cardiologist re-arranges the test when there is better control of the blood pressure/arrhythmia OR repeats the test whilst being on the medication OR cases are referred back to DVLA to make a decision for further action.

Hence DVLA wish to have Panel's advice on how to best deal with these cases consistently.

A lengthy discussion took place on this issue.

Conclusion:

Panel's view is that if these medication(s) are prescribed purely for anti-anginal purposes then these medication(s) need to be stopped 48 hours before the test; if these medication(s) are prescribed purely for anti-hypertensive and anti-arrhythmic purpose then there would **not** be any need to stop the medication for 48 hours before the test. However, consensus was not reached on whether anti-anginal medication must be stopped in the individuals where medication would be prescribed for both anti-anginal and for anti-hypertensive/anti-arrhythmic benefit.

A Panel member suggested that there were recent studies relevant to the issue of cardiovascular disease and survival curves based on the exercise tolerance of individuals. Panel agreed that this area–requires full evidence based discussion and these studies will need to be reviewed before any further advice can be given on this topic.

Hence this topic will be discussed at the next meeting following review of the data available.

Panel also requested that Panel Secretary keep a log of the cases in which the medication had been stopped before the test and the exercise test could not be completed because of very high blood pressure or uncontrolled arrhythmia.

Panel Secretary asked for advice how to deal with these cases in the interim and the advice was as follows:

Continue with the current protocol - if the anti-anginal medication(s) have been stopped 48 hours before the test and individuals cannot do the 9 minutes of exercise tolerance test due to high blood pressure or uncontrolled arrhythmia rather than angina or any ischaemic ECG changes, then in those cases an alternative functional test i.e. stress echo or myocardial perfusion scan with a vasodilator would need to be undertaken (this would be irrespective of the duration that exercise tolerance test completed).

Discussion points:

Panel's view was that ideally beta-blockers must be stopped before the exercise tolerance test to ensure that there is a satisfactory rise in heart rate and that the symptoms of angina are not masked. Panel agreed that in patients with coronary artery disease, there are very few cases where these medication(s) are prescribed purely for hypertension and/or arrhythmia, and in most cases they are providing anti-anginal benefit along with cardio-protection and treating hypertension and/or arrhythmia. In the clinical scenario these cases are dealt with in different ways by cardiologists and it is not uncommon in clinical practice that the exercise tolerance test may have to be postponed due to a high blood pressure or arrhythmia, and also at times it would be difficult to stop the anti-anginal medication before the test if it was treating both angina and hypertension/arrhythmia. Panel felt that if a medication was prescribed purely for angina, and there were additional medication(s) for hypertension/ arrhythmia, then only the medication providing anti-anginal benefit would need to be stopped, the additional medication(s) for hypertension and/or arrhythmia could

be continued. Panel felt that the phrase "or for other reasons, for example, cardio-protection" as in the 'At a Glance' appendix section should be removed as it fails to make the distinction between the indications for medication.

One suggestion was that medication should be stopped before the test in all individuals (to avoid inconsistency), and if they are unable to complete the 9 minutes satisfactorily as per the protocol then licence to be revoked/refused. However, there would be issues with the safety of the test conducted due to the risk of high blood pressure leading to cerebrovascular events although this is not a very common occurrence.

7. Myocarditis: Group 2 licence standards

There had been a request from a cardiologist regarding the need for licence standards (especially Group 2 licences) for myocarditis in view of future risk of arrhythmia.

Conclusion:

Panel's advice was that if there is known arrhythmia associated with the myocarditis then the standards for arrhythmia as in At a Glance should be followed. If there is no known arrhythmia, despite a normal left ventricular ejection fraction, there is still a future risk of arrhythmia although this may not be a high risk and not very easily quantifiable in all cases. Currently, DVLA does not have standards for myocarditis and Panel would need to look into the literature evidence available on myocarditis and associated arrhythmia risk and this will need to be discussed at the next meeting.

In the interim, cases would need to be dealt with on an individual basis and Panel Secretary would keep a log of these cases.

Discussion point:

Although the risk is not very high, it is known that ventricular tachycardia or ventricular fibrillation can occur as a result of myocarditis affecting the heart, due to scarring of the myocardium which becomes a focus of arrhythmia. A Panel member suggested that in clinical practice once a diagnosis of myocarditis is made in an individual, as a general rule, he advises his patients not to indulge in competitive sports for a period of 6 weeks.

However, Panel agreed that often these cases are seen when late events have occurred and it may be very difficult to know when exactly myocarditis had occurred during the lifetime of the individual and hence difficult to predict the risk of future arrhythmias. Panel agreed that patients with severe myocarditis and poor left ventricular ejection fraction have a bad prognosis but there is a variety of myocarditis with a range of prognostic significance.

8. Interpretation of LVEF values when reported as a range (eg. 35-40%)

There have been several occasions when the DVLA echocardiogram report completed by a cardiologist reports left ventricular ejection fraction value as a range (e.g. 35-40%). As the minimum cut-off for Group 2 licensing is 40% it becomes difficult to make a licensing decision when a range of value is given. The general consensus was that 35-40% would mean less than 40% in a clinical scenario. However, Panel appreciated the operational difficulties when making a licence revocation decision if a range is given.

Conclusion:

Panel's view was that the cardiologist reporting the echocardiogram would need to answer the question 2 on CARDECHO ("Was the LVEF at least 40%?") as either 'YES' or 'NO'. Panel's advice was that removing the question 3 on CARDECHO ("If not, what was the LVEF?") would make it more definitive whether it is at least 40% or not. Question 3 on the CARDECHO to be removed.

Discussion points:

The reproducibility of LVEF values on a 2D echocardiogram in clinical practice is 5-10%, and usually it is not a huge issue in clinical practice whether it is 35, 38 or 40%. However, when there is a range given, in general the lower value is taken into consideration in clinical practice. It was also felt that a value 35-40% implies the LVEF is not at least 40%, but at most 40%. The Group 2 standards require at least 40%.

9. Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC): Group 2 licence standards

Group 2 licence standards for Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) was reviewed by Panel in light of a case discussed at the meeting. As per current standards, if an individual has ever been symptomatic from ARVC, they are permanently barred from holding a Group 2 licence. Panel felt that this was too restrictive and may not strictly apply for every case.

Conclusion:

The standards were reviewed and the Panel's advice was as follows:

ARVC Group 2 licence standards:

Asymptomatic – driving must cease but may be permitted following specialist electrophysiological assessment provided there is no other disqualifying condition (no change in this standard).

Symptomatic – driving must cease if an arrhythmia has occurred or is likely to cause incapacity. Re-licensing may be permitted if the individual is on treatment and has remained asymptomatic for at least a period of one year, and under regular electrophysiological review. A 3-year review licence to be issued if favourable EP review with no concerns.

Discussion points:

A case example was discussed (anonymously) where a Group 2 licence applicant diagnosed with ARVC following an episode of exercise induced syncope 10 years ago, was being treated with Sotalol and Mexilitine, had remained asymptomatic for a long period and was being followed-up annually at the EP clinic. As per the current guidelines in 'At a Glance' for a Group 2 licence, if symptomatic he would be barred permanently and if asymptomatic driving would be permitted following specialist electrophysiological assessment to ascertain suitability for holding a Group 2 licence. His case had been referred to Dr Griffith Panel Chairman who advised that he could be issued with a Group 2 licence as he had remained asymptomatic for a long time and his risk of a sudden disabling event would be less than 2% per annum. Panel's view was that if individuals had remained asymptomatic for a period of one year, then it is likely that the per annum risk of a sudden disabling event is less than 2%. Individuals with ARVC who are at high risk of getting significant arrhythmic events would normally be considered for an ICD.

10. 'At a Glance Guide': Wording for the arrhythmia standards

The Senior Medical Adviser asked for Panel's advice to define the word "incapacity" as used in the arrhythmia section of the 'At a Glance guide' for greater clarity (in response to a request from a legal body).

This definition could additionally be used for interpretation of the word "incapacity" elsewhere within 'At a Glance'.

Panel's advice was that the word "incapacity" is a term well known and used in clinical practice amongst cardiologists, and for driving it would imply "inability to control the vehicle safely". This would be in accordance with the way disability is described in the Road Traffic Act as well. (Panel Secretary had included the relevant extract from the Road Traffic Act 1988 regarding the definition of "disability"). The Panel Chairman mentioned that this could also apply to the use of the word "incapacity" elsewhere in the 'At a Glance guide'. Hence if DVLA needed to define the word "incapacity" this should be included in

the introduction section of the 'At a Glance guide' rather than just in the Cardiovascular section.

Conclusion:

The word "incapacity" remains as such in the Cardiovascular section of the 'At a Glance guide' but if greater clarity is needed, it could be defined as "inability to control the vehicle safely", in the introductory section of the 'At a Glance guide'. This would also be in accordance with the definition of "disability" in the Road Traffic Act 1988, Section 92(2)(b) "any other disability likely to cause the driving of a vehicle by him in pursuance of a licence to be a source of danger to the public".

11. A-Z Guide of medical conditions on DVLA's website

The Panel Chairman wished to discuss the issue of discrepancies observed in the advice given on the A-Z Guide of the medical conditions on DVLA's Government website as compared to the advice in the 'At a Glance Guide to the Current Medical Standards of Fitness to Drive'.

Panel Secretary advised that the 'At a Glance guide' predates the A-Z Guide; the 'At a Glance guide' is mainly for medical practitioners and has direct input from Panel Secretaries. The A-Z Guide of medical conditions is for public use in the UK for advice regarding licensing standards and notification to DVLA, and has not had active and direct input from the Panel Secretaries, however, when the Panel Secretaries are alerted of any errors, they do act upon it and advise any amendments if needed. The advice from the Drivers Medical Policy representative Mrs Leach was that the A-Z guide on the Direct.gov website is owned and management by the Government Digital Services and any changes to it have to be approved and agreed by the GDS.

The Senior Medical Adviser advised the Panel that he has had a meeting recently with Government Digital Services and efforts are being made to deal with the inaccuracies in the A-Z Guide.

12. Progress on the European Union Working Group Report on Driving and Cardiovascular Diseases

Panel Secretary updated the Panel on the progress of the European Union Working Group report and further action. She advised that she has been in regular e-mail correspondence with the Working Group making them aware of all the issues/topics where the UK Cardiovascular Panel have sent their views on the proposed standards by the Working Group. The detailed Working Group report and the legal draft recommendations of the guidelines on driving and licence standards were included in the Panel agenda bundle of March 2014 and Panel have been made aware from time to time regarding the progress on these issues. The Driving Licence Committee had sent an action point to all the Member States following the October 2014 Driving Licence Committee meeting, in which the Member States were sent and asked to provide:

1. The completed cardiovascular questionnaire and,
2. Comments on the draft cardiovascular provisions for the medical annexe to the Directive.

The Commission had requested that these were to be sent back to the Commission by the end of December 2014.

Panel Secretary had provided the response on both the questionnaires and the forms in November 2014 with approval from the Senior Medical Adviser. The completed questionnaire was enclosed in the Panel agenda bundle and was reviewed by the Panel in the meeting.

The Drivers Medical Policy representative, Mrs Leach, advised that the next Driving Licence Committee meeting would be in June 2015 where it is expected that they will be voting on the cardiovascular annexe.

13. Cases for discussion

Two cases were discussed, one with a history of syncope and heart block and Group 2 licence eligibility and one case of ICD. Advice was given in both cases.

14. Date of next meeting

The proposed date for the next meeting of the Panel is Thursday, 24 September 2015.

DR A KUMAR MBBS MRCGP
Panel Secretary

26 March 2015