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, 15 MARCH 2018

Present:

Dr R Henderson	Chair (Interim)
Professor C Garratt	
Mr A Goodwin	
Dr S Lim	
Mr B Nimick	

Ex-officio:

Dr S Bell	Chief Medical Officer, Maritime and Coastguard Agency
Dr S Gibbs	Guest speaker, National Pulmonary Hypertension Centre, Imperial College, London
Dr A Kumar	Panel Secretary, DVLA Doctor
Dr W Parry	Senior DVLA Doctor
Dr A Edgeworth	DVLA Doctor
Dr P Rizzi	DVLA Doctor
Mrs R Toft	Driver Licensing Policy, DVLA
Mrs E Melrose	Head of Drivers Medical, DVLA
Mrs K Bevan	PA to Mrs Emma Melrose, DVLA
Mrs S Charles-Phillips	Business Support, DVLA
Mrs S Taylor	Medical Panel Support, DVLA
Mrs Lorraine Jones	Panel Coordinator

The appointment of Chairman to the Cardiovascular Panel is awaited; hence DVLA had requested Dr Robert Henderson to act as the Chairman in the interim for this meeting. Dr Henderson introduced himself as the acting Chairman and welcomed all present. Initial introductions were made by all attendees.

1. Apologies for absence

Apologies have been received from Dr L J Freeman, Dr D Northridge, Dr D Fraser, Mr M Gannon, Dr Hutchison (CAA, Observer).

It was agreed by DVLA that the meeting was quorate.

2. Chairman's remarks

The Chairman drew the attention of the Panel to the description of the role of advisory panel in the standard introduction section of the agenda bundle. 'Role of the advisory panel – The purpose of the advisory panel is to provide the Secretary of State for Transport, in practice the Department for Transport (DfT) and the Driver and Vehicle Licensing Agency (DVLA), with expert advice with the aim of maintaining and improving road safety.'

The Chairman commented that whereas previously the direction to the Panel has been to strike a balance between public road safety and getting individuals back to driving on the roads, there seems to be a shift from this and the remit of the Panel in its advisory role is to focus on public road safety, and this needs to be reflected when Panel provides advice on cases.

3. Minutes of the meeting of 21 September 2017

The minutes of this meeting were agreed and accepted as accurate.

4. Matters arising

Item 2.4

The Chairman stressed the importance of having a cardiac imaging expert on the Cardiovascular Panel especially as there are agenda items which might need input from an imaging expert. The Chairman enquired about progress on the appointment of a cardiac imaging expert. Dr Parry advised that this issue has been addressed by DVLA.

Item 2.9

At the September 2017 Panel meeting, it was mentioned that Panel members would appreciate a letter from the Secretary of State for Transport addressed to their respective hospital trusts in recognition of members' time contribution towards the Panel. DVLA had agreed that a form of correspondence could be sent to the hospitals for the above purpose.

The Chairman asked for an update on this item. DVLA Policy representative advised that such a letter has not been sent yet, but it is on DVLA's agenda to be addressed. The Panel agreed that it may be best to communicate with individual Panel members before sending out such a letter to their respective hospital trusts to ensure that each Panel member would find such a letter helpful. It was agreed that the letter should be sent to the individual Panel member, who can then forward it to their NHS trust as appropriate.

5. Pulmonary hypertension: Presentation by Dr Simon Gibbs, National Heart and Lung Institute, Imperial College, London, Lead Clinician National Pulmonary Hypertension Service, Hammersmith Hospital

The Chairman thanked Dr Gibbs for a very comprehensive presentation on pulmonary hypertension with an emphasis on risk assessment. As per the '2015 ESC/ERS Guidelines for the diagnosis and treatment of Pulmonary Hypertension', the risk assessment in pulmonary arterial hypertension for estimated 1-year mortality has been classified as low risk (less than 5%), intermediate risk (5-10%) and high risk (greater than 10%). After much discussion on this topic, given the significant association with syncope, especially in intermediate and high risk patients, Panel agreed that there needs to be a section in 'Assessing fitness to drive – a guide for medical professionals' for 'cases with an established diagnosis of pulmonary hypertension under the care of a specialist centre', to cover Group 1 and Group 2 licensing standards.

Suggested draft for AFTD:

Established diagnosis of pulmonary hypertension under the care of a specialist centre

Group 1

Must notify the DVLA. May drive provided satisfactory specialist assessment and deemed to be at less than 20% per annum risk of a sudden disabling event. Individual assessment required.

Group 2

Must not drive and must notify the DVLA. Licence will be refused or revoked if in the intermediate or high risk group. If in the low risk group, driving may be allowed provided satisfactory specialist assessment and risk of a sudden and disabling event deemed to be less than 2% per annum.

Classification of low, intermediate or high risk as per 2015 ESC/ERS Guidelines for the diagnosis and treatment of Pulmonary Hypertension'.

Panel agreed that these cases are complex but likely to be few in number. Operationally, it was proposed that these cases would be referred to a Panel member or discussed at a Panel meeting for a licensing decision, unless the information available clearly indicates that an individual is unsafe for driving , especially for Group 2 cases. In such cases in the interest of public road safety, licensing decisions may need to be taken without waiting for panel referral.

Discussion points:

It was clear from the presentation that pulmonary hypertension is a relatively rare condition but does have implications for driving in terms of associated risk of syncope/sudden disabling events and breathlessness, especially in the intermediate and high risk groups or when associated with other diseases. Pulmonary hypertension includes a wide spectrum of disease and Panel were interested to know the risk of sudden and disabling events in various groups and subgroups group of patients.

Dr Gibbs gave a detailed description of the risk assessment criteria as per the '2015 ESC/ERS Guidelines for the diagnosis and treatment of Pulmonary Hypertension'.

As there is a wide clinical spectrum of conditions, and a complex clinical classification of pulmonary hypertension, Panel agreed that there needs to be a specific heading under which licensing standards are formulated. Panel were most concerned about cases with an established diagnosis of pulmonary hypertension requiring specialist centre care and hence the proposed heading for AFTD.

The risk assessment in pulmonary arterial hypertension in terms of estimated 1-year mortality is based on the classification into low risk (less than 5%), intermediate risk (5-10%), high risk (greater than 10%). This is based on the 2015 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. The functional classification for heart failure used in this assessment tool is the WHO functional classification rather than the NYHA classification. Most patients in WHO class III and IV are on IV Prostacyclin for treatment, awaiting lung transplant. These patients are at very high risk of sudden unpredictable events and should not be driving. In general, the medical advice given to individuals in the high risk group is to stop driving but this is a medical/clinical advice at present and not currently included in the DVLA standards. Panel did ask Dr Gibbs whether there is a sub-group in the high risk group where one can be confident that the risk of a sudden disabling event is less than 20% and hence Group1 driving could be allowed. Panel were advised that there is a wide variation in the risk profile of individual patients and hence an individual assessment by the specialist centre would be the most reasonable approach. It was noted that for an individual to be even considered for Group 2 driving, they would have to be in the low risk group, that is, estimated 1-year mortality less than 5%.

6. Heart failure: Functional cardiac assessment in non ischaemic heart failure: Group 2 licence standards

Currently individuals with heart failure need functional cardiac assessment if the underlying aetiology is ischaemic heart disease. Individuals with non ischaemic heart failure do not need cardiac functional assessment for Group 2 licensing purposes and licensing decisions in this group are made on symptom profile (NYHA classification recently added to AFTD). This was discussed at the Autumn 2017 Panel meeting and it was agreed that Panel need to refer to relevant literature available, if any, regarding the risk assessment of heart failure

patients with non ischaemic aetiology before considering any changes to the current standard. Dr Sern Lim gave an interesting presentation on 'Exercise test in heart failure'.

Conclusion:

No change in the current Group 2 licence standards.

The issue of cardiac functional testing in non ischaemic heart failure cases would only be relevant for NYHA class I and II, as NYHA class III and IV would be disqualified for Group 2 regardless. Following the presentation and discussion on this topic, it was agreed that currently there was lack of clear evidence of an increased annual event rate in individuals with non ischaemic heart failure in NYHA class I and II. Hence no changes in current standards were made.

Discussion points:

For Group 2 licensing purposes, currently individuals with heart failure with ischaemic aetiology are required to undertake an exercise tolerance test and if they fail they are disqualified from Group 2 licensing. Individuals with non ischaemic heart failure do not need to undertake an exercise tolerance test and although they may have the same functional impairment as their ischaemic counterparts, they could still be licensed if they are in NYHA class I and II and the left ventricular ejection fraction is greater than 40%. This approach is justifiable if patients with ischaemic heart failure have a higher risk of sudden events as compared to non ischaemic heart failure patients with a similar functional capacity. It was agreed that an exercise tolerance test does identify high risk patients in the ischaemic group and also gives an indication of the severity of ischaemia and the severity of heart failure. Prognosis of heart failure is dependent more on the severity of heart failure rather than the aetiology of heart failure in both ischaemic and non ischaemic groups. From the literature evidence available, for a similar V02 value, the event rates are comparable between the ischaemic and the non ischaemic heart failure patients.

Patients with mild heart failure may find it difficult to complete all 3 stages of the Bruce protocol as it is a very challenging test with steep increase in workload through the various stages of the test. It is not uncommon for a patient in NYHA class II to be unable to complete all 3 stages of the Bruce protocol exercise tolerance test. An individual who completes all 3 stages of the Bruce protocol ETT, is likely to be at very low risk for sudden

cardiac events. The difficulty lies in those borderline NYHA class II cases who may not be able to complete the 9 minutes of ETT. The question arose whether there is evidence /data on the annual event rate in individuals in NYHA class II heart failure but with non ischaemic aetiology. Without such evidence it would be difficult to justify any change in the current standards, and to require the non ischaemic group of heart failure patients to undergo ETT. Generally speaking, NYHA class II patients can achieve a V02 between 18-20 ml/ minute/kg, and the 6-minute walking distance though reduced is not severely reduced. Trials in this group of patients show the annual mortality to be approximately 4-8%, and they are usually in the low risk group for event rates. ETT undertaken in the ischaemic group of heart failure patients is for assessment of ischaemia and functional cardiac capacity as a marker of sudden disabling events in this group for licensing purpose. Due to lack of clear evidence of the annual event rate in the non ischaemic group of heart failure patients, it is currently not justifiable to change the standards. Panel agreed that the NYHA classification has just been introduced into the standards, so we are not aware how many Group 2 drivers/applicants in the non ischaemic group have NYHA class II heart failure and LVEF greater than 40%, and hence would be licensed without the need for ETT. Panel will continue to review this topic.

7. Pacemaker and Functional Cardiac Assessment: Group 2 licence standards

As per DVLA protocol for a myocardial perfusion scan and stress echocardiography the criteria for adequate stress is the achievement of 85% of the age-predicted maximum heart rate (220 minus age) x 85%.

There have been situations in individuals with pacemakers where it has not been possible to achieve this target heart rate due to pacemaker settings. There have also been situations in non pacemaker cases where the above target rate could not be reached but the Group 2 standards for reversible ischaemia and the LVEF criteria were met. The question posed to Panel was that if the individual has met the Group 2 licence standards in terms of reversible ischaemia and LVEF (greater than 40%) but fails to reach the target heart rate should the licence be refused/ revoked as they have not fully met the criteria.

Conclusion:

The current MPS/Stress Echo DVLA protocol needs to be reviewed by a cardiac imaging expert in terms of a stressor agent, and target heart rate. As Panel is currently awaiting the appointment of a cardiac imaging expert, Panel's advice was to request a review of the protocol by Dr Kelion, who has provided input in the past. In the interim if for Group 2 licensing purposes, an individual cannot demonstrate that they can meet the Group 2 standards, then the licence would have to be revoked/refused. If further information from specialists is made available DVLA will consider the information and seek Panel advice if needed.

Discussion points:

The Chairman stressed that ideally a cardiac imaging expert is needed for discussion around this topic. An individual with a pacemaker who cannot exercise to the required level or who does not reach the target heart rate would not meet the Group 2 criteria and the licence would need to be revoked or refused. The protocol clearly states that treadmill stress may be used as a stressor agent if there is no physical disability and the criterion for adequate stress is the achievement of 85% of age-predicted maximum heart rate. The protocol does allow for pharmacological stressor agents to be used (Adenosine, Dipyridamole or Regadenoson or Dobutamine) in cases where treadmill testing cannot be undertaken. It also mentions that this should be combined with at least sub-maximal exercise. However, it does not clarify whether when pharmacological stressor agents are used, the criteria for adequate stress is also the achievement of 85% of age-predicted maximum heart rate in all cases. The pharmacological stressor agents like Adenosine or Regadenoson are known to raise the heart rate but may not be able to achieve 85% of the maximum age-predicted heart rate. In clinical practice target heart rate is not a criterion for adequate stress when Adenosine or other vasodilator agents are used. It is justifiable for Dobutamine as it does increase the heart rate enough to reach 85% of the age-predicted maximum heart rate. Hence the protocol needs to be reviewed to clarify the need for reaching the target heart rate when certain pharmacological agents are used.

8. Coronary artery aneurysm: Group 2 licence standards

For licensing purposes the DVLA considers functional implication of coronary heart disease to be more predictive than anatomical findings. For this reason exercise tolerance testing and where necessary myocardial perfusion imaging or stress echocardiography are the investigation of relevance for licensing purposes. Angiography is therefore not commissioned for licensing purposes, however, Panel had agreed in 2008 that if DVLA is provided with angiogram reports with pressure wire studies and fractional flow reserve (FFR) is greater than 80% (0.8) then a further cardiac functional assessment is not required unless other aspects require this. DVLA sought advice from Panel on the course of action if an individual met the FFR criteria but there were other abnormalities (for example, coronary artery aneurysm) reported on the angiogram.

Conclusion:

After much discussion, Panel's advice was that if there are other significant coronary abnormalities like aneurysm or marked ectasia, cases will need individual assessment via panel referral and in some cases functional testing would be considered appropriate .If the functional test meets the Group 2 criteria then a 3-year review licence as usual would be issued unless a closer follow-up is recommended by their clinician. A standard letter could be sent to the individual to advise them about early notification if any change in the progression in their condition.

As FFR is being used more in clinical practice now, DVLA may see an increase in cases with such scenarios and panel may wish to review this topic in future .

Discussion points:

Coronary artery aneurysm is a rare condition, and it is difficult to predict risk of sudden disabling event in all cases. The previous advice from Panel to issue a Group 2 licence without the need for cardiac functional tests or regardless of the result of functional test in ischaemic heart disease/coronary artery disease cases based on a functional flow reserve of greater than 0.8 (80%), did not take into consideration coronary abnormalities other than that accounting for ischaemic heart disease . Hence, if there are other abnormalities present, then it would be reasonable to refer them for a cardiac functional test to check if they can meet the Group 2 standards in the presence of the abnormality.

9. Cases for Discussion

There were 2 cases for discussion and advice was provided by Panel on both cases.

The first case was that of an aortic transection (traumatic aortic tear), with a descending thoracic aortic pseudoaneurysm associated with a small contained leak managed conservatively. Panel's advice was to revoke the Group 2 licence as there has not been a sufficient period of stability to predict the future risk of rupture and hence a sudden disabling event.

The second case was that of an individual with coronary artery disease and hypertrophic cardiomyopathy due to Fabry disease. On previous renewals, although the ETT had ST changes consistent with HCM they met the Group 2 licence standards, however, the most recent ETT showed significant ST depression (significantly worsened). Panel's advice was to refuse the Group 2 licence renewal application, as clearly it failed to meet the Group 2 licence standards most likely due to a combination of progressive coronary artery disease and/or progression of his cardiomyopathy.

10. AFTD Review

Panel reviewed the cardiovascular section of 'Assessing fitness to drive – a guide for medical professionals' in detail. The changes suggested and agreed are in a separate document attached to the minutes under the heading 'Item 10 AFTD Review (Addendum to Cardiovascular panel minutes 15.3.18)'

11. DVLA Appeals Statistics

At the July 2017 annual Panel Chairmen's meeting, Panel chairmen expressed their interest to know more about any appeals that DVLA lose in court, in particular to understand the reasons for losing cases. The reason the Panel chairmen are keen to see these cases is to reflect upon standards and establish if any changes are needed but also to potentially reinforce the current standards despite a judgement on an isolated case.

Appeal cases since last Panel meeting: October 2017 to date.

DVLA received 72 summonses out of which, one was a cardiac related appeal. This was a case of coronary artery disease, who was issued with a one year review licence, as the individual was due for another ETT in a year's time. The decision is currently pending as the full hearing has not taken place and the applicant, due to the passage of time, has been invited to reapply and referred for an exercise tolerance test.

12. Recruitment Update

DVLA Policy representative updated the Panel that the DVLA recently ran a recruitment exercise following which there was ministerial approval to appoint two new panel members.

13. Any Other Business

Dr Henderson mentioned that there is need for clarification whether Group 2 licence holders or applicants are required to undertake cardiac functional test if they have a history of ischaemic heart disease or coronary artery disease. Under the current headings of angina, acute coronary syndrome, percutaneous coronary intervention or coronary artery bypass graft, individuals are required to undertake functional test only if they have a history of ischaemic heart disease. This does not currently include individuals who have coronary artery disease but may not have any of the above presentations. This needs to be discussed at the next meeting.

14. Date of next meeting

The date of the next meeting was not finalised pending appointment of the new Panel chairman and his/her availability. The Panel members present did request that it would be beneficial to have dates of future Panel meetings as far as a year in advance.

First Draft Minutes prepared by: **Dr A Kumar MBBS MRCGP**
Panel Secretary

22 March 2018

Final Minutes signed off by: **Dr R Henderson**
Interim Panel Chair

1st May 2018.