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, 22 SEPTEMBER 2016

Present:

Dr M Griffith	Chairman
Dr L J Freeman	
Mr A Goodwin	
Dr R Henderson	
Dr D Northridge	
Dr S Lim	
Mr B Nimick	
Mr D Simpson	

Ex-officio:

Dr S Mitchell	Civil Aviation Authority
Dr S Bell	Chief Medical Officer, Maritime and Coastguard Agency
Dr W Parry	Senior Medical Adviser, DVLA
Dr A Kumar	Panel Secretary, Medical Adviser, DVLA
Dr K Davies	Medical Adviser, DVLA
Dr C Maginnis	Medical Adviser, DVLA
Mr M Davies	Joint Head of Medical Licensing Policy, DVLA
Mr J Donovan	Medical Licensing Policy, DVLA

1. Apologies for absence

Apologies have been received from Mr M Gannon, Dr D Fraser.

The Chairman welcomed all attendees and introductions were made by all present.

2. Panel membership changes

The Chairman advised that the nominations for a new Panel member to replace the retired cardiac imaging expert were submitted at the end of 2015. He requested an update on the

recruitment of the replacement member. Mr Mark Davies from DVLA Policy advised that the recruitment process is currently on hold due to the ongoing DVLA Audit on Panels. The Senior Medical Adviser, Dr Parry, advised that the terms and conditions for Panel recruitment/membership is being revised currently and once this is complete the recruitment process will resume. The Chairman mentioned that the Panel is not complete without a cardiac imaging expert, he appreciates the recruitment is on hold, not just for the Cardiovascular Panel but also an issue across other Panels.

3. Minutes of the meeting of 3 March 2016

The Chairman advised the Panel that the minutes of the meeting of 3 March 2016 had been approved by himself and the SMA in March, however, they have not yet had clearance by the DVLA Medical Policy department. Certain sections which had embargoed information have already been removed on Policy's advice before including in the agenda bundle.

There are additional sections which had to be redacted, however, the Chairman is not privy to those changes as yet. It was pointed out that the minutes included in the agenda bundle were not the redacted version as changed by the DVLA Policy (subsequent to Chairman's initial approval). The Chairman asked the SMA if he was happy to agree to the minutes of the last meeting (3 March 2016) which were included in the agenda bundle and the SMA stated he was.

However, the agenda bundles were collected from the Panel members at the end of the meeting as they did not contain the redacted version of the previous minutes. The advice from management is that SMA Dr Parry has agreed to forward the amended minutes to the Panel Chairman within a week. Panel Secretary advised that any changes to the minutes will be incorporated after confirmation of approval from chairman.

4. Matters arising from the minutes of the meeting of 3 March 2016

Item 6: Progress on amendment of the Annex III of EC Directive

The Panel Chairman had suggested at the last meeting that for Group 1 licensing purposes it could be far too restrictive to have Brugada syndrome in section 9.2 and it would be much better placed in section 9.1 of the Annex. Panel Secretary had sent this suggestion to the Driving Licence Committee prior to the voting procedure. Panel had asked for Policy's advice whether it would be possible to contest this clause with the Driving Licence Committee and/or whether exceptionality could be applied just to Brugada syndrome with syncope in aborted sudden cardiac death (for the purpose of a Group 1 licence).

Mr Mark Davies from DVLA Medical Policy advised that the EC Directive for the Annex III was adopted in early July 2016, and published in the Official Journal of the European Union Driving Licence Committee. The wording of the Annex would not be subject to any change, and the DVLA would have to work with the DfT lawyers and Cardiovascular Panel as to how to further transpose this into UK legislation. He further advised that the Cardiovascular Directive will become a legislative requirement and not just a guidance. The Directive is due to be adopted into UK legislation from 1 January 2018. Currently, this is undergoing the process of Government clearance, and once this process is complete consultation with the Cardiovascular Panel and DfT lawyers will begin (hopefully early 2017). The Panel Chairman queried how and if 'BREXIT' would affect the whole process. Mark Davies advised that currently he is not aware of any changes to the process, until further notice. The Panel Chairman commented that the Brugada standards as stated in the EC Directive Annex III are far too restrictive. He added that it has been useful to have Panel involvement from the outset in the development process of these guidelines.

5. Congenital heart disease: Review of licensing standards – Group 1 and Group 2

The standards for congenital heart disease were last updated in 2003. Currently, all forms of congenital heart disease are notifiable to DVLA for both Group 1 and Group 2 licence purposes and licensing decisions are made based on the information made available to DVLA following relevant medical enquiries. DVLA had recently received a letter from a

Member of Parliament in relation to the queries raised by an external stakeholder. The main queries were in relation to the need for notifying DVLA of all forms of congenital heart disease and the assessment process for reaching a licensing decision. It was perceived by the stakeholder that the need for notifying all forms of congenital heart disease to DVLA, especially for Group1 licence, is discriminatory as there are several other cardiac conditions which are not notifiable to DVLA for Group 1 licensing purposes. Panel Secretary had discussed the issue with Dr Leisa Freeman (GUCH expert on Panel) and was advised that the standards for congenital heart disease need to be reviewed by Panel.

Dr Freeman did an interesting presentation on congenital heart disease with particular relevance to DVLA guidelines and the need for notification. This presentation was circulated to all attendees via e-mail prior to the meeting (copy of the presentation enclosed with the minutes).

An interesting and lengthy discussion ensued on this topic.

Conclusion:

I. Changes to Group1 standard , no changes to Group2 standard .

Group 1 licence standards: May drive and need not notify the DVLA if completely asymptomatic and do not fall under any other category which requires notification to DVLA.

Must notify DVLA if symptomatic of congenital heart disease (eg. Angina, arrhythmias, ablation, pacemaker {including CRT}, ICD, hypertension, heart failure, impaired ventricular function, asymptomatic heart valve disease); if symptoms develop after being asymptomatic or if fall under any other category which requires notification to DVLA.
Individual assessment of cases. Certain conditions may require the issue of a medical review licence for 1,2,or 3 years .

The above should be reflected in the 'Assessing fitness to drive – a guide for medical professionals'.

Group 2 licence standards: All cases of congenital heart disease must notify the DVLA.
If symptomatic of congenital heart disease, if CHD complex or severe licence would be revoked/refused .
If asymptomatic, licence may be issued subject to medical review at 1,2 or 3 years depending upon specialist assessment and provided there is

- minor disease
- successful repair of defects/relief of valvular problems, fistulae and so on,
- no other disqualifying condition.

II. It was also discussed that there should be a separate section for TAVI plus other cardiac or pulmonary percutaneous device. The standards should be the same as for open surgery however, it is important to have a separate section for the above.

Discussion points:

Congenital heart disease is a complex area with huge variability and diversity in the disease spectrum and it is difficult to be succinct and accurate in predicting prognosis in a generalised way. Patients often are not fully aware of their underlying condition and often detected/diagnosed when they present with symptoms such as angina, arrhythmia etc. Development of symptoms should trigger notification to DVLA as per relevant section of the driving standards for individual conditions.
Regarding the notification process the SMA mentioned that in the At a Glance the general guide for every condition was 'applicant or licence holders must notify DVLA' unless stated otherwise in the text, this would imply notification for the section on congenital heart disease as well but as it did not specifically/separately mention to notify DVLA in each section , it may well be that up until now many mild congenital heart conditions were not being notified to DVLA ,the general guideline at the top section of each page being overlooked/missed. In the new Assessing fitness to drive guide as each section indicates whether to notify or not, the notification process has become more obvious and hence this

has highlighted the issue of notification for congenital heart disease and been picked up by external stakeholders. Patient groups for congenital heart disease feel the need for notifying all forms of congenital heart disease for Group 1 licence purposes is rather discriminatory against them as a number of other heart conditions like angina, heart failure etc do not need notification for Group 1 purposes. It was mentioned that the number of adults with congenital heart disease are increasing as more patients are surviving into adulthood, and hence the need for a driving licence.

Panel Secretary advised that currently on first notification of congenital heart disease, following individual assessment by DVLA, some cases are issued with a review licence, this is only possible as all cases of congenital heart disease are currently notifiable to DVLA. However, if there is no need for notification, all of these cases will be issued with an unrestricted till 70 licence. Panel Secretary queried whether it would be acceptable for all forms of congenital heart disease to have an unrestricted licence or should there be a distinction by which certain mild asymptomatic simple forms are not notifiable and the complex congenital heart disease are notifiable. Dr Freeman's advice was that for Group 1 purposes as the acceptable risk of a sudden and disabling event is less than 20% per annum, it might become very difficult to segregate and make such distinction. If an individual with congenital heart disease is issued with an unrestricted 'till 70' licence and at any stage in their life they do develop symptoms for example, angina, arrhythmia, dizziness/syncope or they require intervention, for example, pulmonary valve replacement in Fallot's tetralogy or an ICD for an arrhythmia, then they would fall under the respective category of fitness to drive standards and would need to notify the DVLA under that category. The Chairman queried whether for Group 1 licence purpose, are there any groups of patient who may be completely asymptomatic and not fall under any other category in the fitness to drive guidelines, but who could still be at risk of a sudden and disabling event greater than 20% per annum ? Dr Freeman mentioned that the high risk patients for sudden and disabling events are usually picked up early as they become symptomatic and under the symptom criteria they should be notifying the DVLA, for example, patients with corrected transposition of great arteries with systemic ventricle may present with shortness of breath due to right ventricular failure, syncope; similarly patients with right heart with corrected Fallot's tetralogy may present with ventricular fibrillation as the first presentation; patients

with associated systemic pulmonary regurgitation without any correction may have higher risk of sudden and disabling events. The view was that these kinds of high risk patients would need individual assessment with Panel input if needed. It was also mentioned that certain conditions like corrected mild ASD, are at very low risk of a sudden disabling symptom and it would be restrictive to expect these to be notifying DVLA as compared to other significant conditions like acute coronary syndrome, angina, not needing to notify DVLA for a Group 1 licence.

Concerns about under reporting of symptoms by patients due to fear of need to notify DVLA were discussed. However, it was felt that this could still happen with the present situation with a number of other conditions, for example, symptoms of angina not being reported as angina is not notifiable until there is a history of ongoing symptoms. It was also mentioned that it was very difficult to make a true distinction between the various conditions under the umbrella of congenital heart disease and difficulties to identify where to draw the line for the purpose of notification. Often patients are referred for congenital heart disease surgery only having recently developed symptoms, however, there are also groups of patients who do present with disabling symptoms and these definitely would need to notify. A consensus was reached that individuals with congenital heart disease would only need to notify DVLA if they are symptomatic , such as symptoms of angina, arrhythmia, heart failure etc as mentioned in Dr Freeman's presentation or they fall under other conditions needing to notify , for example, pacemaker, ICD , heart valve disease. A licensing decision will be based on individual case assessment once notified. It was agreed that the guidelines in the 'Assessing fitness to drive – a guide for medical professionals' must list the symptoms as in Dr Freeman's presentation. The Panel Secretary clarified whether symptoms would imply 'ever been symptomatic of congenital heart disease or currently symptomatic. Panel advised that if there is development of symptoms which have been controlled completely with treatment/surgery and individual(s) are now completely asymptomatic, they do not need to notify the DVLA. However, if they do become symptomatic following an asymptomatic period after treatment then they would need to notify DVLA'. In summary, any symptoms at any time either before or after intervention or ongoing symptoms will need notification to DVLA.

There was a discussion whether for 'single ventricle' or 'systemic right ventricle' ie. the subaortic ventricle (for example in congenitally corrected transposition of great arteries (ccTGA) or atrial repair of TGA (Mustard/Senning procedure, there should be requirement for systemic (subaortic) ventricular function to be greater than 40% rather than systemic (subaortic) ventricular function at least 40% as in the current Group 2 standards. It was also discussed that the ejection fraction in these above cases would be much more accurately measured by a cardiac MRI rather than a conventional 2-D echo as the systemic RV may be foreshortened on conventional echocardiography. Cases as above with a systemic (sub aortic) ventricle should also need to meet the current Group 2 exercise tolerance test standards (9 minutes of Bruce protocol) however it will be the functional capacity that needs to mainly looked at rather than ECG changes so cases of left or right bundle branch block could also have ETT in these cases. Individuals who will not be able to undertake exercise tolerance testing due to other reasons, for example, mobility issues would not be able to meet the Group 2 standards if they fail to demonstrate the required cardiac functional standards. There was discussion whether there should be a separate section for detailing the ETT criteria in these cases as they would be different from the ischaemic heart disease standards. There was also discussion about whether all case of systemic right (subaortic) ventricle would need ETT and whether medical advisers would need to assess these cases to make a decision for referral for ETT or not. The Chairman's view was the fact that the ejection fraction is a much better predictor of a sudden and disabling event, if these individuals have a systemic (subaortic) ventricular ejection fraction greater than 40% then they may not necessarily need to meet the exercise tolerance test requirement. It was agreed that these individuals would need a systemic (subaortic) ventricular ejection fraction greater than 40% and ideally be measured by cardiac MRI particularly in cases of systemic right ventricle (subaortic). It was recognised that assessment of a systemic left ventricle may be different from a systemic right (subaortic) ventricle and need to be addressed. It was felt that these would be a small group of patients being considered for Group 2 licensing, hence if systemic (subaortic) ventricular function is greater than 40% but they might still be considered at high risk then they would need individual specialist assessment to ascertain whether the annual risk for a sudden disabling event is less than 2% or not. Panel did not feel that the details of requirement for a systemic (subaortic) right ventricle needs to be detailed in the fitness to drive Guidelines, however, these could be detailed in the Best

Practice Guidelines for the use of medical advisors to guide them for specialist referral cases.

6. Marfan's syndrome: Review of licensing standards – Group 1 and Group 2

As per current standards, the cut-off for maximum aortic diameter in case of aortic aneurysm associated with Marfan's syndrome is the same as aortic aneurysm in general (6.5 cm for Group 1 and 5.5 cm for Group 2 licence). Dr Freeman has advised that the standards need reviewing as the familial thoracic aortic aneurysm syndromes such as Marfan's, Loeys-Dietz, bicuspid aortopathy, Ehler-Danlo's type 4 are different from the atherosclerotic aortic aneurysm in terms of rate of growth and risk of dissection.

Dr Freeman gave an interesting presentation on this topic the details of which were circulated to Panel via e-mail prior to the meeting(copy of the presentation enclosed with the minutes).

Conclusion:

Group 1 standards: May drive and need not notify the DVLA if no aneurysm. If there is an aneurysm, must notify the DVLA and must not drive if aortic diameter greater than 5 cm.

Group 2 standards: Must notify the DVLA. Must not drive if maximum aortic diameter greater than 5 cm, or associated with severe aortic regurgitation. Re/licensing will be permitted only if: maximum aortic diameter is less than 5 cm and no family history of dissection, no severe AR and under annual cardiac review to include aortic root measurement ; if family history of dissection then re-licensing only allowed if diameter less than 4.5 cm.
Aortic root replacement will need individual assessment.(see appendix for details)

Discussion points:

Presentation by Dr Leisa Freeman enclosed towards the end of the minutes.

Main issues discussed were:

Familial thoracic aortic aneurysms grow faster and have a different risk of dissection as compared to the atherosclerotic aneurysm. Although it was suggested that in cases of family history of dissection, the maximum aortic diameter allowed for Group 2 should be less than 4.5 cm, it was felt that individual assessment may be needed in such cases as a family history of dissection is a broad term and the relevance of age at the time of dissection in a family member may have a different impact upon the risk of dissection in an individual. It should be up to the supervising consultant to provide information on family history of dissection as a relevance, and hence individual assessment would be needed for Group 2 licence. The Panel Secretary advised that currently cases of Marfan's syndrome are assessed on an individual basis for Group 2 licensing purpose. Although initially it was proposed that severe MR should also disqualify a Group 2 licence it was further agreed that there is no need to include severe mitral regurgitation as one of the disqualifying features. There is no need to specify the standards separately for the arch of aorta or descending aorta, and the standards should be kept under aortic diameter as a general guideline for individual aortopathies like Loeys-Dietz syndrome, Ehler-Danlo's type 4 .As the ESC guidelines for surgery are quite complex and there is lack of evidence currently to predict dissection accurately in these cases , individual assessment was felt to be the best way to deal with these Group 2 licence cases and the cut-off for 2% annual risk remains the mainstay for assessment in these cases. It was felt that generally if surgery has been recommended for any of the aortopathies and surgery is declined by the patient, then this would be incompatible with licensing. It was also felt that bicuspid aortopathies should be specifically mentioned in the aortic aneurysm standards and the standard for bicuspid aortopathy would be as follows:

Group 1 – maximum aortic diameter should be less than 6.5 cm

Group 2 - maximum aortic diameter should be less than 5.5 cm provided no associated coarctation of aorta, systemic hypertension or family history of dissection or growth not greater than 3 mm per year. If any of the above then for Group 2 the maximum aortic

diameter allowed would be less than 5 cm. These standards would need to be reflected in the 'Assessing fitness to drive – a guide for medical professionals' under the aortic aneurysm standards.

7. Hypertrophic cardiomyopathy: Review of licensing standard – Group 2

DVLA had received a letter from a consultant cardiologist requesting review of the current Group 2 standards for hypertrophic cardiomyopathy indicating that the use of measuring blood pressure response during an exercise tolerance test is of little value especially in patients with hypertrophic cardiomyopathy above the age of 40. It was also mentioned that the blood pressure response to exercise is not included in the ESU risk calculator which is generally now accepted as a risk assessment tool in hypertrophic cardiomyopathy. Panel discussed the issue and agreed that as there are new guidelines for risk stratification in hypertrophic cardiomyopathy it would be best to invite an expert on this subject to give a presentation to the Panel at the next meeting. It was agreed to invite Professor William McKenna who has previously advised Panel on this topic.

Discussion Points:

The current standards for hypertrophic cardiomyopathy(HCM) were largely based on the advice from Professor William McKenna to panel in 2003 .The standards was reviewed by panel in 2011 emphasising the need for exercise tolerance test to measure systolic blood pressure response to exercise. Failure of an adequate rise in blood pressure on exercise is a predictor of incapacitating/disabling event and hence Panel felt that exercise testing to measure response of systolic blood pressure is a reasonable test for Group 2 licensing purpose. There was discussion around the evidence base for the use of exercise tolerance testing in risk assessment for HCM. It was mentioned that the ESU calculator is evidence based and a good predictor of incapacity in HCM. It was also pointed out that the Group 1 licence standards for 'Assessing fitness to drive – a guide for medical professionals' may need reviewing as currently it indicates that if an individual with hypertrophic cardiomyopathy is symptomatic they may drive and need not notify the DVLA. It would imply that if patients of HCM are symptomatic of angina, arrhythmia or syncope they may

not need to notify the DVLA and may continue to drive. However, they should be notifying DVLA and would need to meet the standards relevant to their symptom.

8. Cases for discussion

There were no cases for discussion.

9. Any other business

9a Review of 'Assessing fitness to drive – a guide for medical professionals'

There was a lot of discussion on the 'Assessing fitness to drive – a guide for medical professionals' and SMA, Dr Parry agreed that once all the Panels had had their Autumn meetings, he would ensure that an updated version would be sent to all Panel members by the end of November 2016.

Panel requested that the amendments discussed at the March 2016 meeting need to be incorporated in the updated version of 'Assessing fitness to drive – a guide for medical professionals', especially the following amendments were requested:

i) The Panel asked for the GMC guidance to doctors on notifications of their patients to DVLA to be placed at the start of each speciality chapter, as the general practitioner/consultant would normally go straight to the relevant speciality chapter and this is currently being missed.

ii) Panel also requested that the Appendix section for each chapter be placed with the relevant chapter rather than towards the end of the guide. It was much easier to refer to the Appendix section as laid out in the At a Glance towards the end of each respective speciality.

iii) Panel felt that the use of the phrase 'may drive' in the new guidelines in general leads to confusion and may be misleading especially for Group 2 licence standards

where drivers would preferably wish to drive given the choice. In the case of congenital heart disease the Panel suggested the use of phrase 'must not drive if symptomatic' and in addition for Group 2 'must notify DVLA in all cases', and 'licence will be refused/revoked if congenital heart disease causing symptoms or is of complex or severe nature'. In the section of Aortic dissection 'may need to notify' needs to be replaced by 'must notify DVLA if aortic diameter exceeds 6 cm'.

Panel mentioned that the standards for aortic aneurysm in the current 'Assessing fitness to drive – a guide for medical professionals' does not fully reflect the standards as in the At a Glance guide, the standards need to be amended to reflect that all cases of abdominal aortic aneurysm need to have an exercise tolerance test for Group 2 licence purpose whether surgically treated or not.

Aortic dissection: the SMA agreed that this section needs to be rewritten and to add a caveat to refer to Marfan's syndrome if aortic dissection associated with Marfan's syndrome, as the standards for Marfan's syndrome need to be met/overrides.

(iv) Throughout the 'Assessing fitness to drive – a guide for medical professionals' guide it is stated 'driving may be relicensed', the Panel felt that this should be changed to 'drivers/applicants may be licensed/relicensed'

(v) Acute coronary syndrome (ACS), the definition of acute coronary syndrome in the guide is not in line with the current standard definition and it was agreed that this needs to be removed/changed.

(vi) The statement about left ventricular ejection at least 40% (throughout the guide is not very prominent and could be easily missed, hence this should be highlighted in a more prominent manner in each page of the cardiovascular section.

(vii) Aortic stenosis standards should mention at the heading (to include sub-aortic and supra-aortic stenosis). For Group 2 within this section, the first paragraph should

include 2 more comas as follows: 'if, though asymptomatic, aortic stenosis is severe'. Also point 3 should read as follows: 'during exercise test if symptoms develop, blood pressure falls or there is sustained arrhythmia' and remove the point about ECG changes. This was thought to be difficult to interpret as often patients with aortic stenosis may have resting ST changes or worsening ST changes due to left ventricular hypertrophy.

(viii) Coronary artery bypass graft – Group 2: to remove first point 'no evidence of significant ventricular impairment'. This is also under arrhythmia section Group 2 point 3 – to remove this section also.

(ix) Arrhythmias – change 'arrhythmia likely to cause incapacity' to read 'arrhythmia that has caused or likely to cause incapacity'.

(x) At the bottom of each page of the guide there is a note 'the DVLA bars Group 2 bus and lorry licensing whenever the left ventricular ejection fraction is less than 40%'. Panel felt that this was an important note and currently it is in a small font and could be easily missed. This needs to be made more prominent.

9.b Panel chairmen's meeting:

The Panel Chairman mentioned that the Chairmen's meeting which was due to be held in June was cancelled and the Chairmen have not been invited to another meeting as yet. In the previous Panel meeting the SMA had agreed that he would organise a joint meeting between the Cardiovascular and Neurology Panels to discuss the syncope guidelines, they had changed drastically from the original guidelines in the At a Glance and were currently unworkable, and the Chair asked for an update on this as the joint meeting has not gone ahead. Dr Parry (SMA) explained that the Neurology Panel Chair was not keen to meet for a joint meeting however, Dr Griffith stated that he had spoken to the Neurology Panel Chairman and he had advised him that he would be happy to attend the joint Panel meeting. Dr Parry (SMA) agreed to arrange a joint Cardiovascular and Neurology Panel meeting as soon as possible.

10. Date of next meeting

The proposed date of the next meeting is 2 March 2017.

Dr A Kumar MBBS MRCGP
Panel Secretary

7 October 2016