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, 24 SEPTEMBER 2015

Present:

Dr M Griffith	Chairman
Dr A Kelion	
Professor C Garratt	
Mr A Goodwin	
Mr M Gannon	
Dr R Henderson	
Dr Sern Lim	
Mr B Nimick	
Mr D Simpson	

Ex-officio:

Dr W Parry	Senior Medical Adviser, DVLA
Dr A Kumar	Panel Secretary, Medical Adviser, DVLA
Dr S Williams	Medical Adviser, DVLA
Mrs J Leach	Medical Licensing Policy, DVLA

1. Apologies for absence

Apologies for absence had been received from Dr L Freeman, Dr S Mitchell, Mr B Jones, Northern Ireland representative, Dr D Fraser and Dr E Keelan.

2. Panel membership changes

The Panel Chairman welcomed Dr Lim, new Panel Member, to the meeting and all present introduced themselves.

3. Chairman's remarks

The Chairman expressed his concern over the lack of prosecution of licence holders/applicants on failure of disclosure of medical information to the DVLA, Drivers' Medical Group, especially in those cases which have later been associated with fatal accidents. He appreciates that the DVLA is not a prosecuting body but suggested that the DVLA Medical Policy department may need to feed the concern back at higher/ministerial level. The DVLA Medical Policy representative (Mrs Leach) mentioned that sometimes the time elapsed from the road traffic incident to the notification to DVLA poses limitation to the entire process.

The Senior Medical Adviser, Dr Parry, mentioned that the 'loss of consciousness' guidelines as in the 'At a Glance Guide to the Current Medical Standards of Fitness to Drive' came under intense scrutiny in the recent fatal accident inquiries he had attended on behalf of the DVLA. Following this, he has had discussions with the DVLA Executive Board who have asked for the loss of consciousness guidelines to be reviewed, with reference and comparison to other countries' fitness to drive guidelines. The SMA advised Panel that the 'At a Glance' guide is due to undergo major transformation and re-presentation for better clarity and presentation in line with other international guidelines. The Chairman emphasised that in the past one of the main issues identified in the fatal accident inquiry has been centred around failure to disclose medical information to DVLA. The Panel Chairman agreed that a joint Neurology and Cardiology Panel meeting would be needed in the near future to review loss of consciousness guidelines to ensure that it is in line with the current medical practice.

In general, the Chairman did not have particular concerns regarding the current At a Glance Guide, however would be fine with the re-presentation of the At a Glance as long as the medical essence is not lost as in the formulation of the A-Z guidelines. He mentioned that the wording and standards of the current At a Glance have evolved over the years with regular Panel input and review (twice a year, as and when needed).

The Senior Medical Adviser is currently working on the re-presentation of At a Glance and would present the draft version of the loss of consciousness guidelines to the joint Cardiology and Neurology Panel meeting in the near future. The SMA agreed to forward

copies of relevant international guidelines on medical standards of fitness to drive to the Panel.

4. Minutes of the meeting of 19 March 2015

The minutes of the previous meeting (March 2015) were accepted and agreed as accurate.

5. 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 (full ETT protocol in the At a Glance appendix section). It also mentions that when any of the anti-anginal medication(s) are being prescribed purely for the control of hypotension or an arrhythmia, then discontinuation prior to exercise testing is not required.

The majority of cases which the DVLA refer for exercise tolerance testing have a known history of ischaemic heart disease and a significant number of cases do have an associated history of hypertension and/or arrhythmia. So as anti-anginal medication (s) in these cases are not purely for hypertension/arrhythmia, as per protocol, when these medications are stopped 48 hours before the test, in some cases the exercise test cannot be undertaken or completed to the full 9 minutes due to very high blood pressure or uncontrolled arrhythmia before or during the test. Currently these cases are being dealt variably (for example, repeat testing arranged by cardiologist with medication, alternative functional test with vasodilator arranged by MA etc).

Hence DVLA requested Panel's advice on how best to deal with these cases consistently. This issue was discussed at length in the March 2015 Panel meeting and Panel agreed that this area requires full evidence-based discussion and hence this was further discussed at this meeting.

Panel Member, Dr Henderson, gave a very comprehensive and interesting presentation 'ETT to assess fitness for Group 2 licence entitlement', this was based on a systematic review of a selection of studies which were mainly looking at 'the predictors of mortality as relating to the exercise tolerance test'.

Conclusion:

Based on the available literature evidence presented, Panel decided that for the purpose of Group 2 licence assessments, individuals can undertake Exercise Tolerance Test whilst being on their regular anti-anginal medication. The DVLA exercise tolerance test protocol needs to be amended as follows:

"Drivers should be able to complete 3 stages of the standard Bruce protocol or equivalent safely, whilst on their usual /regular anti-anginal medication and should remain free from the signs of cardiovascular dysfunction viz, angina pectoris, syncope, hypertension, sustained ventricular tachycardia, and/or electrocardiographic ST segment shift which accredited medical opinion interprets as being indicative of myocardial ischaemia (usually >2 mm horizontal or down sloping) during exercise or the recovery period."

Discussion points:

Historically, in clinical practice the exercise tolerance test was used more for diagnostic purposes to demonstrate myocardial ischaemia and hence to diagnose underlying ischaemic heart disease. For DVLA Group 2 licence purposes, the prognostic implication of ETT is more important than the diagnostic implication as it deals mainly with known cases of ischaemic heart disease/coronary artery disease.

The main issues around the prognostic implication of ETT done on or off anti-anginal medication were discussed. There is weak evidence to suggest that beta blocker reduces the sensitivity of myocardial perfusion scan or Dobutamine stress echocardiogram for demonstration of myocardial ischaemia. However, evidence is not clear whether being on beta blocker during ETT masks the symptoms of angina to the extent that it helps in longer

duration of exercise. The important question to be asked is whether the masking of the angina symptoms by being on the anti-anginal medication during ETT, indicates a worse prognosis or increased mortality in future or not. Limited evidence suggests that beta-blockade does not adversely influence prognostic value of exercise test –inference is that beta-blocker does not mask ischaemia that has later adverse impact on prognosis.

Among the various predictors of mortality relating to ETT(age , ischaemia etc) , it was noted that ST depression with >2 mm showed poor prognosis, however, most evidence suggested that peak exercise capacity measuring the metabolic equivalent (METs) is the most powerful predictor of outcome, and achieving >10 METs during ETT predicts a low risk of severe inducible ischaemia. This supports the current DVLA protocol of 9 minutes of an exercise tolerance test, achieving 10 or >10 METs. The various graphs and curves included in the studies did support 10 METs as a cut-off if we have to follow the 2% annual risk criteria for a sudden disabling event. Exercise duration and thus reaching adequate METs is the most powerful exercise related determinant of prognosis. The studies indicated that there was no interaction between beta blocker use and association of peak exercise capacity with mortality, in other words it did not matter whether the individual was on or off beta blocker during the ETT, if they could manage to get to a good exercise capacity they had lower future risk of adverse outcome. The amount of ischaemia which is treated on a daily basis whilst being on the anti-anginal medication is more relevant than the amount of ischaemia masked when transiently off anti-anginal medication during ETT.

Panel's view was that under normal circumstances one would expect drivers to be on their anti-anginal medication whilst driving, therefore, it is reasonable to test people on their regular treatment regimen which they should be whilst they would be driving their Group 2 vehicles.

It is well known that beta-blocker do suppress ischaemia but the evidence does not suggest that the amount of suppressed ischaemia during ETT may have a prognostic impact on future adverse events.

Panel Secretary clarified that as the protocol/criteria for the ETT requirement has now been relaxed, should there be a clause in the Group 2 licence issue letter to advise the applicants/drivers to remain compliant on their anti-anginal medication, and also to avoid a situation where individuals would transiently increase the dose of their anti-anginal medication days before the ETT. Panel advised that there is no need for such a clause, however, the ETT referral letter should mention that the ETT needs to be carried out 'on their usual/ regular anti-anginal medication' to avoid the situation where individuals would temporarily or transiently increase their anti-anginal medication before ETT test. Panel also advised that licence holders/applicants would need to notify DVLA if they were to come off their anti-anginal medication following the issue of a Group 2 licence which had been based on ETT done on the medication.

6. Myocarditis: Group 2 licence standards

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

Currently, DVLA does not have specific standards for myocarditis, this was discussed at length at the March 2015 Panel meeting and Panel had agreed to look into the literature evidence available on myocarditis and associated arrhythmia risk and to be discussed at the September 2015 meeting.

Panel Member, Dr A Kelion, gave a comprehensive presentation on this topic mainly discussing the following 2 papers:

"Long term follow-up of biopsy proven viral myocarditis, predictors of mortality and incomplete recovery (published in the Journal of the American College of Cardiology, Volume 59, No. 18 2012); Cardiovascular magnetic resonance predictors of clinical outcome in patients with suspected acute myocarditis, Sanguineti et al, Journal of Cardiovascular Magnetic Resonance (2015).

Conclusion:

At present there is limited data available for post recovery period in myocarditis. There is no need for separate standards for myocarditis in the At a Glance but this may need to be reviewed in future when there is more data available. For current use, if known arrhythmia associated with myocarditis, then standards for arrhythmia need to be met, in particular, the LVEF criteria (>40%). If LVEF >40%, arrhythmia standards are met or no current history of arrhythmia but there is known presence of other factors which could be predictors of future sudden and adverse cardiac outcome (eg. late Gadolinium enhancement on cardiac magnetic resonance imaging{CMR}, history of incapacitating event), then these cases need individual assessment +/- Panel referral.

Discussion points:

Limited data is available on the long term follow-up of myocarditis. The study on the biopsy proven viral myocarditis had included a high risk cohort group and indicated that late Gadolinium enhancement was highly predictive of sudden adverse cardiac events, whereas a normal CMR was predictive of good prognosis, a normal CMR had very minimal risk of a sudden cardiovascular event. The study on the CMR diagnosed myocarditis group had included a low risk group, shorter follow-up period, and more data with long term outcome may be needed.

It was noted that scar tissue in myocarditis provided a substrate for re-entrant ventricular arrhythmia. Generally there are 2 categories of myocarditis patients – those presenting with acute fulminant myocarditis with heart failure and viral myocarditis with a more insidious onset/course. Patients presenting with acute fulminant myocarditis do worse during the acute phase, however, once they recover they generally do well. It was mentioned that there are guidelines which do suggest implantation of ICD in high risk patients with myocarditis, so for licensing purpose , these high risk individuals would be covered under the ICD driving standards. From the studies discussed no inference could be drawn upon a threshold for the left ventricular ejection fraction, hence the 40% left ventricular ejection fraction criteria would apply for the myocarditis group of patients as well.

6. Heart failure, left ventricular device and heart transplantation: Presentation by Dr Sern Lim

Dr Lim gave a comprehensive presentation on heart failure, ventricular assist devices (mainly left ventricular assist device) and heart transplantation, with relevance to driving.

Based on the literature evidence included in the presentation, Panel agreed that it was reasonable to revise the AAG Group 1 (ordinary car) licence standards for left ventricular assist device (LVAD):

Group 1 standards: Driving should cease on insertion. Relicensing can be considered on an individual basis 3 months after device implantation. DVLA should be notified.

Group 2 standards: Permanently bars. (No change in current standards).

The standards for heart or heart/lung transplant were also revised:

Group 1 standards: Driving must cease for 6 weeks after heart transplant. Driving may continue thereafter provided that the driver is not suffering from a disqualifying condition.

Group 2 standards: Disqualifies from driving for at least 3 months. Relicensing may be permitted after this provided asymptomatic, the exercise or other functional test requirements can be met, the LVEF is equal to or greater than 0.4 and there is no other disqualifying condition.

Discussion points:

The presentation detailed the different kinds of ventricular assist devices, their indications, and their role in heart failure patients. Patients with advanced heart failure with LVAD, do have risk of arrhythmia as well, but they do tolerate the arrhythmia better, less likely to get incapacitated by the arrhythmia. The functional status (NYHA class) improves with implantation of LVAD, and hence improves prognosis in severe heart failure patients.

Generally ventricular assist devices are used as a bridging step whilst awaiting heart transplant. The individual assessment with respect to relicensing would usually imply getting updated clinical information regarding symptoms, functional status or functional capacity, history of any recent incapacitating events. The guidelines from different countries for time period off driving following LVAD implantation were discussed and most countries had advised a period of 3 months off following LVAD implantation for Group 1 licence and permanent ban for Group2 licence. Panel agreed looking at the evidence presented it was reasonable to accept this as a standard for UK.

7. ICD standards: Review of Group 1 standards

The current At a Glance ICD standards (ICD section 3a) require that patients with ICD should not drive for a period of 2 years if any therapy following device implantation has been accompanied by incapacity (whether caused by the device or arrhythmia), except if the therapy was delivered due to an inappropriate cause (section 3b) or if the incapacitating shock was appropriate, and steps have been taken to prevent recurrence for example, introduction of anti-arrhythmic drugs or ablation procedure (section 3c). In such cases driving may resume after 6 months in the absence of further symptomatic therapy. Regarding section 3a in the At a Glance ICD section, the majority of cases dealt with at the DVLA do get their licence issued 6 months after ICD therapy even though accompanied by incapacity as they generally meet the criteria 3c, that is, steps have been taken to prevent recurrence. Hence Panel chairman had wished to discuss whether section 3a needed review/revision (ICD standards were last reviewed in 2007, and relevant Panel minutes extracts were enclosed with the Panel bundle). After discussion, Panel advised no changes to the ICD guidelines as currently no evidence to support reduction from 2 years to 6 months in case of ICD therapy associated with incapacity; if steps have been taken to prevent recurrence then the risk is lowered hence justified to reduce the driving ban from 2 years to 6 months in those cases.

8. Carotid artery stenosis: Review of Group 2 standards

The current Group 2 licence standards as in At a Glance states "if the level of stenosis is severe enough to warrant intervention, the exercise or other functional test requirements must be met".

As the clinical management guidelines of carotid artery stenosis (especially asymptomatic carotid artery stenosis) have evolved since the current licensing standards were set, the Group 2 licence standards were discussed to see if there was any need for revision. Clarification was also sought whether 'intervention' refers to just surgical intervention or surgical and/or medical intervention? (A relevant case was enclosed and discussed).

Mr Gannon (Vascular Surgeon) gave a comprehensive presentation on this topic. The cardiac functional standards as required in case of stroke/TIA is already stated in the Neurology section, hence the discussion was mainly centred around 'asymptomatic carotid artery stenosis'.

Conclusion:

In the current standards, the phrase 'intervention' would imply to 'surgical/radiological intervention' and the level of stenosis severe enough to warrant intervention should be considered as '$>50\%$' (on carotid Doppler studies or carotid arteriography). (This level of stenosis $>50\%$ applies to both symptomatic and asymptomatic carotid artery stenosis). The wording in the At a Glance needs amendment:

Group 2 licence standards: If the degree of carotid artery stenosis $>50\%$, the exercise or other cardiac functional test requirements must be met. After a favourable cardiac functional test result the requirement for a review or duration of licence should be the same as in peripheral vascular disease.

Panel agreed it is appropriate for the guidance for asymptomatic carotid artery stenosis to be moved to the Neurology section of At a Glance.

Discussion points:

The risk of a sudden cardiovascular event should be the factor influencing the need for the cardiac functional test in an individual with asymptomatic carotid artery stenosis. Asymptomatic carotid artery stenosis is a marker of systemic artherosclerosis just as peripheral vascular disease, both of these have increased incidents of cardiac events.

Reviewing the current standards:

(a) 'intervention' should imply to surgical/radiological intervention

(b) 'level of stenosis severe enough to warrant intervention' – the evidence supporting intervention in symptomatic carotid artery stenosis is strong, the evidence for intervention in asymptomatic carotid artery stenosis is there, but the risk reduction is not to the same extent as in symptomatic stenosis. In clinical practice, NASCET (North American Symptomatic Carotid Endarterectomy Trial) is accepted as the method for defining carotid stenosis, though commonly most carotid artery stenosis is diagnosed on Duplex scan which does have equivalence to the NASCET criteria but does not measure the exact modalities as in NASCET. There is equivalence between Doppler and arteriographic measurements. Based on the NASCET criteria, a lesion $>50\%$ needs intervention (as practiced in some countries but currently not a routine practice in the UK as the risk of stroke in asymptomatic stenosis is modest and risk reduction in stroke by intervention in asymptomatic carotid stenosis is also modest). In general, the level of stenosis for intervention is accepted as $>50\%$; in UK secondary prevention with medication (statin, Aspirin) is indicated. The duration of licence in carotid artery stenosis $>50\%$ following a favourable cardiac functional test should the same as in peripheral vascular disease after cardiac functional test.

9. Informed consent for cardiac function tests (ETT, MPS and Stress Echo)

The Medical Adviser group at DVLA appreciate that the consultant in charge of the test/investigation has the ultimate responsibility and expertise for obtaining informed consent for the test and also that most licence holders/applicants would consent to the test for their vocational licence. However, in light of the recent Supreme Court ruling that Montgomery principle needs to be adopted for informed consent, a Medical Adviser had requested Panel's advice whether DVLA has a duty of care towards Group 2 licence holders/applicants to make them briefly aware of what the test involves before they agree to undertake it especially as MPS involves radiation exposure and may need repeating at renewal of licences.

The Senior Medical Adviser, Dr Parry, mentioned that he had obtained legal advice from the DVLA legal representative (Ros Cleal) who confirmed that the duty of care lies with the clinical practitioner carrying out the test and not with the DVLA. Panel agreed that it is the clinical practitioner's responsibility to explain the procedure and any potential risks and indications/alternatives for the tests, however, they appreciate that as the tests are not being done for clinical reasons (diagnostic or therapeutic purpose) but for licence renewal, the decision process is slightly different as compared to clinical scenario and they do appreciate that the licence holder may choose not to go for certain investigations especially as they might need to be repeated every 3 years (eg. small but cumulative radiation exposure in MPS). A discussion ensued on the evolving changes regarding informed consent and the current clinical practice.

Panel's advice was that as these tests were being commissioned by the DVLA it would be good practice to advise licence holders/applicants for them to discuss the test with the clinician when they are arranging an appointment with them.

10. Cases for discussion

Two cases were discussed and advice given on both cases. The first case was that of an asymptomatic carotid artery stenosis, and the second was a positive exercise test with normal coronary angiogram on the background.

11. Any Other Business

(i) Panel thanked Dr.Henderson, Dr.Kelion, Mr.Gannon and Dr.Lim for their interesting and informative presentations.

(ii) Mr Andrew Burrows and his team (from the Business Strategy Team at DVLA) gave a short presentation on the 'Fitness to Drive Project'. This presentation made Panel aware of the digital notification process which is currently being piloted at the DVLA with diabetes and vision, working with the Senior Medical Adviser and respective Panel secretaries.

Cardiovascular conditions would be looked at in the future. Panel agreed that digital and electronic processing is the way forward in line with the current IT development and for efficient customer service. Panel were advised that in addition to the digital notification process, currently there would be facilities for notification to DVLA by paper as well. Panel's input would be important in this process, and they would be consulted as and when needed. Panel members agreed that digitalisation is the way forward however, it was important to keep a check that inaccuracies and errors do not creep in during this process.

Currently, it is only Group 1 conditions that are being looked at during this process.

12. Date of next meeting

The proposed date of the next meeting is 3 March 2016.

Dr A Kumar MBBS MRCGP
Panel Secretary

5 October 2015