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

TUESDAY, 25 SEPTEMBER 2012

Present:	Dr M J Griffith Dr A Kelion	Chairman
Lay Members	Mr B Nimick Mr D Simpson	
Ex-officio:	Dr E Keelan Ms J Chandaman Dr J Morgan Dr A Kumar Mr B Jones	Cardiology, University Hospital, Dublin Medical Licensing Policy, DVLA Senior Medical Adviser, DVLA Panel Secretary/Medical Adviser, DVLA Business Change and Support Manager, DVLA

1. Apologies for Absence

Dr L D R Smith, Dr P M Schofield, Dr L Freeman, Dr S Mitchell, Northern Ireland representative, Professor C Garratt and Professor M Cowie.

2. Panel Membership Changes

Dr Peter Schofield, Dr David Smith and Professor Andrew Bradbury are completing their 10 years of membership in November 2012 and DVLA is in the process of recruiting 3 new replacement members – at least 2 members with expertise in the coronary artery disease area and one expert in the peripheral vascular area, and Panel may need to have a further member appointed to represent cardiac surgery.

3. Chairman's Remarks

The summary of the main points from the Panel Chairmen's meeting held on 21 June 2012 was attached as an additional paper to the Panel bundle. The Chairman had attended the Panel Chairmen's meeting on 21 June 2012.

The Chairman made the Panel aware of the meeting with Dr Vijgen, European Cardiology Working Group Lead on 26 June 2012. This was a proactive approach by UK Panel to try and express their concerns over some of the proposed standards by the European Working Group. This was to avoid future problems as has been recently experienced by the UK in other areas. The Chairman expressed his concerns over the entire process of setting the guidelines by the Working Group especially about the quality of scientific evidence used in the process. It is important for the UK Cardiology Panel to express their concern in the relevant area right from the outset so that the UK is able to retain their current standards for drivers where sufficient medical evidence is available and modify current standards where relevant.

4. Minutes of the Meeting of 6 March 2012

The minutes of the meeting were approved and accepted.

5. Matters Arising

Panel Secretary asked for clarification regarding point number 5 in the minutes, regarding Group 2 licence entitlement in individuals who have had a history of TIA/stroke with atrial fibrillation and currently not anti-coagulated but may be on anti-palatelet treatment (eg. Aspirin). The Panel's advice was that individuals with a history of stroke/TIA with atrial fibrillation if not anti-coagulated have a higher risk of a future vascular event and this event rate for stroke, as per current evidence, is 7% per annum which does not meet the Group 2 licensing criteria. (Such

individuals have a CHADs score of at least 2 and current evidence is that they do need anti-coagulation).

6. Coronary CT Angiography and Calcium Scores: Group 2 licence standards

Panel had agreed in the March 2012 meeting that there is a need for determining the hierarchical position of coronary CT angiography and calcium scores in the cardiac functional assessment tree for Group 2 licensing.

A document based on a recent literature search and current medical evidence was prepared and presented to the Panel by Dr Andrew Kelion (a copy of this draft was circulated to members before the meeting and copy to be enclosed with the minutes).

Advances in computer tomography (CT) technology now allow non-invasive anatomical imaging of the coronary arteries in contrast to the functional information provided by the exercise ECG, MPS or stress echocardiogram. Coronary atheroma burden is assessed by CT calcium scoring, while luminal stenosis can be demonstrated using CT coronary angiography.

CT Coronary Calcium Scoring

NICE guidance CG95 (Chest pain of recent onset: Assessment and diagnosis of recent onset of chest pain or discomfort of suspected cardiac origin) recommends coronary calcium scoring as the first line investigation in individuals with chest pain who are considered to be at low risk of coronary disease after clinical assessment.

CCS (coronary calcium score) = 0 : excludes obstructive coronary artery disease, and no further assessment is needed .

CCS = 1-400 : CT coronary angiography. CCS > 400 : invasive angiography.

DVLA deals with mainly 2 groups of population for Group 2 licensing;

Important: These advisory notes represent the balanced judgement of the Secretary of State's Honorary Medical Advisory Panel as a whole. If they are quoted, they should be reproduced as such and not as the views of individual Panel members.

- a) No known coronary artery disease but suspected angina or a history of chest pain which may have been diagnosed with angina in the past or individuals with a history of peripheral vascular disease.
- b) Majority of the licence holders/applicants have had some kind of coronary presentation (acute coronary syndrome/angioplasty/coronary artery bypass graft), that is, a known coronary artery disease.

A stand alone coronary calcium score is only relevant in the (a) group of individuals with suspected coronary artery disease as it measures the coronary atheroma burden. In individuals with known coronary artery disease, a calcium score on its own is irrelevant as it is well known that these individuals do have coronary artery disease.

Recommendation:

For DVLA Group 2 licensing purposes, when no known coronary artery disease, if a calcium score equals to zero and no further cardiological assessment is planned, the individual is unlikely to be suffering from angina and is at very low risk of having a sudden cardiac event (less than 2%). Hence a Group 2 licence can be issued without the need for functional cardiac tests.

If a calcium score is more than zero and a history of chest pain then as per NICE guidelines these individuals will need further assessment by their clinician (CT angiography or invasive angiography) – these individuals will need functional cardiac tests before a Group 2 licence is considered unless there is an angiogram report available already and which shows that they are in low risk group as discussed subsequently in the CT angiography section.

CT coronary angiography

This is a non-invasive anatomical test of the coronary arteries.

- a) If no known coronary artery disease, and coronary CT angiography shows:
 - No stenosis more than 50% Group 2 licence to be issued without need for functional cardiac testing providing no other disqualifying condition (as analysed MACE (Major Adverse Cardiac Event) rate is less than 2% per annum).
 - Any stenosis more than 50% need for functional cardiac testing before a Group 2 licence is considered. If in this group the functional test criteria is met, a 3-year review licence to be issued with repeat functional test. If functional test criteria is not met, Group 2 licence to be revoked/refused.
- b) If an individual has had an acute coronary event/angioplasty/CABG with residual disease cardiac functional testing is required before Group 2 licensing is considered. If the individual fails to meet the criteria and subsequent angiography (CT or invasive) shows a stenosis less than 50% Group 2 licence to be considered if meets the LVEF requirement of 40% as most likely the functional test would be false positive. If angiography shows coronary stenosis > 50% and individual has failed function test, Group 2 licence revoked.

Discussion points:

Mainly based on the paper prepared by Dr Andrew Kelion (copy enclosed).

CT coronary angiography is a non-invasive anatomical test but in comparison to exercise ECG it is expensive and not as widely available as exercise ECG, with a

significant radiation exposure. The Panel's advice is that exercise ECG should remain the first line investigation commissioned by DVLA for Group 2 licensing purposes. However, if DVLA is presented with a report of a coronary CT angiography, the findings should be interpreted in the same light as the findings of an invasive angiography.

For individuals without known coronary disease, the annual cardiac event rate in the absence of obstructive disease on CT (no stenosis more than 50%) is comfortably below 2%. A reassuring CT angiography (no stenosis more than 50%), if already performed for clinical reasons could reasonably be taken as evidence of fitness to hold a Group 2 licence independently of functional assessment.

CT coronary angiography has a high negative predictive value, that is, if unobstructed coronaries on CT angiography, they are likely to be unobstructed on the invasive angiography as well. Hence, if a CT angiography is reassuring, it is good for the DVLA licensing purposes. However, it does not have a very good positive predictive value due to artefact etc.

7. Aortic Stenosis: Group 1 and Group 2 licence standards

As the current Group 2 licensing standards are mainly based on symptomatology, Panel agree that there is a need to address the asymptomatic cases of severe aortic stenosis for appropriate risk stratification especially for Group 2 licensing standards. The following relevant papers were enclosed with the Panel bundle, and were discussed at the meeting:

Management of asymptomatic aortic stenosis; Bernard Lung; Valvular Heart Disease, Heart 2011;97:253-259;

Guidelines on the management of valvular heart disease; European Society of Cardiology 2007, European Heart Journal (2007), 28, 230-268.

Definition of severe aortic stenosis (as per most recent European Society of Cardiology guidelines, August 2012):

- i) A ortic valve area <1 sq cm or <0.6 sq cm per m sq BSA (*body surface area*)
- ii) Mean aortic pressure gradient >40 mmH/g.
- iii) Maximum jet velocity >4 m/s.

Panel's recommendation for Group 2 licence standards for aortic stenosis:

- i) Disqualified if symptomatic;
- ii) If asymptomatic but severe aortic stenosis (as above), individual needs to have annual review with exercise testing.

Disqualified:

- i) If the cardiologist's opinion is that it is unsafe for the individual to undergo exercise testing (as clearly they cannot meet the Group 2 criteria).
- ii) If during exercise test: development of symptoms, fall in blood pressure below base line.
- iii) If unable to undertake exercise testing due to other reasons (as they have failed to demonstrate they can meet the Group 2 licensing criteria).

Discussion points:

- Exercise testing is contradicted in symptomatic severe aortic stenosis, but recommended in physically active asymptomatic patients with severe aortic stenosis for unmasking the symptoms and in the risk stratification.
- Exercising testing is safe in asymptomatic patients provided it is performed under the supervision of an experienced physician monitoring for presence of symptoms, changes in blood pressure and/or ECG changes.

• Often symptoms are not present/under reported due to sedentary lifestyle but it is well known that symptoms of aortic stenosis typically get precipitated on exertion (which might be relevant in Group 2 drivers).

Three relevant cases were discussed. Out of these a decision to revoke group 2 licence had already been made for 2 cases and the decision for the third case was to refer the individual for an exercise test to see if he meets the group 2 licence criteria or not.

8. Heart Failure: Group 1 and Group 2 licence standards

DVLA had received a letter from a Professor of Cardiology regarding the role of the left ventricular ejection fraction in prediction of prognosis in patients with heart failure (anonymised copy of letter attached with Panel bundle). The cardiologist mentioned that many patients with a diastolic dysfunction would have preserved left ventricular ejection fraction but their heart failure could be much worse than those with an ejection fraction less than 40% and vice versa. He had suggested that DVLA need to look at measurement of other indicators like peak oxygen consumption, BNP levels (B-natriuretic peptide level), peak cardiac power output which are more predictive in terms of prognosis as well as functional capacity.

Panel acknowledged this letter from a Professor in Cardiology. Panel's view was that although there are a lot of indicators which can measure the severity of heart failure (as mentioned above in the letter), the left ventricular ejection fraction is still an important prognostic factor and for Group 2 licensing purposes it is easily applicable and interpreted with consistency. The incidence of a sudden cardiac event in an individual with preserved left ventricular ejection fraction is quite low and hence it seems to be a good predictor for a sudden disabling event rate for Group 2 licensing purposes.

When there is information in addition to left ventricular ejection fraction provided by a consultant cardiologist, that may affect a licensing decision, the case should be referred to a Panel member for their opinion.

9. Acute Coronary Syndrome: Group 1 standard

Group 1 standards in cases of acute coronary syndrome successfully treated with angioplasty: DVLA has received a query from a cardiologist :

In cases of minor acute coronary syndrome and when minimal myocardial damage is suspected clinically and it is felt that a major reduction of an LVEF is unlikely, is it mandatory to have an echocardiogram before allowing someone to drive after a week? this would be useful to know especially in cases of patients due to be discharged but an echocardiogram may not be undertaken before discharge due to unforeseen circumstances, for example, weekend discharge, etc.

Panel's opinion: It is important that after a successful angioplasty, there is echocardiographic evidence of a minimum 40% LVEF before an individual can be allowed to resume driving one week after an acute coronary event.

10. Marfan's Syndrome: Aortic Root Replacement: Group 2 licence standards

The current licensing standard in cases of aortic root replacement in Marfan's syndrome debars an individual from holding a Group 2 licence. DVLA has recently received correspondence from cardiologists querying the blanket approach for elective and emergency aortic root replacement in cases of Marfan's syndrome. It has been indicated that an elective aortic root replacement surgery has less risk of a late catastrophic event associated with it when compared to an emergency root replacement and hence an automatic ban on Group 2 licensing post aortic root replacement may not be appropriate in all cases.

Dr Leisa Freeman (GUCH Specialist, recently appointed Panel member) had produced a draft document with some recommendations regarding Group 2 licence standards (as she was unable to attend this meeting). Based on the current available evidence as drafted in a summary by Dr Freeman, Panel agreed that the Group 2 licence standards in cases of aortic root replacement in Marfan's syndrome, needs to be revised. However, the matter needs to be discussed in further detail (with Dr Freeman present at a meeting) before it can be formulated into guidelines. In the interim, such Group 2 cases could be referred to Dr Freeman for individual assessment to see whether they can meet the 2% criteria for Group 2 licensing or not.

11. Progress of the Cardiology Working Group Annex III EC Directive

The Cardiology Working Group is still in progress and the final document is not ready yet. A meeting was arranged in June 2012 by the Department for Transport (UK) on the advice of the Panel to discuss certain areas of the proposed recommendations by the European Union Cardiology Working Group where the UK Panel has some concerns. The summary of this meeting was attached with the Panel bundle.

The Panel Chairman is going to write to Dr Vijgen (Chairman of the Working Group) regarding his comments on the recent Dutch literature on ICD which has reported very low rate of events in the ICD population studied. The Panel's opinion is that the data is not sufficiently robust to support resumption of driving 3 months after a shock therapy as proposed by the European Working Group. Panel's view is that once an individual has had an ICD shock therapy, the risk of them having another shock in the near future is quite high. Hence, Panel maintains its view that there should be a minimum of 6 months ban on driving (Group1) following an appropriate ICD shock therapy. This is also in line with the American/Canadian guidelines on ICD. The shock therapy in itself is disabling enough to distract an individual whilst driving. Panel did agree that the current standards on a 2-year ban

in cases of ICD shock associated with incapacity, may need to be reviewed at a future meeting.

12. Abdominal Aortic Aneurysm: Wording for Group 1 standards as in At a Glance

A member of the public seeks clarification regarding the interpretation and implication of the phrase "despite treatment" in the following sentence: "DVLA should be notified of any aneurysm of 6 cm in diameter, despite treatment". To reflect the At a Glance advice the standard notification advice on the website mentions "DVLA will only be notified if the aortic aneurysm is 6 cm or more in diameter despite treatment". Panel agreed that the phrase "despite treatment" may be misleading and can cause confusion in the notification process. Hence, Panel's advice for the Group 1 standards in ascending and descending thoracic and abdominal aortic aneurysms as follows:

"An aortic diameter of 6.5 cm or more disqualifies from driving."

13. Cases for Discussion

Three cases of asymptomatic severe aortic stenosis were discussed and Panel advice was given in one of them, an appropriate decision had already been made for the other 2 cases.

14. Any Other Business

In addition to 2 new members in the area of coronary heart disease, there is a need for a Panel member with expertise in vascular surgery and in cardiothoracic surgery as well.

15. Date of Next Meeting

The next meeting is scheduled to take place on 14 March 2013.

It has been pointed out that some of the Panel members are unable to attend a meeting on a Tuesday, while others have other commitments on a Thursday. The next meeting is scheduled for a Thursday, perhaps it could be discussed at the next meeting whether a balanced approach would be to alternate between a Tuesday and a Thursday meeting or not.

DR A KUMAR MBBS MRCGP Panel Secretary

10 October 2012