

Minutes of the Secretary of State for Transport's Honorary Medical Advisory Panel on Driving and Disorders of the Cardiovascular System

Meeting held on 17th October 2019

Present:

Panel Members:

Dr A Kelion (Panel Chair)

Dr L Freeman

Dr R Henderson

Mr A Goodwin

Dr D Fraser

Dr S Lim

Dr K Rajappan

Dr S Aziz

Professor C Garratt

Observers:

Dr E Hutchinson Civil Aviation Authority

Dr S Bell Chief Medical Officer, Maritime and Coastguard Agency Professor D Kiely Director of Sheffield Pulmonary Vascular Disease Unit

(via teleconference 11.35 am - 12.10 pm)

Ex-Officio:

Dr A Kumar Panel Secretary, DVLA Doctor

Dr N Jenkins Senior Doctor, DVLA

Mrs R Toft Driver Licensing Policy, DVLA

Mrs S Abbott Operational Delivery and Support, DVLA

Mr M Thomas Panel Co-ordinator, DVLA
Mrs K Howell Service Management, DVLA
Mrs H Harris Driver Licensing Policy, DVLA







Section A: Introduction

1. Apologies for Absence

Dr E Keelan.

2. Chair's Remarks

The Chair welcomed all attendees and thanked them for their co-operation with the change in venue of the meeting at a short notice due to unavoidable circumstances in London. It has been a busy year for the Cardiovascular Panel with 2 additional joint meetings in May 2019. A joint meeting was held with the Neurology Panel to discuss licensing standards on transient loss of consciousness (TLoC). There was also a meeting with representatives from the other panels to discuss changes to the provoked seizure standards as proposed by the Neurology Panel.

The Chair appreciated the form of the agenda bundle sent via email as a PowerPoint presentation prior to the meeting.

(i) The Chair summarised the minutes of the joint Cardiovascular and Neurology Panel meeting held on 9 May 2019 to review the current AFTD standards on TLoC and to ensure the guidance reflects Panels' advice. He advised that the following had been agreed at the joint meeting:

Licensing standards for TLoC should be under the following 3 categories:

- Unexplained transient loss of consciousness standards for this category should be included in both the Neurology and Cardiovascular sections of AFTD.
- Syncope (largely cardiovascular) should be included in the "Cardiovascular" section of AFTD.
- Non-syncopal transient loss of consciousness (largely neurological) TLoC due to underlying neurological causes/blackout with seizure markers should be included in the Neurology section of AFTD.









Syncope (cardiovascular) should be further categorised under the following headings:

- Vasovagal syncope (neurally mediated syncope, including situational syncope, for example, cough syncope, micturition syncope, laugh syncope etc).
- Orthostatic hypotension.
- Structural heart disease
- Arrhythmia

A clear definition of syncope should be published in the guidelines as follows:

"Syncope is defined as transient loss of consciousness (TLoC) due to cerebral hypoperfusion, categorised by a rapid onset, short duration, and spontaneous complete recovery".

The Chair advised that work needs to be undertaken by the Cardiovascular Panel to develop the syncope standards over the next year. In the interim, the current syncope standards should be followed to deal with the cases.

(ii) Provoked seizure joint meeting update:

The Chair updated the Panel on the new standards on provoked seizure as proposed by the Neurology Panel. The Chair advised that there were concerns expressed by other panels especially the Diabetes and the Cardiovascular Panels regarding the 5 year revocation for Group 2 drivers following an episode of provoked seizure. The Diabetes Panel had concerns that the 5 year revocation following nocturnal hypoglycaemia was too harsh especially if steps had been undertaken to prevent the recurrence of further hypoglycaemic episodes.

From a cardiovascular point of view, the main concerns were the provoked seizures secondary to a vasovagal episode, an underlying arrhythmia – a 5 year revocation on Group 2 driving was considered to be harsh especially if the underlying cardiovascular cause had been treated and the standards for the relevant cardiovascular conditions had been met. It was agreed amongst the cardiovascular members present at the joint meeting that for both Group 1 and Group 2 licences, a minimum of 6 month period off driving following the provoked seizure episode would be reasonable, followed by any time period off if required by the standards for the underlying cardiovascular condition.

The Chair commented that the data in the studies (which were used as background) for the proposed standards were limited and most patients included in the studies had either a history of head injury or a primary cerebral pathology, there were very few subjects with systemic causes.







There is an ongoing discussion with the Neurology Panel to get a consensus opinion on this topic. In the interim, DVLA Policy advised that some relevant cases may need to be referred to individual panels for advice depending upon the underlying condition which had caused the provoked seizure.

(iii) British Cardiovascular Society meeting June 2019.

The Chair thanked Dr Henderson, Dr Rajappan, Dr Freeman and Dr Jenkins for their contributions to the session on driving regulations in cardiovascular conditions.

(iv) Panel Chairs' meeting (13 June 2019).

The Chair gave feedback from the Panel Chairs' meeting on the following main points:

- a) Panel member recruitment the difficulties in recruitment are across all the 6 panels. The Chair commented that although DVLA has an open application process for panel member recruitment, it is important to have a balanced approach in the advertisement and selection process to ensure that appropriate experts are appointed to the relevant panels. One of the problems in recruitment is due to the difficulties clinicians are facing to get approval for the time to attend panel meetings and panel work. This was discussed later in the meeting by individual panel members having similar difficulties.
- b) The ongoing operational changes in the DVLA were discussed at the Panel Chairs' meeting. There is a shift towards electronic mode of communication. The Head of Drivers Medical advised on the plans to increase efficiency of the communication amongst doctors, to ensure that DVLA makes the correct licensing decision the first time, every time. This may involve amendment of the DVLA referral letters and licensing decision letters.
- (v) There has been a change in the way panel advice is being used by DVLA in its operational process. Historically, panel's advice would translate into formulation of new licensing standards post panel. However, there has been a shift in this process. Although the DVLA will consider the advice provided by the panels, no changes to the standards will take effect until the impact on the individual and road safety has been fully assessed by the DVLA. This will include consultation with external stakeholders if appropriate. The Chair emphasised that although the panel recognises that its advice may not always be translated into regulation or change in standards, the minutes from the panel meetings should reflect the panel's discussions and advice accurately. Panel members expressed their view that this was not a very efficient use of panel's time if the advice formulated following lengthy and complex discussions is not going to be put into operation or change of licensing standards if needed. Hence, panel were keen to know of the drive for this change in process. Policy advised that







DVLA's intention has always been to follow panel's advice, however, this has to be managed against the workload at DVLA resulting from the action points from all the 6 advisory panel meetings and any potential stakeholder consultation required. Any change resulting from panel meetings will undergo a prioritisation exercise at the DVLA followed by any external stakeholder consultation if required.

(vi) Some panel members mentioned the difficulties they experience in getting time off from their clinical duties to attend panel meetings. Policy mentioned that a letter of acknowledgement for panel work and their contribution has been sent to individual panel members which they can share with their hospital trust, if needed, for attendance at panel meetings. Panel members advised that a letter from DVLA acknowledging the valuable contribution of panel members towards the panel, including the time commitment needed for panel meeting attendances would be more appropriate and helpful in getting the hospital trusts' approval for professional leave to attend the panel meetings. The Panel Chair stressed the importance of attendance at these meetings for the continuation of panel work. It was also mentioned that the increasing difficulties for clinicians to get approval for professional leave to attend such meetings is reflected in the problems with the panel member recruitment process.

3. Actions from Previous Meeting

- (i) Panel recruitment status ongoing Policy advised that chairs to 4 panels have been appointed, succession planning/recruitment for a Cardiovascular Panel Chair replacement is ongoing and the post is due to be advertised imminently.
- (ii) DVLA to formulate a process to facilitate easier access of imaging data to panel members for advice status in progress though there are ongoing problems in this process. Chair advised that DVLA should advise the relevant hospital trusts to send the required imaging data to DVLA without which the case cannot be processed further. It is not possible for panel members to access imaging data via the hospital PACS system as there are password authorisation problems. The most efficient way is to get raw imaging data from the relevant hospital trust to be forwarded to the panel member for them to review the case fully with the imaging data and provide consequent advice to the DVLA.
- (iii) Group 2 licence cases where MPS/stress echo reports indicate a drop in left ventricular ejection fraction at stress as compared to resting value. The Chair to formulate guidance to deal with cases which are appropriate to be referred to panel members the following advice was provided by the Panel Chair at this meeting:







In most of the recent cases referred to the Panel Chair (imaging expert), the variation in the LVEF at stress as compared to rest have usually been due to reproducibility issues. The cases where there are no unfavourable comments and/or no comments regarding myocardial ischaemia or TID (transient ischaemic dilatation): it is reasonable to issue a Group 2 licence if the AFTD Group 2 standards have been met. If the reports have any unfavourable comments or comments regarding myocardial ischaemia attributing to the drop in LVEF – such cases need to be referred to a panel member enclosing the relevant imaging data.

- (iv) Dr Rajappan (electrophysiology expert) to formulate appropriate wording for the ICD and Ablation section of the AFTD standards He presented at this panel meeting.
- (v) DVLA: AFTD standards for 'Pacemaker implant' to be amended to include:
 - For pacemaker box change: "Need not notify the DVLA":

Marfan's syndrome – Group 1 licence standards: AFTD standards to be amended to include guidance post surgery. – Both of these changes are awaiting implementation.

4. Pulmonary Hypertension Standards – DVLA Update

(Professor Kiely joined via teleconference following the DVLA update).

Dr Jenkins (Senior DVLA Doctor) and Rachael Toft (DVLA Policy) provided an update to the panel on the correspondence and recent meeting they have had with the Pulmonary Hypertension Association UK (PHA UK) and Professor Kiely (via teleconference). Professor Kiely joined panel meeting via teleconference (11.30 am – 12.10 pm) and

introduced himself as a Consultant Chest Physician and Director of Sheffield Pulmonary Vascular Disease Unit. The Chair welcomed Professor Kiely and summarised the current Pulmonary Hypertension standards in AFTD and the amended draft proposal following the Spring 2019 panel meeting. He emphasised that the AFTD has not been updated yet with the amendments from the Spring meeting due to the ongoing correspondence with the PHA (UK). The Chair welcomed Professor Kiely to express his views on any concerns he had regarding the Pulmonary Hypertension standards.

There was a lengthy discussion on this topic and the concerns regarding the use of risk stratification (as per 2015 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension) into licensing standards. The assessment process of cases at DVLA (including forms and questionnaires) were also addressed.

Conclusion: Professor Kiely was in agreement with the Pulmonary Hypertension standards drafted at the April 2019 panel meeting as below:

Group 1







Must notify the DVLA. Individual assessment required.

Low, intermediate risk cases: May drive provided no other disqualifying condition, review 3 year licence to be issued.

High risk cases: May drive provided satisfactory specialist assessment and deemed to be at less than 20% risk of a sudden disabling event per annum; should be no other disqualifying condition, and syncope standards need to be met. Review one - three year licence to be issued.

Group 2

Must not drive and must notify the DVLA. A 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 the risk of a sudden disabling event is deemed to be less than 2% per annum; should be no other disqualifying condition, and syncope standards to be met. An annual licence to be issued.

Classification of low, intermediate or high risk categories as per 2015 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension.

The caveat regarding a small group of patients in the intermediate risk group and the application of the Group 2 standards was discussed and a reasonable process agreed (as in the detailed discussion section below).

Discussion points:

Dr Jenkins mentioned that the main aim for bringing this topic to the panel meeting was to get confirmation of the Pulmonary Hypertension licensing standards in light of the concerns raised by PHA (UK) and Professor Kiely. The panel formulated the standards for Pulmonary Hypertension in March 2018 following advice and presentation from Dr Simon Gibbs, National Pulmonary Hypertension Centre expert and the new standards were published in the Assessing Fitness to Drive guide in August 2018. DVLA requested the panel to review the standards to facilitate the operational process at DVLA, and hence the standards were reviewed and revised at the Spring 2019 panel meeting. The revised standards following the Spring 2019 panel meeting have not been translated into the AFTD pending the ongoing discussions with the PHA (UK). The main concerns raised by the PHA (UK) and Professor Kiely were that the licensing standards are based on the risk stratification groups as per the '2015 ESC/ERS guidelines for the Diagnosis and treatment of Pulmonary Hypertension'.

This risk classification is based on the mortality risk associated with Pulmonary Hypertension rather than sudden disabling event risk; other medical conditions have their standards based on sudden disabling risk rather than mortality risk. The risk of a sudden disabling event in







Pulmonary Hypertension (usually in the form of syncope) would be related to physical activity which may not be relevant for driving.

The Chair advised that there are conditions which do have standards based on the mortality risk and mortalities are not always sudden and disabling, for example, mortalities related to coronary artery disease, (heart failure due to coronary artery disease). It may not always be possible to formulate licensing standards based strictly on sudden disabling events as there may be lack of such data to base the standards upon. At times guidelines have to be formulated based on the opinion of an expert body using the best available relevant scientific data/literature.

The Chair summarised the current Pulmonary Hypertension standards in AFTD and the amended draft proposal following the Spring 2019 panel meeting. He emphasised that the AFTD had not been updated yet with the amendments from the Spring meeting due to the ongoing correspondence with the PHA (UK). Professor Kiely gave a brief background of the reasons for his correspondence with DVLA and for joining the panel meeting today. PHA (UK) had requested Professor Kiely (in his capacity as one of their medical advisers) to discuss the standards and concerns about the DVLA process of assessment of these cases.

Professor Kiely was keen to provide his input to facilitate the licensing assessment process at DVLA for Pulmonary Hypertension patients. Key points from Prof Kiely:

Pulmonary Hypertension is not a rare condition, it is commonly associated in patients with significant cardiovascular diseases. As per the National Audit Data, 8,351 patients of Pulmonary Hypertension attended the National Pulmonary Hypertension centres (data from March 2019), 70-80% of these patients were Pulmonary atrial hypertension or chronic thrombo-embolic hypertension.

The risk stratification scores (2015 ESC/ERS guidelines) may be very sensitive but not very specific. Looking at a specific registry group, it has been seen that individuals who are in the low risk group at the time of diagnosis may be actually in the intermediate risk group and a small number of them could be in the high risk group (mortality greater than 20% per year), though the number of these individuals in high risk group with a mortality greater than 20% per year are quite small. Hence in completing the DVLA forms Professor Kiely tries to give supporting information to aid the licensing decision, for example, severity of disease, effects of exercise, history of blackouts and risk of sudden disabling events. The Chair emphasised that DVLA only need to be notified of established cases of Pulmonary Hypertension under the care of a specialist centre. He advised the data for sudden disabling events are not always available and the mortality data may have to be used as a surrogate marker for sudden disabling events when formulating guidance for the population so that appropriate licensing decisions are taken.

The importance of keeping the guidelines simple and effective was mentioned. Professor Kiely's main concern was that there is a small group of patients in the intermediate risk group









as per the criteria used in the ESCR/ERS guidelines for pulmonary hypertension, who in reality on a clinical basis could be in the low risk group for sudden disabling events.

His concern was that this small group of patients may be unfairly dealt with for the purpose of Group 2 licensing if they were assessed under the intermediate risk group standards. However, this is a small group of patients. It was agreed that if an individual has their Group 2 licence revoked due to them being classified in the intermediate risk group (ESC/ERS guidelines), it would be reasonable for DVLA to consider any favourable information from a specialist post licence refusal/revocation. The revocation letter would need to include the options as above. Professor Kiely and panel were in agreement with the above process as this would potentially affect only a small group of licence holders/applicants. It was mentioned that the majority of intermediate risk group patients are likely to have greater than 2% of risk of sudden disabling event per annum.

5. <u>Takotsubo Cardiomyopathy: Presentation by Dr S Lim</u>

DVLA had received a few queries regarding Takotsubo cardiomyopathy, it was agreed at the Autumn 2018 panel meeting that this will be discussed and Dr Lim kindly agreed to prepare a brief presentation on this topic. The Panel Chair thanked Dr Lim for a very interesting and informative presentation of Takotsubo cardiomyopathy and following discussion on this topic the following was agreed:

Due to its presentation as an acute coronary syndrome and related complications in the acute setting, for Takotsubo cardiomyopathy, the AFTD standards for Acute Coronary Syndrome need to be applied—4 weeks off driving for Group 1 and 6 weeks off driving for Group 2 (no need for an exercise tolerance test or alternative cardiac functional test if no associated coronary artery disease). Panel advised that 'Takotsubo cardiomyopathy' should be included under the heading of 'Acute coronary syndrome' as in AFTD (Acute coronary syndrome (ACS) to include type 1 and type 2 myocardial infarction; Takotsubo cardiomyopathy).

Group 1 – if not treated by successful coronary intervention or any of the above are not met OR Takotsubo cardiomyopathy, driving may resume only after 4 weeks from the acute event, provided there is no other disqualifying condition.

Group 2 – current standards, addendum – individuals with Takotsubo cardiomyopathy do not need ETT unless associated coronary artery disease.

Discussion points:

Takotsubo syndrome (broken heart syndrome, stress cardiomyopathy, apical ballooning syndrome, happy heart syndrome).







The main relevant points from the presentation – Takotsubo syndrome constitutes 2% of patients presenting with acute coronary syndrome, with emotional and/or physical triggers, or no identified triggers. The diagnostic criteria are in accordance with the Heart Failure Association of ESC, the Mayo clinic criteria, inter-TAK diagnostic criteria. It presents as acute coronary syndrome including symptoms, ECG changes (less than 12 hours: ST elevation/LBBB, 24-48 hours - Q waves, T-wave inversion prolonged QT, more than 48 hours – ventricular arrhythmia and AV block. Coronary angiogram may show co-existent coronary artery disease in 15% of cases, and the differential diagnosis is acute coronary syndrome, myocarditis and phaeochromocytoma. Complication rate is about 20-35% of cases, 2-5% mortality. Frequent in-hospital complications include acute heart failure, left ventricular outflow tract obstruction (LVOTO), mitral regurgitation (MR), cardiogenic shock; moderate complications include atrial fibrillation, LV thrombus, cardiac arrest, AV block. The rare complications include tachy and brady-arrhythmias, torsades de pointes, Ventricular Tachycardia / Ventricular Fibrillation, acute VSD and death. ACE inhibitors are found to be beneficial in treatment. The recovery of Left Ventricular function is usually in 4-8 weeks, LVOTO and MR resolves with LV recovery. There may be some persistent symptoms. It is more common in the older age group and in women. Heart failure is common, the mortality similar to ACS? (Non cardiac deaths), rates of acute disabling events are likely to be low.

6. <u>ICD and Catheter Ablation: Group 1 Licence Standards – Presentation by Dr K Rajappan</u>

Dr Rajappan gave a brief presentation on the issues surrounding the current standards of 'successful catheter ablation' and the current ICD standards in relation to the interpretation of 'symptomatic anti-tachycardia pacing'.

He also presented the draft document with proposals for the amended AFTD ICD standards. The panel greatly appreciated Dr Rajappan's contribution and the draft was discussed at length and largely agreed with some modifications. The final draft is as enclosed as a separate attachment.

Main discussion points:

The definition of the term 'incapacity' was discussed. There have been several queries regarding the interpretation and application of the term 'incapacity' in the current AFTD standards, there is lack of consistency in the interpretation and application among the







clinicians. Panel agreed that for the purpose of AFTD guidance 'incapacity' is defined as: A condition in which the individual is distracted or disabled and may be unable to safely control a vehicle/stop a vehicle. Therefore, any symptoms or treatment that is likely to cause an individual to be unable to safely control a vehicle/stop a vehicle would be defined as causing 'incapacity'. This definition of 'incapacity' could be used across AFTD and not just in the cardiovascular standards. DVLA do not have a documented definition of 'incapacity' for use in AFTD at present. Policy advised that DVLA would consider and discuss this further whether the definition of 'incapacity' could be used in the introduction chapter and subsequent chapters of AFTD. It was noted that the term 'incapacity' has been used in several places in the AFTD apart from the cardiovascular chapter.

Successful catheter ablation – The current guidelines based on incapacity were formulated at a time when ablations were largely undertaken for relatively benign conditions such as atrial fibrillation, AV nodal re-entrant tachycardia (AVnRT), which were non life-threatening conditions with higher success rates following ablation. However, the indications for ablation have evolved over time and ablations are nowadays being done for more serious and life-threatening arrhythmias and due to the severity of underlying conditions success rates are moderate. Hence the guidance needed reviewing in light of this. Generally, individuals undergoing VT ablation with impaired ventricular functions, are in the high risk group for sudden disabling events and hence the standards must reflect the arrhythmia licensing standards. If they are in a particularly high risk group they are likely to have an ICD implanted and would follow the ICD standards.

ICD - Group 1 licence standards – Panel advised amendment of the current ICD standards in AFTD in light of the draft proposals from Dr Rajappan. The phrase 'symptomatic ATP' in the current ICD standards has raised a number of queries among the EP specialists across the UK regarding the interpretation and application of the standards. There could be a range of symptoms associated with ATP (anti-tachycardia pacing) ranging from mild awareness of a flutter to more severe palpitations, pre-syncope/dizziness or even syncope. Under the current standards even mild symptoms associated with ATP would require 6 months off driving, this was perceived as being too strict by panel. Under the new proposed standards ICD shock therapy or ATP associated with incapacity or likely to cause incapacity would require 2 years off driving (if appropriate therapy). However, if they met the exceptional criteria as stated, they would be licensed 6 months following therapy. It was recognised that having an ICD shock therapy would imply that the therapy was associated with an incapacitating event.

7. Planning for Spring 2020 Panel







There was a brief discussion on this item and panel agreed that the following topics merit discussion and review of the standards in the forthcoming panel meeting.

(i) Syncope: Dr Rajappan kindly agreed to prepare a draft document for discussion at the next panel meeting.

(ii) Hypertrophic cardiomyopathy:

Hypertrophic cardiomyopathy. Current standards for group 2 licensing require asymptomatic patients with HCM to satisfy the exercise tolerance test requirements. In contrast to those with coronary artery disease, patients with HCM unable to satisfy these requirements for non-cardiac reasons have no recourse to an alternative functional imaging test, and no ability to retain their licence. Exercise test parameters are not included in the ESC HCM Risk-SCD calculator, and the continued value of exercise testing as part of the standards has been questioned. Dr Henderson kindly agreed to prepare a draft document for discussion at the forthcoming meeting. The main aspect to be discussed would be available scientific evidence regarding the role of exercise tolerance test in the risk stratification process above and beyond the current ESC HCM-SCD risk calculator.

(iii) Brugada syndrome:

The interpretation and the application of the current standards especially the time-frame relevant to the history of syncope would need to be considered once the syncope guidelines are formulated.

8. Cases for Discussion

A case of ICD was discussed and appropriate advice was provided by panel.

9. Provoked Seizures

DVLA Policy advised that a further update will be provided following discussion at the Neurology Panel meeting.

10. Road Safety Statement

Policy advised the panel that the updated Road Safety Statement was published in July 2019. Link below:







Panel were advised that there may be further discussion required around older vulnerable road users, especially in relation to co-morbidities associated with cardiovascular conditions.

https://www.gov.uk/government/speeches/road-safety-recent-progress-and-future-work

11. <u>Tests, Horizon Scanning, Research and Literature</u>

The Chair advised that these are covered under the agenda items discussed at the panel meeting.

12. <u>AOB</u>

DVLA advised that as DfT is undergoing refurbishment over the next year, panel meetings would be held at alternative venues.

Recruitment exercise for a Chair to this panel is imminent.

13. <u>Date of Next Meeting</u>: 12 March 2020.

First Draft Minutes prepared by: Dr A Kumar MBBS MRCGP

Panel Secretary 24 October 2019

Final Minutes signed off by: Dr A Kelion

Panel Chair

07 November 2019







The DVLA will consider the advice provided by the panel and no changes to standards will take effect until the impact on individuals and road safety is fully assessed.





