

MINUTES OF THE SECRETARY OF STATE FOR TRANSPORT'S HONORARY
MEDICAL ADVISORY PANEL ON DRIVING AND DIABETES MELLITUS
HELD ON WEDNESDAY, 31st OCTOBER 2001

Present: Professor B M Frier (Chairman)

Dr J L Day

Dr N Essex

Dr S Gilbey

Dr A Stevens

Professor S A Amiel

Ms M Jackson Lay Member

Mrs B Hatton Lay Member

Ex.Officio:

Dr T Carter

(Chief Medical Adviser DTLR)

Professor A Nicholson (Project Manager DTLR Research Programme)

Dr S Heller

Dr J C Durston (Senior Medical Adviser DVLA)

Dr D A Sheppard (Medical Adviser DVLA)

Dr C Jenkins (Medical Adviser DVLA)

Dr C Dayson (Medical Adviser DVLA)

Ms Sue Lloyd (Drivers Medical Development Group)

Ms Sarah Martin (Drivers Policy Group, DVLA)

Apologies: Dr D Kerr

Dr A E Gold

1. Introduction

Professor Frier welcomed Professor Amiel as a new Panel member. He also welcomed the new lay members, Mrs Hatton and Ms Jackson, and also welcomed the Lead Physician in the Diabetes Research.

2. Minutes of the Last Meeting

Both Dr Stevens and Dr Day were of the opinion that the minutes did not reflect the depth of discussion that had ensued regarding the nature of the research that was being considered. Concerns had been raised that the research was aimed at assessing risk factors and would not provide information on real risk of accidents. It was requested that the reservations of the Panel regarding the basis of the proposed research should be documented.

3. Matters Arising

The Panel had previously requested information regarding the number of C1 licences that have been issued. This unfortunately is not available at present but will be provided at the next Panel meeting.

4. Research Update

4.1 The lead clinician of the investigators for the research project on diabetes related to driving, thanked the Panel for the opportunity to present the protocol of this project to the Panel for discussion. The Panel were advised that the research would be a multi-centre study, involving six centres in the UK.

4.2 The Panel were advised that the project had been approached on the basis that hypoglycaemia is a potential risk to road safety and at present current regulations bar insulin-treated drivers with diabetes from driving Group 2 vehicles.

4.3 It was considered that if certain groups of people with insulin-treated diabetes could be demonstrated to have a minimal risk of hypoglycaemia then driving licence policy could be adjusted accordingly. The Panel were advised there is epidemiological evidence that people with type 2 diabetes treated with insulin have a much lower risk of hypoglycaemia, i.e. up to 30 times less than that of type 1. It was noted that there had been very few studies on patients with type 2 diabetes on insulin and the preservation of some endogenous insulin secretion may reduce the risk of severe hypoglycaemia.

4.4 The Panel were advised that the groups of people to be studied are as follows.

Patients with type 2 diabetes

- (a) recently transferred from oral agents to insulin (within 6 to 24 months),
- (b) who have been using insulin for over five years,
- (c) on oral agents (those stimulating insulin secretion) and with a known duration of diabetes of over two years and not likely to require conversion to insulin with the course of the study.

Also groups with type 1 diabetes with

- (d) a duration of diabetes less than 5 years,
- (e) a duration of diabetes of more than 15 years (as controls).

Also, one centre will study 20 non-diabetic subjects as controls for the continuous blood glucose monitoring system.

4.5 In addition to continuous blood glucose monitoring the participants will have to perform blood glucose measurements for calibration purposes and record episodes of symptomatic hypoglycaemia in a diary. Thus both asymptomatic and symptomatic episodes can then be related to the blood glucose monitoring.

4.6 The Research Registrars who will be involved in each centre will be in regular contact with the participants in the project.

4.7 A clinical assessment will be undertaken to ascertain if there are any predictors of those who may be prone to developing hypoglycaemia. Biochemical investigations will include the measurement of the C-peptide response to glucagon stimulation as a measure of residual pancreatic beta cell function to ascertain whether this is a useful predictor of susceptibility to hypoglycaemia.

4.8 The Panel were advised that the power calculations had proved to be difficult for this project as continuous blood glucose monitoring has not been extensively used previously.

4.9 Statisticians have suggested that 120 subjects in each group will provide 80% power to detect a doubling of hypoglycaemia rates between the two main groups of interest, i.e. those on oral agents only and those with additional insulin.

4.10 The Panel were also advised that MiniMed who make the equipment for continuous blood glucose monitoring have data on people with type 2 diabetes which

they have provisionally agreed to be made available to reassess the power calculations. If deemed necessary, more patients will be recruited for the project.

4.11 Conclusion. The project should be able to ascertain:

(1)

Whether a significant difference in rate of hypoglycaemia exists between the different groups.

(2) Whether C-peptide status can predict the risk of severe hypoglycaemia.

(3) Whether other clinical markers can be identified which can predict the risk of hypoglycaemia.

4.12 The Chairman indicated that at the last Panel meeting it had been hoped the proposed protocol would have been made available to Panel members soon afterwards. Unfortunately, it had taken longer to prepare than anticipated and had only recently been distributed to the Panel. This had not allowed much time for perusal or comment. The Panel were also advised that the protocol had been sent for peer review to two experts in Europe and North America.

4.13 The Chairman reiterated his apologies for the late access to this document and assured the Panel that there is still opportunity for amendment. Open discussion of the protocol was invited.

4.14 It was considered important to record the BMI of each subject.

4.15 Concerns were raised as to whether the data would be relevant to road traffic accidents. The Lead Clinician pointed out that a level of 3-mmol/l blood glucose reading is recognised as producing cognitive impairment. If several readings of this level or lower are obtained in the course of the project it would be appropriate to extrapolate this to affect safe driving in the individuals demonstrating this level of hypoglycaemia. It was suggested to the Panel that if people with insulin treated type 2 diabetes can be demonstrated not to have an increased liability to hypoglycaemia then licensing policy could be amended.

4.16 The Chairman agreed that this was not an accident rate study, but a study of hypoglycaemia rates within different groups of people with diabetes, many of whom are drivers.

4.17 The Panel raised concerns that a group of people who are on basal (bedtime) insulin only had not been included. This is a group that the Panel felt from clinical experience at low risk with regard to hypoglycaemia rates. It was indicated that the Licensing Authority do not distinguish between these individuals and those on insulin therapy taken more than once daily especially as with regard to Group 2 licensing insulin treatment is per se prescribed in law

4.18 The Lead Clinician agreed that this had been discussed by the investigators, however, due to the power calculations it was not considered possible to study these as a separate group, however agreed that these could be looked at as a sub-group within the project and also, if it is demonstrated that those on a bd dosage are demonstrated to have a decreased risk of hypoglycaemia then this finding can itself be extrapolated back to those who are on a single background insulin regime only.

4.19 The Chairman advised that there is a small study in progress at present in his own centre regarding the frequency of hypoglycaemia in people taking basal insulin for type 2 diabetes. Although it appears that hypoglycaemia is uncommon, it does occur in this group.

4.20 Concerns were raised regarding possible bias due to patient selection. As recruitment is based on the patient volunteering to enter the research project it is

impossible to avoid bias. It is recognised that this is a common limitation of many clinical research projects.

4.21 The Panel were assured that the participants in the project will be advised that this is a study of glycaemic control and driving performance is not an outcome measure.

4.22 It was also confirmed that the participants need not necessarily be drivers as the aim of the project is to look at risk factors for hypoglycaemia.

4.23 The Panel raised concerns regarding the upper age limit of 75 years and this was considered possibly to be too high as other factors become involved in the older age group regarding road safety. It was explained that there is a need to include older drivers as a significant number of drivers over the age of 70 wish to continue with Group 2 licensing and especially those wishing to hold the C1 licence.

4.24 It is recognised that the project may produce further questions which will need to be separately assessed, the age factor being one of these. However, it is possible that an age analysis could be incorporated into the final analysis of data.

4.25 The Panel suggested that people treated with thiazolidinediones should be included in the exclusion criteria if not on sulphonylureas also.

4.26 The Panel were advised that the project may establish whether there is an exceptional group of drivers with type 2 diabetes treated with insulin who could be considered to hold the full Group 2 licence.

4.27 Concerns were raised regarding the age/sex matching of groups although it was noted that the age matching between Group 1 and Group 2 is difficult to obtain.

4.28 The Panel questioned the likelihood of the project being able to demonstrate clinical predictors of risk and it was acknowledged that this may not be possible although it is possible the C-peptide status could be used as an indicator. It was considered that if as a result of this project a significant number of people could be licensed to Group 2 standards then this would be of benefit to all drivers with diabetes. It is acknowledged that the project cannot answer all the questions that would like to be addressed on diabetes and driving.

4.29 The Chairman advised the Panel that there is very little research available on people with insulin-treated type 2 diabetes.

4.30 Concerns were raised regarding the inclusion criteria for the HbA1c level as being less than 9% as it was felt this did not reflect the clinical situation. However, it was considered that if people with this overall degree of glycaemic control were considered to have a low risk with regard to hypoglycaemia (and therefore to road safety) then this could safely be extrapolated to those with a higher HbA1c.

4.31 The Panel was advised that the groups would be identified from clinical records and will be contacted by mail-shot. The Panel felt there should be a random selection supervised by the clinical scientists involved in the project.

4.32 The Panel were advised that the Investigators will be meeting for discussions on a regular basis.

4.33 Panel concerns were raised regarding potential patient bias resulting from publication of Panel minutes. The assurance was given that the centres involved would not be identified.

4.34 Another concern was that the patients being considered for inclusion on the project may not have the same lifestyle of Group 2 drivers for whom licence implications may apply. However, this is unavoidable as the requirement to hold a driving licence is not included in the selection criteria.

4.35 Dr Carter reminded the Panel regarding the necessity to instigate the research as soon as possible to utilise the funding available. He acknowledged that the present project may not answer all the questions and that follow-up work may be required.

4.36 Panel concerns were raised regarding the decisions on licensing that may be made based on results of the research. Reassurance was given that changes will be made according to the outcome of the research whether they be advantageous or disadvantageous to drivers with diabetes.

4.37 Professor Nicholson informed the Panel that he is currently in correspondence with Dr Kenneth MacLeod regarding a proposed study related to accident rates and drivers with diabetes.

4.38 Professor Nicholson acknowledged that the research is addressing a multi-faceted problem and consequently sub-groups may be identified by this project for further research.

4.39 The Panel were appreciative of the report provided by QinetiQ on the role of risk analysis. Dr Carter advised the Panel as to the broader implications of this report.

5. The Panel Chairmen's Meeting

5.1 The Chairman had been unable to attend this meeting and Dr Day had deputised on his behalf. He advised that at the meeting papers on risk analysis were discussed and the literature review on medical conditions and driving. Concerns were raised as to whether the literature search in the latter had been comprehensive.

5.2 Dr Carter also expanded on the Chairmen's meeting to advise that there had been two joint Panel meetings including Neurology and Cardiology, and Neurology and Alcohol which had proved very successful and it was mooted that it may be considered that in the future other such joint Panel meetings could be advantageous.

5.3 Dr Carter also highlighted the Phillips report with regard to the BSE enquiry and explained the effect this enquiry has on the role of expert advisory panels and officials in government. Concerns were raised by the Panel that previous decisions had been coloured by apparent departmental direction.

5.4 The Panel were informed that although they will be asked for advice, this will be considered by the Department before implementation if indicated.

6. Oral/Inhaled Insulin Trials

6.1 Concerns were raised by the Panel that patients recruited into these trials have not been informed about the implications for driving entitlement and that this may not have been included in the consent form.

6.2 After discussion it was considered appropriate that these patients should be treated in a similar manner as patients requiring insulin during pregnancy and following myocardial infarction, i.e. that they are required to inform DVLA of their requirement for insulin treatment but their licence will not be restricted unless this requirement continues after three months.

6.3 The Panel also noted the problems with patients who are using a placebo drug, but again this has to be referred back to the original consent form and to the participating centres and the pharmaceutical companies supplying the medication.

7. Advice to Doctors on Driving and Diabetes

7.1 The Panel suggested some minor amendments to the draft document including clarification of the licensing categories B, C and D. It was also suggested the term "patients" should be replaced by the term "applicants".

7.2 In section 3 it was suggested that the phrase beginning, "when carrying out an assessment" should read, "you therefore need to be satisfied to the best of your knowledge that etc".

7.3 The Panel noted the problem in the applicant providing fabricated results, a situation which is well recognised by the DVLA. It is therefore only possible for their examining doctor to advise as to the best of their knowledge.

7.4 It was also considered that an addendum could be included regarding the advice to drivers who require insulin during pregnancy, post myocardial infarction and participation in an oral/inhaled insulin trial.

7.5 The Panel concluded that a document regarding driving and diabetes would be considered useful by the medical profession. Dr Durston will amend the document to include the Panel's suggestions.

8 Voluntary Mini-Bus Concession Anomalies

The anomaly of a person not being able to satisfy the criteria for C1 licensing but being able to drive minibuses under the volunteer concession has previously been considered by the Department as being incongruous. Dr Durston advised the Panel that there has been discussion with Policy regarding this anomaly. Any change would require consultation particularly with regard to the volunteer groups and therefore this would take a period of time of at least twelve months. In addition, the Department is awaiting the publication of the draft Third EC Directive, which may have implications regarding medical licensing issues.

9. Panel Membership

9.1 After the Phillips enquiry the terms of reference of the Panels were revised and these were approved at the Chairmen's meeting. The members were given copies of the new Terms of Reference.

9.2 The Panel were also informed of a problem with another of the Secretary of State's Advisory Panels, in which a conflict of interest had occurred with the Chairman in his role as Panel Chairman and also his role on a patient interest group.

9.3 Following the recommendations from the Select Committee and the Phillips enquiry, the Department is looking at fixed terms of membership and rolling recruitment and retirement policy. It is advised that when a Panel member retires from their normal area of specialism for which they were recruited that they should step down from the Panel.

9.4 Professor Frier and Dr Stevens indicated that they are members of the Driving and Employment Working Party of Diabetes UK. However they were assured that this did not constitute a conflict of interest regarding their Panel membership.

10. Diabetes Forms and Letters

It was suggested that on the TAB1 that the Diabetes UK telephone number and website should be included. With regard to the DIABETIC3 questionnaire, question 2 the word "especially" should be removed.

11. Cases for Discussion

None

12. Any Other Business

12.1 It was noted that the Panel previously advised that C1 examination should always be conducted by a Consultant Diabetologist. The Department had received correspondence from a rural General Practitioner in Orkney who indicated that he was providing the diabetes care for the local community. After discussion the Panel reiterated their previous recommendation that such examination should only be provided by a Consultant Diabetologist. The Panel acknowledged that some General Practitioners have a greater interest and expertise in diabetes, but reiterated that at present this examination should be performed by a Consultant Diabetologist.

12.2 The Panel noted the possibility of accreditation of GP Specialists occurring in the future and may then wish to review the situation. The Panel confirmed that they were confirming their view expressed at the previous meeting.

13. Date and Time of Next Meeting:

1st May 2002 at 12.30 p.m.

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 NOT AS THE VIEWS OF INDIVIDUAL PANEL MEMBERS.