UNIVERSITY OF BIRMINGHAM

Literature Search on How the Results of On Road Driving Assessments in Drivers with Dementia Relate to a Clinician's Opinion Regarding 'Fitness to Drive'

**Aggressive Research Intelligence Facility
West Midlands Health Technology Assessment Collaboration**

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For the Drivers Medical Group
DVLA
Swansea

ARIF

WMHTAC

West Midlands
HTA Collaboration

About ARIF and the West Midlands Health Technology Assessment Collaboration

The West Midlands Health Technology Assessment Collaboration (WMHTAC) is an organisation involving several universities and academic groups who collaboratively produce health technology assessments and systematic reviews. The majority of staff are based in the Department of Public Health and Epidemiology at the University of Birmingham. Other collaborators are drawn from a wide field of expertise including economists and mathematical modellers from the Health Economics Facility at the University of Birmingham, pharmacists and methodologists from the Department of Medicines Management at Keele University and clinicians from hospitals and general practices across the West Midlands and wider.

WMHTAC produces systematic reviews, technology assessment reports and economic evaluations for the UK National Health Service's Health Technology Assessment (HTA) programme, the National Institute for Health and Clinical Excellence (NICE). Regional customers include Strategic Health Authorities, Primary Care Trusts and regional specialist units. WMHTAC also undertakes methodological research on evidence synthesis and provides training in systematic reviewing and health technology assessment.

The two core teams within WMHTAC are the Aggressive Research Intelligence Facility (ARIF) and the Birmingham Technology Assessment Group (BTAG)

ARIF provides a rapid on-demand evidence identification and appraisal service primarily to commissioners of health care. Its mission is to advance the use of evidence on the effects of health care and so improve public health. The rapid response is achieved by primarily relying on existing systematic reviews of research, such as those produced by the Cochrane Collaboration, the National Institute for Health and Clinical Excellence (NICE), the NHS Centre for Reviews and Dissemination, and the NHS Health Technology Assessment (HTA) programme. In some instances, longer answers to questions are required in which case mini rapid reviews of existing systematic reviews and key primary studies are compiled, typically taking 1-2 months to complete.

Occasionally a full systematic review is required and then topics are referred to BTAG who coordinate the production of systematic reviews for several customers under a number of contracts. ARIF is intrinsically involved in the production of these systematic reviews.

Aggressive Research Intelligence Facility (ARIF)
West Midlands Health Technology Assessment Collaboration (WMHTAC)
Department of Public Health and Epidemiology
University of Birmingham
Birmingham
B15 2TT

arifservice@bham.ac.uk
0121 414 3166

1   Aims

The aim of this report was to identify and appraise research evidence in relation to the following questions:

1.1   Primary Question

Is there any evidence comparing clinicians' views of driving ability among those with dementia (following routine clinical assessment, rather than following the conduct of specific cognitive tests) with the assessment of driving ability made through On Road Assessment (ORA)?

1.2   Secondary Questions

What constitutes ORA in different countries?

Have any audits of the longer-term outcomes (eg. accidents) been undertaken in cohorts who have passed ORA

2   Further details are given in the request submitted by the Drivers Medical Group (

Appendix 1 – Details of Request)

3   Background

4   Background information concerning driving and dementia is given in the documentation supplied by the Drivers Medical Group contained in

Appendix 1 – Details of Request. In particular the report produced by Monash University Accident Research Centre provided with the request, gives a comprehensive summary of the most relevant issues (1). This report together with other reviews (2) indicate that collaborative work between clinicians and licensing authorities is essential in securing sensitive and timely decisions in relation to driving cessation among those with dementia.

It is clear that a wide range of clinicians, and in particular doctors, have a role to play in determining fitness to drive. Numerous guidelines have been produced to assist doctors in assessing driving competence and to help raise the standard and consistency of the decision-making process (3). Doctors ultimately make recommendations regarding competence to drive among those with dementia based on some or all of the following:

- A physical examination
- A cognitive assessment
- Specific neuro-psychological tests

- Evaluation of driving history
- The views of the driver and/or carers
- Medication use
- An assessment of continued driving on the safety of the driver and the wider public

In the UK the DVLA are notified that a driver may be unsafe to drive. They seek the driver's permission for medical information to be provided and on the basis of medical reports the DVLA make the majority of their decisions concerning licence tenure. On occasion a decision cannot be made, in which case the driver may undergo independent medical examination, or undertake a driving assessment or driving test (2). There have been some criticisms of the DVLA procedures (4) but it is understood that recent changes have been made to address some of these concerns.

Whilst determining whether someone with dementia is fit to drive or otherwise is clearly important, experts in the field believe that critical issues in this area remain under-researched (5). There does, however, appear to be a good degree of consensus in relation to the following:

- Impaired driving competence should be the pre-requisite for driving cessation, rather than a diagnosis of dementia per se.
- Moderate to severe dementia is associated with driving impairment, but there is less clarity in relation to those with mild dementia
- ORA is the gold standard for assessing driving competence

Whilst risk factors for impaired driving among those with mild dementia have been identified (6) none of the factors are sufficiently predictive to be solely relied upon, either individually or collectively, in decisions to revoke a driving license. A range of processes have been advocated for identifying unsafe dementia drivers including:

- Assessing the views of the driver and/or their carer
- Reviewing information on accidents, violations and 'near misses'
- Conducting a battery of psychological and cognitive tests
- Multi-disciplinary assessments
- Driving simulator examinations

The literature shows that ORA is believed to be the most sensitive measure of driving ability and as such it does have the greatest face validity (7). In this context it is accepted that it would be unethical to let an individual who failed an ORA continue to drive (8). This inevitably gives rise to an inability to prospectively compare the outcome of ORA with any other potential mechanism for revoking a driving license. This is important because whilst the ORA is recognised as the best assessment tool currently available, it is not without problems. For example there are concerns that not all ORAs are based on research evidence (8), that they may not predict performance in stressful situations (such as may be encountered outside the assessment situation) (8), that the ORA itself provokes stress among those with dementia (9) and that the tests are expensive, time consuming and are as such impractical for routine use (8).

The fact that ORA is considered to be the Gold Standard means that it is highly unlikely that there will be research comparing outcomes following ORA with any other assessment of fitness to drive. Despite this inherent limitation to the evidence base it is feasible for research looking at the degree of correlation between different methods of driving assessment to have been undertaken.

5 Methods

Outline methods were submitted to the Drivers Medical Group by email as shown in Appendix 2 and acceptance was subsequently confirmed by telephone (Appendix 2 – Outline methods).

Briefly, the methods used were:

- To undertake a search for studies describing:

  - clinicians' views, or recommendations, concerning driving ability among those with dementia, as compared to the outcome of an ORA.
  - audits of the longer-term driving outcomes in cohorts who have passed an ORA

- To initially search for existing systematic reviews.
- To concentrate on primary studies if no systematic reviews were identified
- To appraise the studies and comment on their methodological quality
- Where appropriate and possible data on relevant outcomes was to be extracted and tabulated.
- Data analysis would depend on information identified.

In addition to the above, information identifying what constitutes ORA in different countries was to be sought from public information sources.

5.1 Searches

5.1.1 Existing Reviews.

Searches to identify existing systematic reviews on this topic were performed utilising the well-established ARIF search protocol (

Appendix 3 – Search strategies)

5.1.2   Primary Studies

Searches were undertaken for primary studies in the Cochrane Library, MEDLINE and EMBASE. The search strategies employed included text and index terms for dementia, Alzheimer's, driving ability, road test and clinicians. The databases of the Transport and Road Laboratory (TRL) and the National Transport Laboratory (TRIS) were also interrogated. The strategy was developed iteratively and modified accordingly.

The detailed search strategies can be found in

Appendix 3 – Search strategies page xx.

An information specialist predominantly undertook searches with additional searches by a research reviewer. Both interacted to ensure searches were conducted appropriately.

An information specialist and a research reviewer scanned the search results for relevance based on information in the title and abstract. In order to answer the primary question (clinicians' assessment of driving ability as compared to the outcome of an ORA) articles that adhered to the following broad criteria were obtained in full for further scrutiny:

Design:	Any, except case reports
Population:	Drivers with dementia
Intervention:	Clinician assessment of driving ability
Comparator:	Outcome of ORA
Outcome:	Correlation between the intervention and the comparator

For the secondary question concerning any audits of the longer-term outcomes for those who pass an ORA, articles that adhered to the following broad criteria were obtained in full for further scrutiny:

Design:	Audits or retrospective analyses
Population:	Drivers with dementia who passed an ORA
Outcome:	Accidents, traffic violations or other relevant measures of driving ability

Full copy articles were assessed for their match to the questions being addressed (external validity) and the most informative articles were subjected to further scrutiny and reporting.

The reference lists of the most relevant articles were also checked in order to identify further relevant papers.

In order to determine what constitutes ORA in different countries licensing websites were accessed for the countries/states for which evidence relating to the primary question had been identified.

6   Results

6.1   Reviews identified

No systematic reviews were identified in relation to either clinician's assessments of driving competence as compared to the outcome of ORA or in respect of the secondary question concerning audits of the longer-term outcomes among those who pass ORA.

6.2   Primary studies identified

In relation to the primary question, of approximately 200 publications retrieved from searches three were considered to be directly relevant to the question in that they provided direct comparison of clinicians' assessment of driving ability with the outcome of ORA (10,11,12).

In relation to the secondary question no directly relevant articles were found in the medical literature. Three reports that described repeated driving assessment among those with dementia were identified but these did not look at driving related outcomes (13,14,15). However, a study undertaken by the Washington State Department of Licensing on driving outcomes in a population including those with dementia and/or psychiatric disorder was identified among the references provided with the Monash report (16). The findings of this study are summarised in this report.

6.3 Clinicians' Assessment Compared to ORA

Two of the three papers considered relevant for appraisal gave separate reports of what was essentially the same study (i.e. data in both reports related to the same cohort of dementia patients). Whist both reports were appraised details of only one will be presented (Ott), with a brief summary of the second provided (Brown). In addition to the Ott study, appraisal of the research undertaken by Fox et al (10) is included.

Table 1 shows key features of the two studies exploring the relationship between clinicians' predictions and the outcome of ORA, outlining the study objective, design and main outcomes.

Table 1 – Summary of Studies Comparing Clinician Assessments of Driving Ability Among those with Dementia, Compared to ORA

Study	Objective	Method	Subjects	Clinical Assessments	Results	Conclusion
Fox et al 1997	To examine the validity of standardised medical examination and standardised neurological assessment as predictors of the outcome of ORA	Prospective referred subjects underwent assessment by clinicians. Clinicians assessments were compared to the outcome of ORA	n=19 recruited from specialist dementia clinics. Mean age 74.3(6.4) Dementia duration 4yrs (2)	Undertaken once on each patient by a physician. A total of 4 different physicians participated. In addition each patient was seen by a neuropsychologist and underwent a battery of tests. Both the physician and the neuropsychologist predicted the outcome of ORA as: PASS or FAIL or BORDERLINE	12/19 Failed ORA. Physician identified 2 of the 12 who failed ORA. Number not reported for neuropsychologist.	Neither physician nor neuropsychologists prediction of PRA results were significant. "The use of a standardised ORA in preference to a neuropsychological examination, medical examination or mental state examination alone is recommended for the determination of driver competence in individuals with AD"
Ott et al 2005	To assess the validity and reliability of clinicians' ratings of driving competence among patients with mild dementia.	Observational study of a cross section of drivers. Each subject's driving performance was assessed with a view to predicting the outcome of ORA.	n=50 recruited as part of a longitudinal study of dementia. Mean age 75.7 (6.6) Dementia duration 3.3 yrs (1.8)	Six separate clinicians made an assessment and predicted the outcome of ORA. Clinician one (senior dementia specialist) undertook a detailed patient/carer assessment and documented this. Five other clinicians subsequently reviewed the records and made their prediction on this basis. All six made a prediction of driving competence as: "good…" or "drives with some difficulty…" or "unsafe"	The outcome of ORA as judged by the driving examiner was: 22/50 safe drivers 19/50 marginal 9/50 unsafe Driving examiner and clinician's individual ratings were dichotomised into safe vs unsafe by combining marginal and unsafe categories. Following combination 28/50 drivers were deemed unsafe. Clinician one, and the other dementia specialists were 72% to 78% accurate. GPs were 62% to 64% accurate.	Whilst accuracy was greatest for physicians with dementia training the authors concluded "…the consistency between physicians in their degree of positive and negative predictive values is insufficient to justify making them the final or sole arbiters of the decision to revoke driving privileges in patients with dementia.

6.3.1 Study 1 – (Fox et al) Objectives and Methods

This study was undertaken in Sydney, Australia and was reported in 1997 (10). The objective of the research was to compare clinicians' predictions (ie. that of a physician and of a neuropsychologist) of the outcome of ORA with the actual outcome as assessed by a professional examiner. The primary outcome of ORA was a consensus global judgment of driving performance made together by the driving examiner and an accompanying Occupational Therapist (OT). A second outcome of ORA was the total percent correct driving score collated from the ratings given by the OT during the ORA for 138 separate test actions.

The study was undertaken on 19 subjects, 2 female and 17 males, who were prospectively referred from specialist dementia clinics associated with teaching hospitals in Sydney. Each participant underwent an examination by any one of four physicians. The clinical examination was compliant with New South Wales medical guidance and included, amongst other things, administration of the Mini Mental State Examination (MMSE). Following assessment the physician recorded whether there were possible contraindications for driving according to the medical guidelines and made a prediction regarding driving performance in the ORA as either:

- Pass
- Fail
- Borderline

The neuropyschologist administered a battery of tests and then likewise predicted the outcome of ORA on the same basis as the physician.

6.3.1.1 Study 1 – Results

Twelve of the 19 participants (63%) failed the ORA as reflected in the global assessment of driving made jointly by the driving examiner and the OT. Three of the failures were predicted by the physician but the numbers and nature of the predictions made by the neuropsychologist are not reported.

The physicians' predictions of outcome were associated with the total driving score ($r = -.629$, $p = .004$), as was the MMSE ($r = 0.632$, $p = .004$). However the physicians' predictions of the global assessment made by the examiner and the OT were not significantly associated, although the relevant statistic reflecting the degree of association was not reported.

The authors report that the neuropsychologist's prediction was likewise found not to be a significant predictor of the global assessment of driving competence, but again a statistic was not provided. The separate predictions of the neuropsychologist and the physicians were not associated with each other ($r = .214$, $p = .379$).

6.3.1.2 Study 1 – Conclusions

The authors conclude that as the physicians' predictions of the outcome of ORA were not a significant indicator of the expert examiners judgment, reliance on medical evaluation to determine fitness to drive may not be justified except in circumstances where medically quantifiable factors, such as poor eyesight, preclude driving. They further go on to state that "The use of a standardized road assessment in preference to a neuropsychological examination, medical examination or mental state examination alone is recommended for the determination of driver competence in individuals with AD (dementia)."

6.3.1.3 Study 1 – Quality Assessment

This was a small study and the method of recruitment of participants means that bias cannot be ruled out. The use of four different physicians in making predictions on 19 participants could further undermine confidence in the study. Likewise the failure to present the numerical findings, for example the numbers predicted as a 'pass', 'fail' or 'borderline' by the clinicians is unhelpful.

On the positive side a good level of detail concerning the content of the physicians' and the road assessments is provided and blinding of the instructor to all but the diagnosis of dementia was afforded.

6.3.2 Study 2 (Ott et al) – Objectives and Methods

This study by Ott et al was undertaken in Rhode Island, USA and was reported in 2005 (12). The objective of the research was to assess the validity and reliability of clinicians' ratings of driving competence. It was undertaken as an extension to the study reported by Brown et al (11), brief details of which are provided below.

The study was undertaken on 50 subjects, 19 female and 31 males, who were enrolled as part of a longitudinal study into dementia. One clinician, a senior dementia specialist, undertook a full clinical assessment including interview with the participant and carer, administration of MMSE and review of neuropsychological and laboratory tests. Following assessment he attempted to predict the outcome of ORA as follows:

- Drives alone with good sense of direction and good driving skills
- Drives but with some difficulty
- Unable to drive safely

Five other clinicians then reviewed records of the assessments made on each of the participants and made a prediction in line with the approach adopted by the senior clinician. Each participant underwent a driving examination whereby they were classified by an experienced instructor as either:

- Safe
- Marginal
- Unsafe

To assist analysis of the data the driving instructors and clinicians' individual ratings were dichotomized into 'safe' versus 'unsafe', by combining the marginal and unsafe categories.

6.3.2.1   Study 2 - Results

Through the ORA 22 of the 50 participants were rated as safe drivers, 19 as marginal and 9 as unsafe. Thus following combination of the marginal and unsafe categories 28 drivers were classified as being unsafe. The clinicians' predictions, with 'drives with some difficulty' combined with 'unable to drive', were then compared to this finding and the results are summarised in Table 2.

Table 2. Clinician Predictions of Drivers Rated Categorically Safe by the Driving Instructor

	1	2	3	4	5	6
Sensitivity	59.1	95.2	49.5	59.1	40.9	45.5
Specificity	92.9	59.3	96.4	82.1	82.1	75
+ve pred value	86.7	64.5	90.9	72.2	64.3	58.8
-ve pred value	74.3	94.1	69.2	71.9	63.9	63.6
Correct classification	78*	75*	74*	72*	64*	62

* $P < .05$, chi-square

Clinician 1: Geriatric psychiatric fellow

Clinician 2: Senior dementia specialist

Clinician 3: Geriatric neurology fellow

Clinician 4: Dementia specialist

Clinician 5: Geriatric nurse practitioner

Clinician 6: General practitioner

A clinician with high sensitivity is one who predicts a driver to be safe, where this is subsequently confirmed by ORA. By way of contrast a clinician with high specificity identifies drivers as being unsafe where this is then confirmed by ORA. It can be seen that the dementia specialists had an overall accuracy of between 72% to 78%, whist the General Practitioners, a nurse and a doctor, had 62% to 64% accuracy.

Figure 1. ROC Plot showing the sensitivity and specificity of individual clinicians predictions.

Positive Likelihood Ratio
2.91 (1.85 to 4.56) Random Effects Model
Cochran-Q = 7.62; df = 5
(p = 0.1784)

Negative Likelihood Ratio
0.55 (0.41 to 0.74) Random Effects Model
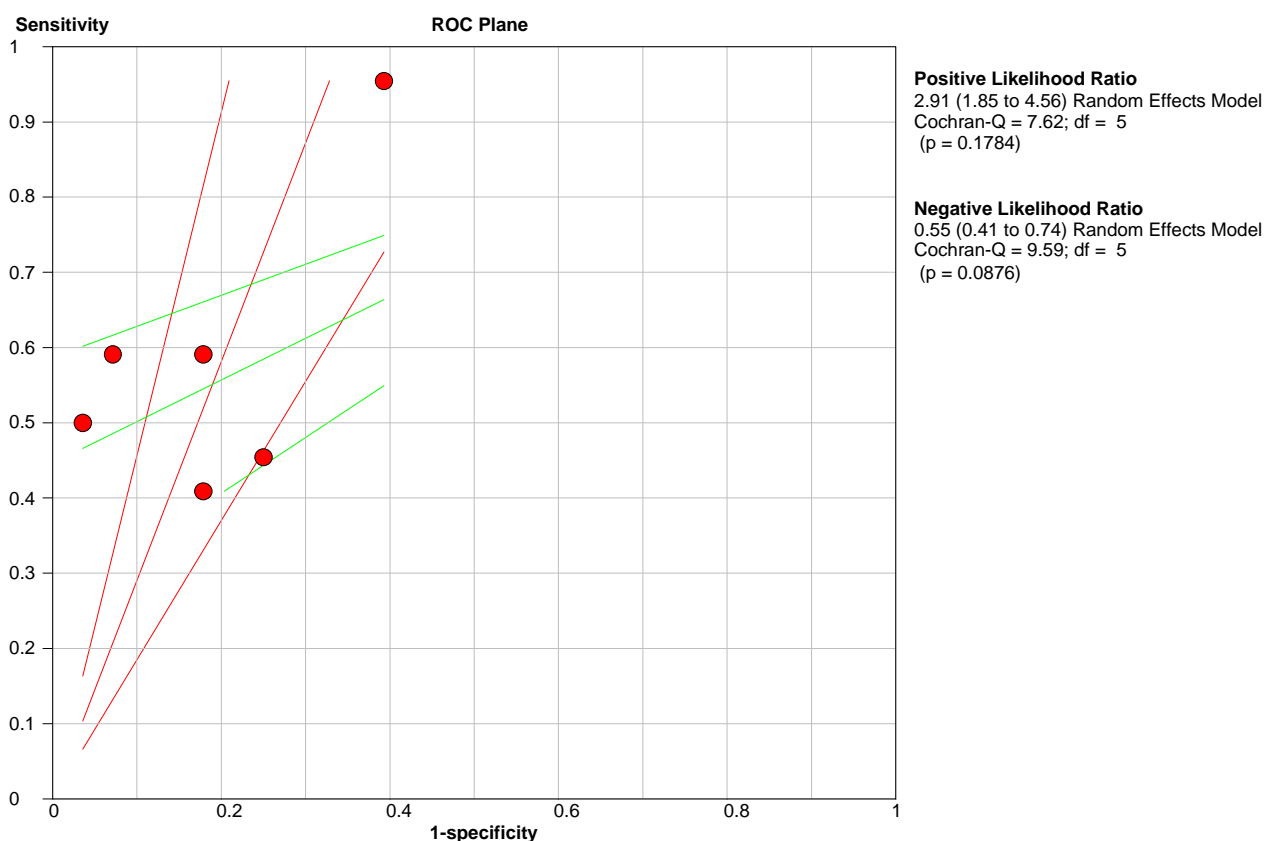Cochran-Q = 9.59; df = 5
(p = 0.0876)

Figure 1 shows the Receiver Operator Characteristic (ROC) curve associated with the predictions of the 6 clinicians. Each point on the ROC reflects the sensitivity and specificity of one clinicians' predictions. If a clinician had maximum sensitivity and specificity the point reflecting this would fall in the top left corner of the graph. Points falling close to this position indicate precision in prediction. It can be seen none of the points are close to this position reflecting the relatively poor precision of the individuals' predictions.

The positive likelihood ratio is…. To complete

6.3.2.2   Study 2 – Conclusions

Accuracy in predicting the outcome of ORA was greatest for physicians with dementia training. Having noted this the authors go on to conclude that "the consistency between physicians in their degree of positive and negative predictive values is insufficient to justify making them the final or sole arbiters of the decision to revoke driving privileges in patients with dementia"

6.3.2.3   Study 2 – Quality Assessment

Whilst larger than Fox's study, this study is likely to be too small to show definitive patterns with confidence. A major limitation with this study is the fact that only one clinician undertook a clinical assessment of the subject and interviewed both the subject and the subject's carer; the other 5 clinicians had access to records only. The assessment made by the additional five clinicians appears to have been made after the ORA rather than before it.

A further difficulty is presented through the combining of classifications of outcome. There were many more subjects in the 'marginal' than in the 'unsafe' category as determined by the driving instructor following the ORA, yet all were ultimately classified as 'unsafe'.

The raw data showing the classification by clinicians into the three categories is not given in the report and as such only the summary figures such as sensitivity and specificity are available to inform interpretation.

6.3.3   Study 3 (Brown et al)

This study was undertaken in Rhode Island and was reported in 2005 (11). It was the primary study that served as the basis for the study reported by Ott et al, as described above (12). The objective of the study was to assess the validity of independent assessments of driving performance made a physician, a carer and the driver him or herself by comparing these assessments to the outcome of ORA. The study population was the 50 patients with dementia, as described above and 25 controls.

The key difference between this report and the report provided by Ott et al is that this study incorporated only the prediction of the senior dementia specialist and not the 5 additional clinicians as described above. In addition the carers and drivers own assessments were analysed in relation to the outcome of ORA.

This study found that "Overall, the instructor was the most stringent rater of participant driver ability, followed by the neurologist (ie. senior dementia specialist), the informant (ie. carer) and the participant". The report concluded that "An experienced neurologist's assessment of driving competence may be a valid predictor of driving performance of patients with early AD." It was presumably because of this conclusion that the study team designed an extension to the study in order to incorporate the assessment of other clinicians so that these could be compared to the assessments made by the senior dementia specialist.

6.4   Audits of Longer-term Outcomes of ORA

Searches of the medical databases did not lead to the identification of any reports providing details of driving outcomes among drivers with dementia who passed ORA. One study that followed three cohorts of drivers who passed ORA over time was retrieved (13). Whilst this study identified that driving skill declined more rapidly in those with mild as opposed to very mild dementia and that those with very mild dementia declined more rapidly than healthy controls, no quantification of accidents or traffic violations among the various groups were made.

Other studies involving repeat ORA were identified. One report described the concept of environmental cueing (ie. where the driver follows an example set by other road users at the time of the test to inform their own driving behaviour) as having an impact on the outcome of a test and potentially explaining a reduction in re-test reliability (15). Another study of repeat ORA was undertaken to assess the reliability of the road test itself (14). Whilst this indicates that the medical literature is not replete with such reports a relevant article was identified from a reference cited in the Monash University report and is described below.

6.5   Audit of ORA Outcome (Salzberg et al) – Background

The Washington State Department of Licensing (DoL) operates a Special Examination Programme for drivers with medical, vision and physical impairments (16). Drivers who are brought to the attention of the DoL have their driving competence re-examined. Those who fail this re-examination have their licenses withdrawn unless they undertake a "special exam". The special examination includes an in-depth interview and an extended or specialized driving test.

Drivers who fail the special examination are required to stop driving. Those who pass the examination can continue to drive but most commonly have driving restrictions imposed upon them. Driving restrictions include:

- Only driving within a given radius of the driver's residence
- Driving between the hours of 10am to 3 pm
- Daylight driving only
- No freeway driving
- Driving within city limits only

6.5.1   Audit of ORA Outcome – Objective and Method

The purpose of the study was to evaluate the effectiveness of the special examination programme in identifying drivers with impairments and in reducing their risk of collision involvement. The traffic citations and collisions of those who had been subject to a special examination were compared to a control group.

The study subjects were identified in 1997. The examination group consisted of drivers who had undertaken a special examination in 1994. Control group subjects were drivers matched by year of birth, sex and city of residence to the subjects in the examination group.

There were a total of 449 special examination drivers of whom 380 passed the exam and carried on driving, albeit some with restrictions on their ability to drive freely. There were 449 control group drivers. The average age of the study (passed special examination) and control populations was 75.2 and 75.6 years respectively. Of all the study subjects 57% were male and 43% female.

In 1997 the five-year driving records of the study population were retrieved (ie. From 1992 to 1997). This period gave data relating to the pre-examination period (1992 to 1994); an average of 1.75 years before the exam and 3.25 years after it.

Of the 449 subjects in the examination group 66 had a psychiatric disorder as the primary reason for the driving examination. The psychiatric subgroup included those with Alzheimer's, bipolar disorders, dementia and confusion/memory loss. Of these 66 subjects 46 passed the examination and as such could continue to drive.

6.5.2 Audit of ORA Outcome – Results

The annual collision and traffic violation rates (per 100 licensed users) were calculated for the study and control groups for the periods before and after the examination. Rates were also calculated for subgroups including the psychiatric disorder group.

Table 3 Collision and Traffic Violation Rates (per 100 Licensed Users) for Study and Control Groups.

Group	n	Pre-exam collision rate	Post-exam collision rate	Pre-exam violation rate	Post-exam violation rate
Failed exam	69	12.4	0	15.7	0
Passed exam	380	7.1	3.2	13.4	5.3
Control group	449	3.8	1.2	7.5	2.3
Psychiatric group	46	12.4	4.6	23.6	8.0
No medical problem	173	5.9	3.6	11.6	6.0
Diabetes	27	6.3	1.1	8.5	2.3
Cardiovascular	47	7.3	2.0	20.1	2.6
Neurological	20	8.6	3.1	17.1	7.7
Stroke	21	5.4	4.4	8.2	7.3
Other medical	46	6.2	2.7	6.2	2.0

Table 3 shows that those who failed the examination (n=69) tended to have the highest pre-examination collision and traffic violation rates. The only group with rates equating to or exceeding those seen among the failed group was the psychiatric sub-group. The psychiatric sub-group also had the highest post-examination incident rates of all groups, having 3.8 times the rate of collisions (ie. 4.6 collisions per 100 licensed users) and 3.5 times the rate of traffic violations (ie. 8 collisions per 100 licensed users) than those seen among the control group.

It is notable that the incident rates in the control group decreased substantially between the pre-examination and post-examination periods. The fact that the study subjects were in their mid-seventies when recruited to the study and over a five year period are likely to have driven less and in less risky situations could in part explain this decrease.

6.5.3 Audit of ORA Outcome – Conclusion

The authors of this report conclude that drivers selected for special examination do pose a threat to public safety but that post examination statistics indicate that incident rates more closely equate to rates seen among the control group.

It is clear that the psychiatric sub-group had higher pre-examination incident rates than other sub-groups and that whilst rates reduced following the special examination they remained higher than the rates seen in other groups.

6.5.4 Audit of ORA Outcome – Quality Assessment

It is unclear how generalisable the results of this study are. It is not known how closely the special examination referred to in the research relates to ORA and in addition the diagnostic sub-group contains patients with psychiatric disorders other than dementia.

There are also wider methodological issues that need to be considered. These include the following:

- It is unclear how any imposed driving restrictions might have reduced the amount of driving those who passed the test were able to undertake. As such they may have driven fewer miles but still incurred the same number of incidents. An incident rate calculated on distance driven may have reflected badly on those in the study as opposed to the control group.

- The study reported aggregate outcome measures, masking the potential impact of individuals with particularly high accident and traffic violation rates within the sub-groups.

- There were no statistical analyses estimating the role of chance in explaining the findings or in estimating the likely precision of the estimates derived from the research.

Despite these limitations the report does provide some evidence that the collision and traffic violation rates among a population that includes dementia suffers are higher than among a control group and higher than other sub-groups.

6.6 Content of On Road Assessment

The two studies comparing ORA with clinicians' assessments of driving competence give detailed accounts of the ORA process and procedure. The ORA undertaken in New South Wales described by Fox et al (10) had the following features:
- It was assessed by an OT and driving instructor, using a standardized route, based on recommended procedures
- It was undertaken in daylight with light to moderate traffic density
- The OT rated the subjects performance in relation to 138 pre-determined actions

In addition the number of instructor interventions and evasive actions taken by other road users were recorded. Following discussion between the instructor and the OT, a consensus global judgment on driving performance was made; pass or fail.

The ORA performed in Rhode Island as described by Ott et al (12), was conducted as follows:

- It was undertaken in daylight under good conditions
- A 10 to 15 minute pre-test was completed in a parking lot to confirm the driver was safe to drive
- The 45 minute road test was based on published criteria (14)
- The final on road score was based on the completion of specified maneuvers

Whilst these testaments describe the approach to driving assessment used in a research setting it remains uncertain the extent to which these procedures reflect every day practice in New South Wales or Rhode Island. The websites for the licensing authorities in Rhode Island and New South Wales were accessed but descriptive information concerning ORA was not available. In order to try to get further information the authors of the two papers have been contacted with the hope that they may be able to say in what ways the procedures they employed differed from those routinely employed. This information will be forwarded to DVLA when it arrives.

6.7   Limitations of This Report

This is not a systematic review but a rapid assessment for relevant literature. Although the search strategies were broad and comprehensive for both systematic reviews and primary studies it cannot be guaranteed that relevant studies were omitted. However, brief citation checking of relevant articles did identify relevant work that has been included in this review.

7   Conclusion

There has been very little research looking at the correlation between a clinician's assessment of driving competence and that established through ORA. As the research accessed was undertaken in the USA and Australia it may not be wholly applicable to the UK driving population. This being said both the studies reached broadly the same conclusion: a clinician's assessment is not considered a suitable alternative to ORA as the determinant of driving status among those with dementia.

There has likewise been little research looking at driving outcomes among those with dementia who have passed ORA. The study appraised in this report has significant limitations but nonetheless does provide some evidence that road crashes and traffic violations may be higher among those with dementia than other diagnostic sub-groups.

Accessing detailed information about the content of ORA in Australia and the USA is not possible using routine public information sources and as such the extent to which the procedures used in a research setting reflect those used in everyday practice remains uncertain.

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7.   Kakaiya R., Tisovec R., Fulkerson P. 'Evaluation of fitness to drive: The physician's role in assessing elderly or demented patients.' Postgraduate Medicine. 107(3)(pp 229-236), 2000.

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10.   Fox G.K., Bowden S.C., Bashford G.M., Smith D.S. 'Alzheimer's disease and driving: Prediction and assessment of driving performance.' Journal of the American Geriatrics Society. 45(8)(pp 949-953), 1997.

11.   Brown L.B, Ott B.R, Papandonatos G.D, Sui Y, Ready R.E., Morris J.C. 'Prediction of on-road driving performance in patients with early Alzheimer's disease'. Journal of the American Geriatrics Society. 53(1)(pp 94-98), 2005.

12.   Ott B.R, Anthony D,.,Papandonatos G.D., D'Abreu A.,Burock J., Curtin A., Wu C.-K.,Morris J.C. 'Clinician assessment of the driving competence of patients with dementia' Journal of the American Geriatrics Society. 53(5)(pp 829-833), 2005.

13.   Duchek J.M.,Carr D.B.,Hunt L., Roe C.M., Xiong C, Shah K., Morris J.C. 'Longitudinal driving performance in early-stage dementia of the Alzheimer type.' Journal of the American Geriatrics Society. 51(10)(pp 1342-1347), 2003.

14.   Hunt L.A., Murphy C.F., Carr D., Duchek J.M., Buckles V.,Morris J.C.'Environmental cueing may affect performance on a road test for drivers with dementia of the alzheimer type.' Alzheimer Disease and Associated Disorders. 11(SUPPL. 1)(pp 13-16), 1997.

15.   Hunt L.A., Murphy C.F., Carr D., Duchek J.M., Buckles V., Morris J.C.'Reliability of the Washington University road test: A performance-based assessment for drivers with dementia of the Alzheimer type.' Archives of Neurology. 54(6)(pp 707-712), 1997.

16.   Salzberg P., Moffat J. 'The Washington State Department Licensing Special Exam Program: An Evaluation.' Washington Traffic Safety Commission, Olympia, WA

9 Appendices

Appendix 1 – Details of Request

ARIF REQUEST FORM

Date of request

17/08/2007

Lead Medical Adviser
issuing request

Contact details

| Name – Dr Andrew White | |
Secretary to the Psychiatry Panel	
Drivers Medical Group	██████████████
DVLA	
Sandringham Park	████████████████████
Swansea Vale	
Llansamlet	
Swansea	

1. Without worrying about the structure of the question, state in full the nature and context of the problem.

> We need to know how do the results of On Road Driving Assessments (ORA) relate to/correlate with, a clinician's opinion regarding 'fitness to drive', specifically where the driver has a diagnosis of dementia or cognitive impairment.

2. Please give a background to the question. Why has DMG raised this problem?

> ORAs are increasingly being used to determine a driver's suitability to continue driving where there is diagnosis of dementia; the Agency is also seeing an increase in drivers self-referring for assessments either prior to, or as part of, licence applications. This has been generally welcomed, the ORA increasingly being seen as a 'gold standard'.
>
> Concerns have however been raised by clinicians treating patients with dementia that the ORA sometimes does not reflect their clinical opinion as to whether or not a driver should continue to drive. Usually the context of this has been where a driver has completed an ORA satisfactorily possibly in a 'quiet location' and the clinician does not feel that the nature of the condition would allow sufficient reserve to deal with the unexpected or unfamiliar.

3. Giving references where appropriate, briefly detail the sources you have used to obtain background information on the *options* and *issues,* which might be important for the problems, you describe.

1) Sources currently used include the literature review 'Influence of chronic illness on crash involvement of motor vehicle drivers,' report number 213, April 2004 from
Monash Accident Research Centre. In particular, pages 103-125 (attached).

2) Fitness to Drive: A neuropsychological perspective. McKenna P, *Journal of Mental Health* (1998) 7,1, 9-18

4. Please give name and contact details of any expert or clinical contact e.g. relevant Panel Chairman/expert Panel member.

Ed Passant
Chief Executive
The Forum Mobility Centres
██████████████

Professor Malcolm Lader (Chairman)
OBE PhD DSC MD FRCPsych FmedSci
Professor of Clinical Psychopharmacology
Institute of Psychiatry
King's College London
De Crespigny Park
Denmark Hill
LONDON
SE5 8AF

████████████

Dr P Divall
Consultant in Old Age Psychiatry
Dept of Old Age Psychiatry
St Martin's Hospital
Midford Road
BATH BA2 5RP

████████████

Dr Kathryn Watts
Forum Liaison Medical Adviser
████████

5. What is the nature of the target population of the issue detailed above? Eg. age profile, vocational drivers, young drivers, other co-morbid features.

> The main population affected by dementia will be the older driver – from 60 years of age onward, there may be some younger onset, but would expect 60 to cover most.
>
> Cognitive impairment from head injury, trauma will involve a much younger group. However our prime concern is really that of the driver with a potentially progressive rather than a static deficit, the older dementing population will largely capture these.

6. What are the outcomes you consider particularly important in relation to the question posed? What decisions rest on these outcomes?

> Of particular importance is the degree of 'correlation' between ORA and the clinical opinion: which potentially has the highest degree of reliability in determining whether a driver will be able to continue to drive safely?
>
> The expanding size of the elderly driver population over the coming decades will increasingly require assessment as to whether driving can continue safely. This generation unlike prior

7. What is the latest date that an ARIF response would be of value

2 / 11 /07

Please either:

Fax this form to: 0121 414 7878 marking FAO ARIF

E-mail as a word document or pdf attachment to: ▮▮▮▮▮▮▮▮▮

Post to: -   Dr David Moore
              Senior Research Reviewer and Analyst
              Aggressive Research Intelligence Facility
              West Midlands Health Technology Assessment Collaboration
              Department of Public Health
              University of Birmingham
              Edgbaston
              Birmingham
              B15 2TT

Please ring 0121 414 3166 or 6769 if you have any queries, or you want to check the progress with your request.

9.1 Appendix 2 – Outline methods

From: Berni Lee
Sent: 03 December 2007 14:14
To: ████████████████████████████████████
Cc: Chris Hyde; David Moore; Ann Massey
Dear Andrew

RE: DVLA REQUEST

Literature search on how the results of On Road Driving Assessments (ORA) in drivers with dementia relate to a clinician's opinion regarding 'fitness to drive'.

Following discussion with yourself, Kathryn Watts and more recently Chris Hyde I thought it would be helpful to summarise the questions that ARIF should seek to answer in response to the above request.

In summary there are three questions that can be addressed. The primary question that the report will focus on is:

1. Is there any evidence comparing clinicians' views of driving ability among those with dementia (following routine clinical assessment, rather than following the conduct of specific cognitive tests) with the assessment of driving ability made through ORA.

In order to identify the fundamental components of an ORA and to help interpretation of international evidence regarding the relationship between ORA and clinical assessment it would seem helpful to seek evidence in relation to a second question:

2. What constitutes ORA in different countries?

Given the Gold Standard status of an ORA, which essentially precludes any scientific comparison of its validity compared to clinical assessment as a means of assessing driving competence, it would be helpful to identify:

3. Have any audits of the longer-term outcomes (eg. accidents) been undertaken in cohorts who have passed ORA?

ARIF will employ the following method in constructing the report to answer the above three questions:

- MEDLINE, EMBASE, the Cochrane Library and other relevant databases will be searched for background information and studies using a comprehensive search strategy.
- The identified articles will be screened for relevance by an analyst
- In relation to question 1 systematic reviews and prospective primary studies will be selected where possible. Other study types, for example case series, may be included as appropriate, based on the volume of relevant robustly designed studies identified through the search.
- In relation to question 2 descriptions of ORA and guideline documents will be sought
- In relation to question 3 any audits or retrospective analyses will be identified

- The methodological quality of studies will be discussed
- The evidence will be presented in relation to the three stated questions

As agreed some time ago the deadline for this request has been extended. ARIF would like to agree a provisional deadline of the end of January, with the proviso that should any evidence emerge that may be worthy of further searches and/or analysis, we might agree with DVLA an extension. This being said we do not anticipate the final response to this request outstanding beyond the end of February.

I hope the above action plan concurs with your understanding of what ARIF has been asked to do and I would appreciate it if you could confirm at your earliest convenience that you are happy for us to proceed as outlined. If you have any queries or wish to further clarify any particular points please let me know.

Best wishes

Berni Lee

Aggressive Research Intelligence Facility
WM Health Technology Assessment Collaboration
Department of Public Health
University of Birmingham
Edgbaston
Birmingham B15 2TT

ARIF Reviews Protocol

SEARCH PROTOCOL FOR ARIF ENQUIRIES

(October 2007)

In the first instance the focus of ARIF's response to requests is to identify systematic reviews of research. The following will generally be searched, with the addition of any specialist sources as appropriate to the request.

1. Cochrane Library

- Cochrane Reviews
- Database of Abstracts of Reviews of Effects (DARE)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Health Technology Assessment (HTA) database

2. ARIF Database

An in-house database of reviews compiled by scanning current journals and appropriate WWW sites. Many reviews produced by the organisations listed below are included.

3. NHS CRD

- DARE
- Health Technology Assessment Database
- Completed and ongoing CRD reviews

4. Health Technology Assessments

- NICE guidance (all programmes)
- West Midlands Health Technology Assessment Collaboration
- Evidence Based Commissioning Collaboration (Trent R & D Support Unit). Links to Trent Purchasing Consortia reports and Wessex DEC reports (both no longer published)
- SBU – Swedish Council on Technology Assessment in Health Care
- NHS Coordinating Centre for Health Technology Assessments
- Canadian Agency for Drugs and Technologies in Health
- New Zealand Health Technology Assessment
- Agency for Healthcare Research and Quality (AHRQ)
- Alberta Heritage Foundation
- McGill Medicine Technology Assessment Unit of MUHC (McGill University Health Centre)
- Monash reports – Centre for Clinical Effectiveness, Monash University
- US Department of Veterans Affairs
- NHS QIS (Quality Improvement Scotland)
- SIGN (Scottish Intercollegiate Guidelines Network)

5. Clinical Evidence

6. Bandolier

7. National Horizon Scanning Centre

8. TRIP Database

9. Bibliographic Databases

- Medline – systematic reviews
- Embase – systematic reviews
- Other specialist databases

10. Contacts

- Cochrane Collaboration (via Cochrane Library)
- Regional experts, especially Pharmacy Prescribing Unit, Keele University (& MTRAC) and West Midlands Drug Information Service for any enquiry involving drug products.

Search strategies

Source – MEDLINE (Ovid) 1950 –October week 2 2007

1   cognition/ (38498)
2   cognition disorders/ (26365)
3   neuropsychological tests/ (34398)
4   memory disorders/ (8687)
5   cognitive dysfunction$.mp. (3220)
6   cognitive function$.mp. (15499)
7   executive function$.mp. (3932)
8   cognitive disabilit$.mp. (259)
9   cognitive impairment.mp. (10790)
10   dementia.mp. (57631)
11   alzheimer$.mp. (57722)
12   Alzheimer Disease/ (43250)
13   or/1-12 (178691)
14   automobile driver examination/ (991)
15   automobile driving/ (8981)
16   (driver or driving or drivers).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (31773)
17   13 and 16 (917)
18   limit 17 to "reviews (optimized)" (226)
19   limit 17 to "reviews (specificity)" (14)

1   dementia.mp. (57758)
2   alzheimer$.mp. (57915)
3   Alzheimer Disease/ (43364)
4   automobile driving/ (9003)
5   (driver or driving or drivers).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (31902)
6   on road.ti,ab. (409)
7   road test$.ti,ab. (97)
8   off road$.ti,ab. (159)
9   clinician$.ti,ab. (65856)
10   instructor$.ti,ab. (3075)

11   physician$.ti,ab. (179000)
12   neurologist$.ti,ab. (5326)
13   clinical.ti,ab. (1415220)
14   neurological.ti,ab. (85049)
15   gp$.ti,ab. (69976)
16   general practitioner$.ti,ab. (24867)
17   Physicians, Family/ (11315)
18   or/1-3 (96869)
19   or/6-17 (1733021)
20   4 or 5 (31902)
21   18 and 19 and 20 (156)
22   or/1-3 (96869)
23   or/4-5 (31902)
24   or/6-17 (1733021)
25   22 and 23 and 24 (156)

1   dementia.mp. (58502)
2   alzheimer$.mp. (58862)
3   Alzheimer Disease/ (44008)
4   automobile driving/ (9051)
5   (driver or driving or drivers).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (32155)
6   on road.ti,ab. (414)
7   road test$.ti,ab. (98)
8   instructor$.ti,ab. (3098)
9   or/1-3 (98215)
10   4 or 5 (32155)
11   Automobile Driver Examination/ (997)
12   driving test$.mp. (161)
13   driv$ assessment$.mp. (101)
14   6 or 7 or 11 or 12 or 13 (1599)
15   8 and 10 (46)
16   9 and 14 (75)
17   9 and 15 (8)
18   or/16-17 (75)

Source – Cochrane Library 2007 Issue 4

#1 dementia
6223

#2 alzheimer*
3529

#3 MeSH descriptor Dementia, this term only
817

#4 MeSH descriptor Alzheimer Disease, this term only
1530

#5 (#1 OR #1 OR #2 OR #3 OR #4)
7072

#6 driver* or driving or drive* or road*
9070

#7 MeSH descriptor Automobile Driving explode all trees

423

#8 (#6 OR #7)
9070

#9 (#5 AND #8)
295

#10 on next road
49

#11 road next test*
9

#12 off next road*
16

#13 clinician*
6065

#14 instructor*
244

#15 physician*
15241

#16 neurologist*
351

#17 clinical*
382312

#18 neurological
5337

#19 gp$
5

#20 general next practitioner*
3032

#21 MeSH descriptor Physicians, Family explode all trees
329

#22 (#10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21)
386845

#23 (#9 AND #22)

1 dementia
6223

#2 alzheimer$
3

#3 MeSH descriptor Alzheimer Disease, this term only

1530

#4 (#1 OR #2 OR #3)
6702

#5 MeSH descriptor Automobile Driving, this term only
418

#6 (driver or driving or drivers)
4475

#7 on next road
49

#8 road next test*
9

#9 instructor*
244

#10 MeSH descriptor Automobile Driver Examination, this term only
15

#11 driving next test*
63

#12 driv* next assessment*
7

#13 (#5 OR #6)
4475

#14 (#7 OR #8 OR #10 OR #11 OR #12)
127

#15 (#9 AND #13 AND #4)
0

#16 (#4 AND #14)
2

Source – EMBASE (Ovid) 1980 – 2007 week 43

1   dementia.mp. (48341)
2   alzheimer disease/ (55451)
3   alzheimer$.mp. (62051)
4   (driver or driving or drivers).mp. (26322)
5   driving ability/ or car driving/ or driver/ or car driver/ (7004)
6   or/4-5 (26322)
7   or/1-3 (89895)
8   on road.ti,ab. (470)
9   road test$.ti,ab. (83)
10   off road$.mp. (146)
11   clinician$.ti,ab. (57640)
12   instructor$.ti,ab. (1501)
13   physician$.ti,ab. (126472)
14   neurologist$.ti,ab. (5060)

15   clinical.ti,ab. (1154174)
16   neurological.ti,ab. (75482)
17   gp$.ti,ab. (62585)
18   general practitioner$.ti,ab. (20126)
19   general practitioner/ (27449)
20   or/8-19 (1402971)
21   6 and 7 and 20 (167)

1   dementia.mp. (48741)
2   alzheimer disease/ (55939)
3   alzheimer$.mp. (62597)
4   (driver or driving or drivers).mp. (26545)
5   driving ability/ or car driving/ or driver/ or car driver/ (7052)
6   or/4-5 (26545)
7   or/1-3 (90663)
8   on road.ti,ab. (475)
9   road test$.ti,ab. (84)
10   instructor$.ti,ab. (1512)
11   driving test$.mp. (165)
12   driv$ assessment$.mp. (105)
13   6 and 10 and 7 (6)
14   8 or 9 or 11 or 12 (729)
15   7 and 14 (52)
16   13 or 15 (52)

Other sources searched

TRIS Online (National Transportation Library)
TRL (Transportation Research Laboratory)
Search terms: Cognition, cognitive, dementia, alzheimers