Improving the assessment of driving safety in dementia (IMPASS)

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Abstract

Background: It is estimated that two thirds of people aged over 70 in the UK currently hold a driver's licence. Dementia can impair the cognitive skills that are needed for driving (Camilleri & Whitehead, 2023). Clinicians are expected to advise people on their safety to drive as part of a comprehensive clinical diagnostic assessment, but many feel under-equipped to do this (Bennett, Chekaluk, Batchelor, et al., 2019; Neilson et al., 2019).

Aims: The aims were:

- Comprehensively review the current evidence for clinical predictors of driving safety
- Understand how clinicians currently make a decision about driving safety
- To investigate the discriminant ability of routinely collected clinical information to predict driving safety in those who have had an independent on-road assessment of driving
- Use this data to develop a simple driving decision aid tool that will classify people as low-risk, indeterminate-risk and high-risk

Methods: Clinicians from a broad range of disciplines were interviewed about what information they used to make an assessment of driving safety and what would improve current practice.

A retrospective review of clinical notes was performed in people who had an on-road assessment of their driving to identify predictors of driving safety.

A predictive driving decision aid tool was developed from the data and tested in an independent cohort to assess the sensitivity and specificity to identify at risk drivers.

Results: The developed driving decision aid tool comprised two items, increased age and reduced ACE III visuo-spatial score demonstrating 50% specificity and 95% specificity to detect unsafe drivers. When tested in an independent cohort the tool demonstrated 10% sensitivity and 47% specificity to predict unsafe drivers.

Conclusions: It was not possible to predict driving safety in a mild dementia cohort using routinely collected clinical information. Future focus is needed on development of clinical screening tools and comprehensive training for clinicians.

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COVID 19 Impact statement

The COVID-19 pandemic had a significant negative effect on the IMPASS study. The impact of the pandemic resulted in significant changes to the study protocol. The dates of the PhD were October 2019 to September 2024.

The original project

The original protocol for the project had two major parts. Fifty participants would be recruited before having an on-road assessment of driving with Drive Mobility. The researcher was to visit the participants at home and complete a battery of cognitive, non-cognitive and driving questionnaire assessments prior to the on-road assessment taking place. The home assessment by the researcher needed to be carried out at least two weeks before the on-road assessment. The data from this first 50 group of participants would be analysed to identify possible predictors of driving safety.

The second part of the project entailed recruitment of a further fifty participants before an on-road assessment of driving and apply the predictors in this independent cohort of participants to test the predictive validity of the model/tool developed in the first cohort.

Timeline of COVID-19 closures

Detailed below is the timeline of closures due to COVID-19. The project was affected by measures related to COVID-19 taken by both the NHS and the DVSA, as Driving Mobility assessments require the presence of both a clinician and a qualified driving assessor. Drive Mobility experienced longer closures than many other NHS services due to the enclosed space of an assessment that requires three people to be in a car.

Date recruitment opened	21/02/2020
Date study paused (national lockdown 1)	17/03/2020
Date of application to sponsor to re-open study	25/08/2020
Date recruitment was able to recommence	21/09/2020
Date Drive Mobility ceased assessments (national lockdown 2)	05/11/2020

Date assessments recommenced at Drive Mobility	02/12/2020
Date Drive Mobility ceased assessments (national lockdown 3)	05/01/2021
Date recruitment was able to resume	12/04/2021
Meeting with Drive Mobility	23/08/2021

Thirteen to fourteen months of recruitment time were lost, and when recruitment resumed it continued to present a challenge and resulted in the rate of less than 1 participant per month. Meetings were held with Drive Mobility in this time period in order to try and increase participant referrals. There were several issues identified that contributed to the poor recruitment, which unfortunately continued to cause problems throughout the rest of the project. These were:

- Following the re-opening of the study/re-start of assessments at Drive Mobility following the three lockdowns, many people turned down the study as they were concerned about having someone coming to their house. Because this was an older dementia population, many were classed as extremely vulnerable and still shielding.
- As memory clinics were either not operating, or operating a minimal service during this period, no new referrals were being made to Drive Mobility for assessment.
- During the lockdown periods, many people who had been referred for an assessment of driving had either chosen to give-up driving themselves, or their condition had deteriorated to the point where an assessment of driving was no longer needed, meaning there were greatly reduced numbers moving through the Drive Mobility assessment process.
- Referrals for driving assessments did start to rise again once memory clinics were operational again (in Newcastle this was approximately October 2020), however due to the smaller number of referrals instead of the usual 6 week wait between referral and assessment, people were able to be seen sooner. This changed to 1-

2 weeks, meaning there was not enough time before the driving assessment for the researcher to conduct the home visit for those interested in taking part.

- The backlog of patients to be seen in memory clinics caused by the shut-down, so that when people did attend for a diagnostic appointment, they were already at the stage where they were no longer able to drive, meaning that there was a greatly reduced number of referrals to Drive Mobility.

In October 2022 it was estimated that around 50% of those approached by Drive Mobility agreed to study team contact. Timing remained an issue, with often there being a tight turn around between the approach and assessment date, resulting in not enough time for the study assessment to take place. An amendment to extend the recruitment period for this part of the study was submitted, and the recruitment end date was extended to June 2024. However, it was clear that the original recruitment target needed of 100 participants would not be reached, and so they project needed to undergo major changes to mitigate this.

Changes made to the project

In order to mitigate the effects of the C-19 pandemic on the progress of the project, it was decided to add an additional element to the main study. The aim was to supplement the original IMPASS study with a complimentary retrospective cohort study. We identified clinical predictors of driving safety in dementia and mild cognitive impairment (MCI) through a retrospective notes review and the outcome of a Driving Mobility Assessment. In the protocol this replaced the recruitment of the first 50 participants, and the collection of data to identify potential predictors before the on-road assessment had taken place (this is Chapter 4 in the thesis).

Originally this was to be done by using the CRIS (Clinical Record Interactive Search) system would be used to conduct an anonymised retrospective search for clinical predictors. The CRIS system allows researchers to search and use anonymised data from clinical records in the Cumbria, Northumberland Tyne & Wear NHS Foundation Trust. When someone is seen in a memory clinic, a record of the consultation is entered onto the system. This can include, but is not limited to, diagnosis, symptoms experienced, cognitive test scores and level of functional impairment. In addition, results of scans or blood tests may also be entered. The software enables search via

key words for example ‘driving’, ‘driving assessment’ and ‘dementia’. The results are records returned containing these key words. Data is anonymised by replacing names, date of birth, address and telephone number with ‘ZZZZZZZZZZZZZZZ’ in the text. A project plan was formulated and the project was granted approval by the CRIS oversight committee. However, the anonymisation of clinical notes on the CRIS platform did not function correctly and so access to CRIS was not permitted from April 2021 to September 2022. Additionally, problems persisted with the platform not returning the correct data until January 2023. As such CRIS was no longer a feasible option to carry out this work. The decision was made to plan a different approach.

Retrospective clinical notes addition

Due to the on-going problems with the CRIS system, the retrospective clinical notes arm was added to the study. People with MCI or dementia who had an assessment from North East Drive Mobility in the preceding 12 months were approached for inclusion. When signed consent was obtained, the participant’s NHS record was accessed by the study team. Information relating to possible predictors of driving safety were extracted. A substantial amendment was prepared in November 2022, and REC and HRA approvals for this part of the study were obtained on 28/11/2022 (chapter 4 in the thesis).

Abbreviations

ACE III	Addenbrooke's Cognitive Examination
AD	Alzheimer's Disease
AD-8	Washington University Dementia Screening Test
ADL	Activities of Daily Living
AEC	Anticholinergic Effect on Cognition
AMIPB	Adult Memory and Information Processing Battery
AUC	Area Under the Curve
AUROC	Area Under the Curve Receiver Operating Characteristic
AVLT	Auditory Verbal Learning Test
BADL	Bristol Activities of Daily Living scale
BADS	Behavioural Assessment of Dysexecutive Syndrome
BNF	British National Formulary
bvFTD	behavioural variant Frontotemporal Dementia
BVMT	Brief Visual Memory Test
BVRT	Benton Visual Retention Test
CCI	Charlson Comorbidity Index
CDAS	Composite Driving Assessment Scale
CDR	Clinical Dementia Rating Scale
CFS	Clinical Frailty Scale
CFT	Complex Figure Test
ChEI	Cholinesterase Inhibitor
CI	Confidence Interval
COWA	Controlled Oral Word Association
CRT	Choice Reaction Time
CTRL	Control
CVA	Cerebrovascular Accident
DCFS	Dementia Cognitive Fluctuation Scale
DLB	Dementia with Lewy Bodies
DSST	Digit Symbol Substitution Test
DV	Dependent Variable
DVT	Digit Vigilance Task
DVLA	Driver and Vehicle Licencing Agency
EF	Executive Function
ESS	Epworth Sleepiness Scale
FAQ	Functional Assessment Questionnaire
FTD	Frontotemporal Dementia
GDS	Geriatric Depression Scale
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HVLT	Hopkins Verbal Learning Test

IADL	Instrumental Activities of Daily Living
IMPC	Participant codes for clinicians
IQR	Inter Quartile Range
IV	Independent Variable
JLO	Judgement of Line Orientation
KSS	Karolinska Sleepiness Scale
MC	Mean Correct
MCI	Mild Cognitive Impairment
MDRS	Mattis Dementia Rating Scale
MMSE	Mini-Mental State Examination
MoCA	Montreal Cognitive Assessment
ms	Milli-seconds
MS	Multiple Sclerosis
MSNAP	Memory Services National Accreditation Programme
NART	National Adult Reading Test
NBRS	Neurobehavioural Rating Scale
NHS	National Health Service
NIA-AA	National Institute on Ageing and Alzheimer's Association
NICE	National Institute for Health and Care Excellence
NINCDS-ADRDA	National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association
NINDS-AIREN	International Workshop of the National Institute of Neurological Disorders and Stroke and the Association Internationale pour la Recherche et l'Enseignement en Neurosciences
NNDA	Nottingham Neurological Driving Assessment
NorSDSA	Nordic Stroke Driver Screening Assessment
NPI	Neuropsychiatric Inventory with caregiver distress
NS	Not Significant
PD	Parkinson's Disease
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RDB	Rookwood Driving Battery
REM	Rapid Eye Movement
Rey-AVLT	Rey Auditory Verbal Learning Test
Rey-O	Rey-Osterrieth Complex Figure
RIDE	Rhode Island Driving Evaluation
RIRT	Rhode Island Road Test

RR	Relative Risk
RT	Reaction Time
SD	Standard Deviation
SDSA	Stroke Drivers Screening Assessment
SILS	Shipley Institute of Living Scale
SOP	Standard Operating Procedure
SORT	Salford Object Recognition Test
SRT	Simple Reaction Time
TEA	Test of Everyday Attention
TMT	Trail Making Test
UFOV	Useful Field of View
VaD	Vascular Dementia
VFDT	Visual Form Discrimination Test
VOSP	Visual Object and Space Perception
WAIS-R	Wechsler Adult Intelligence Scale (Revised)
WCST	Wisconsin Card Sorting Test
(m)WURT	(modified) Washington University Road Test

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Chapter 1. Introduction

1.1 Dementia

Dementia is an age-related condition that is described as the onset of a cognitive impairment that is a decline from the individual's previous level of function (McKhann et al., 2011). The cognitive impairment is characterised as being severe enough to interfere with the capability to function independently and must be more marked than changes in normal ageing (McKhann et al., 2011). It is a clinical syndrome that can be caused by either a singular or combination of underlying processes, with the most common being neurodegenerative diseases or cerebrovascular disease. At present the number of people with dementia is expected to rise to just under 153 million cases worldwide by 2050 (Nichols et al., 2022). In the UK it is estimated that there are currently over 1 million people living with dementia, with this set to rise to just under 1.6 million in 2040 (Wittenberg et al., 2019).

1.1.1 Clinical presentation of dementia

The core clinical features of dementia are deficits in the domains of memory, executive function, language and visuo-spatial skills. In order for a dementia to be present, there should be impairment in a minimum of two domains (McKhann et al., 2011).

1.1.1.1 Memory

In the domain of memory, impairment in learning and retaining new information is the core feature (McKhann et al., 2011) and can present as forgetting conversations, repetitive questions, forgetting appointments or upcoming events and losing belongings (Arvanitakis et al., 2019; Dröes et al., 2011).

1.1.1.2 Language

For language, the most common deficit is word-finding difficulties. Other symptoms can include hesitations in speech and writing and spelling errors (Klimova & Kuca, 2016; Weiner et al., 2008).

1.1.1.3 Visuo-spatial

Common deficits in the visuo-spatial domain are impaired face recognition, the inability to recognise objects and difficulty reading or comprehending written language and can

present as difficulty using simple objects or dressing incorrectly (Johnson et al., 2005; Pal et al., 2016).

1.1.1.4 Executive function

In the executive function domain impaired reasoning, problem-solving and judgement are common, and can present as poor sequencing, decline in ability to manage finances, poor understanding of risk and reduced ability to plan ahead (Guarino et al., 2019; Voss & Bullock, 2004).

1.1.1.5 Non-cognitive features

Non-cognitive symptoms can present as fluctuations in mood, apathy and/or social withdrawal, lack of motivation, loss of interest in previous hobbies, reduced empathy, repetitive or obsessive behaviours, agitation or aggression and speaking or acting in a socially unacceptable way (McKhann et al., 2011; Montero-Odasso et al., 2020).

1.1.2 Alzheimer's disease

Dementia due to Alzheimer's disease is the most common form of dementia (Barker et al., 2002) and accounts for around 77% of dementias. It is a neurodegenerative disease characterised by the accumulation of tau proteins that form neurofibrillary tangles within neurons and amyloid beta proteins that cause plaques in the brain (Hyman et al., 2012; Spillantini & Goedert, 2013).

1.1.2.1 Clinical presentation of Alzheimer's disease

The core clinical feature, and most common symptom of Alzheimer's disease is memory deficit and impairment in learning and retaining new information (Lane et al., 2018; McKhann et al., 2011; Zvěřová, 2019). Deficits in other cognitive domains can also be present. In Alzheimer's disease the most common presentations in cognitive domains other than memory are word finding difficulties in the domain of language; executive dysfunction e,g, impairment in judgement and problem solving; and deficits in the visuo-spatial domain e.g. recognising objects, word blindness and difficulty recognising faces (Lane et al., 2018; McKhann et al., 2011; Zvěřová, 2019).

1.1.2.2 Diagnosis of Alzheimer's disease

For a diagnosis of probable Alzheimer's disease to be made using the NINCDS-ADRDA criteria, the individual should either have the core feature of an amnestic impairment

such as difficulty in learning and recalling new information, as well as at least one of the core non-amnestic cognitive deficits; or non-amnestic presentation of deficits in the visuo-spatial, executive function or language cognitive domains. The onset of impairment should be gradual over time, not sudden, and demonstrate a clear history of worsening over time (McKhann et al., 2011). In the future biomarkers are set to become increasingly important in dementia diagnosis (Jack et al., 2024).

1.1.3 Vascular dementia

Vascular dementia is the second most common form of dementia after Alzheimer's disease (Hebert & Brayne, 1995) and in the UK has an incidence rate of 0.99/1000 person-years in those aged over 65 (Imfeld et al., 2013), accounting for around 15% of cases (O'Brien & Thomas, 2015). Vascular dementia is defined as a dementia caused by ischemic and haemorrhagic brain lesions caused by a cardiovascular event (e.g. cardiac arrest) or cerebrovascular disease (Roman et al., 1992).

1.1.3.1 Clinical presentation of vascular dementia

The clinical presentation of vascular dementia is dependent on the neural substrates that have been affected by the cerebrovascular event (O'Brien & Thomas, 2015) and so the changes in cognition can vary. The most common impairment is seen in executive function, attention and information processing (O'Brien et al., 2003; O'Brien & Thomas, 2015). The cognitive changes and impairments in vascular dementia are more variable than other dementias and memory, language and praxis can be affected, with non-cognitive features also present, particularly apathy and depression (O'Brien et al., 2003).

1.1.3.2 Diagnosis of vascular dementia

The NINDS-AIREN core clinical criteria for a diagnosis of probable Vascular dementia are the presence of a dementia (as defined above), the presence of cerebrovascular disease, and an interaction between these two things (Roman et al., 1992). Supporting clinical features include gait disturbance, history of falls, urinary symptoms (frequency and urgency), mood or personality changes and deficits in executive function (Roman et al., 1992). The development of vascular dementia can vary depending on the underlying cause and type of vascular lesions and can present with onset three months following a

stroke, a sudden decline in cognition or a stepwise or fluctuating decline in cognition (Roman et al., 1992).

1.1.4 Dementia with Lewy bodies

Dementia with Lewy bodies is the second most common form of neurodegenerative dementia (McKeith, 2004) and accounts for around 7.5% of dementias in secondary care and 4.2% in the community in the UK (Jones & O'Brien, 2014). The underlying cause of Lewy body dementia is the deposition of abnormal proteins containing alpha-synuclein throughout the central and peripheral nervous system (McKeith, 2004).

1.1.4.1 Clinical presentation of dementia with Lewy bodies

The clinical presentation of Lewy body dementia combines both cognitive and Parkinsonian symptoms (McKeith et al., 2017). The cognitive domains most impaired are attention, visuo-spatial function and executive function (Morra & Donovick, 2014). Additionally, neuropsychological features are prevalent, with fluctuations (defined as episodes of variable cognition, attention, behavioural changes, speech difficulties, lethargy and altered consciousness), visual hallucinations (defined as well-defined people or animals, passage hallucinations, illusions and feelings of a presence) and REM sleep behaviour disorder (defined by an individual acting out their dreams, particularly attack or chase dreams) being core symptoms (Moylett et al., 2019). Parkinsonism is also a core feature of dementia with Lewy bodies and is defined by slowness of movement (bradykinesia) and tremor and/or rigidity (McKeith et al., 2017; Morra & Donovick, 2014; Moylett et al., 2019). Supportive clinical symptoms include antipsychotic sensitivity, falls, autonomic dysfunction (such as constipation or urinary incontinence), delusions, apathy, anxiety, depression and excessive daytime sleepiness (McKeith et al., 2017).

1.1.4.2 Diagnosis of dementia with Lewy bodies

Diagnosis of a probable Dementia with Lewy bodies using the DLB consortium criteria (McKeith et al., 2017) is the diagnosis of a dementia (as described above) and the presence of core feature/s and indicative biomarkers (McKeith et al., 2017).

1.1.5 Frontotemporal dementia

Frontotemporal dementia is a common form of dementia and accounts for around 2.7 % of dementia diagnosis in those aged over 65 (Hogan et al., 2016). It is collective term for

three neurodegenerative diseases that are characterized by degeneration in the frontal and temporal lobes (Bang et al., 2015). The deficits are progressive and affect the cognitive domains of executive function and language, as well as behavioural changes (Bang et al., 2015).

1.1.5.1 Clinical presentation of frontotemporal dementia

The most common form of frontotemporal dementia is the behavioural variant. Core symptoms include disinhibition (which can encompass impulsivity, socially inappropriate behaviour, new criminal behaviour and personal remarks), apathy (defined as loss of interest in social activities, work, hobbies and hygiene) and a lack of empathy or sympathy (Bang et al., 2015; Rascovsky et al., 2011), compulsive behaviour (described as repetitive movements, ritualistic behaviours or repetitive speech) and dietary changes (such as changes in eating habits or food preferences) (Bang et al., 2015; Rascovsky et al., 2011). Cognitively, executive function is impaired (Bang et al., 2015; Rascovsky et al., 2011).

1.1.5.2 Diagnosis of frontotemporal dementia

International consensus criteria for the diagnosis of possible behavioural variant frontotemporal dementia requires the presence of a dementia (as described above), and the presence of three of the behavioural or cognitive symptoms (Rascovsky et al., 2011), these symptoms should be persistent. Probable diagnosis requires the above and the presence of significant functional decline and imaging results consistent with bvFTD (Rascovsky et al., 2011).

1.2 Mild cognitive impairment

Mild cognitive impairment (MCI) is characterised as a cognitive impairment that is not severe enough to have a marked impact on an individual's level of daily function (Albert et al., 2011). It can be a pre-cursor to a diagnosis of dementia. Those with amnestic MCI, in which memory impairment is the predominant symptom, are at higher risk of progression to Alzheimer's disease (Huey et al., 2013). Non-amnestic MCI is characterised by the predominance of other cognitive symptoms such as executive function, visuo-spatial and language (Albert et al., 2011). Globally the prevalence has been estimated to be between 15-20% in people aged over 60 (Petersen, 2016). In the

UK it is estimated that there are approximately 650,000 people living with Mild Cognitive Impairment (Richardson et al., 2019).

1.3 How dementia affects driving

1.3.1 Cognitive domains and driving correlates

Driving utilises a variety of cognitive skills (Camilleri & Whitehead, 2023), which can be impaired in dementia (Albert et al., 2011; Langa & Levine, 2014; McKeith et al., 2017; McKhann et al., 2011; Zekry et al., 2002). Previous research has linked impaired cognition to unsafe driving behaviours on the road in people living with a dementia (Barco et al., 2015; Camilleri & Whitehead, 2023; Davis et al., 2018; Devlin et al., 2012; Eby et al., 2012; Pavlou et al., 2017), Table 1 below summarises these driving behaviours and their associations with cognitive domains (Harvey, 2019).

Cognitive domain	Associated impaired driving behaviour
Attention	Control of speed, route following, braking, driving awareness and safety, incorrect turns, collision detection
Memory	Safety errors, route following, incorrect turns, lane errors and identification of traffic signs and landmarks
Visuo-spatial	Control of speed, braking, lane errors, route following, response to traffic, collisions, incorrect turns
Executive function	Response to traffic, collision avoidance, braking, route following, identification of traffic signs and landmarks
Language	Road sign comprehension
Processing speed	Response to traffic, braking
Motor skills	Delayed response to events on the road

Table 1: Cognitive domains and associated impaired driving behaviours

1.4 Crash risk

The impairment of driving ability due to dementia may result in a higher risk of accidents or crashes. There is conflicting evidence in the literature as to the crash risk that these drivers pose, relative to the un-impaired ageing population, with some studies reporting a crash risk of 2-4x higher (Ott, Heindel, et al., 2008; Rizzo et al., 1997; Tuokko et al., 1995), and some finding that no significant increased risk is posed (Carr et al., 2000; Davis et al., 2012; Fraade-Blanar et al., 2018). Most of these studies corrected for driving exposure using either miles driven (Carr et al., 2000; Davis et al., 2012; Ott et al., 2008) or driver years (Fraade-Blanar et al., 2018; Tuokko et al., 1995).

1.5 Comparison of cognitively normal older drivers and those with dementia

A systematic review and meta-analysis found medium to large effects of dementia on driving skills and an increased risk of failing an on-road test (RR=10.77) (Chee et al., 2017), although crash risk may remain low immediately following a diagnosis of dementia (Fraade-Blanar et al., 2018). Drivers with a diagnosis of dementia are more likely to have an impaired awareness of their driving ability when compared to cognitively normal older drivers (Brown et al., 2005; Paire-Ficout et al., 2018), and are likely to drive fewer miles (Davis et al., 2018). When on-road driving behaviours have been compared between drivers with a dementia and cognitively normal older drivers, those with dementia are more likely to:

- Have poor road position, lane maintenance and lane changes (Chee et al., 2017; Davis et al., 2018, 2020; Dawson et al., 2009; Fuermaier et al., 2019; Grace et al., 2005; Uc et al., 2004; Yamin et al., 2016)
- Have poor control of speed (Davis et al., 2020; de Simone et al., 2006; Duchek et al., 2003; Economou et al., 2020; Paire-Ficout et al., 2018; Yamin et al., 2016)
- Have poor response times to or poor awareness of events on the road (Davis et al., 2020; Duchek et al., 2003; Venkatesan et al., 2018)
- Have difficulty with landmark or road sign recognition (Luzzi et al., 2015; Uc et al., 2005)
- Have poor route learning/following ability or forget their destination (Fujito et al., 2016; Luzzi et al., 2015; Uc et al., 2004)
- Have difficulty with turns (Fuermaier et al., 2019; Grace et al., 2005)
- Have difficulty with brake control (either braking suddenly or not coming to a full stop) (Crivelli et al., 2019; Yamin et al., 2016)
- Drive too close to the car in front (Davis et al., 2020; Economou et al., 2020; Paire-Ficout et al., 2018)
- Show poor judgement and anticipation to events on the road (Davis et al., 2018, 2020; Duchek et al., 2003; Fuermaier et al., 2019)
- Have poor response to traffic lights or signs (Crivelli et al., 2019; Luzzi et al., 2015)
- Be involved in a collision (Frittelli et al., 2009; Yamin et al., 2016)

1.6 Current licencing

Around 85% of people aged 60-69 years, and 67% of those aged over 70 hold a current driving licence in the UK (Department of Transport, 2020), with an estimated 6.6% of the population over 65 having a diagnosis of dementia and 15.2% a diagnosis of mild cognitive impairment (Richardson et al., 2019), a large proportion of people who are diagnosed with dementia or mild cognitive impairment are likely to be drivers.

1.7 DVLA guidelines

The DVLA guidelines for medical professionals (DVLA, 2024) state that clinicians are expected to:

- Advise the person on how their medical condition may affect driving safety
- Advise the person of their legal requirement to notify the DVLA of the diagnosis of a relevant condition
- Monitor, manage and treat that person's medical condition with the ongoing consideration of their safety to drive
- Notify the DVLA of a person's medical condition if they cannot or will not do so themselves.

1.7.1 Mild cognitive impairment

Where a person is diagnosed with a cognitive impairment (and not mild dementia), the DVLA guidance states that if there is no likely driving impairment then both Group 1 (car and motorcycle) and group 2 (bus and lorry) licence holders may continue to drive and do not need to inform the DVLA.

The guidance acknowledges the difficulty in assessing safety to drive in those with cognitive impairment due to the variability of presentations and rates of progression. For both licence groups clinician considerations are detailed in Figure 1.

1.7.2 Dementia

For a diagnosis of dementia, the guidance states that for those holding a Group 2 licence, they must not drive and must inform the DVLA, their licence will be refused or revoked (DVLA, 2024).

Individuals with a Group 1 licence may be able to drive but must notify the DVLA of their diagnosis. Again, the difficulty in assessing driving safety in those with a diagnosis of

dementia due to the different presentations and progression rates is recognised, Figure 1 details DVLA clinician considerations.

- That poor short-term memory, disorientation and a lack of judgement and insight will mean that a person is almost certainly not safe to drive
- Disorders of attention causing impairment
- For those with early dementia, if sufficient skills are retained and progression is slow, a licence may be issued and reviewed annually

Figure 1: Clinician considerations when making an assessment of driving safety in Mild Cognitive Impairment and Dementia, adapted from Assessing fitness to drive: a guide for medical professionals (DVLA, 2024)

1.8 Driving and clinical assessment for dementia

Memory clinics are secondary care services specialising in the assessment, diagnosis and management of individuals with a suspected cognitive impairment or dementia (Jolley et al., 2006; Phipps & O'Brien, 2002). The most common point of referral to a memory service is from the GP (Samsi & Manthorpe, 2014), but referrals can also be made via other NHS services (e.g. Neurology departments) and are usually initiated by a hospital stay or visit to an emergency department where there is a concern about cognitive impairment (Samsi & Manthorpe, 2014).

Once a referral has been made, an appointment invitation letter will be sent to the person and needs to include an explanation of the assessment process and the name and role of the clinician they will see (Jethwa et al., 2022) as depending on the structure of the memory service this could be a number of different clinical roles. Consent is an important part of the assessment process and individuals should be asked if they wish to know the outcome, and with whom it can be shared (Jethwa et al., 2022).

The assessment process should be a comprehensive assessment and include an assessment of mental state and cognitive function including the domains of concentration and attention, short and long-term memory, language, executive function, orientation and praxis; an in depth medical history including comorbidities, medications, lifestyle (e.g. exercise, smoking, alcohol use), an assessment of mobility,

hearing and vision; an assessment of functional abilities; a neuropsychological assessment; an informant or carer report and referral for appropriate additional clinical measures such as brain imaging when required (Jethwa et al., 2022; NICE, 2018).

As part of this comprehensive assessment an assessment of driving safety with the person is recommended, and standard 45 of the Memory Services National Accreditation Programme (MSNAP) (Jethwa et al., 2022) quality standards for memory services states that a local written protocol should exist to help clinicians manage issues around driving, and should contain information about informing the DVLA, insurance companies and clinician responsibilities if a person refuses to comply with advice (Jethwa et al., 2022). Additionally, NICE guidelines state that information (either orally or written) should be given to people and their families about how dementia can affect driving, and that there is a need to inform the DVLA and their insurance company at diagnosis (NICE, 2018).

1.9 Clinical assessment of driving safety

Current UK guidelines for the assessment and management of people with mild cognitive impairment or dementia who drive are based upon expert consensus and advocate for a holistic approach to assessing driving risk, incorporating cognitive scores, comorbidities, medication review, functional assessment and collateral information from relatives or carers (Driving & Dementia Working Group, 2018). The 'gold standard' for determining driving safety is a referral for an independent on-road assessment (Allan et al., 2016). It is not practicable to refer everyone who is being assessed for a diagnosis of dementia for an on-road assessment, but where uncertainty exists, clinicians can refer to Drive Mobility for an independent assessment of driving safety.

1.10 Challenges of assessing driving safety in a clinical setting

Clinicians are expected to make an assessment of driving safety as part of the diagnostic process, but this can prove challenging in a clinical setting. Driving is an emotive subject, and clinicians can be concerned about the impact on the therapeutic relationship (Neilson et al., 2019). Additionally, clinicians recognise that they are not experts in driving assessment (Neilson et al., 2019). When surveyed in one study, almost all of the clinicians asked felt that they had possibly missed unsafe drivers (Bennett, Chekaluk, & Batchelor, 2019), and used variable methods for assessing driving safety in

the clinical setting (Bennett, Chekaluk, & Batchelor, 2019; Neilson et al., 2019). The barriers to clinician confidence in addressing this with their patients include a lack of formal training or professional development in this area and the lack of consistent or objective tools available to assess driving safety in a clinical setting (Bennett, Chekaluk, & Batchelor, 2019; Neilson et al., 2019).

1.11 Rationale for this research

Clinicians feel under-equipped to make an informed assessment of driving safety in a clinical setting and feel that a lack of knowledge and an objective tool to help with this difficult area is a barrier in practice. Current guidelines available are based on expert consensus and not evidence based, additionally a Cochrane review concluded that there was a lack of good quality studies in driving and dementia (Martin et al., 2013). Previous research in this area is lacking and has mainly focused on the association between cognitive assessment and driving safety (Bennett et al., 2016; Molnar et al., 2005; Rashid et al., 2020), but there is a large knowledge gap in what might be predictive of on-road driving safety. There is a need for an objective predictive tool that can be used in a clinical setting that has been developed by investigating not only cognitive predictors, but also non-cognitive predictors such as comorbidity, medication, functional and neuropsychiatric features.

1.12 Chapter overview

This research describes the background and process of the investigation into possible clinical predictors of driving safety, and the development and testing of a driving decision aid tool.

1.12.1 Chapter 2 – Literature review

This chapter reviews and reports on the previous literature and current evidence for clinical predictors in the assessment of driving safety for those with a diagnosis of mild cognitive impairment or dementia. The discriminant ability of cognitive tests that have been previously reported are considered and the sensitivity and specificity examined, as well as a critical review of currently available test batteries. Recommendations of what clinicians might find useful in a clinical setting when making an assessment of driving safety based on the previous body of research are proposed.

1.12.2 Chapter 3 – Qualitative study of clinician experiences in assessment of driving safety in dementia

Chapter 3 describes a qualitative study that was carried out to inform the design and useability of a driving decision aid tool. Clinicians were interviewed about their experiences of making an assessment of driving safety in their clinical practice, and how they currently make a decision. Also examined is what is currently available to help clinicians in this process, and what features a useable and useful driving decision aid tool should have.

1.12.3 Chapter 4 – Retrospective notes study – Tool development

In this chapter the investigation of potential clinical predictors in those who had an independent on-road assessment of driving is explained. Individuals who had an on-road assessment of their driving in the preceding 12 months, and had been referred as part of their routine care were recruited. Permission was sought to carry out a retrospective, clinical notes review and data such as cognitive scores, medication, comorbidities, recorded clinician or informant concerns about driving safety and on-road assessment outcome extracted. Potential clinical predictors are identified, and the formation of the driving decision aid tool is described.

1.12.4 Chapter 5 – Test of the decision aid tool in an independent cohort and investigation of advanced assessments

This chapter describes the testing of the driving decision aid tool developed in chapter 4 in an independent cohort. Participants were recruited prospectively, and an assessment incorporating medical history, cognitive measures, functional measures, neuropsychological measures, informant measures and driving questionnaires administered before the on-road assessment of driving safety had taken place. The discriminant ability of advanced assessments, not routinely administered in a clinical setting, are investigated and results reported. Previously published thresholds for cognitive tests are investigated by testing them in this prospectively recruited cohort.

1.12.5 Conclusions

The overall outcomes from the three arms of this research are briefly summarised, and the clinical implications, importance of findings and future directions are discussed.

Chapter 2. Literature review

2.1 Introduction

Clinicians are expected to advise people with dementia or mild cognitive impairment (MCI) about the impact their condition may have on safety to drive (DVLA, 2024). Most clinicians report feeling under-equipped to make this decision (Bennett, Chekaluk, Batchelor, et al., 2019; Lovas et al., 2016; Neilson et al., 2019), and express concern of a negative impact on the therapeutic relationship (Neilson et al., 2019). When asked to predict on-road outcome, clinician accuracy was between 62-78% (Brown et al., 2005; Ott et al., 2005), with clinicians likely to both overestimate and underestimate safety to drive (Bixby, Davis and Ott, 2015; Ranchet et al., 2017). On-road assessment of driving is seen as gold standard, however, this is usually not feasible for all drivers with dementia. Therefore, clinicians may be expected to assess likely driving safety themselves and refer a proportion of people for on-road assessment where appropriate, based on local or national guidelines.

2.2 Driving guidelines

Guidelines based upon expert consensus on the assessment and management of people with dementia or MCI who drive have been developed in countries such as Belgium (Versijpt et al., 2017), the USA (Iverson et al., 2010; Selway, 2018), Canada (Rapoport et al., 2018) and the UK (Driving & Dementia Working Group, 2018). These guidelines advocate a holistic approach to assessing driving risk, in addition to cognitive assessment, also taking into account a report on driving skills from relatives, an assessment of functional ability and consideration of other factors such as comorbidities and sedative medications (Driving & Dementia Working Group, 2018; Iverson et al., 2010; Rapoport et al., 2018; Selway, 2018; Versijpt et al., 2017). Currently available guidelines are primarily based on consensus rather than clear research evidence.

2.3 Previous reviews

Previous reviews in this area have focused on the relationship between cognitive testing and driving performance (Bennett et al., 2016; Brown & Ott, 2004; Kay et al., 2012; Molnar et al., 2006; Rashid et al., 2020; Reger et al., 2004; Silva et al., 2009). Often studies report correlation or effect size differences in cognitive performance in relation

to driving safety, but these are difficult to interpret in clinical practice. This review will place particular attention on studies that reported sensitivity/specificity of cognitive tests to identify unsafe drivers, and those that reported discriminant measures, such as the area under the receiver operating characteristic (AUROC). In addition, previous reviews have given little attention to non-cognitive clinical predictors of driving safety. This review will include evaluation of the evidence for these non-cognitive clinical variables.

2.4 Methods

2.4.1 Aim

The aim of this systematic review was to report the current evidence for clinical predictors of driving safety for those with a diagnosis of dementia or mild cognitive impairment, with the key aim of aiding clinicians assessing driving safety in their clinical practice.

2.4.2 Literature search

A search was made in March 2022, following Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines, of three online databases: Medline (1946 - March 2022), PubMed (1960 - March 2022) and PsycInfo (1967 – March 2022). Due to the differing search mechanisms of each database, different search strategies were used. The search terms used included Dementia, Alzheimer disease, Vascular dementia, Multi-infarct, Neurocognitive disorders, Pick disease of the brain, Lewy body disease, Frontotemporal lobar degeneration, Frontotemporal dementia, Mild Cognitive Impairment, MCI, Automobile/s/driving/driver examination, car, vehicle, motorist.

2.4.3 Detailed literature search

The following mesh terms were used in the detailed search.

2.4.3.1 Medline

(MHX= (Automobile Driving OR Automobile Driver Examination OR Automobiles)) AND ((MHX=(dementia OR Alzheimer Disease OR Dementia OR Dementia, Vascular OR Dementia, Multi-Infarct OR Neurocognitive Disorders OR Pick Disease of the Brain OR Lewy Body Disease OR Frontotemporal Lobar Degeneration OR Frontotemporal Dementia)) OR TS=(MCI) OR TS=(mild cognitive impairment)).

2.4.3.2 Pubmed

(((automobile[MeSH Terms]) OR (automobile driver examination[MeSH Terms])) OR (automobile driving[MeSH Terms])) AND ((((("dementia"[MeSH Terms]) OR ("alzheimer disease"[MeSH Terms])) OR (mild cognitive impairment)) OR (MCI)).

2.4.3.3 PsycInfo

((TS= driver OR driving) OR (KW=automobile OR car OR vehicle OR motorist)) AND (KW= dementia OR Alzheimer OR MCI OR mild cognitive impairment).

2.4.4 Inclusion and exclusion criteria

The inclusion criteria were studies reporting participants with a diagnosis of a dementia or mild cognitive impairment, a measure of driving safety (e.g. on-road assessment, simulator driving assessment or crash data) and data for clinical predictors of the driving safety measure e.g. cognitive tests or other clinical data. As driving simulators are not currently widely available in clinic, simulators were included as an outcome measure but were not considered as a clinical predictor.

The exclusion criteria were studies in which results specific to a dementia and/or MCI cohort could not be extracted (e.g. because they were only reported mixed with other disorders such as head injury) and articles that were not in English, guidelines, books, editorials, reviews, conference abstracts or unpublished data.

2.4.5 Study selection

The results of the literature search, title, abstract and full-text screening are presented in Figure 2. The initial search of databases was completed by the main author (KO). Title, abstract and full text screening were carried out by two reviewers (KO, PCD) independently using Rayyan.ai software. Where there was disagreement between the two raters, the manuscript was included at the title and abstract screening stage. At the full text screening stage, the raters met to discuss disagreements and arrived at a consensus decision.

A further level of screening was carried out on the studies included in the final review to identify those that reported discriminant ability of measures to detect unsafe drivers.

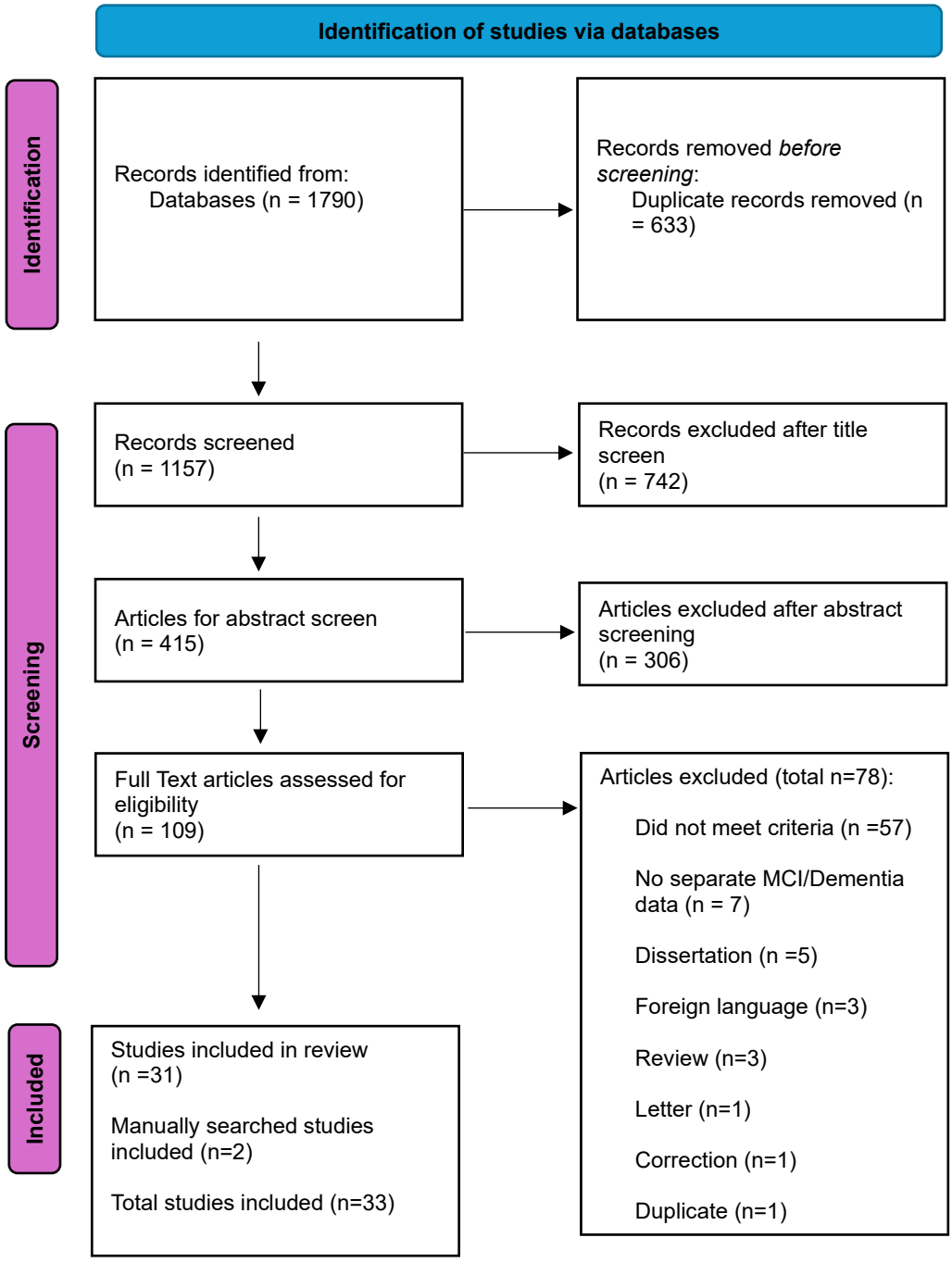

Figure 2: PRISMA flowchart for study selection

2.5 Results

The initial search returned 1790 records, and 1157 were title screened after duplicates were removed. This resulted in 415 abstracts screened, leading to 109 full text records being screened for inclusion and exclusion criteria. Of studies that were excluded, 57 were not studying a relevant topic, 7 had no separate MCI/dementia data, 5 were dissertations, 3 were not in English, 3 were reviews, 1 was a letter without original data,

1 a correction and 1 a duplicate. This resulted in 33 studies included in the final review. From these 33 studies a sub-set of 9 were identified that reported discriminant ability.

Associations between cognitive tests and on-road driving performance are reported in Tables 3-8. The association of cognitive tests with on-road performance has been the focus of previous reviews (Bennett et al., 2016; Brown & Ott, 2004; Kay et al., 2012; Molnar et al., 2006; Rashid et al., 2020; Reger et al., 2004; Silva et al., 2009). This narrative results section will focus specifically on publications reporting the discriminant ability of cognitive tests to detect safe or unsafe drivers (e.g. publications reporting sensitivity/specificity or area under the receiver operating characteristic). However, due to the lack of research in non-cognitive variables it was decided to include these in the review, so no potentially useful tests that could be included in the protocol were missed.

2.5.1 Quality review of selected studies

The sub-set of 9 studies (see Table 2) were also evaluated for quality using the Newcastle-Ottawa scale (Wells et al., 2000). The Newcastle-Ottawa scale contains three items which are individually scored; selection (0-4 points), comparability (0-2 points) and exposure (0-3 points). An overall score of 0-2 indicates poor quality, 3-5 fair quality and 6-9 good or high quality.

Non-cognitive variables have received much less attention in systematic reviews, and therefore all data relating to these variables will be reviewed.

2.5.2 Measures of global cognition

Brief tests of global cognition, such as the Mini Mental State Examination (MMSE) (Folstein et al., 1975), or the Montreal Cognitive Assessment (MoCA) (Nasreddine et al., 2005), are often used in the clinical setting to screen for dementia and monitor disease progression.

2.5.2.1 MMSE

The MMSE demonstrated an AUROC of 0.76 in one study (AD n=81)(Piersma et al., 2018), this study applied cut-off scores of above >=25 and <=19, previously suggested by Belgian consensus guidelines (Versijpt et al., 2017). All participants who scored below the <=19 cut-off failed an on-road driving assessment, however, only 63% scoring

above the >=25 cut-off point passed the on-road assessment (Piersma, Fuermaier, de Waard, et al., 2018). Very similar figures can be derived from another study (Berndt et al., 2008) (dementia n=117), in which 95% of participants with MMSE<=20 failed the on-road assessment, and 65% of participants with an MMSE>=25 passed the on-road assessment.

2.5.2.2 MoCA

In one study (dementia n=34), the subsections of attention alone and visuo-spatial/executive function and attention sub scores combined, demonstrated an AUROC of .81 and .78 respectively. Optimal cut-off scores derived for the attention sub score reports sensitivity of 73% and specificity of 72% to detect unsafe drivers for a score of <5, and sensitivity of 80% and specificity of 67% for a score of <8/11 in the combined attention and visuo-spatial/executive function subsections to detect those likely to fail an on-road assessment (Ma'u & Cheung, 2020).

Author/Year	Study design	Participants	Selection	Comparability	Exposure	Total
Papandonatos (2015)	Cross sectional Case/control	(Combined data) Cognitive impairment n=153/150, Control n=89	4	1	2	7
Carr (2011)	Cross sectional cohort	Dementia n=99	4	1	3	8
M'au (2020)	Cross sectional cohort	Dementia n=34	4	0	3	7
Lincoln (2006)[a]	Cross sectional Case/control	Dementia n=37, Control n=33	4	1	2	7
Lincoln (2006)[b]	Cross sectional cohort	Dementia n=17	4	1	3	8
Lincoln (2010)	Cross sectional cohort	Dementia n=65	4	0	3	7
McKenna (2007)	Cross sectional cohort	Dementia n=68	4	1	2	7
Piersma (2016)	Cross sectional Case/control	Dementia (AD) n=81, Control n=45	4	1	3	8
Piersma (2018)	Cross sectional cohort	Dementia n=34 (VaD n=14, FTD n=12, DLB n=8)	4	0	3	7

Table 2: Literature review results – the Newcastle-Ottawa scale for studies that reported AUC or sensitivity & specificity

Note: Lincoln (2006)[a/b] refer to separate cohorts reported in one paper.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Fox (1997)	Probable AD n=19	On-road Driver Performance Test (total driving score) (Pass (n=7)/Fail (n=12))	MMSE	**Correlation**: total driving score (r=.63, p=.004).
Bieliauskas (1998)	AD n=9	On-road (Safe/Unsafe, Number of Driving Errors)	MMSE	**Correlation:** ns.
Whelihan (2005)	Questionable dementia n=23	On-road (Pass/Fail) Rhode Island Driving Evaluation (RIDE) Score (0-570)	MMSE	**Correlation**: ns.
			MDRS	**Correlation**: ns.
Lincoln (2006)	Dementia n=37	On-road Nottingham Neurological Driving Assessment (Safe (n=27)/Unsafe (n=10))	MMSE	**Group comparison safe vs unsafe (median (IQR)):** 24(21-26) vs 21(15.8-25.5), p=0.11.
Berndt (2008)	Dementia n = 117	On-road WURT (Pass (n=50)/Fail (n=65))	MMSE	**Group comparison (mean (SD)):** 25.1 (2.6) vs 21.8 (3.5), p=<.001. d= 1. 07. **Cut-off score sensitivity for unsafe:** (MMSE 25-29), 17/26 passed – 9/26 failed, 35%. (MMSE 21-24), 28/66 passed – 38/66 failed, 58%. (MMSE 13-20), 1/19 passed – 18/19 failed, 95%.
Ott (2008) (maze)	AD n=88	On-road Rhode Island Road test score (0-108)	MMSE	**Correlation:** road test score (r=-.28, p<.005).

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Frittelli (2009)	Probable AD n=20 MCI n=20	Simulated road driving (mean score of 5 variables).	MMSE	**Correlation:** ns.
Carr (2011)	Dementia n=99	On-road mWURT (Pass (n=34)/Fail (n=65))	MMSE	**Group comparison:** ns.
			Short Blessed Test	**Group comparison (Mean (SD))**: 5.8(5.3) vs 10.5(7.2); d=0.74, p=.003.
Barco (2015)	Dementia n=53	On-road mWURT (Pass (n=23)/Fail(n=30))	Short Blessed Test	**Group comparison (Mean (SD))**: ns.
Esser (2015)	Brain Injury n=17 Dementia n=50 Stroke n=39 PD n=13 MS n=16	On-road (Pass (n=14)/Fail (n=36))	MoCA	**Dementia group:** (score<12, pass n=0, fail n=8), (score>12, 14=pass, 28=fail).
Yamin (2015)	DLB n=15	Simulated road driving (simulator error/rater score/number of crashes)	MMSE	**Correlation:** (total errors) r= -.53, p=.43. (rater score) r= -.62, P=.013. (crashes) r=.-.32, p=.23.
			MDRS	**Correlation:** (total errors) r= 0.55, p=.85. (rater score) r= -.45, p=.10. (crashes) r=-.35, p=.21.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Yamin (2016)	Mild AD n= 20	Simulated road driving (simulator error/rater score/number of crashes)	MMSE	**Correlation:** (rater score) r=-.40, p=.08. (total errors) r=-.13, p=.6. (crashes) r=-.19, p=.42.
			MDRS	**Correlation:** (rater score) r=-.38, p=.1. (total errors) r=.11, p=.63. (crashes) r=.1, p=.38.
Unsworth (2016)	AD n=47 Cognitive decline n=14	On-road (fit (AD n= 30/Cd n=10) vs unfit (AD n=17/Cd n=6))	MMSE	**Group comparison (mean (SD))**: AD: 23.89 (3.31) vs 22.35 (3.52), d=0.75. Cog Decline Fit: 27.50(2.17) vs 24.67(3.33), d = 1.0.
Piersma (2016)	Dementia n=73	On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Pass (n=35)/Fail (n=38))	MMSE	**Correlation:** (FitToDrive) r=.46, p<.001. **Group comparison (mean (SD)):** 25.11 (2.23) vs 21.98(3.98), d=0.95, p<.001.
Fuermaier (2017)	MCI n=18	On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Pass (n=12)/Fail (n=6))	MMSE	**Group comparison (mean (SD)):** 27.25 (2.90) vs 26.27 (1.86), d =0.24.
Piersma a (2018)	VaD n=14 FTD n=12 DLB n=8	On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Pass (n=14)/Fail (n=19))	MMSE	**Group comparison (Mean (SD)):** 24.9 (2.7) vs 23.6 (3.3), d=0.46.
Piersma b (2018)	Mild AD n= 81	On-road (Pass (n=35)/Fail (n=46))	MMSE	**ROC:** AUC=.76, p<.001. **Cut-off score vs classification**: (MMSE >=25), 22/35 (63%) passed. (MMSE 20-24), 13/33 (39%) passed. (MMSE <=19), 0/13 (0%) passed.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Ma'u (2020)	Dementia n=34	OTRS driving assessment: On-road (Pass (n=19)/Fail (n=15)).	MoCA	**MoCA Attention Group comparison (Mean (SD)):** 4.5(1.4) vs 3.5(1.4), d=0.71, p=.002. **ROC:** AUC=.81, p=.003. **Cut-off score:** <5 sensitivity = 73%, specificity = 72%. **MoCA Visuo-spatial/Executive & attention combined Group comparison (Mean (SD)):** 8.3(1.9) vs 6.3(1.8), d=1.08, p=.005. **ROC: AUC=**.78, p=.006. **Cut of score:** <8 sensitivity = 80%, specificity = 67%.

Table 3: Literature review results for global cognitive domain

Abbreviations: AD=Alzheimer's Disease; DLB=Lewy Body Dementia; FTD=Frontotemporal Dementia; MCI=Mild Cognitive Impairment; MDRS=Mattis Dementia Rating Scale; MMSE=Mini=Mental State Examination; MoCA=Montreal Cognitive Assessment; MS=Multiple Sclerosis; NS=Not Significant; PD=Parkinson's Disease; VaD=Vascular Dementia; (m)WURT=(modified) Washington University Road Test.

2.5.3 Attention, concentration and executive function

2.5.3.1 Trail Making Test A&B (TMT)

The Trail Making test (Reitan, 1958) is a frequently researched measure and comprises part A (which is also a measure of processing speed) and part B. In a large study, Papadonatos and colleagues developed cut-off values for TMT A and B from a development cohort (cognitive impairment n=153) and then tested these in an independent cohort (cognitive impairment n=150) (Papandonatos et al., 2015). Using a cut-off of > 48 seconds for safe/marginal vs unsafe drivers, a sensitivity to detect unsafe drivers of 63%and specificity of 70% was reported for TMT-A. Using a cut-off of >108 seconds for safe/marginal vs unsafe drivers a sensitivity of 0.88 and specificity of 0.40 was reported for TMT-B.

2.5.3.2 Mazes

In one study (dementia n=34), completion time of the maze navigation test (Whelihan et al., 2001) demonstrated an AUROC discriminant ability (AUC .74), and an optimal cut-off score of >443 seconds was reported to give sensitivity of 73% and specificity of 68% for detecting those likely to fail an on-road assessment (Ma'u & Cheung, 2020). A second study found that the Snellgrove Maze (Snellgrove, 2005), time, TMT-A time, AD-8 (Galvin et al., 2005) score and clock drawing task each had an AUC of .75-.77 (Carr et al., 2011).

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Fox (1997)	Probable AD n=19	On-road Driver Performance Test (total driving score) (Pass (n=7)/Fail (n=12))	TMT A	**Correlation:** ns.
			DSST	**Correlation:** ns.
Bieliauskas (1998)	AD n=9	On-road (Safe/Unsafe, Number of Driving Errors)	Visual Search Test	**Correlation:** ns.
			Simple Reaction Time	**Correlation:** ns.
			Choice Reaction Time	**Correlation:** ns
Whelihan (2005)	Questionable dementia n=23	On-road (Pass/Fail) Rhode Island Driving Evaluation (RIDE) Score (0-570).	TMT A	**Correlation:** ns.
			Letter cancellation (omissions)	**Correlation:** ns.
			Action Fluency	**Correlation:** ns.
			UFOV 1	**Correlation:** r=.61, p=<.01.
			UFOV 2	**Correlation:** r=.46, p=<.05.
			UFOV 3	**Correlation:** r=.46, p=<.05.
Grace (2005)	Mild AD n=21	On-road (Safe (n=9)//Unsafe (n=11)) Rhode Island Road test score (0-108)	TMT A	**Group comparison (Mean (SD)):** 42.1(17.3) vs 106.6(56.1)**;** d = 1.55; p<.01.
			NAB Driving Scenes (score 0-70)	**Group comparison (Mean (SD)):** 27.8(6) vs 25.4(7); d = 0.37; p<.01.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Lincoln (2006)	Dementia n=37	On-road Nottingham Neurological Driving Assessment (Safe (n=27)/Unsafe (n=10))	Test of everyday attention (Elevator counting/distraction); (Telephone dual)	**Group comparison:** ns.
			Test of everyday attention (Telephone search)	**Group comparison (Median (IQR):** 6(5.5-8.0) vs 5(4.8-6.0), p=.008.
			Dot cancellation (Time/Errors/False +)	**Group comparison:** ns.
			Balloons Test A/B	**Group comparison:** ns.
Ott (2008)	AD n=88	On-road Rhode Island Road test score (0-108)	TMT A	**Correlation:** r = .36, p< .005.
Dawson (2009)	AD n=40	On-road Iowa DOT Drive test scoring (total safety errors)	TMT A	**Correlation Coefficient estimate (SE):** b= 2.97(1.46), p=<.05.
			UFOV (Sum 4 subsets)	**Correlation Coefficient estimate (SE):** b= 3.44(1.72), p=<.10.
Selander (2010)	Cognitive deficits/dementia n=119	On-road (Pass (n=54)/Fail (n=65))	Dot cancellation (time(s)/errors/false+)	**Group comparison (Mean (SD)):** ns.
Carr (2011)	Dementia n=99	On-road mWURT (Pass (n=35)/Fail (n=65))	TMT A	**Group comparison (Mean (SD)):** 45.8 (17.2) vs 79.9(42.8); d=1.05, p=<.001
			UFOV (subtest 2(msec))	**Group comparison (Mean (SD)):** 216.8(129) vs 342.9(136.5); d=0.95, p=.01.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Barco (2015)	Dementia n=53	On-road mWURT (Pass (n=23)/Fail(n=30))	TMT A	**Group comparison (Mean (SD)):** ns.
			Useful field of vision	**Group comparison (Mean (SD)):** ns.
Yamin (2015)	DLB n=15	Simulated road driving (simulator error/rater score/number of crashes)	Test of everyday attention (Visual selection/sustained/switching)	**Correlation:** ns.
			Useful field of view (processing speed).	**Correlation:** Rater score: r=−.55, p=.03. Errors: ns.: Crashes: ns.
			Useful field of view (divided attention)	**Correlation:** ns.
			Useful field of view (selective attention)	**Correlation:** ns.
Papandonatos (2015)	Dementia n=303	On-road mWURT (Safe (n=48)/Marginal (n=15)/Unsafe (n=87)/Total n=150))	TMT A	**Test cohort: AUC(CI):** Safe/Marginal vs Unsafe: 0.74 (0.66–0.82). Cut-off score >48. Safe/Marginal vs Unsafe: **Sensitivity** 0.63, **Specificity** 0.70.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Yamin (2016)	Mild AD n= 20	Simulated road driving (simulator error/rater score/number of crashes)	Test of everyday attention (Visual selection/sustained/switching)	**Correlation:** Visual selection: ns. Sustained: Rater: r=.65, p=.002, Error/Crash: ns. Switching: ns.
			Useful field of view (processing speed).	**Correlation:** ns.
			Useful field of view (divided attention)	**Correlation:** Rater score: r=.56, p=.01). Errors/Crashes: ns.
			Useful field of view (selective attention)	**Correlation:** ns.
Piersma (2016)	Dementia n=73	On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Pass (n=35)/Fail (n=38))	Reaction Time (RT1) (visual)	**Correlation:** RT1(msec): r=-.31, p=.005, d=0.68. RT1 Motor time (msec) r=-.34, p=.002, d=0.78. RT1 (variability in RT): r=-.22, p=<.05, d=0.47. RT1 (variability in MT): ns.
			Reaction Time (RT2) (auditory)	**Correlation:** RT2(msec): r=-.37, p=.001, d=0.84. RT2 Motor time (msec): r=-.4, p=<.001, d=0.90. RT2 (variability in RT): r=-.29, p=.009, d=0.60. RT2 (variability in MT): ns.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
			Reaction Time (RT3) (inhibition)	**Correlation:** RT3(msec): r=-.28, p=.01, d=1.01. RT3 Motor time (msec) r=-.29, p=.008, d=0.67. RT3 (variability in RT): r=-.23, p=.04, d=0.46. RT3 (variability in MT): r=-.27, p=.02, d=0.60.
Fuermaier (2017)	MCI n=18	On-road (Pass (n=12)/Fail (n=6)) Test Ride Investigating Practical Fitness to drive	RT S2 RT (ms)	**Group comparison Mean (SD):** 262.8(53.6) vs 270.5(54.2), d = 0.14.
Venkatesan (2018)	AD n=42	On-road (RIRT Total errors/Driving awareness/Speed control) and Naturalistic (CDAS Total errors/Response to traffic/Lane keeping)	Visual Search (Luminance-Motion/Color-motion)	**Correlation:** L+M Hit Rate vs RIRT Speed control, r=-.34, p<0.05. C+M False alarm vs RIRT total errors, r=.33, p<0.05. C+M False alarm vs RIRT Driving awareness, r=.37, p<0.05. C+M False alarm vs CDAS Total errors, r=.47, p<0.05. C+M False alarm vs CDAS Response to traffic, r=.41, p<0.05. All others: ns.
			TMT A	**Correlation:** TMTA errors vs RIRT total errors, r=0.34, p=.03. TMT A errors vs RIRT Driving awareness, r=0.32, p=.04.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Piersma (2018)	VaD n=14, FTD n=12, DLB n=8.	On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Pass (n=14)/Fail (n=19))	RT S2 RT (ms)	**Group comparison (Mean (SD))**: 281.3 (47.5) vs 426.9 (258.5), d=0.75.
Ma'u (2020)	Dementia n=34	OTRS driving assessment: On-road (Pass (n=19)/Fail (n=15)).	TMT A	**T Test:** ns.

Table 4: Literature results for attention and concentration cognitive domain

Abbreviations: AD=Alzheimer's Disease; CDAS=Composite Driving Assessment Scale; CRT=Choice Reaction Time; DLB=Lewy Body Dementia; DSST=Digit Symbol Substitution Test; MCI=Mild Cognitive Impairment; NS= Not Significant; RIRT=Rhode Island Road Test; RT=Reaction Time; TEA=Test of Everyday Attention; TMT-A=Trail Making Test A; UFOV=Useful Field of View; (m)WURT=(modified) Washington University Road Test.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Fox (1997)	Probable AD n=19	On-road Driver Performance Test (total driving score) (Pass (n=7)/Fail (n=12))	TMT B	**Correlation:** ns.
Bieliauskas (1998)	AD n=9	On-road (Safe/Unsafe) (Driving Errors)	Shipley institute of living scale - Abstraction	**Correlation:** Total errors (-turning errors): r = –.74, p = .02.
			Wisconsin card sorting test (errors/responses)	**Correlation:** ns.
Grace (2005)	Mild AD n=21	On-road (Safe (n=9)//Unsafe (n=11)) Rhode Island Road test score (0-108)	TMT B	**Group comparison (Mean (SD)):** 184.6(94) vs 289.9(24.4); d=1.53, p<.001.
			Computerised Mazes (Draw time/Planning time)	**Group comparison (Mean (SD)):** Planning time: 45.8(29.4) vs 60.7(27.1); d=0.53, p<.001. Draw time: 99(59.7) vs 160.6(100.5); d=0.75, p<.001.
			Rey-Osterrieth Complex Figure (Organisation)	**Group comparison (Mean (SD)):** 5(1.6) vs 3.5(1), d=1.16, p<.01.
Whelihan (2005)	Questionable dementia n=23	On-road (Pass/Fail) Rhode Island Driving Evaluation (RIDE) Score (0-570).	Ruff unique designs	**Correlation:** ns.
			TMT B	**Correlation:** r=.46, p=<0.5.
			Maze navigation (time/Errors)	**Correlation:** Errors ns. Time: r=.52, p=<.01.
			Wisconsin card sorting test (responses/errors)	**Correlation:** ns.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Lincoln (2006)	Dementia n=37	On-road Nottingham Neurological Driving Assessment (Safe (n=27)/Unsafe (n=10))	Stroop	**Group comparison (Median (IQR):** 19.5 (10.3-33.5) vs 11 (-10-114), p=.49.
			Behavioural Assessment of the Dysexecutive Syndrome (BADS) (Key Search/Rule Shift)	**Group comparison (Median (IQR):** Rule shift: ns. Key search: ns.
			Square matrices (directions/compass/road sign recognition)	**Group comparison (Median (IQR)):** Directions: ns. Compass: ns. Road sign recognition: 4(2-5) vs 2(0.8-4.3), p=0.07.
Ott (2008)	AD n=88	On-road (Safe/Marginal/Unsafe) Rhode Island Road test score (0-108)	TMT B	**Correlation:** ns.
			Rey-Osterrieth Complex Figure (Organisation)	**Correlation**: ns.
			Computerised Mazes (Total score/total drawing time/total overall time)	**Correlation:** Total score r=-.28, p <.05. Total drawing time: r=.38, p<.005. Maze overall time: r=.40, p<.0005.
Dawson (2009)	AD n=40	On-road Iowa DOT Drive test scoring (total safety errors)	TMT B	**Correlation Coefficient estimate (SE):** ns.
Selander (2010)	Cognitive deficits/dementia n=119	On-road (Pass (n=54)/Fail (n=65))	Road sign recognition (3 mins/5 mins)	**Group comparison:** 3 mins: d=0.58, p=0.001. 5 mins: d=0.59, p=0.001.
			Square matrices (Compass/directions)	**Group comparison:** ns.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Carr (2011)	Dementia n=99	On-road mWURT (Pass (n=35)/Fail (n=65))	TMT B (Seconds)	**Group comparison (Mean (SD**)): 151.8(75.7) vs 226.9(79.6); d=0.97, p=<.001
			Digit Span (Forwards)	**Group comparison (Mean (SD)):** ns.
			Digit Span (Backwards)	**Group comparison (Mean (SD)):** 5.6(1.9) vs 4.4(2); d=0.62, p=0.009.
			Maze (seconds)	**Group comparison (Mean (SD**)): 35.2(12.3) vs 62.5(43.9); d=0.85, p=<.001.
Barco (2015)	Dementia n=53	On-road mWURT (Pass (n=23)/Fail(n=30))	TMT B (Seconds)	**Group comparison:** ns.
			Snellgrove maze test (Seconds)	**Group comparison:** ns.
Papandonatos (2015)	Cognitive impairment n=303	On-road mWURT (Safe (n=48)/Marginal (n=15)/Unsafe (n=87)/Total n=150))	TMT B	**Logistic regression model: AUC(CI):** Safe/Marginal vs Unsafe: 0.76 (0.68–0.84). Cut-off score >108. Safe/Marginal vs Unsafe: **Sensitivity =** 0.88, **Specificity =** 0.40.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Piersma (2016)	Dementia n=73	On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Pass (n=35)/Fail (n=38))	TMT B (TMT B-TMT A)	**Correlation:** r=.23, p=.039, d=0.43.
			Maze 1(sec)	**Correlation:** ns.
			Maze 2 (sec)	**Correlation:** r=.33, p=.003, d=0.73.
Venkatesan (2018)	AD n=42	On-road (RIRT Total errors/Driving awareness/Speed control) and Naturalistic (CDAS Total errors/Response to traffic/Lane keeping)	TMT B	**Correlation:** TMT B errors vs CDAS Response to traffic, r=0.37, p=.02. TMT B errors vs RIRT Driving awareness, r=0.41, p=.01.
Ma'u (2020)	Dementia n=34	OTRS driving assessment: On-road Pass (n=19/Fail (n=6)).	Maze navigation test (time/errors)	**Group comparison Maze navigation time (Mean (SD)):** 410.7(217.6) vs 583.8(212.6), d=0.8, p=.02. **ROC:** AUC=.74, p=.019. **Cut of score:** <443 (seconds), sensitivity = 73%, specificity=68%. **Errors:** ns.
			TMT B	**T test:** ns.

Table 5: Literature review results for Executive function cognitive domain

Abbreviations: AD=Alzheimer's Disease; BADS= Behavioural Assessment of the Dysexecutive Syndrome; CDAS=Composite Driving Assessment Scale; DLB=Lewy Body Dementia; MCI=Mild Cognitive Impairment; NS=Not Significant; Rey-O= Rey-Osterrieth Complex Figure; RIRT=Rhode Island Road Test; SILS= Shipley Institute of Living Scale; TMT-B=Trail Making Test B; WCST=Wisconsin Cart Sorting Test; (m)WURT=(modified) Washington University Road Test.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Fox (1997)	Probable AD n=19	On-road Driver Performance Test (total driving score) (Pass (n=7)/Fail (n=12))	Visual form discrimination test	**Correlation:** ns.
			Judgement of line orientation test	**Correlation:** ns.
			Picture completion	**Correlation:** ns.
			Block design	**Correlation:** Total score: r=.54, p=.02.
Bieliauskas (1998)	AD n=9	On-road (Safe/Unsafe) (Driving Errors)	Figure ground test	**Correlation:** Total errors (-turning errors): r= (1) –.76, p=0.28.
Whelihan (2005)	Questionable dementia n=23	On-road (Pass/Fail) Rhode Island Driving Evaluation (RIDE) Score (0-570).	Visual form discrimination test (total score/peripheral errors)	**Correlation:** Peripheral errors: ns. Total score: ns.
Grace (2005)	Mild AD n=21	On-road (Safe (n=9)//Unsafe (n=11)) Rhode Island Road test score (0-108)	Rey-O complex figure (BQSS Presence)	**Group comparison Mean (SD):** 13.8 (3.7) vs 11.8 (3.3); d =0.56.
Lincoln (2006)	Dementia n=37	On-road Nottingham Neurological Driving Assessment (Safe (n=27)/Unsafe (n=10))	VOSP Incomplete letters	**Group comparison:** ns.
			VOSP Cube analysis	**Group comparison:** ns.
Ott (2008)	AD n=88	On-road (Safe/Marginal/Unsafe) Rhode Island Road test score (0-108)	Rey-O complex figure (BQSS Presence/Accuracy)	**Correlation:** ns.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Dawson (2009)	AD n=40	On-road Iowa DOT Drive test scoring (total safety errors)	Rey-O complex figure (Copy)	**Correlation Coefficient estimate (SE):** b= 3.54 (1.54), p=<.05.
			WAIS-R Block design	**Correlation Coefficient estimate (SE):** ns.
			Judgement of line orientation test	**Correlation Coefficient estimate (SE):** ns.
Carr (2011)	Dementia n=99	On-road mWURT (Pass (n=35)/Fail (n=65))	Clock (Freund scoring)	**Group comparison (Mean (SD)):** 6.2(1.2) vs 4.2(2.5); d=1.10, p=<.001.
Barco (2015)	Dementia n=53	On-road mWURT (Pass (n=23)/Fail(n=30))	Clock (Freund scoring)	**Group comparison:** ns.
			Visual closure	**Group comparison:** ns.
Yamin (2015)	DLB n=15	Simulated road driving (simulator error/rater score/number of crashes)	Visual Object and Space Perception (VOSP) (Object/Space)	**Correlation:** Object vs Rater score: ns. Object vs Errors: ns. Object vs Crashes: ns. Space vs Rater score: r=−.62, p=.013. Space vs Errors: ns. Space vs Crashes: ns.
Yamin (2016)	Mild AD n= 20	Simulated road driving (simulator error/rater score/number of crashes)	Visual Object and Space Perception (VOSP) (Object/Space)	**Correlation:** Object vs Rater score: ns. Object vs Errors: ns. Object vs Crashes: r=.65, p=.002. Space vs Rater score: ns. Space vs Errors: ns. Space vs Crashes: ns.
Piersma (2016)	Dementia n=73	On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Pass (n=35)/Fail (n=38))	Drawings (House/Star/Cube/Clock)	**Correlation:** Drawings (total score): r=.43, p=<.001, d=0.96.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Venkatesan (2018)	AD n=42	On-road (RIRT Total errors/Driving awareness/Speed control) and Naturalistic (CDAS Total errors/Response to traffic/Lane keeping)	Clock	**Correlation:** Clock vs CDAS Total errors, r=0.37, p=.02.

Table 6: Literature review results for Visuo-spatial cognitive domain

Abbreviations: AD=Alzheimer's Disease; CDAS=Composite Driving Assessment Scale; DLB=Lewy Body Dementia; JLO=Judgement of Line Orientation; MCI=Mild Cognitive Impairment; NS=Not Significant; Rey-O= Rey-Osterrieth Complex Figure; RIRT=Rhode Island Road Test; VFDT=Visual Form Discrimination Test; VOSP=Visual Object and Space Perception; WAIS-R=Wechsler Adult Intelligence Scale (Revised); (m)WURT=(modified) Washington University Road Test.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Fox (1997)	Probable AD n=19	On-road Driver Performance Test (total driving score) (Pass (n=7)/Fail (n=12))	Benton visual retention (Correct/Errors)	**Correlation:** ns.
Grace (2005)	Mild AD n=21	On-road (Safe (n=9)//Unsafe (n=11)) Rhode Island Road test score (0-108)	Hopkins verbal list learning test - revised (total learning/delay/discrimination)	**Group comparison (Mean (SD)):** Total learning:11.22 (5.70) vs 9.54 (4.18); d=0.34, p<.001. Delay:0.56 (1.67) vs 1.45 (1.81); d=0.51, p<.001. Discrimination: 3.11 (3.14) vs 6.30 (2.31); d=1.16, p<.001.
Whelihan (2005)	Questionable dementia n=23	On-road (Pass/Fail) Rhode Island Driving Evaluation (RIDE) Score (0-570).	Brief visual memory test - Revised (total learning/Delayed recall)	**Correlation:** Total learning :ns. Delayed recall: ns.
Lincoln (2006)	Dementia n=37	On-road Nottingham Neurological Driving Assessment (Safe (n=27)/Unsafe (n=10))	Salford objective recognition test (Faces (Immediate/Delayed)/Words (Immediate/Delayed)	**Group comparison (Median (IQR):** Faces immediate: ns. Faces delayed: ns. Words immediate: ns. Words delayed: ns.
Ott (2008)	AD n=88	On-road (Safe/Marginal/Unsafe) Rhode Island Road test score (0-108)	Hopkins verbal list learning test (total learning/delay)	**Correlation:** Total learning: r=-.47, p=<.005. Delay: ns.
Dawson (2009)	AD n=40	On-road Iowa DOT Drive test scoring (total safety errors)	Benton visual retention test	**Correlation Coefficient estimate (SE)**: b=4.12 (1.55), p=<0.05.
			Rey - O Complex figure test (recall)	**Correlation Coefficient estimate (SE):** b=-4.44 (2.38), p=<0.05.
			Rey-AVLT	**Correlation Coefficient estimate (SE):** ns.

Table 7: Literature review results for Memory cognitive domain

Abbreviations: AD=Alzheimer's Disease; AVLT=Auditory Verbal Learning Test; BVMT=Brief Visual Memory Test; BVRT=Benton Visual Retention Test; CFT= Complex Figure Test; DLB=Lewy Body Dementia; HVLT=Hopkins Verbal Learning Test; MCI=Mild Cognitive Impairment; NS=Not Significant; Rey-AVLT=Rey Auditory Verbal Learning Test; Rey-O= Rey-Osterrieth Complex Figure; SORT=Salford Object Recognition Test; (m)WURT=(modified) Washington University Road Test.

Author (Year)	Cohort	Type of driving assessment & outcome measures	Measure	Results
Bieliauskas (1998)	AD n=9	On-road (Safe/Unsafe) (Driving Errors)	Shipley institute of living scale - Verbal	**Correlation:** r=-.67, p=<.05.
Whelihan (2005)	Questionable dementia n=23	On-road (Pass/Fail) Rhode Island Driving Evaluation (RIDE) Score (0-570).	Controlled oral word association (Naming/Animals)	**Correlation:** ns.

Table 8: Literature review results for Language cognitive domain

Abbreviations: AD=Alzheimer's Disease; COWA=Controlled Oral Word Association; NS=Not Significant; SILS=Shipley Institute of Living Scale.

2.5.4 Test batteries for predicting driving safety

The Nordic Stroke Driver Screening Assessment (NorSDSA) was developed for stroke patients and comprises dot cancellation, compass and road sign recognition tasks. When applied to a cohort of cognitive deficit/dementia patients it showed sensitivity of 54% and specificity of 46% to detect unsafe drivers (Selander et al., 2010).

Three test batteries were identified that were developed in cohorts including participants with dementia and then tested in dementia/MCI cohorts.

2.5.4.1 Rookwood Driving Battery (RDB) (McKenna & Bell, 2007)

This battery was originally developed on a mixed cohort (e.g. head injury, stroke) n=142 of which dementia n=17, with items significantly correlated with on-road score included in the final battery. These include tests of visual perception, executive function, praxis, comprehension and pre-morbid IQ. Full details of what was tested for inclusion in the battery and cohort demographics can be found in Table 9.

A cut-off score of >10 was developed and tested in the mixed disease cohort (McKenna et al., 2004). In a dementia cohort (n=60), this cut-off yielded a sensitivity to detect unsafe drivers of 54% and specificity of 66% (McKenna & Bell, 2007).

Tests in battery	Development cohort and On-road Measure	Test cohort and On-road Measure	Test Cohort Results
Visual Perception Incomplete Letters (VOSP) Position discrimination (VOSP) Cube analysis (VOSP) Letter cancellation *Executive Function* Letter cancellation/listening task Weigl sorting task Key search test (BADS) Action programme (BADS) Rule shift cards test (BADS) *Praxis* Copying six hand movements Produce five gestures Mime use of six objects *Comprehension* Shortened version of Modified Token Test *Premorbid IQ* NART	CTRL n=200 (Age 20-79), *Experimental Group* n=142 (Age 20-85) n=Right CVA (35) n=Left CVA (27) n=Head Injury (18) n=Dementia (17) n=Sub cortical CVA (4) n=PD/Huntington's (9) n=Anoxia/Cerebral infarction (6) n=Mixed/Stroke (10) n=Other (16), On-road score	Dementia n= 60 (Age 50-88) Full n=543, On-road Score	**Full cohort:** Cognitive Score vs On-road score (r=.66 p=<.001). **Test**: On-road fail (n=41): predicted fail 19/41, sensitivity 46% On-road pass (n=12): predicted pass 8/12, specificity 67%

Table 9: Literature review results – The Rookwood test battery

Abbreviations: BADS=Behavioural Assessment of Dysexecutive Syndrome; CTRL=Control; CVA=Cerebrovascular Accident; NART=National Adult Reading Test; VOSP=Visual Object Space Perception battery.

2.5.4.2 Nottingham Neurological Driving Assessment (NNDA) (Lincoln et al., 2006, 2010)

This test battery was developed in a dementia cohort (n=37) with participants completing an on-road assessment. Discriminant function analysis was used to identify the best combination of tests to predict on-road safety, with the battery comprising tests of global cognition, attention and reasoning skills, executive function, recognition memory, speed of information processing and visuo-spatial skills (see Table 10 for full details of tests and details of excluded tests and missing values). Two equations were developed utilising cognitive tests that were predictive of either being safe or unsafe (see Table 10). If the result of the 'safe' equation was higher than the 'unsafe', the driver was predicted to be safe, and vice versa. This was initially tested in an independent cohort of 17 dementia participants, reported in the same paper. Five patients were found to be definitely unsafe on the on-road test, of which two were predicted to be unsafe in the cognitive test (sensitivity 40%). Twelve participants were found to be 'probably' or 'definitely' safe on the on-road test. Eight of these participants were predicted to be safe in the cognitive battery (specificity 67%).

Further validation of the equations was carried out in another dementia cohort (Lincoln et al., 2010). In this sample eight of eighteen participants who failed the on-road test were predicted to fail (sensitivity to predict unsafe drivers = 44%), and forty of forty-five drivers that passed the on-road assessment were predicted to pass (specificity = 89%).

Tests in development and included in final battery (bold)	**Development cohort and On-road Measure**	**Test and validation cohort and On-road Measure**	**Test and validation Cohort Results**
SDSA Dot cancellation (**time/errors**/false +), Square matrices (**directions/compass/road sign recognition), MMSE**, **Stroop**, TEA (elevator counting/elevator counting with distraction/telephone search/telephone search dual task), BADS (**rule shift profile/key search**), VOSP (**incomplete letters**/cube analysis), SORT (faces immediate/faces delayed/**words immediate/words delayed**), AMIPB (**task A/task B**), Balloons test (A/B).	Dementia n=37 (Age 52-87), On-road Nottingham Neurological Driving Assessment (Safe/Unsafe)	Test: Dementia n=17 (Age 60-89), Validation: Dementia n=65 (Age 59-88), On-road Nottingham Neurological Driving Assessment (Safe/Unsafe)	**Test:** Safe n=12 vs Unsafe n=5. **Safe** = Sensitivity 67%, Specificity 73%. **Validation:** On-road fail (n=18): predicted fail 8/18, sensitivity 44% On-road pass (n=45): predicted pass 40/45, specificity 89%

Table 10: Literature review results – The Nottingham Neurological Driving Assessment (NNDA)

Abbreviations: AMIPB=Adult Memory and Information Processing Battery; BADS=Behavioural Assessment of Dysexecutive Syndrome; DV=Dependent Variable; IV=Independent Variable; MMSE=Mini=Mental State Examination; SDSA=Stroke Drivers Screening Assessment; SORT=Salford Object Recognition Test; TEA=Test of Everyday Attention; VOSP=Visual Object Space Perception battery.

2.5.4.3 Piersma et al. 2016 (Piersma et al., 2016)

This battery comprises three elements: Clinical Interviews (the final battery comprising the CDR and recent driving experience), Neuropsychological Assessment (the final battery comprising MMSE, reaction time, hazard perception and traffic theory tests) and Driving Simulator Rides. The battery was developed in a dementia cohort (n=81) with predictors of on-road test performance identified using binary logistic regression. Full details can be found in Table 11.

The three elements and a combined variable were applied to a mixed group of dementia participants (VaD n=14, FTD n=12, DLB n=8) (Piersma et al., 2018a). ROC analysis showed that in this patient group, neuropsychological assessment was predictive of fitness to drive (n=33; AUC=0.79, p=0.006), but that clinical interviews (n=34; AUC=0.56, p=0.56), simulator rides (n=20; AUC=0.42, p=0.54) and the combined equation (n=20; AUC= 0.64, p= 0.32) were not.

These predictive equations have also been tested in an MCI (n=18) cohort (Fuermaier et al., 2017). ROC analysis revealed that both neuropsychological assessments (AUC = 0.82, p=0.03) and driving simulator rides (AUC= 0.86, p= 0.02) were significantly predictive (with an accuracy of >80%), but that clinical interviews (AUC=0.53, p=0.85) were not. The combined equation when applying predefined cut-off scores derived in the original study (Piersma et al., 2016) gave a sensitivity to detect unsafe drivers of 67 % and specificity of 83%.

Tests in development and included in final battery(bold)	**Development cohort and On-road Measure**	**Test and validation cohort and On-road Measure**	**Test and validation Cohort Results**
Clinical Interviews **CDR**, **Judgement of driving safety (participant**), Opinion cease driving (participant), Judgement of driving safety (informant), Opinion cease driving (informant), *Driving questionnaire (*Mean Score, **Recent driving experience)** Neuropsychological assessment *Global* **MMSE (Total score)** *Attention and concentration* TMT A (TMT B - TMT A Sec) Reaction Time (RT1) (visual) **Reaction Time (RT2) (auditory)** Reaction Time (RT3) (inhibition) *Executive function* TMT B (TMT B - TMT A Sec) Maze 1 (Sec) Maze 2 (Sec) *Visuo-spatial*	AD n=81 (Age 52-91), On-road Test Ride Investigating Practical Fitness to drive (FitToDrive) (Fit/Unfit) (Pass/Fail)	MCI n=18 (Age 49-79), On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Fit/Unfit) (Pass/Fail) Mixed dementia VaD n=14, FTD n=12, DLB n=8, On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Fit/Unfit) (Pass/Fail)	MCI Cohort (n=12 pass, n=6 fail). Clinical interviews: AUC=0.53, p=.85. Neuropsychological assessment: AUC= 0.82, p=0.03. Mixed dementia cohort (n=14 pass, n=20 fail) Clinical interviews: AUC =0.56, P= 0.564. Neuropsychological assessment: AUC of 0.79, p=0.006.

Tests in development and included in final battery(bold)	**Development cohort and On-road Measure**	**Test and validation cohort and On-road Measure**	**Test and validation Cohort Results**
Drawings - house, star, cube, clock (total score) *Other* Adaptive tachistoscopic traffic perception test (Performance parameter) **Traffic theory test (Response time,** correct trials) **Hazard perception test** (Response time, **correct trials**)			

Table 11: Literature review results for the Piersma et al. test battery

Abbreviations: AD=Alzheimer's disease; AUC=Area Under the Curve; CDR-Clinical Dementia Rating Scale; DLB=Lewy Body Dementia; FTD=Frontotemporal Dementia; MCI=Mild Cognitive Impairment; TMT=Trail Making Test; VaD=Vascular Dementia.

2.5.5 Non-cognitive clinical predictors of driving risk

There has been little research into non-cognitive predictors of driving safety. Therefore, this section includes studies examining discriminant ability and also those investigating correlation between non-cognitive clinical features and driving performance.

2.5.5.1 Activities of daily living and measures of dementia stage/severity

Level of daily function/dementia stage has demonstrated association with driving safety; for example, when correlated with fitness to drive all sub-categories of the CDR were significantly associated, and when comparing pass and fail, judgement and problem solving (d=1.00) and total score (d=0.93) showed the largest effect sizes (Piersma et al., 2016). Functional impairment in activities of daily living has also demonstrated association with an increased risk of involvement in a motor vehicle crash (Zuin et al., 2002); however when characteristics of an Alzheimer's disease cohort who had (n=30) and had not (n=67) been involved in crashes were compared, no significant difference was demonstrated in global function (Drachman & Swearer, 1993). In an AD cohort, 44% of those with CDR 0.5 (23/52) were rated safe in an on-road test compared to 34% for CDR 1 (11/32) (Ott, Heindel, et al., 2008).

Author (Year)	Measure	Cohort	Type of driving assessment & outcome measures	Results
Drachman (1993)	Global severity (Mild/Moderate/Severe)	AD n=97	Crashes (No crashes (n=67)/Crashes(n=30)	**Group comparison:** ns.
Ott (2008)	CDR	Probable AD n=65	On-road (Safe/Marginal/Unsafe) (score 0-108)	Longitudinal study (time to failure). CDR=0.5 median time to failure of 605 days (95% [CI] =391–925), CDR=1 median time to failure of 324 days (95% [CI] =196–562) (p=.03).
Carr (2011)	AD-8	Dementia n=99	On-road mWURT (Pass (n=35)/Fail (n=65))	**Group comparison (Mean (SD)):** 4.3(0.5) vs 5.8 (1.6); d = 0.97**,** p=<.0001.
Barco (2015)	AD-8	Dementia n=53	On-road mWURT (Pass (n=23)/Fail(n=30))	**Group comparison (Mean (SD)):** 4.8(1.5) vs 5.9(1.5), d=0.73, p=.009.
Piersma (2016)	CDR (Memory, Orientation, Judgement and Problem Solving, Community affairs, Home & Hobbies, Personal Care, Total)	Dementia n=73	On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Pass (n=35)/Fail (n=38))	**Correlation:** (FitToDrive). Total: r=-.42, p<0.001. **Group comparison (Mean (SD)):** Total = 2.2(0.97) vs 3.5(1.74); d=0.93, p<.001.
Fuermaier 2017	CDR (Orientation, Judgement & Problem Solving)	MCI n=18	On-road (Pass (n=12)/Fail (n=6)) Test Ride Investigating Practical Fitness to drive	**Group comparison (Mean (SD))**: Orientation = 0.33(0.39) vs 0.50(0.32); d=0.47. J&PS = 0.42(0.36) vs 0.42(0.38); d=0.37.
Piersma (2018)	CDR (Orientation, Judgement & Problem Solving)	VaD n=14, FTD n=12, DLB n=8.	On-road Test Ride Investigating Practical Fitness to drive (FittoDrive) (Pass (n=14)/Fail (n=19))	**Group comparison (Mean (SD))**: Orientation = 0.3(0.3) vs 0.6(0.5); d=0.77. J&PS = 0.6(0.4) vs 0.7(0.4); d=0.22.

Author (Year)	Measure	Cohort	Type of driving assessment & outcome measures	Results
Barco 2021	Functional Assessment Questionnaire	Dementia n=179	On-road mWURT (Pass/Fail)	**Simple logistic regression (test failure) ROC:** Positively associated with road test failure = Independence in bill paying AUC=.66, assembling taxes/papers AUC=.66, shopping AUC=.65, game playing AUC=.67, stove use AUC=.62, meal prep AUC=.6 and memory AUC=.64 (p<.05).

Table 12: Literature review results – Activities of daily living and dementia severity

Abbreviations: AD=Alzheimer's Disease; AD-8=Washington University Dementia Screening Test; CDR-Clinical Dementia Rating Scale; DLB=Lewy Body Dementia; FAQ=Functional Assessment Questionnaire; FTD=Frontotemporal Dementia; MCI=Mild Cognitive Impairment; VaD=Vascular Dementia; (m)WURT=(modified) Washington University Road Test.

2.5.5.2 Patient and informant report

Patient and informant opinion on whether someone should cease driving demonstrated weak or no correlation with on-road assessment of safety to drive in three studies (Fuermaier et al., 2017; Piersma et al., 2016; Piersma et al., 2018). Another study demonstrated that only 11% of individuals, 48% of informants and 61% of physicians correctly identified those who would fail an on-road test (Brown et al., 2005). However, a recent large study found that caregiver rating of driving quality was a predictor of road test failure (AUC=0.71) (Barco et al., 2021). Recent driving experience, defined as the total in kilometres driven in the previous 12 months, ($r=.42$, $p<.001$) also significantly correlated with fitness to drive in one study (Piersma et al., 2016).

2.5.5.3 Medications

In early-stage Alzheimer's disease, Cholinesterase inhibitor (ChEI) treatment in n=24 drivers was found to be associated with improvement in tests of visual attention and executive function, and enhanced accuracy in a simulated driving task when pre-treatment and three months post treatment were compared (Daiello et al., 2010). The same study also compared a group of n=35 early-stage Alzheimer's disease non-ChEI users with a matched group on stable doses of ChEI, and found enhanced driving simulator accuracy, as well as an association with better visual search accuracy and response time. We did not identify other evidence for the effect of medications on driving safety in MCI or dementia.

2.5.5.4 Comorbidities

Visual acuity has been included in the initial investigations as a predictor of driving outcome in a number of dementia studies (Dawson et al., 2009; Fox et al., 1997; Ott et al., 2013), however, none of these reported any association with on-road outcomes.

2.5.5.5 Non-cognitive symptoms

In an MCI cohort, a measure of subjective sleepiness (Karolinska Sleepiness Scale) was not found to be correlated with any measure of driving performance in a simulated driving task (Cross et al., 2017). However, the same study found associations between objective measures of sleep disordered breathing and driving performance in the MCI cohort, with the oxygen desaturation index significantly correlated with crashes, speed and steering deviation in the simulator ($r=0.66$, $p=.003$; $rho=0.51$, $p=.03$; $r=0.52$, $p=.03$

respectively). The number of arousals per hour of sleep was also positively correlated with a greater number of crashes in the simulator (rho=0.48, p=.04) (Cross et al., 2017).

In a small cohort of patients with a diagnosis of FTD (n=15), speeding ($r=0.61$, $p<0.05$) and number of stop signs ignored ($r=0.52$, $p=0.05$) was significantly correlated with the total score of the Neurobehavioral Rating Scale (NBRS) and agitation on the NBRS was positively correlated with number of collisions ($r=0.75$, $p<0.01$) in a driving simulator (de Simone et al., 2007).

One study in MCI found that depressive symptoms were associated with driving variables including number of crashes and speed violations in a driving simulator (Beratis et al., 2017).

2.6 Discussion

Clinicians are often expected to make an assessment of driving safety prior to an on-road assessment with the clinical information available to them. It is an important decision given the risk of harm to others if an unsafe driver is allowed to continue driving, and the risk of harm to the person with dementia or MCI, if they are prevented from driving unnecessarily.

Previous reviews in this area have mainly focused on the association between neuropsychological tests and driving safety (Brown & Ott, 2004; Kay et al., 2012; Molnar et al., 2006; Reger et al., 2004; Silva et al., 2009), and the strength of association between cognitive domains and on-road driving ability (Rashid et al., 2020); and there is consistent evidence that an association exists (see tables 3-8). However, it is difficult to apply reported correlation and effect size differences to clinical practice. Even with substantial effect size differences, there can be significant overlap in the distributions of results between safe and unsafe drivers. In this review, assessment of driving safety is considered in the context of current clinical practice and what information might be available to clinicians as part of their clinical assessment process and adds to previous reviews (e.g. (Iverson et al., 2010)) by looking further at potentially useful non-cognitive clinical information. We have sought to examine the discriminant ability of cognitive tests and batteries, where these have been reported. In addition, non-cognitive measures are considered, as these are highlighted as important features to assess when considering driving safety but have received little attention in the literature. It is recognised that some of the tests featured will span more than one cognitive domain, for ease of reference they have been situated in one domain.

There is no agreed acceptable sensitivity and specificity at present for clinicians using these tests to assess driving safety. The acceptable level may vary depending upon the context of the assessment e.g. if being used to screen for onward referral to an on-road driving assessment, sensitivity may be most important for that clinician.

In the following sections, we will highlight some cognitive tests and other clinical predictors with the best evidence for association with driving safety and make some pragmatic recommendations for what clinicians may wish to consider when assessing driving safety in the clinic.

2.6.1 Global cognition

In evidence from two studies with very similar results (Berndt et al., 2008; Piersma et al., 2018), almost no participants with an MMSE<20 passed an on-road assessment. Therefore, low MMSE score may be a strong predictor of driving impairment. However, a high proportion of participants with MMSE>20 also failed the on-road assessments, including around one third of those with a score >=25. Therefore, an MMSE>20 cannot be taken as indicative of driving safety. These findings are in agreement with a recent meta-analysis that found only moderate correlation with tests of mental and cognitive status and on-road driving ability (Rashid et al., 2020). For the clinician assessing driving safety, a low MMSE score may be indicative of unsafe driving, but higher scores are not necessarily indicative of driving safety. The MoCA is also commonly used in a clinical setting, however, with evidence available from only one study it is difficult to draw any conclusions at present.

2.6.2 Attention, concentration and executive function

Few studies have developed cut-off scores for cognitive tests and then tested these in independent cohorts. In one such study (Papandonatos et al., 2015), a TMT-B time of >108s had sensitivity of 88%, though specificity was poor (40%). Most other studies have demonstrated poor sensitivity to detect unsafe drivers, therefore TMT-B may be the best candidate as a screening test for unsafe drivers, but the very low specificity may limit its usefulness.

2.6.3 Test batteries for predicting driving safety

The Rookwood battery (McKenna & Bell, 2007) and NNDA (Lincoln et al., 2006) both had limited sensitivity to detect unsafe drivers (44-54%), though specificity was better, particularly for the NNDA. The battery designed by Piersma (Piersma et al., 2016) and colleagues had superior sensitivity (67%), but most centres would be unable to use this scale due to the requirement for a driving simulator assessment. In addition, the time taken to administer these test batteries, as well as the use of equations to determine the outcome, may make them impractical for use when driving safety is not the sole focus of the clinical assessment.

2.6.4 Cognitive tests and mild cognitive impairment

There is very little evidence for cognitive predictors of driving on-road driving ability in MCI, however, clinicians may be expected to determine driving safety in this group, e.g. some jurisdictions, such as the UK (DVLA, 2024) ask that people with MCI inform the driver licensing agency of their diagnosis if there is 'likely driving impairment'.

As MCI by definition involves preservation of daily function, with minimal aids or assistance (Albert et al., 2011), it would be expected that most people with MCI would have preserved driving abilities. However, of eighteen people with MCI tested, six failed an on-road test (Fuermaier et al., 2017), and other studies comparing on-road driving characteristics of MCI and healthy control cohorts show that those with MCI perform poorer on driving assessments (Anstey et al., 2017; Kawano et al., 2012; Wadley et al., 2009). This evidence suggests that changes to driving skills can occur before the development of dementia, and that those with an MCI could be included in clinical studies of driving safety. There is an urgent need for research to help clinicians understand how to identify people with MCI who are likely to have impaired driving.

2.6.5 Non-cognitive clinical predictors of driving risk

Non-cognitive predictors of driving safety have been given little attention in the research literature. However, guidelines for healthcare professionals have emphasised the importance of a holistic assessment to help determine driving risk including consideration of functional impairment, comorbidities, medications and sensory impairment (Driving & Dementia Working Group, 2018; Iverson et al., 2010). The effects of non-cognitive factors on driving in the absence of dementia have been reviewed elsewhere e.g. psychiatric disorders (Rapoport et al., 2023; Wickens et al., 2014; Williams et al., 2011), medication (Hetland & Carr, 2014; Rudisill et al., 2016) and sleep (Moradi et al., 2019; Saleem, 2022) and at present there is no good evidence on how these might interact with dementia, but these factors should be considered by clinicians.

2.6.5.1 Activities of daily living and dementia severity

The evidence to date for functional scales is limited and thresholds for functional impairment and dementia severity to indicate driving safety have not yet been identified (e.g. in one study the fail rates for CDR score 0.5 and CDR 1 were similar (Ott, Heindel,

et al., 2008)). However, the CDR and AD8 have shown a positive association with on-road performance (see Table 12), and a clinical assessment of driving safety should include consideration of daily function, and dementia severity as recommended in consensus guidelines (Driving & Dementia Working Group, 2018).

2.6.5.2 Medications

The effect of medications on driving has been reviewed elsewhere (Hetland & Carr, 2014; Rudisill et al., 2016). We found no papers examining the association between medications and driving risk in dementia. However, in older drivers, risk of crash or motor vehicle accident has been reported to be increased with the use of benzodiazepines (Fournier et al., 2015; Meuleners et al., 2011; Ray et al., 1992), anti-depressants (Fournier et al., 2015; Leveille et al., 1994; Ray et al., 1992) and opioid analgesics (Meuleners et al., 2011), as such medication history should be considered when assessing driving risk.

2.6.5.3 Comorbidities

There is evidence from previous reviews that comorbidities such as psychiatric disorders may impact driving ability (Rapoport et al., 2023; Wickens et al., 2014; Williams et al., 2011). Evidence from an MCI cohort demonstrated that depression has a negative impact on some elements of driving (Beratis et al., 2017). There is little evidence for the effects of other comorbidities. In people without dementia, frailty has been associated with car crashes (Doi et al., 2020) and poorer performance on-road (Carr et al., 2016). Clinicians should consider the effect comorbidities and frailty may have on their patients' driving, and this needs more investigation in relation to driving ability.

2.6.5.4 Sensory impairment

Visual acuity has been included in some studies of driving safety in dementia and has not emerged as a predictor. This is likely due to selection bias i.e. those with severe visual acuity deficits are deemed unsafe to drive and are therefore not entered into studies. Visual acuity should clearly be considered as an important factor in driving safety. No studies have investigated the effect of hearing impairment in the prediction of driving safety in a dementia cohort.

2.6.5.5 Dementia type

To date, most studies investigating prediction of driving safety has focussed on Alzheimer's disease. When compared to those with Alzheimer's disease, those with a diagnosis of frontotemporal dementia are at higher risk of causing an accident based on carer report (Fujito et al., 2016). This may be expected, given the executive dysfunction and behavioural changes that occur in behavioural variant frontotemporal dementia. There is little evidence available on the impact of other dementia subtypes on driving. Clinicians should consider how cognitive and non-cognitive symptoms of specific dementias, including behavioural disturbance in frontotemporal dementia and visual disturbance in dementia with Lewy bodies, may impact on driving.

2.6.5.6 Patient and informant report

Clinicians often place emphasis on caregiver rating of driving when assessing driving in clinic, however the evidence has demonstrated weak to no association with driving safety (Barco et al., 2021; Piersma et al., 2016) and limited predictive value. Whilst caregiver report is an important part of the assessment, it is not a highly accurate predictor of on-road outcome, and so disproportionate weighting should not be placed on this information alone.

2.7 Limitations

It is recognised that there is limited evidence presented due to the small number of studies available that reported the discriminant ability of the measures. Because of this the review needed to be presented in the wider context of the data that is available, as we did not want to exclude any potentially novel assessments. However, it was possible to make a recommendation of at least two tests (MMSE and Trail Making Tests) that may be useful to clinicians, as well as highlighting that carer/informant report does not correlate strongly with driving safety and carers will not identify a significant proportion of unsafe drivers, which many clinicians may not be aware of.

At present there is no 'gold-standard' on-road measure and the use of varied on-road outcome measures weakens the evidence base. The meaning of dichotomous outcomes of pass/fail or safe/unsafe, and quantitative on-road scores may differ across on-road assessments. Simulator-based driving assessments were also included, which may not always closely replicate on-road performance (Wynne et al., 2019), they were

included in this review so as not to miss any potential novel findings, and because some non-cognitive variables have only been investigated with simulator assessment and not on-road assessment.

Many of the studies used small cohorts and many used multiple predictor and outcome variables, increasing the risk of false positives. Due to the limited number of larger studies, it was decided to include smaller studies in this review so as not to miss any potential novel findings. It can be noted that out of the 33 studies that met the inclusion criteria for the final review, only nine reported results on discriminant ability, highlighting the challenge of applying the currently available research to clinical practice.

The fact that some of the studies only reported AUC results is an important limitation, as this encapsulates the full range of sensitivity and specificity for that test, when a specific threshold is more useful in a clinical assessment setting.

Some clinical features which would clearly affect driving safety (e.g. visual acuity, impulsive or reckless behaviour) have not been studied as predictors of driving safety in dementia or MCI. However, these are still vital elements of the assessment of driving safety, as indicated by consensus guidelines (Driving & Dementia Working Group, 2018). Unfortunately, there is no available sensitivity, specificity or AUC results for non-cognitive measures, and this is a key issue that should be addressed in future research.

2.8 Future directions

There is an urgent need to understand how cognitive and clinical scales can be applied to identify unsafe and safe drivers, either as part of a test battery or as individual 'red flag' indicators of driving risk. In order to determine this, the threshold score for the test needs to be identified in one cohort, then tested in an independent cohort and finally validated in another independent cohort. Future studies could examine alternative ways to combine data (e.g. using individual 'red flag' thresholds in multiple tests rather than a single combined score from multiple tests). Additionally, at present there is a need for testing and validation of which functional assessment scales are the most appropriate for use in an assessment of driving safety. Clinicians should be included in any research in this area to ensure the practicality of the tests in a clinical setting and encourage acceptance.

None of the tests described have high sensitivity and specificity, suggesting that a simple binary approach (safe and unsafe) may not be feasible in clinical practice. A trichotomization approach (which places people into three categories – no immediate safety concern, immediate safety concern and unclear) could be more practical, but this requires further research.

2.9 Clinical implications

When making an assessment of driving safety in MCI or dementia, useful cognitive tests to consider may include the MMSE and Trails A&B. No cognitive test or battery has sufficient sensitivity and specificity to be used in isolation to determine driving safety. A holistic assessment should include an informant interview where possible, and a consideration of functional ability, comorbidities and medication.

2.10 Conclusions

There is clear evidence that cognition is associated with driving safety, however, at present the evidence base has limitations, particularly the absence of replicated findings or clinically useful cut-off scores. Tests that are useful to consider when making as assessment of driving safety include the MMSE and Trail Making Test (A&B), along with the degree of functional impairment present. However, these tests are not effective in isolation, and those who score well may still fail an on-road assessment. These tests would be best used in conjunction with recommendations from local and national guidelines, taking into account other factors such as comorbidities and medication.

There is a need for a screening tools or decision aids to support clinicians in their decision making to help detect unsafe drivers. Researchers need to look at alternative ways of developing these tools to overcome the current issues with sensitivity in the best available batteries and may benefit from looking at a wider range of features, including non-cognitive clinical features.

Clinicians should be encouraged to contribute to any research in this area to enhance acceptance and useability of and emerging tests and thresholds.

Chapter 3. Qualitative study of clinician experiences in assessment of driving safety in dementia

3.1 Introduction

Clinicians often feel under-equipped when making an assessment of driving safety in persons with a diagnosis of dementia (Adler & Rottunda, 2011; Neilson et al., 2019). The literature review in chapter 2 illustrated the absence of objective, effective and time-efficient tools to help clinicians in their decision-making process. This is consistent with previous research that has identified the need for an objective tool (Bennett, Chekaluk, & Batchelor, 2019a) and a standardised approach to improve consistency in decision making among clinicians (Neilson et al., 2019) when assessing driving safety.

3.1.1 Aim

The aim of this qualitative research was to inform the development of the driving decision aid tool by:

- Exploring the experiences of a wide range of clinicians when addressing the issue of driving with dementia
- Exploring how clinicians make current decisions about driving safety at present, including which clinical factors are taken into consideration and their relative importance
- Examining what tools/decision aids or guidance are used at present, and how useful these are in practice
- Asking clinicians what format a driving decision aid tool should take to be useful in a clinical setting
- Exploring what else would be helpful to supplement a driving decision aid tool

3.1.2 Statement of positionality

As someone who has been involved in the research of driving safety and dementia for 15 years it is important to acknowledge the influence that this has had on my perspective of the issue, and the potential for bias due to this. My experience through the years of working with and speaking to individuals with a diagnosis of dementia and their families has strengthened my understanding that the issue is not as simple as 'people with a

diagnosis of dementia are not safe to drive and should be prevented from doing so'. Driving, and the independence and freedom it brings is often intrinsic to a persons sense of self, and well-being. I believe that people should be supported and enabled to drive for as long as they are able to do so safely, and that this position is an important one given that the advances in early detection and diagnosis of dementias mean that many people will be living with the condition for a longer period of time than in the past. I plan to mitigate this by including perspectives from a wide range of clinicians and being mindful that their personal experiences of addressing this issue with patients and their families may have given them a different viewpoint on the issue than my own.

3.1.3 Rationale

Quantitative research aims to establish the frequency with which known events or attitudes occur; in contrast qualitative research aims to understand the factors at play in determining the range of events that occur and how these unfold in practice. Relatively little is known about current practices in assessing driving safety in dementia. This qualitative component of the study was therefore essential to increase our understanding of:

- The nature of the challenges facing clinicians when assessing driving safety in dementia
- The context in which the driving decision aid tool will be used
- The type(s) of tool(s) most acceptable to clinicians
- This work will ensure that the driving decision aid tool developed is appropriate, fits with existing practice and will maximise the likelihood that the driving decision aid tool will be used

3.2 Methods

3.2.1 Methodological approach

Assessing the driving safety in persons with dementia is a complex issue, and clinicians with different roles and responsibilities may approach the topic differently. Semi-structured interviews were selected for data collection due to their ability to:

- Explore feelings around this sensitive issue
- Encourage respondents to speak freely by developing rapport

- Enable respondents to introduce aspects they identified as important
- Allow for more thoughtful answers (Byrne, 2004)

Semi-structured interviews were therefore identified as most appropriate for generating meaningful and in-depth data (Rubin & Rubin, 2011). Although focus groups were considered due to their ability to generate discussion between respondents, they were not thought appropriate due to the hierarchical nature of the group to be interviewed which could potentially deter honest responses (Morgan, 1996).

3.2.2 Approvals

Ethical approvals for this research were obtained from the Northern Ireland Health and Social Care Research Ethics Committee B (HSC REC B) in September 2020 (Ref: 19/NI/0220).

3.2.3 Recruitment strategy and consent

Clinicians from all disciplines in three North East England memory services (Newcastle upon Tyne, Gateshead and Northumberland) were approached via e-mail. All three memory services were based in Old Age Psychiatry departments. This included a short synopsis of the research and invited clinicians to contact the researcher for further information if they wished to take part. Once interest was established, potential participants were sent an information sheet and invited to contact the researcher with any questions or concerns. Written informed consent was then obtained from those who wished to participate, by sending the study information and consent from to the participants via e-mail. This was then signed and returned to the researcher for counter signature.

3.2.4 Inclusion and exclusion criteria

The inclusion criteria for this study were a clinical background with experience of assessing driving safety in those with dementia in a memory clinic or community setting. There were no exclusion criteria.

3.2.5 Sample

This was a convenience sample of participants selected for approach due to their occupations and experience of the subject matter. The aim was to achieve a sample that contained a broad range of roles reflecting the typical structure of a memory

assessment team. This was a self-selecting sample, with sample size decided by reaching data adequacy.

3.2.6 Interview process

The interview was arranged at each clinician's convenience, and they were given a choice of the interview taking place face to face or virtually (via Microsoft Teams). All twelve participants chose to be interviewed virtually.

Interviews took place between August 2022 and January 2023 and were conducted by one researcher (KO).

At the beginning of the interviews, the researcher re-iterated the purpose and scope of the research and invited the interviewee to express any concerns or questions they had about the project or interview process (the script the researcher used is available in Appendix A). Verbal permission was then obtained to record the interview via Teams, this was a video as well as an audio recording, it was made clear to the participants that the resulting data would be anonymised and video recordings (used to check transcripts) only accessible by the research team.

A topic guide was developed (see Appendix A) comprising seven open ended questions with additional prompts for the interviewer. Respondents were encouraged to speak freely and advised that they were free to go beyond the questions asked and asked to give examples from their personal experiences.

3.2.7 Data analysis

All interviews were transcribed and anonymised by the researcher (KO). These were transcribed as soon as possible after each interview and during this process the researcher made preliminary notes on the responses, allowing them to see when data adequacy has been reached (Saunders et al., 2018).

Data was analysed using the six phases of thematic analysis (Braun & Clarke, 2006). Full details of the process and stages are presented in the table below.

Phase	Process for this research
Familiarisation with the data	The transcripts were read a number of times by KO to familiarise herself with the data.
Generating initial codes	The transcripts from the interviews were read again line by line by the researcher (KO), from this initial key codes were identified and noted from recurring items in the data. This was conducted in a systematic fashion, and descriptions for each code were noted by the researcher. These codes were then discussed with research colleagues (PD & CB), and definitions were ascribed to each code. These were then further discussed and refined by the research team.
Search for themes	The codes produced from the initial framework were then applied to the interview transcripts using NVivo14 software. This allowed the researcher to collate the codes into potential theme groups. These initial themes were then discussed and refined with the research team.
Reviewing themes	A 'map' of the data was then constructed by hand to sort the themes into relevant groupings and identify the larger themes of the data. This was achieved by noting each theme onto a piece of paper and grouping together related themes to form a narrative structure.
Defining and naming themes	Once the themes were sorted into larger key groups, these were named, and definitions and descriptions were attributed to each one. These were then checked against the data to ensure that they fitted within the overall account that the data was giving. Codes within the themes were also rechecked to ensure that they fitted well within the group they were assigned to and did not fit better within another theme.
Producing the report	The themes that emerged were then written up to illustrate the key findings that emerged from the data. This was done by forming a narrative structure that fitted the data set and answered the aims of the research questions. Relevant quotes were selected and included to highlight the key points and findings of the data.

Table 13: Thematic analysis process

3.3 Results

3.3.1 Participants

In total, twelve clinicians were interviewed from a broad range of backgrounds (see Table 14). The interviews lasted on average 28 minutes (range 16 minutes to 40 minutes).

Discipline	Number
Speciality Doctor	1
Team Manager (Nursing)	1
Psychologist	2
Consultant Psychiatrist	2
Community Practitioner (OT & Nursing)	6

Table 14: Participants by discipline

3.3.2 Themes

Data adequacy was reached by interview twelve, and no further unique codes were produced (Saunders et al., 2018). Thematic analysis (Braun & Clarke, 2006) revealed five themes (see Table 15) and these themes are presented below. Due to the small sample in this study, roles are not attributed to quotes as this may allow for identification of some individuals.

Theme	Title	Description
One	Clinician attitudes, experience and expectations	Clinician experiences of difficulties raising the issue of driving and how perception of their role (from both clinician and patient) can shape this (including feelings and attitudes to the recent DVLA legislation change). Where the responsibility for addressing the issue lies. Clinicians' emotional responses to patient reactions, clinician concerns regarding legalities, and formal and informal coping strategies.
Two	Managing mismatched expectations	This theme explores the differences in expectations between clinicians and patients about addressing driving safety, minimising conflict that can arise from this, the issue of consent and maintaining the therapeutic alliance.
Three	Gathering and weighing information	This theme explores what information clinicians utilise when making a decision about driving safety, and the weighting placed on these different elements.
Four	Communicating the recommendation and managing conflict	This theme explores managing conflict when communicating the decision to the patient, approaches used to achieve this and the importance of communication.
Five	Shaping a prospective tool and training needs	This theme explores the need for a clinical decision aid tool to aid decision making, what elements are important for it to contain, the desired characteristics of a tool and the related training needs.

Table 15: Description of the five themes that emerged from the thematic analysis of clinician interviews

3.3.2.1 Theme one – Clinician attitudes, experience and expectations

3.3.2.1.1 Responsibilities

The key finding in this theme was that respondents across all disciplines felt that anyone who has contact with the patient should feel a responsibility for addressing the issue of driving in those with a diagnosis of dementia, and that it should be raised at the earliest opportunity with respondents reporting that it is almost always raised at the initial assessment appointment.

> *"anybody who's involved in that assessment process and who is hopefully having some kind of therapeutic relationship with the patient, and can act, and can assess that situation, and can offer advice if they feel confident and competent to do so"* (IMPC01)

> *"So, at the first face to face contact. First face to face contact in the memory service"* (IMPC08)

However, many felt that there were missed opportunities in the process to address the issue earlier and that it was often left to secondary services, when clinicians who have first contact with the patient and/or referred them to memory services, in particular GPs, would be best placed to raise this.

> *"Instead of just saying they got memory problems and have been like this six months and they scored this on our test, if they know they're driving I think they should be talking about it there and then instead of leaving it to secondary services to address"* (IMPC10)

3.3.2.1.2 Role perception

When considering if discussing driving should be part of their role, the clinician's perception of their clinical role informed their approach to addressing the issue of driving with their patients. While still acknowledging the importance of raising the issue, it is always a secondary aspect to their main purpose, which is to assess the person for a possible dementia.

> *"first and foremost, my role is of course, checking whether someone has a dementia or not. So yes, the driving is in there, but I'm not assessing is the person fit to drive. This is part of it, maybe that is something that I'm checking as well as checking whether there is a neurodegenerative disorder"* (IMPC03)

This perception of the person's clinical role was also important when performing some of the more formal aspects of the processes around driving safety. Recently the DVLA made a change to their guidance for their medical questionnaire for driving (DVLA, 2022). The change now expands the types of medical professionals who can complete and submit the questionnaire. Respondents were asked if they were aware of this change and how they felt about it. There were mixed responses, with most not aware of the recent changes. There were also mixed feelings about the changes, with those that had already been doing it as part of their role welcoming the change, but those for who it would be a new responsibility not as favourable.

> *"No, and when it was mentioned, it caused great anxiety and I think, gosh, I'm even anxious and concerned about referring someone for a driving assessment."* (IMPC06)

Some clinicians did feel that some training might be helpful, and that then they might be more willing to take on the extra responsibility, but the overall impression was that it was going to be a difficult change to implement. Many felt that it went beyond the remit for their role, and that it was a responsibility that belonged with a more senior role. Participants also expressed concerns about potential liability issues.

> *"I certainly think if we're going to be looking at us filling those in, we'd have to have some sort of training. You know, some support around filling those in. I don't think I'd feel very comfortable about doing it at the minute."* (IMPC04)

> *"Filling any questionnaire formally about somebody's ability to drive to drive safely. Do you know what I think? That's what they get paid the big bucks for. And I think sometimes. Sometimes that ultimate decision does need to come from somebody that's getting paid for those types of decisions in terms of responsibility." (IMPC08)*

3.3.2.1.3 Raising the issue

Across all of those interviewed, there was agreement that this was a difficult issue to raise with patients and their families.

> "*you know it's one of the things I hate doing at times. Sometimes you can tell it's gonna be a contentious issue."* (IMPC07)

However, this difficulty can vary depending on role and experience. The length of time a clinician has been in their role may affect how comfortable people were with raising the issue, with those who have been in the role longer finding it less challenging than those who were newer to their role. Additionally, the role a clinician holds can also affect the confidence they have with raising the issue, depending on the other aspects of their role, with a respondent reporting that as their role usually involved many difficult conversations, that this can be viewed as just another one of those.

> *"I think, maybe if you'd ask me that a couple of years ago, I might have felt a bit less confident"* (IMPC01)

> *"I'm quite comfortable raising the process…It's not nice telling somebody that everything suggests that they needed driving assessment and so on. And that's uncomfortable, but then … we do some (have some) uncomfortable conversations."* (IMPC11)

3.3.2.1.4 Patient responses to the subject of driving

Clinicians were aware of how difficult this subject is for the patient, particularly given the potential implications of not being able to drive anymore and described a range of responses from accepting to hostile. However, safety was deemed more important and an emphasis on safety could help mitigate the emotional effect of the adverse response.

> *"when you have to tell somebody that they can't do something they've been doing since there were seventeen years old and it's their lifeline, it can be really sad to do."* (IMPC11)

> "*Did it make me feel great? Possibly not. Did I think that's the right thing to do and it's safer for everyone because that could have led to many deaths? …I think on reflection I'm fine with it."* (IMPC03)

3.3.2.1.5 The therapeutic relationship

Whilst accepting that it was part of their role to address this issue with patients, respondents felt that it didn't always sit well with other aspects of the job and expressed concerns about the potential impact on the therapeutic relationship.

> *"It's difficult because people are just so attached to their driving. I think at any point if you, raise it with any particular person who has a strong regard to that…It's going to be a problem in terms of the patient-doctor, therapeutic relationship."* (IMPC12)

Additionally, the perception that some patients saw professionals in some clinical roles having more legitimacy, may impact the compliance of the patient with the advice given. Regarding this, a number of clinicians expressed concern about the legal implications of addressing this issue with patients and expressed a need for more clarity with this. It can be difficult for clinicians to determine whether a patient has followed the advice given, which may be disregarded if the patient feels that the clinician does not have the relevant authority, and a lack of transparency on what legal routes may be open to them are a source of anxiety.

> *"I think from a member of the public view, if it's a doctor that carries more weight."* (IMPC02)

> *"Obviously, as clinicians, we have a concern for safety and the safety of the patient, the safety of others, but we also have to have a full understanding of what our responsibility is in that situation. And who is who is legally responsible for anything that might happen? Really? I think if we're not clear on that, it can create a lot of anxiety for clinicians."* (IMPC01)

3.3.2.1.6 Pressures of the initial assessment appointment

A further challenge to assessment of driving was the pressure and burden such discussions created for the initial appointment, since there is a lot of ground to be covered. Concerns were also expressed about the risk of information overload for the person and their family. Due to time pressures, clinicians reported that they were not

always able to discuss it as thoroughly as they would like. This created tensions for clinicians in including driving in the initial assessment.

> *"Yes, because it has to be addressed and we don't want people waiting six months or three months to see a doctor, then be told and be unsafe to be on the road. But no, because there's a lot of pressure on that first visit."* (IMPC10)

3.3.2.1.7 Support structures

Despite the challenges that clinicians faced when addressing this contentious issue, they felt supported in managing difficult interactions with patients. Interviewees described various coping mechanisms for dealing with this, utilising both formal and informal support structures available to them. This can involve using formal supervision, taking the opportunity to discuss it at team meetings or chatting with colleagues.

> *"The nurses would bring that back to the MDT, to that discussion, and get some guidance from one of the doctors."* (IMPC05)

> *"You think oh I've just had a really tricky assessment, or I've had a really tricky phone call and just speaking to a colleague, really helps."* (IMPC06)

3.3.2.2 Theme two – Managing mismatched expectations

The key finding here related to mismatched expectations between clinicians, patients and their families regarding if, why and how the issue of driving is raised in a memory assessment. This can lead to difficult interactions in the assessment appointment and there is the need to bridge the gap between these expectations. There are also differences between the expectation that clinicians have of what should be happening in primary care when a referral is made, and their experience.

3.3.2.2.1 Potential conflicts

As previously described clinicians viewed discussing driving as part of their role when assessing a person for dementia. However, patients are not necessarily expecting their driving to be a part of a memory assessment, and this may lead to conflict.

> "*I've had a mixture... So, I've had some people say, yeah, I wasn't really happy driving anyway, and I was thinking about it giving up anyway. Then I've had the complete opposite end of the spectrum"* (IMPC07)

Some family members were reported to be relieved when the issue of driving was raised, as they were aware that it needed to be addressed but were worried about doing so themselves. Other family members, however, appeared to find it difficult to understand why it was a safety issue, particularly if they had already developed strategies to mitigate the difficulties the patient may be having.

"*I have had the wife of somebody on the phone to us saying, well, why has he got to stop? He's safe if I go with him, I'll tell him if he needs to do anything"* (IMPC10)

To minimise this potential conflict, clinicians used a range of strategies. One key strategy was to emphasise that driving was an issue that was raised with all patients thus normalising it as a usual part of the assessment process and stressing that it was not personal to the patient. Some respondents also reported using their role as justification for addressing the issue.

> *"I normalise it. So, I will say I will ask this everyone"* (IMPC03)

> "*It's just that actually that this is what we have to do as doctors"* (IMPC01)

3.3.2.2.2 Timing of addressing driving and potential consequences

In order to mitigate the impact of the patient perhaps not expecting driving to be raised as an issue, respondents felt that it needs to be addressed earlier in the process (the potential role of GPs is discussed further below). Similarly, some respondents felt that it would be beneficial, as part of pre counselling, for people to be informed ahead of the initial assessment appointment that it is an issue that will be asked about.

> *"You know, I suppose if it had been maybe discussed a little bit before the person arrives, you know, if it was being discussed somewhere else before they got here, that maybe that would be helpful so that people were a bit more a bit more prepared"* (IMPC04)

However, a potential consequence of this is that prior knowledge may lead to patients cancelling assessment appointments with the memory clinic, or refusing to complete the assessment, and this is not a desired outcome.

"I think the danger of that is that, uh, that would put some people off coming for an assessment, which is something we've got to avoid." (IMPC09)

The mismatch of expectations highlighted the importance of the issue of consent for respondents. Clinicians felt that that it was important that patients know what they are consenting to with the assessment, including potential implications for driving. However, they were aware that some patients might refuse the assessment if fully aware of the potential outcomes of a diagnosis of a dementia. Clinicians managed this tension in different ways; some felt it was best to explore consent at the outset of the assessment, despite the potential for the patient to disengage from the process.

"I think it's a really tricky one because I think somebody needs to know at the beginning, because it gives them the opportunity to decide if they want to go ahead with an assessment or not." (IMPC06)

Others, however, preferred to raise driving later in the assessment either because initial assessments or discussions would aid them in exploring the issue, and/or to avoid the risk of disengagement or setting a difficult tone for the assessment.

"I sometimes it's query about timing when to when to approach the matter. Yeah. You know, I tend to leave at the end of the assessment, if I start off saying we might be telling you to stop driving that sort of sets the tone for a for a difficult assessment as we go on." (IMPC07)

"It's quite a way through my report … it's usually at the end when I do it, so (they) don't kick me out before I've got what I need. "(IMPC10)

Even delaying the discussion until later in the assessment did not always avoid damage to the patient-clinician relationship.

"there's been people who've refused to come back and see me because I've brought up the driving at the first assessment" (IMPC12)

3.3.2.2.3 The role of GPs

The second key mismatch related to the perceived role of GPs in discussing driving. While respondents felt that GPs could take more responsibility for exploring driving prior to referral, in their experience, evidence that such discussions had taken place was rarely provided.

> *"Personally, I think it needs to be raised with GPs. The GP is the first point of contact"* (IMPC02)

The need for GPs to address this issue did not only relate to preparing the patient for the assessment, but also to safety concerns if a person who was not safe to drive continued to do so during the period between referral and assessment which could be several months.

> *"Yeah, I've seen referrals from GP saying this man still driving and has been driving, you know 30 miles an hour down the A1 or something... I can't help thinking shouldn't something have been done by the GP at that time? Why he is sort of letting us tackle that?"* (IMPC07)

3.3.2.3 Theme three – Gathering and weighing information

The key finding here was that there was a lack of consistency in the information clinicians used to determine driving safety and how they used this information in the decision-making process. There was little agreement across respondents as to what weighting they placed on the different types of information used to make a decision about a person's driving. At the moment there is no standard pathway for this, and so there were a range of responses, with individual clinicians taking into account differing combinations of the information gathered, and this being tailored to the individual patient depending on what information emerges, rather than a constant uniform approach.

> *"what we've got is pure judgment. It's individual judgment. Which is... One person may tell them to stop, the other might ignore it. No, it's not a good way to work."* (IMPC10)

3.3.2.3.1 Cognitive testing

Cognitive testing featured highly in the responses, with specific elements of the cognitive assessment reported as being part of the decision process, with the visuo-spatial element being the most widely reported. Other cognitive elements that clinicians reported using in their decision-making were attention and executive function, although less frequently. This may depend upon the clinical role of the respondent, as some roles entail doing a more in-depth cognitive assessment than is typically carried out at the initial assessment appointment.

"we use the ACE III and there is a visuo-spatial part in that "(IMPC05)

"I also take into consideration executive functioning" (IMPC03)

However, despite cognitive testing emerging as the most popular response, clinicians emphasised that they did not make their decision solely on cognitive scores, but instead considered the 'whole picture'. Identifying, assessing and managing risk emerged as an important element for the respondents. This required combining cognitive test scores with other information.

"I'll make a judgment based on not just a score of something, but on a lot of information." (IMPC08)

3.3.2.3.2 Clinical information

Other clinical information used in the decision process related to comorbidities and medication. Another element that was often reported by interviewees as being an important part of the decision about driving, was that of insight, judgement, and neuro-psychological symptoms such as impulsivity and functional ability/activities of daily living. The responses tended to differ according to the core features of the respondent's role, with Doctors more likely to mention comorbidities and medication and Occupational Therapists more likely to take into account functional assessment.

"physical health and what other sort of physical health comorbidities they have that that might be potentially affected in their driving" (IMPC04)

"And any hallucinations? Perceptual disturbance? Also, I think it is any kind of. Like they're really anxious yet really sort of jittery." (IMPC07)

Clinicians felt that a lack of insight can also make it difficult to rely on the patient's report of their driving ability, and that when being asked about this they may not want to admit to any difficulties.

"I'll be brutally honest and say one thing I do not do is I don't trust the patient…I believe that it's, it's so infrequent that I see somebody says oh my driving isn't very good. We all overestimate our driving abilities you know." (IMPC09)

3.3.2.3.3 Collateral information

Gathering collateral information from an informant or carer was very important to clinicians, and was the most reported method after the visuo-spatial element of the ACE III. Respondents acknowledged that this may be difficult for the informant in that situation, and they may not want to speak about it in front of the person. In this case, efforts are made to speak to the person later, in a more appropriate setting in order to be able to gather the correct information. In the rare instances when they were not able to get collateral information e.g., the person had attended the assessment alone, other efforts were made to gather this information form other sources.

> *"I suppose the most important thing is to get that collateral information and it's really important. If sometimes you can tell that people aren't able to speak openly in front of the patient … then through an elaborate system of nods and winks, you imply that you can have speak to them later by telephone. And I think that's the most important thing, you have to try and get that information from a third party who has seen them or knows about their driving."* (IMPC05)

Despite the emphasis placed on collateral information from the informant, respondents were aware that that information still needed to be evaluated carefully, and that family members may be biased or have vested interests in keeping the person driving.

> *"Concerning informants now, I think I've become a little bit more sceptical, and maybe after some more recent information that I learned about, maybe the lack of reliability of informants"* (IMPC01)

An important question that was asked to both patients and informants was whether there had been any recent accidents, near-misses or traffic violations. Other driving specific information that was felt to be important was any physical or sequencing problems when driving the car, or delayed response to events on the road e.g. traffic lights or ignoring traffic signs. Many respondents also reported using observational techniques to collect this information such as checking the car for scrapes or dents.

> *"I have some sort of questions that I normally ask which is about ever had any accidents as or incidences. And have they, you know had any near misses. How are they? How are they in terms of getting around? Do they get lost?"* (IMPC04)

"I will go and look at the car and see if there's any scrapes and bumps." (IMPC08)

Beyond this many individual informal methods were reported on which there was no consensus. They ranged from informal observation of people as they enter/leave the clinic, or how well they engaged with the assessment process to adding questions in conversationally as part of the assessment, that can yield important information about how a person is managing driving, without asking the question outright. Additionally, any self-imposed restrictions such as not driving alone or driving at night were reported as a cause for concern.

> *"So, I … throw out questions and said. Do you find the roads really fast nowadays and lots of conversation and then I said, what does your wife think about your driving? She tells me all the time I'm too far in the middle of the road and I'm too far over, and I was like OK"* (IMPC11)

> *"I never drive by myself, but …I'd be thinking, why? Why are you not driving by yourself? And so do they only drive on known local routes and that's another red flag because although that would maybe protect them. Why are they only doing that? "(IMPC02)*

3.3.2.3.4 Relative importance of information gathered

Clinicians found it difficult to be definitive about which information was deemed most important in their decision-making process. The majority emphasised that it was a combination of the different information, and that often one element is not prioritised over any others. Despite this many of those interviewed identified some elements as being very important, most frequently the information given by family/informants. Although few respondents placed the majority weight of their decision on one point of information, a number did report 'red flags' that would feature heavily in their decision process or indicate to them that action would need to be taken. These varied across respondents, from visuo-spatial impairment, comorbidities and medication to police reports.

> *"I'd probably say across, across the board they're all as equally as important"* (IMPC06)

"But if family members raised concerns, then I will definitely take those seriously and that will be a real red flag" (IMPC01)

3.3.2.4 Theme four – Communicating the decision and managing conflict

The key finding here related to the importance of clear communication, both between the clinician and patient and their family, and between health care professionals. Clinicians also felt it was important to help the patient understand why the issue was being addressed. There is also a lack of support available beyond driving cessation.

3.3.2.4.1 Communicating safety concerns

Respondents reported that one of the important things that they try to communicate to the patient and their family is that this is being raised as it is a legitimate safety concern, and that it is a joint responsibility that the patient is legally required to engage with (e.g. by informing the DVLA). Clinicians also reported that it was helpful to explain that ultimately it is another entity, the DVLA, that makes the final decision about the persons driving.

"I always say we are obliged by the law to do this. This is not something that we choose to do is something that we have to do." (IMPC12)

"I said this is a decision made by the DVLA, not by us" (IMPC03)

3.3.2.4.2 Managing change

Communicating well with the patient is not just about understanding why a decision is being made, clinicians raised that it was important to be able to help the patient prepare for and manage change, as well as looking beyond driving. This was seen as an integral part of meaningful communication to the patient about what was happening to them. There was a consensus that at present the information available to clinicians to do this is fragmented, and there needs to be something to offer patients to help them cope with the decision and offer alternatives.

"*OK, what I want you to do at this point is consider if you had to stop driving in five years, 10 years, whenever it might be start to consider what you might use as alternatives. And I try and encourage them to do that because if they do that at this point, then the transition of having to stop driving if they've learned a bus*

route and a taxi route and alternatives then It's a lower blow, it doesn't impact on their functioning and getting things done" (IMPC08)

"maybe a bit of education on that would be good because a lot of people don't know much about mobility scooters, or they don't know much about public transport and accessibility for things so" (IMPC01)

3.3.2.4.3 Responses and engagement with the decision

As with raising the issue of driving, respondents reported to experiencing varied responses to their communication of the advice about driving. Interviewees felt that the usual response was one of acceptance, and often people had already realised that their driving had been affected and so it consolidated a decision they had already arrived at independently. However, they did report receiving some strong negative reactions also, particularly when people were not expecting to have their driving challenged.

"Sometimes people are very accepting of it and some people say, oh well, I'm getting on anyway. I was thinking I wasn't gonna renew my driving licence, but then other people can be quite annoyed and irritated and how dare you tell me to stop driving?" (IMPC06)

3.3.2.4.4 Clinician concerns regarding engagement with the decision

A concern raised by respondents was that patients, and sometimes family members, would not engage with the advice that has been given, although this seemed to be rare. Some respondents reported helplessness in what can be done when this happens and acknowledged that they can only give advice on what needs to be done and have no power to make sure this advice is followed. When faced with a situation like this, respondents reported emphasising the law, and the illegality of driving against advice.

"You can tell them not to drive, but they could choose to ignore your advice." (IMPC12)

"If they've been asked to inform the DVLA and inform the car insurance company and they haven't done that. I'm really quite clear and confident about my advice in terms of if you don't do that, you're illegal, you're driving illegally." (IMPC08)

Clinicians are aware that this is an emotive area for people and their family, and that conflict can often arise between the person and their relatives when they do not agree.

The family may be aware that the person is no longer safe to drive but will not engage with the process. In these situations, clinicians report that they take on the responsibility of being the 'bad guy' in order to resolve the situation and maintain family relationships.

> *"I have had families ring before I've gone to see the person and said 'I'm worried about my Dad's driving', well, we do address that. He says, 'well, I've tried, but he'll not listen to me.'"* (IMPC10)

3.3.2.4.5 Strategies to manage conflict and maintain the therapeutic alliance

When managing conflict about an individual's driving, either with the clinician or between the person and family members, respondents reported the importance of maintaining the therapeutic alliance through empathy, compassion and validating the difficult feelings that can arise. A strategy reported to achieve this was working in partnership with the family member and helping to steer the person to come to the decision themselves was felt by clinicians to be a compassionate way to help the person accept the decision and maintain their well-being.

> *"acknowledge what they're feeling and also, try and work with the carer, the family, and if the family member is clearly struggling to say that to their relative that they need to stop driving... try and sort of work with the carer...and sort of between you, advise, in an empathetic sort of caring way that this probably needs to happen"* (IMPC07)

3.3.2.4.6 Referrals for an independent assessment of driving

When a concern has emerged about a patient's driving from the assessment process, or there is uncertainty about their safety to drive, clinicians reported referring the person for an independent driving assessment. This is carried out as a separate process at an independent driving centre, who following the assessment, will advise the person as to whether they are safe or unsafe to drive and produce a written report to be sent to the memory service with the outcome. Clinicians reported that mainly people are happy to go for a driving assessment and emphasising that they are independent and separate from the memory assessment process is helpful to encourage engagement.

> *"I think what we probably would do is suggest to them that they do go for an assessment, but I usually sell it to people by saying, you know, it's completely*

independent, nothing to do with us, they'll give you a really detailed report. Often, they'll say, yes, it's fine to keep driving. Sometimes they won't, but at least you'll have it all in writing." (IMPC05)

3.3.2.4.7 Follow up

At present there is no identified pathway for a follow up process, either when a concern has been raised or a person has been referred for a driving assessment. However, despite this the memory assessment process does allow for the opportunity to follow up on the actions previously taken regarding driving. Clinicians ensure that it is documented so those who will have contact with the person further on in the diagnostic process will be aware of the advice given and actions taken so that it can be reviewed and followed up on at that point.

"But in terms of following it up. It's on a case-by-case basis, I would say. I don't think there is an identified pathway for that." (IMPC05)

"it's in our report then and when we feed back to the doctors, it's documented. If we've given advice on driving and the assessment plan. So, the doctors follow it up when they're seeing them." (IMPC10)

The opportunity to follow up can be role dependent, as well as process dependent, but many clinicians reported taking personal responsibility to ensure the correct actions had been taken. Information dissemination is also important for the follow up process, so that any clinician who may be coming into contact with the patient is aware of the advice that has been given, or the outcome of the driving assessment. This can also include informing the GP, and respondents reported making sure that this information is included in any letters regarding the patient, or correspondence to the GP. Respondents also noted there are information packs that are given to patients.

"I've always seen that as something that I have to take responsibility for." (IMPC09)

"I'll put it in the letter and I'll make sure that person is reviewing the patient would know to check … We'll make sure that the GPs are aware of that." (IMPC01)

3.3.2.5 Theme Five – Shaping a prospective tool and training needs

The key finding was that at present, clinicians do not have a decision aid or tool that they use when making a decision about driving safety, and that one would be helpful.

> "*No, it's a quite simple answer to that. Not really, no.*" (IMPC11)

3.3.2.5.1 The driving decision aid tool

Any driving decision aid tool would need to be simple and not add undue burden to an already busy assessment appointment.

While some respondents felt that the clinician consensus guidelines were an excellent reference, they were not regularly used to aid decisions in the clinical setting due to the length of the document.

> "*the consensus guidelines are excellent*" (IMPC01)

Although many clinicians have developed their own heuristics over time, these were not available to those new to the role. Clinicians also felt that the quality of information that they have currently to base their decisions on is sub-optimal, and that they have limited resources available to them.

> *"I don't think the ACE scores an accurate reflection of somebody's ability to drive because it's such an ingrained process."* (IMPC12)

There was a consensus that additional training around driving and dementia would be helpful. When considering the design and useability of a driving decision aid tool, the most common response was that it needed to be quick and easy to use. A number of designs were proposed with some respondents preferring something with tick boxes, and others a decision tree or flow chart, but agreed that it would need to include supplementary information.

> *"straightforward and to the point"* (IMPC07)

> *"Tick box. I think that tick box is good but also a little bit of description would be helpful." (IMPC03)*

Many respondents would like a tool to include a scoring system of some type, and different scoring systems were described by respondents. There was a preference for

linking scores to actions (such as a referral for a driving assessment) or indicating that the person might still be safe to drive or need to stop driving immediately.

> *"then the overall score will give you choice, like choices available and… So over 15, you would do this or over 8 you would do this."* (IMPC06)

In terms of which clinical elements should be included in a tool, responses suggested that a holistic assessment would be the most helpful, and so it should include not just neuropsychological scores, but other elements such as medications, frailty, functionality, comorbidities, driving history, insight and include space for informant report. The weighting of each of these elements is also important, and it needs to be based on up-to-date research. However, a tool or decision aid would still need to leave space for an element of clinical judgement.

> *"weighting each of those elements is helpful to know"* (IMPC01)

3.3.2.5.2 Useability of a driving decision aid tool

Clinicians thought a driving decision aid tool would be useful, but for a variety of reasons. Some respondents felt that it would be helpful for those new to the role, to ensure that everything that needed to be addressed in the assessment has been, or giving clarity and consistency to the decisions. The value of the driving decision aid tool would also extend beyond the clinical setting, with some respondents commenting that it could be used for explaining the decisions to the patient and their family, and as deflection from the potential negative responses.

> *"and it's something… that the patient can use, so they can see what they're doing as well, because sometimes when they actually see … that might make them a little bit more amenable."* (IMPC12)

3.3.2.5.3 Training and benefits of a driving decision aid tool

Clinicians also thought that training would be helpful to supplement the proposed tool, but that that training should be more comprehensive, that it would be beneficial to be able to explore the issue of driving in more depth.

> *"I think having some training or teaching on how memory problems or dementias can impact on driving so that we can relay that to patients and carers."* (IMPC02)

Clinicians felt that the benefit of a driving decision aid tool and supplementary training would introduce some needed consistency to the decision-making process. At present, it was acknowledged that individual clinicians would have differing thresholds for what they consider safe driving, and a tool could support a universal approach. Respondents also felt that there was a lack of awareness and expertise about what alternatives to driving are available, and that supplementary training could help empower clinicians by raising their knowledge level.

> *"I think it would be helpful to have training. So that the tool can be used as a guide. And so that everybody's on the same wavelength"* (IMPC08)

When thinking about what form they would like the training to take, there were mixed responses with some clinicians preferring online, but most preferring face-to-face interaction. Clinicians felt that face-to-face training would also have the advantage of peer-to-peer learning and giving the opportunity to discuss case studies and scenarios. It was also suggested that it would fit well into the regular team meetings and/or training sessions. As well as formal training, an e-learning package would be a good supplemental resource and could be used for reference, or for those unable to attend training. However, this introduced the element of what would be ideal vs practice in the real world, as most acknowledged that finding the time could be difficult.

> *"Online, I mean, it's partly the distance thing, you know, to come to a face-to-face training is really very difficult"* (IMPC09)

> *"What would be nice is to get a group of people together so they can exchange cases" (IMPC03)*

3.4 Discussion

This qualitative study used in depth interviews with a broad range of clinicians to examine how they perceived the issue of driving with a diagnosis of dementia and explore their experiences of addressing this with patients in a clinical setting. The purpose of this was to inform and shape the development of a tool for use in a clinical setting to help clinicians responsible for decisions about driving safety.

The findings supported the need for the development of a driving decision aid tool for use in a clinical setting as well as identifying a number of broader training needs.

Implications for clinical practice have also been identified, as well as examples of good current clinical practice when assessing driving safety. In addition, implications for the development of a tool, along with useful supplementary materials, were identified.

3.4.1 Implications for the driving decision aid tool

One of the important underpinning reasons for this piece of research was to explore with clinicians if they found a need for a driving decision aid tool in their practice and how this should take shape. The consensus was that there was a need for the development of a tool. Careful consideration needs to be given to the form that the tool will take, with those who will deliver it in mind. It will need to have effective content and face validity and be useable across disciplines.

Respondents felt that there were no formal tools available to them beyond the clinician consensus guidelines (Driving & Dementia Working Group, 2018) which are felt to be an excellent reference but not useable in a clinical assessment. As a result, clinicians are using personal heuristics that they have built up over time with experience. A clinical decision aid tool and training would introduce an element of consistency around decision making for driving safety that is currently lacking, as highlighted previously (Neilson et al., 2019).

Assessing driving safety was a measured clinical judgement, using all available information available, in line with current published clinical guidelines advocating for a holistic assessment (Driving & Dementia Working Group, 2018). At present these are consensus guidelines, and apart from some cognitive tests, there is little evidence for the role that other factors such as functionality, effect of medications/comorbidities etc. has on making a decision about driving safety (see chapter 2). Research is needed to determine the utility of these elements, which will be addressed in future chapters.

Time pressure in the initial assessment appointments is a priority for clinicians and to enhance useability the tool should be short and fit easily into the current assessment process. Driving assessment test batteries or tools that are currently available can take between 30-45 minutes to administer which is not feasible in a clinical setting (Kay et al., 2009; Lincoln et al., 2006; McKenna & Bell, 2007). However, a tension did emerge, with the respondents stating that the tool needs to be quick to use and succinct, but also wide-ranging combining different elements that they felt was an important part of

the decision-making process. The driving decision aid tool would need to balance these elements successfully.

The lack of consistency on the elements clinicians utilised in their assessment of driving safety reflects previous findings that a standardised approach is needed (Neilson et al., 2019) Differences were reported between professionals according to role, with community practitioners being more likely to identify the visuo-spatial element as important, while those with an occupational therapy background reported placing more emphasis on functional information. The tool would ideally incorporate the significant elements from across all roles to strengthen its face validity to clinicians from different professional backgrounds. A driving decision aid tool embedded within a SOP protocol would introduce this needed consistency to service delivery.

Clinicians would like a holistic tool that encompasses all aspects of information to guide the decision including assessment of function, comorbidities, medications and informant report and not solely focus on cognitive scores. They also expressed a preference for the inclusion of clear cut-off scores/binary options linked to specific actions. Although a scoring system is desired, is should not be rigid, leaving room for clinical judgement. The tool needs to be based on the most up to date research evidence, and this included as part of the composition so it is clearly referenced and users can be confident in its value. All of these desired elements need to be considered in the design of the driving decision aid tool.

3.4.2 Clinical implications

Respondents commented on the use of formal (e.g., supervision) and informal (e.g., debriefing with colleagues) support structures in place to support clinicians with the responses they may sometimes receive from patients to this difficult area. From these responses it is clear that there is a need for formal training in memory services focused on the issue of assessing driving safety in patients particularly for those new to the role. It should include emphasis on role responsibilities and the legalities of the issue and incorporate the national guidelines (Driving & Dementia Working Group, 2018). In addition, it should make clear the pathways available for both clinical and emotional supervision and support.

There is a need to balance consent (i.e. that the patient is aware that consenting to their

assessment will include addressing driving safety), and the need to complete the assessment and maintain the rapport with the person. This could be addressed by introducing an element of pre-counselling to the referral pathway, either at the initial point of referral from the GP or prior to the assessment appointment by secondary services and is considered further below. At present this decision is something that falls within the experience and clinical judgement of the individual and highlights a possible training need for those new to assessing the issue.

When managing conflict that may arise from addressing driving safety, it was reported that the response that they receive most often is one of acceptance, however, some strong negative responses have also been received and this can lead to clinician anxiety about the implications of a person refusing to follow the advice given to them, and feelings of helplessness. This highlights the clear importance of support for clinicians through formal supervision and case discussion, along with informal peer support and that they should be aware of the routes open to them.

3.4.3 Future editions of current guidelines

Clinicians felt that addressing driving safety is often not expected by the patient. Both patients and carers can disagree with the need of driving to be included as part of the assessment, and this suggests that an element of pre-warning should be considered. As with the consent issue previously discussed the use of pre-counselling could address this issue. A more formal approach to this could be the inclusion of a 'what to expect in your assessment' section in the appointment letter that includes that there will be a conversation about driving. Alzheimer's Society have excellent online resources, including information about driving, and a more informal approach could be signposting the person to explore this before the assessment appointment. Those developing guidelines and measures of good practice (e.g., the Memory Services National Accreditation Programme (Royal College of Psychiatrists, 2022)) may wish to consider this for inclusion in future.

3.4.4 Comparison between clinical practice and the research evidence base

A key finding of this research was the mismatch between the importance placed on some of the data used in the decision-making process for assessing driving safety by clinicians and the current research evidence for the efficacy of these. The most

important supplemental information was felt to be that of collateral information from an informant, which was weighted highly, although possible informant bias was acknowledged. While this information is undoubtedly important, caution needs to be applied. Previous research (Brown et al., 2005), found informants were only able to predict an unsafe on-road outcome half of the time. Although studies have shown some discriminant ability in caregiver prediction of driving fitness, it is neither high (Barco et al., 2021; Bixby et al., 2015) nor a highly accurate predictor on an on-road test outcome. Caregiver report is useful but should not be given disproportionate weight in the decision-making process. It is reasonable to recommend that a report of unsafe driving should be taken seriously and that a report of safe driving should be approached with more caution with a need for additional information to make an informed decision. Given the significance that clinicians place on collateral information this knowledge needs to be disseminated to clinicians.

Visuo-spatial ability was also weighted with high importance, but although there is an association with driving safety (Carr et al., 2011; Dawson et al., 2009; Fox et al., 1997; Grace et al., 2005; Piersma et al., 2016; Venkatesan et al., 2018), the discriminatory ability of tests used for this alone has not been established (see chapter 2). At present there have been no studies that have established the predictive value of the visuo-spatial domain of the ACE III, which respondents reported using as part of their assessment, and this will be explored in subsequent chapters.

Knowledge gaps were also identified. It was felt that helping to manage life after stopping driving should be addressed, but that this can be difficult at present as the information available about alternatives is fragmented and not consistent. This highlights a knowledge gap that needs to be addressed at a local level and can be incorporated into future training needs with tailored information for the locality.

3.4.5 Improvement opportunities in current practice

There is no pathway at present for follow up specific to driving, however, the initial assessment process allows a number of opportunities for a clinician to follow up on the actions that were previously taken. This highlights an area for possible improvement in clinical practice, as introducing a defined pathway for follow up could ensure that an important opportunity is not missed e.g. this would be particularly important for a

person who is assessed as safe to drive at present, and no referral is made for a driving assessment at that time but may need one at a point in the future. There needs to be a system in place to make sure that this could be picked up by another clinician who may be seeing that person in the future.

The importance of life after driving and the current lack of resources for both clinicians and patients is an important area that needs to be addressed. Previous research has highlighted that patients often feel the loss of driving is just another in a series of losses due to dementia (Sanford et al., 2019) and the importance of support and counselling in addressing the emotional and identity-related effects of loss of driving privileges (Sanford et al., 2019). There exists a huge gap in service delivery of an intervention and support program for patients and their families such as the CarFreeMe program (Scott et al., 2020), could be adapted for local use and integrated into current services.

North East Drive Mobility offer a Mobility Advice Service Hub, that offers a bespoke service and advice on alternative travel options for those no longer able to drive. Clinicians did not seem to be aware of this service, and there is the need to raise awareness within clinical services. Current patient literature also needs to be updated and adapted to highlight the provision and availability of this service. Future research is also needed to assess the efficacy of this service on patient well-being following driving cessation.

Previous research has highlighted the importance of advanced planning in driving cessation (Carmody et al., 2023), but there is no provision for that in present service delivery. It is important that a person living with dementia is encouraged to think about advanced planning for when they will need to cease driving. The adaptation of a currently available decision aid designed for this purpose (Carmody et al., 2014, 2023) and inclusion in the current driving and dementia information pack given to patients would improve this provision

3.4.6 Examples of current good clinical practice

Clinicians reported that driving is almost always addressed, unless there are some unusual or other urgent circumstances, at the initial assessment, and in the services interviewed this was usually done by the community practitioner. Other clinicians also

reported raising driving at their contact with the patient, further on in the process, and so all opportunity to address the issue is utilised.

When conflict does arise clinicians report approaching the subject with care and compassion, and using the strategy of gently steering the person to come to the decision for themselves. Previous research has demonstrated that satisfaction in the decision to cease driving was improved in patients who felt it was autonomous (Carmody et al., 2023). This is an example of good practice to defuse the situation and help maintain the therapeutic alliance.

Clinicians reported seeing addressing driving safety as a personal responsibility and ensuring that information dissemination regarding the actions that take place happens by including this in letters that other clinicians will have access to, and GP correspondence. These examples of good practice could be included in training on driving and dementia.

These examples of good practice were taken from respondents based in the North-East of England where driving and dementia has quite a high profile among clinicians due to the amount of research that has been carried out in this locality, it is likely that clinicians are more involved and aware of the issues than those in other services.

3.4.7 Key training needs and the scope of driving assessment training

Accompanying training would be an opportunity to include and discuss elements of driving safety assessment that clinicians felt was important to consider but would be impractical for inclusion in a driving decision aid tool. This should include elements such as good practice, guidance on law and pathways available when a person refuses to accept the decision, and examples of good assessment methods used from across all disciplines.

In addition to this, as previously discussed clinical perspective may influence what is considered important in decision making when assessing driving safety. Good training should allow for the knowledge that arises from the experiences of differing roles to be shared to enhance skill sets. Effective training needs to be developed by consensus, and involve GPs as well as clinicians from secondary care in order to address the disparity between what clinicians in secondary care think GPs should be doing and what is practical and possible in a primary care setting.

It was important that patients and their families understood that it was being raised as a legitimate concern, with safety in mind, and that it was not personal to that person. There were a number of ways clinicians did this, e.g. by using the responsibilities of their role, and normalisation of it as part of the assessment process. They also reported making sure that the person understands that there are external, legal requirements, and that ultimately the decision lies with the DVLA and not themselves. This experience and knowledge could be particularly helpful for those new to the role, or for those who are not confident in their approach to communicating this difficult aspect of the assessment and should be included in driving safety training.

Some clinicians expressed the need for clarification about the legal implications of advising patients about their driving, especially in view of updated DVLA guidance broadening the range of professionals who can take on this responsibility. This could be addressed relatively easily at the local level with a short training seminar by experienced colleagues.

Previous research has demonstrated that an increase in the availability of training in the assessment of driving safety in those with a dementia improves clinician confidence and willingness to address the issue (Neilson et al., 2019). In future there is the need to develop a comprehensive training course incorporating all of the elements discussed above, and to address the issue of the mis-match between what clinicians utilised in their decision making process and the current research evidence, with an accompanying on-line training resource available.

3.4.9 Changes to DVLA guidance for medical professionals

There were mixed feelings to the recent DVLA guidance changes to allow healthcare professionals other than doctors to complete the DVLA medical form. These were split according to role, with those for who it would be a new responsibility feeling that it sat within the senior clinical roles. The responses suggest an immediate training need for those who would be new to completing this element of the assessment, and a short course could enhance confidence and the potential to delegate this component within services enhancing efficiency.

3.4.10 Strengths and limitations

One strength of this research lies in the use of interviews as the data collection method. This enabled the generation of a rich data set that was able to achieve all of the aims that were set out for this research. In addition, the researcher was able to interview clinicians with varied roles and experiences in assessing driving safety in dementia. A further positive outcome from this research was the finding that clinicians were aware of their responsibilities with regards to raising and addressing the issue of driving safety in those with a dementia and were aware of the relevant laws and guidelines surrounding this.

A key strength in this research was the inclusion of perspectives from clinicians who worked in both urban and rural regions allowing for exploration of the unique challenges that may be faced when making an assessment of driving safety in these different environments.

This study also has several limitations, we were unable to get a primary care perspective on the issue as no GPs were interviewed as part of the research, while the research was focused on secondary care the perceived lack of input from GPs was discussed. Additionally, a GP perspective would have been useful when considering the role of pre-counselling. Some participants emphasised the importance of GPs exploring driving more consistently since they will usually be the initial contact with the person. However, we were unable to gain their perspective on this issue, and increasing clinical workload and time pressures in primary care assessments could make this challenging (Hobbs et al., 2016).

A further limitation is that all clinicians interviewed were from Old Age Psychiatry services. There are also memory services in Neurology and Elderly medicine departments, and we may not have captured the opinions and experiences that were unique to these services.

This research was conducted in services in the North East of England, which has good provision for an independent assessment of driving, and so the perspective of the clinicians interviewed may be different to others in different parts of the country where this is not the case. Recommendations for improvement in clinical service delivery, or

the identification of service provision gaps may not be the same across all memory services.

Due to the small sample size data adequacy may not have been reached and those with different views were missed due to the limited scope of this research. It should also be noted as a limitation that the interviewees in this study were aware of the researcher's involvement in the development and publication of the current driving and dementia clinical guidelines (Driving & Dementia Working Group, 2018), and that they may have been better informed than clinicians in other part of the country due to their locality. Further to this the sample was self-selecting, and so it is likely the views represented are those who are particularly engaged with the subject of assessing driving safety in dementia and it would have been beneficial to speak to clinicians who aren't as familiar with this subject.

3.5 Conclusions

A key finding was the support for the development of a driving decision aid tool for assessing driving safety. Respondents felt that it would help clarify what is helpful in making a decision and help introduce an element of consistency to clinical practice. The tool will need to be quick and simple to use due to time pressures but needs to have face validity to enhance useability in a clinical setting. An objective tool needs to compliment more comprehensive guidelines that outline the roles and responsibilities of clinicians (Driving & Dementia Working Group, 2018).

A further key finding was the mis-match in expectations between clinicians and patients in addressing driving safety, and clear communication is needed to manage any conflict this might produce. It was clear that there is very much an individual emphasis on clinician approached to assessing driving safety and the weighting placed on what is utilised when making a decision.

Knowledge gaps between what is being used in clinics and the research evidence were found that need to be addressed, and clear training needs were identified. There is the need for a wider course about assessing driving safety in those with dementia to address this.

Chapter 4. Retrospective notes study - Tool development

4.1 Aims, Objectives and Hypotheses

4.1.1 Aims

The primary aim was to develop a simple driving decision aid tool to help identify safe and unsafe drivers for use by a broad range of clinicians in a clinical environment.

4.1.2 Objectives

The objectives for this section are:

- Retrospectively review digital NHS clinical notes to compare people with a diagnosis of a dementia or MCI who were judged safe or unsafe in an on-road assessment on a range of measures including cognitive measures, comorbidities, medication and functional measures
- Determine the discriminant ability of these measures to identify safe and unsafe drivers
- Development of a tool that will use the optimum combination of these factors to identify those who are likely to be low risk or high risk in an on-road assessment
- To apply this tool in a prospectively recruited independent cohort to determine accuracy (Chapter 5)

4.1.3 Hypotheses

1. Clinical variables collected as part of a routine clinical assessments such as ACE III, MoCA, comorbidities, medications, informant concerns about driving and clinician concerns about driving will be predictive of the outcome of an on-road assessment of driving. Specifically, the following clinical variables will be associated with being assessed as unsafe to drive:
    a. Decreased ACE III visuo-spatial score
    b. Decreased ACE III attention score
    c. Decreased MoCA score
    d. Higher amount of comorbidities
    e. Use of medications that have a high anticholinergic burden

2. We will be able to identify a simple battery of predictive variables that will be able to accurately categorise people as 'low risk', 'high risk' and 'indeterminate risk' for driving. This will help to identify drivers who were safe to continue driving, should stop driving, and those who needed further assessment at a Drive Mobility centre (Figure 3).

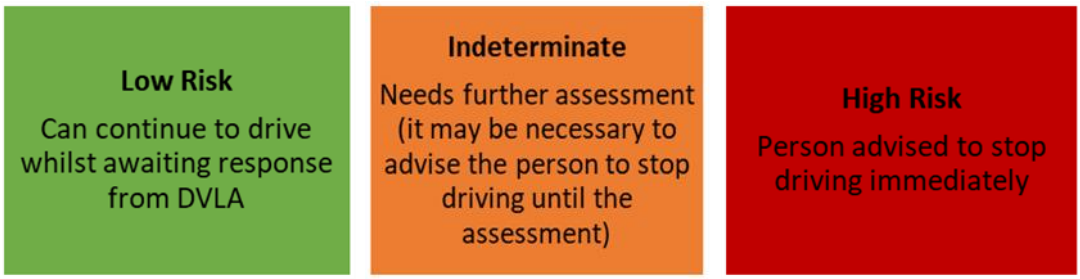

Figure 3: Outcomes of proposed driving decision aid tool

4.1.4 Ethical and Research and Development Approvals

Documentation for ethical approvals was submitted on 09/12/2019. Favourable opinion was received from HSC REC-B committee on 17/12/2019, and Health Research Authority (HRA) approval on 06/01/2020. Capacity and capability to commence from Cumbria, Northumberland Tyne & Wear NHS trust was received on 20/02/2020.

A substantial amendment and supporting documents for the retrospective case notes study was submitted to HSC REC-B committee on 01/11/2022, in order to add the collection of retrospective data from electronic clinical records to the study. A favourable opinion was received from the REC committee on 28/11/2022 and from the HRA & HCRW on 28/11/2022. Capacity and capability to commence from Cumbria, Northumberland Tyne & Wear NHS trust was received on 11/01/2023.

4.2 Methods – Tool development

4.2.1 Participants

This retrospective case notes study recruited participants who had previously undertaken a Drive Mobility on-road assessment of their driving as part of their routine clinical care between February 2022 and October 2023. Participants fulfilled criteria for all-cause dementia or MCI using NIA-AA criteria (Albert et al., 2011; McKhann et al., 2011).

4.2.2 Recruitment of participants

Potential participants, who had previously completed an on-road driving assessment, were identified by the Drive Mobility Centre at Walkergate Park in Newcastle-upon-Tyne. Only people who had indicated on their consent form for on-road assessment that they were happy to be approached about research were contacted. Contact details were provided to the study team, the initial approach was made by letter with the inclusion of the participant information sheet. If no response was received, a follow up telephone call took place after two weeks to assess interest in participation and discuss the study further. It was made clear to the potential participants that this was for a review of their clinical notes only and participation involved the consent process only.

4.2.3 Inclusion and exclusion criteria

Inclusion criteria:

- Age ≥60
- Referred for a Drive Mobility assessment of their driving in the previous 12 months as part of their routine clinical care
- Capacity to give informed consent
- Fulfil NIA-AAA diagnostic criteria for an all-cause dementia or MCI (Albert et al., 2011; McKhann et al., 2011)

Exclusion criteria:

- Absence of capacity to give informed consent
- Did not complete full on-road assessment

4.2.4 Consent

Those who were willing to participate in the study gave informed, written consent, witnessed by an appropriately trained member of the study team. A copy was held on record in the site file, and a copy was given to the participant.

4.2.5 Data collection

Data was collected from the participant's electronic medical record, using the information routinely collected and documented as part of clinical appointments. The information that was extracted was recorded prior to the on-road assessment.

The original data was extracted from the Cumbria, Northumberland Tyne and Wear NHS Trust electronic records system, Rio. The data was obtained from several different sources within the system:

- Progress notes – a series of notes in date order entered into the record by any clinician that has contact with the patient. These are recorded for every contact and for this study the information of interest was:
    - assessments carried out as part of the diagnostic process, including scores
    - details of assessment appointments, including informant contributions (of particular importance was any conversation regarding safety to drive)
    - details of any clinician completed scales such as Clinical Frailty Scale or Clinical Dementia Rating scale
    - details of current medications
    - details of comorbidities
    - details of referrals to other services (including for an on-road driving assessment)
    - recorded outcomes from referrals to other services
    - details of diagnosis
    - recorded details of any clinician advice regarding driving
- Core clinical documents – a section containing all important clinical documents. These will vary from patient to patient depending on service contact and will contain information such as care plans, risk management plans, screening tools and discharge summaries. For this study the information of interest was:
    - medication information
- Document uploads – this section contains an upload of all relevant paper documentation for the patient. Documents of interest for this study were:
    - correspondence from and to the GP including medical history and diagnosis
    - copies of memory assessments (ACE III, MMSE)
    - letters of referral to Drive Mobility for an on-road driving assessment
    - detailed outcome letter from Drive Mobility, including details of MoCA score

The planned data extraction included:

- Demographics and clinical history
    - diagnosis
    - age
    - sex
    - comorbidities
    - current medications
- Cognition assessments
    - Addenbrooke's Cognitive Examination (ACE III)
    - Mini-Mental State Examination (MMSE)
    - Montreal Cognitive Assessment (MoCA)
- Neuropsychiatric symptoms
    - Geriatric Depression Scale (GDS)
    - Hospital Anxiety and Depression Scale (HADS)
- Functional assessments
    - Bristol Activities of Daily Living scale (BADL)
- Clinician completed scales
    - Clinical Frailty Scale (CFS)
- Informant report/opinion of driving safety
- Clinician advice to participant about driving safety
- Outcome of Drive Mobility on-road assessment

The process of data extraction revealed that several of these were not routinely conducted and recorded as part of the clinical diagnostic process. The data available for extraction is detailed in the next sections. All data extracted were within 6 months of the on-road assessment of driving.

4.2.6 Demographic Data

The sex and age of the participant at the time of referral for an on-road driving assessment were recorded.

4.2.7 Non-cognitive variables

The clinical history included recorded medical history to gather information on any comorbidities and the current medication for the participant and included alcohol intake if recorded.

4.2.7.1 Comorbidity measure – The Charlson Comorbidity Index (CCI)

The CCI is a method developed to classify comorbid conditions (Charlson et al., 1987). It is a weighted index that accounts for the number and seriousness of any conditions that the person may have. Weighted scores are assigned to age, myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular accident or transient ischemic attack, dementia, chronic obstructive pulmonary disease, connective tissue disease, peptic ulcer disease, liver disease, diabetes, hemiplegia, chronic kidney disease, solid tumour, leukaemia, lymphoma and AIDS, giving an overall total comorbidity score. A higher score indicates an increased comorbidity risk. For this research, age was not included as it was investigated separately. Dementia was also not scored due to the population under investigation. The total score was recorded. Data was derived from the GP referral letter and the record of the initial assessment in the memory service.

4.2.7.2 Medication measure – Medichec

Medichec is an online tool that assesses the anticholinergic effects of medication, and the negative effects that it may have on cognitive function in older people (Bishara et al., 2017). Medications that are routinely used in older people were identified using the British National Formulary (BNF), and scores of (0-3) are assigned to each one based on the anticholinergic potency, the ability to cross the blood-brain barrier and reports of adverse cognitive effects. It produces scores that are colour categorised from green (safe to use, score 0) through yellow (score 1) and orange (score 2) to red (withdraw or switch if appropriate/possible, score 3) and produces a total Anticholinergic Effect on Cognition (AEC) score. A higher numerical score indicates a higher burden.

It also identifies medication that can cause dizziness and drowsiness and ranks them according to the frequency of reported adverse events, using the same colour coded system.

Dizziness score was the number of medications in which dizziness is listed as a common or very common side effect. Drowsiness score was the number of medications where drowsiness is reported as common/very common and/or has an additional warning in the BNF for drowsiness.

Data was derived from the GP referral letter and the written record of this initial memory assessment in the clinic.

4.2.8 Cognitive assessments

4.2.8.1 Addenbrooke's Cognitive Examination – ACE III

The Addenbrooke's Cognitive Examination (ACEIII) is used in the diagnostic process to detect early dementia and has been reported to have a high sensitivity and specificity for the established cut-off scores (using the cut-off score of 88 sensitivity is 100% and specificity 96%, and the cut-off of 82 yields sensitivity of 93% and specificity of 100%(Hsieh et al., 2013)). It is scored on a 100-point scale and assesses five cognitive domains (attention, memory, fluency, language and visuo-spatial skills) (Hsieh et al., 2013). The total score, domain scores and individual item scores were extracted, as well as a combined total for the drawing tasks (Piersma et al., 2016).

4.2.8.2 Montreal Cognitive Assessment (MoCA)

The MOCA is a short measure of cognitive function and is particularly effective in detecting mild cognitive impairment (sensitivity 90%, specificity 87%) (Nasreddine et al., 2005). The MoCA is scored on a 30-point scale and measures the domains of visuo-spatial/executive function, naming, language, attention, memory, delayed recall, abstraction and orientation (Nasreddine et al., 2005). The total score only was extracted.

4.2.9 Informant measure – Concerns about driving

As part of the clinical assessment process, where possible, an informant will often be asked to provide additional information to supplement the information gathered from the person. As part of this, they may be asked if they have any safety concerns around driving. This was recorded as a simple yes/no response and was derived by assigning 'yes' if any concern about driving safety from the informant was documented, even if they were not directly asked. 'No' was assigned to any participant that had no documentation recorded of informant concerns.

4.2.10 Clinician advice about driving

Where it was recorded as part of the clinical assessment, it was noted if the clinician had advised the person to stop driving until the on-road driving assessment with Drive Mobility took place. This was recorded as a simple yes/no response.

4.2.11 Driving assessment

Participants had all been referred to Drive Mobility for a comprehensive on-road assessment of driving. The driving assessment includes a pre-driving assessment and on-road driving assessment.

For all those referred, the pre-driving assessment includes (where possible), medical history, tests of vision, range of movement, perceptual and cognitive deficits and objective measures of steering strength, brake pressure and reaction/decision times.

The on-road component of the assessment can vary depending on the local geography, but needs to include junctions, roundabouts, crossroads, lane changes, independent driving, sections of varying speed restrictions and pedestrian crossings.

Individual aspects of the drive are scored on a four-point scale:

- 1=good (no evidence of impairment of increased road risk)
- 2=acceptable (some minor evidence of impairment but no significant increase of road risk)
- 3=poor (evidence of impairment and increased road risk)
- 4=very poor (significant impairment and significantly increased road risk)

A score of 1-2 are considered to represent safe driving, with the dividing line between 2 and 3 marking the transition to potentially unsafe driving. The on-road items scored are physical ability to operate the controls of the car, higher driving skills and additional aspects such as speed control/emergency stop/lane discipline/observation etc.

At the end of the assessment the driver is rated as safe and may continue to drive, or unsafe and are advised against driving, based on the comprehensive assessment. This outcome was reported to the researcher, no other data from the independent driving assessment was available to the researcher.

4.2.12 Missing data

Due to the retrospective nature of data collection, it was not possible to retrieve a full data set for all participants. Due to the small data set, data imputation was not used.

4.2.13 Data analysis plan

All data was analysed using IBM SPSS statistics version 29.0. The collected data was analysed to identify which of the collected variables were predictive of the on-road assessment outcome and develop a combination to give optimum sensitivity and specificity to identify potentially high risk drivers. The independent variable was the rating of safe or unsafe by Drive Mobility. The data analysis went through a series of stages.

4.2.13.1 Stage 1: Tests of normality

Continuous data was tested for normality using the Shapiro-Wilk test. Data was considered not normally distributed if this was significant to the <.05 level.

4.2.13.2 Stage 2: Group comparisons

Individual variables were then tested to identify differences between safe and unsafe drivers. Due to the non-normal distribution of the data, non-parametric tests were used. For continuous variables, the Mann Whitney U test was used, and the median and inter-quartile range reported for the safe and unsafe groups. Chi Square or Fisher's exact tests were used on binary/nominal data.

4.2.13.3 Stage 3: Discriminant ability

Discriminant ability of the individual variables was established by using area under the curve (AUROC) analysis and reported with confidence intervals. Sensitivity and specificity were calculated for variables with an AUROC above 0.5. This cut-off was selected as any variable under this would have a predictive value worse than chance, and was based on a priori hypothesis of the direction of association (i.e. that worse cognition and higher co-morbidity, increased informant concerns about driving would be associated with an unsafe on-road assessment). To identify potential optimum score thresholds, classifier evaluation metrics were also calculated using the leave one out technique, and the sensitivity and specificity were calculated and reported.

4.2.13.4 Stage 4: Potential predictors made binary

The variables with AUROC>.50 were made binary using the optimal threshold determined in the discriminant analysis. A binary score of 0 was assigned to scores associated with being low risk, and 1 to those associated with being high risk from the score threshold.

4.2.13.5 Stage 5: Generation of the driving decision aid tool

The binary variables generated in previous stage 4 were entered into a binary logistic regression to generate the tool. The stepwise forward selection method was selected, in this method the model starts with no variables included and then tests the addition of each variable. Variables are added that give the most statistically significant improvement in the model and this process is repeated until no more variables will improve the model to a statistically significant extent. In order to include as many cases as possible in the analysis, due to missing data, the analysis was performed four times to identify the optimum combination of predictors. The analyses run were:

1. Variables that were present for all cases
2. Analysis 1, plus MoCA total score
3. Analysis 1, plus clinician advice about driving
4. Analysis 1, plus informant concerns about driving

Analyses 2-4 were used exclusively to determine if the additional variable (e.g. MoCA total for analysis 2) was included in the final model.

4.2.13.5.1 Selection of optimum clinical tool from stage 5 analysis

The output from each analysis was examined and used the Wald values to determine which model contained the most statistically significant contributing variables. This model was selected as the basis for the clinical tool.

The final driving decision aid tool was then derived from this model using only the significant contributing variables.

4.2.14 Application of the driving decision aid tool to the retrospective cohort

The tool was applied to the retrospective cohort. Crosstabulation was used to plot the clinical tool score against the on-road outcome to determine if the clinical tool indicated a binary or trichotomous scoring approach. Discriminant ability of the final tool was

established by AUROC analysis and classifier evaluation metrics determined the sensitivity and specificity of the scoring.

4.2.15 Testing the driving decision aid tool

The resulting tool was later applied to an independent cohort of participants (Chapter 5).

4.3 Results – Tool Development

4.3.1 Participants

Thirty-one eligible participants were recruited into the study with an overall median age of 75, with 23 male and 8 female. Fourteen (45%) of the participants were prescribed anti-dementia medication and 10 had a diagnosis of MCI, 14 a diagnosis of Alzheimer's disease, 3 vascular dementia and 4 mixed dementia. Nineteen were classified as safe (median age 75.0) and twelve as unsafe (median age 82.5) in the on-road assessment.

4.3.2 Cognitive measures

Data extraction was possible for all 31 cases for the ACE III total score, and 5 domains. Scores for individual items on the ACE III was available for 30 cases, and the MoCA total score was available for 26 cases.

4.3.2.1 ACE III scores

The ACE III total score was not significantly predictive of on-road driving safety (AUROC=0.61 (0.41-0.82), p=0.31).

Of the five ACE III domain scores, only the visuo-spatial was a significant predictor (AUROC=0.73 (0.53-0.92, p=0.04). No other domain score, or item score within those domains discriminated significantly between safe and unsafe drivers.

From the individual items on the ACE III the clock emerged as a significant predictor variable (AUROC=0.75 (95% CI 0.56-0.93), p=0.02). A number of individual variables were over the AUROC cut-off of 0.5 but did not reach significance (Table 16).

The total drawing score (infinity, cube and clock) was also a significant predictor (AUROC=0.72 (0.53-0.92), p=0.04).

	Safe (n=19)	Unsafe (n=12)	p	AUROC (95 %CI)	Optimal threshold	Sensitivity	Specificity
Age, median (IQR) n=31	75.0 (72-77)	82.5 (74.5-84.0)	**0.02**[a]	0.75 (0.57-0.93)	80.5	0.67	0.84
Sex, n=23, male (74%)	12 (63%)	11 (92%)	0.11[b]	0.64 (0.45-0.84)	n/a	0.92	0.37
Anti- dementia medication prescribed, n=14 (45%)	9 (47%)	5 (42%)	0.76[c]	0.53 (0.32-0.74)	n/a	0.58	0.47
ACE III clock item score	5.0 (3.8-5.0)	3.0 (2.3-3.8)	**0.02**[a]	0.75 (0.56-0.93)	3.5	0.75	0.78
ACE III Attention domain score	14.0 (12.0-17.0)	15.5 (13.3-16.6)	0.48[a]	0.42 (0.22-0.63)	-	-	-
ACE III Memory domain score	14.0 (11.0-19.0)	13.0 (9.3-14.8)	0.51[a]	0.57 (0.36-0.79)	15.5	0.83	0.37
ACE III Fluency domain score	9.0 (5.0-11.0)	8.0 (6.0-8.8)	0.33[a]	0.61 (0.41-0.83)	9.5	0.92	0.47
ACE III Language domain score	25.0 (24.0-26.0)	25.0 (20.5-3.8)	0.51[a]	0.58 (0.35-0.80)	22.5	0.33	0.90
ACE III Visuo-spatial domain score	14.0 (14.0-16.0)	13.0 (11.0-13.0)	**0.04**[a]	0.73 (0.53-0.92)	13.5	0.83	0.79
ACE III Total score	75.0 (68.0-84.0)	69.5 (64.0-77.5)	0.31[a]	0.61 (0.41-0.82)	78.5	0.83	0.42
ACE III Drawing total item score	6.5 (5.8-8.0)	5.0 (3.3-5.8)	**0.04**[a]	0.72 (0.53-0.92)	5.5	0.75	0.78

	Safe (n=19)	Unsafe (n=12)	p	AUROC (95 %CI)	Optimal threshold	Sensitivity	Specificity
MoCA Total	20.0 (18.0-23.0)	17.0 (15.0-20.3)	0.07[a]	0.73 (0.52-0.94)	18.5	0.75	0.72

Table 16: Demographics and Cognitive measures by on-road outcome group in the development cohort. Median (IQR) except where stated otherwise.

Abbreviations: ACE III = Addenbrooke's Cognitive Examination, CI=Confidence Interval, IQR=Inter Quartile range, MoCA=Montreal Cognitive Assessment.

a=Mann Whitney U test, b=Fisher's Exact test, c=Chi Square.

4.3.2.2 MoCA total score

MoCA total score was close to significance (see Table 16) but did not reach it. However, it demonstrated a discriminant ability similar to the ACE III visuo-spatial domain (AUROC=0.73 (0.52-0.94)).

4.3.3 Non-cognitive measures

Data extraction was possible for all 31 cases for medication and comorbidities. Clinician advice about whether the person could continue driving until the assessment was documented in 26 cases, and any informant concerns about driving were recorded in 25 cases.

4.3.3.1 Medication

None of the medication measures discriminated significantly between the safe and unsafe groups or reached the 0.5 threshold for discriminant ability. The median scores for those in the safe group for AEC total, and total medications causing dizziness were numerically higher than for those in the unsafe group (Table 17).

4.3.3.2 Comorbidities

The Charlson comorbidity index did show significant differences in discrimination, (AUROC=0.25 (0.07-0.43), p=0.02) between the safe and unsafe groups however, the AUROC was poor.

4.3.3.3 Informant concerns about driving and clinician advice about driving

The discrimination between the safe and unsafe groups was not significant for informant concerns about driving (AUROC=0.58 (0.34-0.81), p=0.66) or clinician advice to stop driving (AUROC=0.63 (0.40-0.85), p=0.23).

	Safe (n=19)	**Unsafe (n=12)**	p	AUROC(CI)	Optimal threshold	Sensitivity	Specificity
AEC Total, Median (IQR)	0 (0-1)	0 (0-1)	0.95[a]	0.49 (0.28-0.70)	-	-	-
Number of medications causing dizziness Median (IQR)	4.0 (3.0-5.0)	3.5 (1.3-4.8)	0.16[a]	0.35 (0.15-0.55)	-	-	-
Number of medications causing drowsiness (Median, IQR)	1.0 (1.0-2.0)	1.0 (0.0-2.0)	0.18[a]	0.35 (0.15-0.55)	-	-	-
CCI Total score (Median, IQR)	2.0 (1.0-4.0)	0.5 (0.0-1.8)	**0.02[a]**	0.25 (0.07-0.43)	-	-	-
Informant concerns raised about driving, n=7 (28%)	3 (21%)	4 (36%)	0.66[b]	0.58 (0.34-0.81)	n/a	0.36	0.79
Clinician advised stop driving until assessment, n=9 (36%)	4 (25%)	5 (50%)	0.23[b]	0.63 (0.40-0.85)	n/a	0.50	0.75

Table 17: Non-cognitive measures by on-road outcome group in the development cohort

Abbreviations: AEC= Anticholinergic Effect on Cognition, AUROC=Area under the curve, CCI=Charlson comorbidity index, CI=Confidence Interval, IQR=Inter Quartile range.

a=Mann Whitney U test, b=Fisher's Exact test, c=Chi Square.

4.3.4 Generation of the driving decision aid tool

The binary logistic regression excluded cases with any missing data, resulting in the loss of 12 cases if all variables were analysed simultaneously. Due to the small numbers, to mitigate this, four stages of analysis were undertaken. Where variables were not already binary, the thresholds in tables 16-17 were used to binarise them.

4.3.4.1 Analysis1: Variables present for all cases

Thirty cases were included in the analysis, one case was excluded as not all ACE III scores were available for that person.

The four-step model comprised ACE III visuo-spatial domain, age, sex and ACE III orientation score. Only ACE III visuo-spatial domain (X^2=8.89, 1, p=0.003) at step one and ACE III visuo-spatial domain (x^2=6.65, 1, p=0.010) and age (x^2=4.59, 1, 0.032) at step two were significant within the model. All variables in steps three and four of the model were not significant at the individual variable level, therefore these models were not taken forward (see Table 18).

This binary (low risk/high risk) model at step two yielded 50% sensitivity and 94% specificity to predict unsafe drivers and gave an overall percentage correct prediction rate of 77% (see Table 19). The Hosmer and Lemeshow test was not significant (p=1.0) showing goodness of fit for the model.

Step	Variable(s)	(Wald, df, p)			Odds ratio (95% CI)
1	ACE III Visuo-spatial domain	8.89	1	**0.003**	0.06 (0.01-0.38)
2	ACE III Visuo-spatial domain	6.65	1	**0.010**	0.05 (0.00-0.47)
	Age	4.59	1	**0.032**	0.75 (0.01-0.80)
3	ACE III Visuo-spatial domain	0.0	1	0.998	0.00 (0.0 - .)
	Age	0.0	1	0.998	0.00 (0.0 - .)
	Sex	0.0	1	0.998	1158477584.5 (0.0-.)
4	ACE III Visuo-spatial domain	0.0	1	0.996	0.00 (0.00-.)
	Age	0.0	1	0.996	0.00 (0.00-.)
	Sex	0.0	1	0.996	2.577E+23 (0.00-.)
	ACE III Orientation score	0.0	1	0.997	0.00 (0.00-.)

Table 18: Binary logistic regression analysis 1- variables in model

Step	**Model coefficients (X^2, df, p)**			**Model summary (Nagelkerke R^2)**	**Goodness of fit (X^2, df, p)**			**Sensitivity (%)**	**Specificity (%)**	**Overall correctly classified (%)**
1	11.57	1	<.001	0.43	0.0	0	-	83.3	77.8	80.0
2	17.62	2	<.001	0.60	1.53	2	0.47	50.0	94.4	76.7
3	24.43	3	<.001	0.75	0.0	4	1.0	75.0	88.9	83.3
4	29.97	4	<.001	0.85	0.0	4	1.0	100.0	83.3	90.0

Table 19: Binary logistic regression results for analysis 1

4.3.4.2 Analysis 2 - 4

In analyses two to four, in each case the variable of interest (MoCA (n=25), clinician advice about driving (n=25) and informant concerns about driving (n=25)) were not significantly associated with on-road assessment outcome in the model (see Tables 20-22) and so these variables were not included in the driving decision aid tool.

Step	Variable(s)	(Wald, df, p)			Odds ratio (95 %CI)
1	ACE III Visuo-spatial domain	5.22	1	**0.022**	0.10 (0.02-0.72)
2	ACE III Visuo-spatial domain	4.47	1	**0.035**	0.07 (0.01-0.83)
	Age	3.76	1	0.053	0.09 (0.01-1.03)
3	ACE III Visuo-spatial domain	3.23	1	0.070	0.08 (0.01-1.26)
	Age	0.0	1	0.998	0.0 (0.0-.)
	MoCA total score	0.0	1	0.998	0.0 (0.0-.)
4	ACE III Visuo-spatial domain	0.0	1	0.998	0.0 (0.0-.)
	Age	0.0	1	0.997	0.0 (0.0-.)
	MoCA total score	0.0	1	0.997	0.0 (0.0-.)
	Anti-dementia drug prescribed?	0.0	1	0.998	366367485.97 (0.0-.)

Table 20: Binary logistic regression analysis 2 with MoCA added- variables in model

Step	Variable(s)	(Wald, df, p)			Odds ratio (CI)
1	ACE III Visuo-spatial domain	7.09	1	**0.008**	0.04 (0.00-0.43)

Table 21: Binary logistic regression analysis 3 with clinician advice added - variables in model

Step	Variable(s)	(Wald, df, p)			Odds ratio (CI)
1	ACE III Visuo-spatial domain	7.02	1	**0.008**	0.07 (0.01-0.49)
2	ACE III Visuo-spatial domain	5.4	1	**0.020**	0.06 (0.01-0.64)
	Age	3.75	1	0.053	0.09 (0.01-1.03)

Table 22: Binary logistic regression analysis 4 with informant concerns added - variables in model

4.3.4.3 Selection of optimum driving decision aid tool from Analysis 1 to 4

The model of predictors generated by analysis 1 was selected as the optimum tool. This comprised ACE visuo-spatial domain, age, sex and ACE orientation score.

4.3.4.4 Selection of final driving decision aid tool to detect unsafe drivers

The final clinical tool was selected from step two of the model, rather than step four as after that step the unique contribution of the remaining variables were non-significant (see table 18).

4.3.5 Driving decision aid tool scoring and application

The clinical tool produced a score from 0-2, with a score of 0 suggesting low risk driving, a score of 1 indeterminate risk and may need further assessment and a score of 2 suggesting high risk driving.

Score and cut-off	**No/Yes (0/1)**
ACE visuo-spatial domain <=13.5	
Age >80.5	
Total (0-2)	

Figure 4: Driving decision aid tool

The clinical tool demonstrated good discriminant ability (AUROC=0.86). Classifier evaluation metrics identified the optimum threshold as 0.5. Co-ordinates of the ROC curve gave a sensitivity of 92% and specificity of 68% at the 0.5 cut-off, and a sensitivity of 50% and specificity of 95% at the 1.5 cut-off to detect high risk drivers.

When applied to the development cohort, described in this chapter, the clinical tool correctly classified 6/12 high risk drivers giving a positive predictive value of 85.7% and 13/14 low risk drivers giving a negative predictive value of 92.9%. Of the 10 scored to be indeterminate risk, 5 were found to be low risk and 5 high risk.

	Safe	Unsafe
Tool score 0	13 (68%)	1 (8%)
Tool score 1	5 (26%)	5 (42%)
Tool score 2	1 (6%)	6 (50%)

Table 23: Driving decision aid tool classifications of safe and unsafe drivers in development cohort, sensitivity & specificity using 1.5 cut-off

The testing of the tool in an independent cohort will be described in chapter 5.

4.4 Discussion – Tool development

4.4.1 Brief summary of aim and results

The aim of the tool development stage in this research was to use both cognitive and non-cognitive data routinely collected in clinical assessments to develop a driving decision aid tool to identify unsafe drivers in those with a diagnosis of a dementia or MCI. The data was collected retrospectively from clinical records from people who had undergone an on-road assessment of their driving. Cognitive data extracted were scores from the ACE III and MoCA, non-cognitive data extracted were age, sex, any comorbidities, medication, informant concerns about driving and clinician advice about driving.

Data was analysed in four stages using binary logistic regression generating four models, and the clinical tool was generated by selecting the model with the most significant Wald values. The final clinical tool was created by using the step from this model containing the significant variables. The final clinical tool included comprised of two features, the ACE III visuo-spatial score and age. It is scored from 0-2 with 0 = low risk, 1 = indeterminate risk and 2 = high risk.

In the development cohort this clinical tool was able to correctly classify 6/12 high risk (PPV=85.7%) drivers, and 13/14 low risk drivers (NPV=92.9%), 10 drivers were found to be indeterminate risk. The specificity was 50% and sensitivity 68%.

4.4.2 Cognitive measures

4.4.2.1 Measures of global cognition (ACE III and MoCA)

This research produces novel data on the predictive ability of the ACE III and its components with respect to driving safety, having not been tested in the literature previously.

The total score of the ACE III was also not a significant predictor, however this test is designed to detect dementia and aid in clinical diagnosis rather than assess driving safety, and these findings are consistent with previous literature that shows that other dementia screening assessments such as the MMSE are poor indicators of driving ability (Bennett et al., 2016).

From the ACE III domain domains, the visuo-spatial domain was a significant predictor (see Table 16). It is difficult to assess this outcome in the context of previous literature as this is the first time this has been tested. However, it is in agreement with the inclusion of visuo-spatial assessment elements in previously published predictive test batteries (Lincoln et al., 2006; McKenna et al., 2004).

All of the elements that were significantly predictive of unsafe driving from the ACE III were visuo-spatial in nature. From a large range of ACE sub scores, only the visuo-spatial scores were significantly different in safe and unsafe drivers. In chapter 3 clinicians described this as one of the most important factors when they make a decision about driving safety in a clinical setting, and these findings are consistent with that practice. In addition, clinicians described time pressures, and the need for simplicity in the assessment of driving safety, and these results suggest that the visuo-spatial domain of the ACE III can do this, as it is already used in many memory clinics. It would also be useful in clinical settings where a full cognitive assessment might not be carried out, such as primary care or geriatric services and can be easily adapted for this.

Total score for the MoCA was close to significance and demonstrated good discriminant ability, sensitivity and specificity (75% and 72% respectively). Only one previous study has investigated the discriminant ability of the MoCA in respect to driving safety prediction, and although the total score was not found to be predictive of on-road outcome, the sub domains of attention, and combined visuo-spatial/executive function and attention were (Ma'u & Cheung, 2020). Due to the way the data was extracted for this research, it was only possible to retrieve a total score as individual item scores were not recorded in the clinical notes so it is not possible to make a direct comparison, however the above reported sensitivity and specificity for our established cut-off for total score was similar to that reported for the calculated cut-off scores for the sub-domain of attention (73% and 72 % respectively) and combined visuo-spatial/executive

function and attention (80% and 67% respectively) reported in this study (Ma'u & Cheung, 2020).

MoCA total score was included in the model from analysis 2 of the binary logistic regression, however did not significantly contribute to the model. The data from this research suggests that the MoCA is not useful as a predictor of driving safety in a clinical setting, however the MoCA is designed to specifically identify memory impairments and not assess driving safety (Nasreddine et al., 2005). These findings are consistent with those in previous literature that global measures of cognition are not good predictors of driving safety (Bennett et al., 2016).

4.4.2.2 Visuo-spatial domain

From the individual elements of the ACE III, the clock drawing was also a significant predictor (see Table 16). Previous studies have demonstrated the correlation between the clock drawing task and on-road outcomes (Carr et al., 2011; Venkatesan et al., 2018), however there is no comparable date on the predictive ability of this test alone.

When the drawing elements of the ACE III visuo-spatial tasks are combined they are significant predictors of unsafe driving, and also demonstrate good discriminant ability, sensitivity and specificity (see Table 16). Only one previous study published comparable results for drawing demonstrating significant correlation with on-road outcome (Piersma et al., 2016). However, for the purposes of this research it was not entered into the regression analysis for the final predictive model, as the visuo-spatial domain containing these elements, and demonstrated better discriminant ability, sensitivity and specificity.

4.4.2.3 Other cognitive domains

Despite previous research demonstrating a correlation between attentional assessment measures and on-road outcome (Carr et al., 2011; Dawson et al., 2009; Grace et al., 2005; Ott, Festa, et al., 2008; Piersma et al., 2016; Venkatesan et al., 2018; Yamin et al., 2016), and reporting good discriminant ability (Papandonatos et al., 2015) the results of this research did not correspond with these findings, with both the attention domain and individual attention items on the ACE III emerging non-significant, however with the exception of Grace (2005) and Yamin (2015, 2016) the number of participants in this cohort was much smaller. This was an unexpected outcome as it would be anticipated that that attention would be important in an assessment of driving safety, and previously

published batteries to specifically determine driving safety do include a measure of attention (Lincoln et al., 2006; Piersma et al., 2016).

4.4.3 Non-cognitive measures

4.4.3.1 Medication

None of the medication measures investigated in this research were significantly predictive of driving safety. In opposition to the expected directional outcome of this measure (i.e. that higher scores would be associated with unsafe driving), the scores for medication that can cause dizziness or drowsiness were numerically higher in the safe group than the unsafe group, suggesting that this is not an important factor in determining driving safety. A possible reason for this is that the measure used may not have been optimal for the purposes of this research, with the developers of the Medichec resource stating it was not possible to classify all of the drugs that may have an effect on cognition in older people (Bishara et al., 2017). It was also not possible to record dose and concordance with medication regimen in this study and so it is possible this could have impacted the results; it would be expected that higher dosages of these medications could have an effect on driving safety but this cohort may have been prescribed relatively low dosages.

4.4.3.2 Comorbidities

The overall score for comorbidities in this cohort found significant differences between safe and unsafe groups. This cohort was relatively healthy, and had a low level of comorbidities, and this coupled with the small numbers in the study may mean that any effect on driving safety may not have been detected. In addition scores were opposite to the expected direction, with those in the safe group having a higher co-morbidity score than those in the unsafe group, suggesting that comorbidities do not appear to be important in prediction of driving safety and these findings are in alignment with findings in previous literature in cognitively normal older adults (Carr et al., 2016) and in a retrospective study of memory clinic patients (Fausto et al., 2016).

4.4.3.3 Informant concerns about driving

Informant concerns about driving safety were not a significant predictor of on-road outcome. These findings are supported by previous research that found that informant concerns do not relate significantly to the outcome of an on-road test (Bixby et al., 2015;

Brown et al., 2005), in one study only 8% of informants rated their relative as possibly unsafe with 55% of participants subsequently failing the on-road test (Bixby et al., 2015). In the other 0% of informants rated their relatives driving as impaired, and 15% of participants with very mild AD and 24% of participants with mild AD participants failed the on-road test (Brown et al., 2005).

Cumulatively this evidence suggests that informant report is not important when determining driving safety. However, these findings are in direct opposition to the high importance clinicians place on these reports when making an assessment of driving safety in a clinical setting (see Chapter 3) and the recommendations in published guidelines that also place emphasis on the importance of caregiver report (Allan et al., 2016; Iverson et al., 2010; Selway, 2018). The findings from this research add to the evidence that indicate clinicians should be cautious about placing high importance on informant report when making a decision about driving safety in a clinical setting.

4.4.3.4 Clinician advice about driving safety

Clinician advice about driving safety was not a significant predictor of on-road outcome, with 50% of unsafe drivers being advised to stop driving prior to the on-road assessment. Previous research has produced mixed results in this area, with some studies finding that clinician predictions have been significantly associated with driving safety, correctly classifying 60% of unsafe drivers (Brown et al., 2005), and others no significant association (Bixby et al., 2015; Fox et al., 1997) with 44% of unsafe drivers and 25% of unsafe drivers predicted to be unsafe by clinicians. These results collectively suggest that there is a pattern of clinicians underestimating driving impairment, with 40% of unsafe drivers still being missed in the best performing study. In the context of this research these findings support the conclusions in Chapter 3, that clinicians feel there is a need for a clinical tool to aid the decision-making process. This is supported by previous research findings that show that clinician opinion alone is not a sufficient indicator of driving safety (Ott et al., 2005; Ranchet et al., 2017); that clinicians do not feel confident making these decisions and support the need for an objective tool (Bennett, Chekaluk, & Batchelor, 2019; Neilson et al., 2019) and that the use of a tool can increase knowledge and confidence in making these decisions (Byszewski et al., 2003).

All of the findings discussed in this section do not provide support to the current consensus in published guidelines advocating for a holistic assessment approach (Driving & Dementia Working Group, 2018) as well as reported current practice described by clinicians in chapter 3, who felt a 'whole picture' approach is needed. However, these findings alone are not strong enough to conclude that this is the wrong approach, with perhaps the exception of the importance that is placed on informant report. Due to the relatively healthy nature of this cohort, and small numbers, it is possible that not enough participants had severe enough comorbidities to detect an effect on driving safety. Additionally, those with severe comorbidities may have been excluded by other means such as deciding to give up driving prior to referral for an on-road assessment, or being advised by the clinician that they need to stop driving.

4.4.4 Generation of the driving decision aid tool

Previously published batteries to determine driving safety use raw scores with complex equations to predict an on-road outcome (Carr et al., 2011; Lincoln et al., 2006; Piersma et al., 2016). In a clinical setting, it is not practical for clinicians to need to calculate complicated scores, and they are accustomed to using assessments with clear, simple established thresholds (e.g. HADS (Zigmond & Snaith, 1983) or the GDS (Brink, 1982)). In addition, a central problem in this area of research is that few studies report validated cut-off scores (Molnar et al., 2006) making them difficult to apply in a clinical setting (Molnar et al., 2006). In order to address these issues, it was decided to make the variables binary, by establishing cut-off thresholds. This also helped make the clinical tool conform to the desired characteristics of simplicity and ease of use described by clinicians in chapter 3.

4.4.4.1 Rationale for the analysis

In order to generate the clinical tool, binary logistic regression analysis was used. The preferred method of backwards stepwise regression did not identify any variables in the model(s). Significant predictor variables were identified in the initial analysis and so a model should have been produced. Due to this the next method available was used which was forwards stepwise regression which did generate model(s). Due to the small numbers in this research it is possible that this method was not the optimum one, it has been previously reported that stepwise models may not work well in small datasets (Steyerberg et al., 1999); using a discriminant analysis was another possible option,

however as it does not work well with binary variables this was rejected. As the outcome of interest is binary (low risk/high risk), and in line with recommendations for clinicians developing a prediction model for use in clinical decision-making (Shipe et al., 2019) this analysis was selected as the most appropriate.

4.4.5 Driving decision aid tool scoring

The scoring system was data driven, and the results from Table 23 examined to determine if the data appeared to fit a trichotomization approach. The three-tier system of low risk, high risk and indeterminate risk naturally emerged, and the simple clinical tool produced aligns with the desired features described by clinicians in chapter 3. Equal weighting was given to each variable in the clinical tool as the data does not suggest a significant difference in contribution to the overall model.

4.4.6 Use of the driving decision aid tool in a clinical setting

The clinical tool produced appears to have good face validity in prediction of low risk, high risk, and indeterminate risk drivers but it does appear to be simplistic and includes age that could be judged to be discriminatory. However, given that in the UK once a person reaches the age of 70 they are expected to renew their licence every three years, age is a reasonable consideration when assessing driving safety. Additionally, the simplicity in in alignment with the desired characteristics of a useable clinical tool in chapter 3 by clinicians. Currently published test batteries are not suitable for use in a clinical setting. Time in a clinical appointment is often limited (see chapter 3) with driving forming only a small part of the overall assessment and current batteries take a long time to administer needing additional assessments to be completed that are not already routinely done in a clinical setting (see tables 9-11) (Carr et al., 2011; Lincoln et al., 2006; McKenna & Bell, 2007; Piersma et al., 2016; Unsworth & Chan, 2016), with some including elements that are impractical for implementation in a clinical setting e.g. the use of driving simulator rides (Piersma et al., 2016). As previously mentioned these batteries utilise complicated equations (Carr et al., 2011; Lincoln et al., 2006; Piersma et al., 2016) to give the predicted outcome that are not realistic for use in a time constrained clinical appointment. In comparison this clinical tool gives clinicians a quick to use tool with a straightforward scoring system that has clear cut-off scores and utilises assessments that have already been completed as part of the clinical appointment.

In chapter 3 when clinicians were asked about what they currently use in their decision-making process when assessing driving safety, visuo-spatial skills were cited frequently which is in accordance with the variables in the clinical tool, in addition, the tool meets the desired criteria of a quick and simple tool that can be easily integrated into an already busy assessment. The inclusion of the visuo-spatial element and briefness should improve the suitability of the clinical tool for use in a clinical setting.

4.4.7 Demographics

The participants in this stage of the research were a selected convenience cohort and none had a severe cognitive impairment (mean ACE = 73.4). In a clinical setting concerns about driving are addressed early in the diagnostic process and so it would be probable that at this stage most of the people seen would be at the mild stage of a dementia. The dementia severity of this cohort is comparable to published studies in this field where this information is available, e.g. Fox et al., (1997); Frittelli et al., (2009); Grace et al., (2005); Piersma et al., (2018); Whelihan et al., (2005); Yamin et al., (2016).

The development cohort contained a mixture of dementia diagnoses, which increased heterogeneity. In addition it does not correspond with much of the published research in this field as the focus has typically been on participants with a diagnosis of Alzheimer's type dementia; however it is an accurate representation of what would be seen in a clinical setting.

Due to the small numbers in the study, it was not possible to include the effect that the type of dementia diagnosed might have on a person's driving, and subsequently the on-road assessment outcome. The effects that different types of dementia may have on driving remain under-reported, and where a previously developed predictive battery has been applied to a cohort of participants with non-Alzheimer's type dementia it was unable to significantly predict safety to drive (Piersma et al., 2018). However, the clinical tool developed in this research was produced using a group of participants representative of those it is designed to be applied to, i.e. a group of clinical patients with a mix of diagnoses.

4.4.8 Limitations

There are a number of limitations in this research, the first is the small number of participants in the study, meaning that it was not possible to factor in the impact of the

type of dementia diagnosed and it is likely that this is a potentially important omission in the development of a predictive tool. Memory clinics will typically be seeing people who will go on to have a range of dementia diagnoses, and as driving is typically assessed at the beginning of the diagnostic process (see chapter 3), dementia type is a potentially relevant predictive factor that was unable to be assessed in this research. Additionally, the small number of cases may have impacted the effectiveness of the chosen analysis to determine the predictive model, as stepwise models do perform poorly in small datasets (Steyerberg et al., 1999).

In this development cohort there was a high preponderance of male participants in the study, likely due to most drivers in this age group being male (in older drivers males make up a larger proportion of total licence holders than female drivers) (Department for Transport, 2022).

The convenience nature of the sample is a further limitation in this research. Respondents who were found to be safe in the on-road assessment are likely to be more agreeable to taking part in the research producing a biased sample and limiting generalisability of the results. However, they were recruited from the population that the findings are to be applied to.

It was not possible to collect a full data set for all of the variables, so potentially predictive items that had a smaller number of cases and were close to significance like the MoCA were not included in the final model (Smith, 2018).

A further limitation was that due to changes that needed to be made to the original study plan to mitigate the impact of the Covid-19 pandemic on the research, the development of the tool needed to be data driven. The original plan was to gather the data from one cohort, develop the tool and then test this tool in an independent cohort where the researcher was blind to the on-road outcome. The need to use data collected retrospectively from clinical records to develop the driving decision aid tool meant that it was not possible to include measures that previous research has indicated might be predictive of on-road outcome (e.g. mazes (Ma'u & Cheung, 2020; Ott, Festa, et al., 2008)).

Due to the retrospective nature of the data collection, it was not possible to have a clinician-driven selection of variables. When using regression models, variables

selected for inclusion should be expected to predict the outcome based on previous research and theory (Derksen & Keselman, 1992) but variables were dictated by the clinical information that was recorded only, possibly missing potentially important predictors. An example of this is that in chapter 3 clinicians described the importance of attention, visual processing and functionality when making decisions about driving safety, but no objective measures of these were used in clinic, or recorded in clinical notes, so it was not possible to include them in the analysis.

Data that is routinely collected in a clinical setting may not be optimal for what this research set out to achieve. Assessments like the ACE III are measures used to detect and diagnose cognitive impairments (Hsieh et al., 2013) and are not aligned to the skills needed for driving. Previous research has indicated that functional ability (Barco et al., 2021; Piersma et al., 2016) is predictive of driving safety, but these are not routinely recorded in clinical notes.

The cohort used to develop the tool was relatively unimpaired, which would be expected from clinical data as when being assessed for diagnosis the individual is likely to be presenting with mild impairments at this stage. However, this means that the data produced a limited range of scores that fell mainly into the 'mild' impairment range. This may have influenced the level of the cut-off scores i.e. that they were set to a relatively high threshold, meaning the clinical tool using this threshold may not yield the same sensitivity and specificity to detect high risk drivers in a different cohort, with the majority of people falling into the indeterminate risk range. The driving decision aid tool will be tested in an independent cohort in the next chapter.

4.5 Conclusions

The clinical data collected retrospectively from clinical records produced a simple, useable predictive clinical tool that correctly classified 86% of unsafe drivers at the 1.5 cut-off level when tested in the development cohort. It is expected that it would perform well in the development sample and so needs to be tested in an independent cohort to determine the accuracy. The clinical tool that emerged was in accordance with the characteristics of a desired clinical tool described by clinicians in chapter 3.

The tool will be tested in an independent cohort in the next section. Additionally, the discriminant ability of advanced assessments suggested to be predictive in previous

research that were not available in a retrospective clinical notes study will be considered.

Chapter 5. Testing the tool and investigation of advanced assessments

5.1. Aims, objectives and hypotheses

5.1.1 Aims

The primary aim of this chapter is to test the simple predictive driving decision aid tool developed in chapter 4 in an independent cohort of participants and investigate advanced assessments that may enhance the predictive ability of the clinical tool.

5.1.2 Objectives

The objectives for this section are:

- Determine the discriminant ability of the clinical tool to detect low risk and high risk drivers by applying the clinical tool to an independent cohort of participants
- Explore the discriminant ability of a range of additional advanced assessments, including cognitive, functional, neuropsychological and specific driving questions by comparing people with a diagnosis of MCI or dementia who were found to be safe or unsafe in an on-road assessment
- Apply previously published cognitive thresholds to an independent cohort to determine discriminant ability

5.1.3 Hypotheses

1. The clinical tool developed in chapter 4 will be able to detect unsafe drivers in an independent cohort in accordance with the sensitivity of 50% and specificity of 95% previously calculated.
2. Additional advanced cognitive assessments will be predictive of the outcome of an on-road assessment of driving. Specifically, the following variables will be associated with being assessed as unsafe to drive in an on-road assessment:
    a. Decreased MoCA attention domain (Ma'u & Cheung, 2020)
    b. Decreased MoCA attention and visuo-spatial/executive function domain combined (Ma'u & Cheung, 2020)
    c. Decreased MMSE score (Berndt et al., 2008; Piersma et al., 2018)
    d. Increased Trails A&B time to complete (Papandonatos et al., 2015)
    e. Increased time to complete Snellgrove maze (Ma'u & Cheung, 2020)
    f. Increased errors completing the Snellgrove maze (Ma'u & Cheung, 2020)

g. Increased reaction times (Piersma et al., 2016)

3. In non-cognitive measures it is expected that higher scores on functional ability assessments will be predictive of unsafe driving, in particular the following variables:
    a. Increased CDR memory score (Piersma et al., 2016)
    b. Increased CDR orientation score (Piersma et al., 2016)
    c. Increased CDR judgement & problem-solving score (Piersma et al., 2016)
    d. Increased CDR community affairs score (Piersma et al., 2016)
    e. Increased CDR sum of boxes score (Piersma et al., 2016)
    f. Increased functional assessment scores indicating impairment in activities of daily living (Barco et al., 2021)
    g. Increased frailty score
    h. Decreased miles driven per week (Piersma et al., 2016)

5.1.4 Ethical and Research and Development Approvals

Details of ethical approvals for the research have previously been detailed in section 4.4 in chapter 4.

A substantial amendment and supporting documents to add the Snellgrove maze to the assessments and additional questions to the driving questionnaires was submitted to HSC REC-B committee on 15/07/2020. A favourable opinion was received from the REC committee on 03/09/2020, and HRA approval received on 18/09/2020.

5.2 Methods – Investigation of advanced assessments

5.2.1 Participants

This prospective assessment study recruited participants who had been referred for a Drive Mobility on-road assessment of their driving as a part of their routine clinical care between January 2020 and June 2024. Participants had been diagnosed with a dementia of MCI using NIA-AA criteria (Albert et al., 2011; McKhann et al., 2011).

5.2.2 Recruitment of participants

Potential participants were approached by the Drive Mobility Centre at Walkergate Park in Newcastle upon Tyne. The Drive Mobility Centre approached all service users by including information about the study and a return slip to indicate whether they were

happy to be approached by a member of the study team to discuss participation in the study with their driving assessment appointment letter. If no response was received, the Drive Mobility team contacted the participant by telephone to confirm attendance for their driving assessment and ask if they were willing to be approached by a member of the study team. It was made clear to potential participants that the study assessments would take place in their home before their on-road assessment, and that they would have no bearing on the outcome of the independent on-road assessment of driving. Participants were asked to have an informant available for the assessment appointment.

5.2.3 Inclusion and exclusion criteria

Inclusion Criteria:

- Age ≥60
- Referred for a Drive Mobility assessment as part of their routine clinical care
- Are able to give informed consent
- Fulfil NIA-AAA diagnostic criteria for an all-cause dementia or MCI (Albert et al., 2011; McKhann et al., 2011), received in clinical services

Exclusion Criteria:

- Absence of capacity to give informed consent
- Significant co-morbidity or physical illness that may limit full participation in the study

5.2.4 Consent

Those who were willing to participate in the study gave informed, written consent, witnessed by an appropriately trained member of the study team. A copy was held on record in the site file, and a copy was given to the participant. There were separate consent forms for participants and informants.

5.2.5 Testing the clinical tool in an independent cohort

The clinical tool was applied to the independent cohort of participants and the sensitivity and specificity was assessed.

5.2.6 Assessments

Cognitive assessments were selected as they were freely available, simple to carry out in a clinical care setting or were already routinely done as part of the clinical assessment process and chosen based on previous evidence of the association between cognitive tests and driving ability (Bennett et al., 2016; Rashid et al., 2020). Additional assessments were added to assess the predictive ability of other elements expected to be associated with on-road driving such as functional measures, neuropsychological measures, dementia severity, a driving questionnaire and a frailty measure based upon the recommendation for a holistic assessment of driving safety in a clinical setting (Driving & Dementia working group, 2018). Finally novel measures were added that previous research had suggested were predictive of driving safety (the Snellgrove Maze (Carr et al., 2011; Ma'u & Cheung, 2020; Snellgrove, 2005)) as well as some short, computerised tasks assessing visuo-spatial skills, concentration, attention and reaction time in order to assess their predictive ability.

5.2.6.1 Participant assessments – Cognitive measures

5.2.6.1.1 Addenbrooke's Cognitive Examination – ACE III

The Ace III has been previously described in chapter 4. The total score, sub scores and individual item scored were recorded.

5.2.6.1.2 Montreal Cognitive Assessment (MoCA)

The MoCA has been previously described in chapter 4. The total score and individual item scores were recorded.

For MoCA total score one group published cut-off scores of >27 (with a 100% specificity to predict safe drivers) and <12 (with a 100% sensitivity to predict unsafe drivers) (Esser et al., 2016). Domains from the MoCA were found to be predictive in one study (Ma'u & Cheung, 2020) and thresholds were published as <5/6 for attention to give 73% sensitivity and 72% specificity; and <8/11 for combined domains of attention & visuo-spatial/executive function to give sensitivity of 80% and specificity of 67%.

5.2.6.1.3 Standardised Mini-Mental State Examination (MMSE)

The MMSE is a widely used and quick to administer measure of cognitive function, scored on a 30-point scale, it measures orientation, memory, attention, language and

visuo-spatial domains (Folstein et al., 1975). The total score and individual item scores were recorded.

For the MMSE similar cut-off thresholds of <19, 20-24 and>25 have been suggested by two groups (Berndt et al., 2008; Piersma et al., 2018).

5.2.6.1.4 Digit span

The digit span task measures the domains of concentration, attention, sequencing and short-term auditory memory (Blackburn & Benton, 1957). Participants are required to repeat back a sequence of numbers in the correct order increasing in size (from 2 digits to 9), and there are 2 sequences for each span size (e.g. 258 & 967 or 68571 and 83759). Participants are scored 1 point for each correct sequence, and this is totalled to give a forwards digit span total score (maximum 14). This process is repeated in the backwards condition, but sequences must be repeated back in reverse order. The forwards and backwards totals are then added together to give an overall digit span score. The maximum possible score is 28 and lower score indicates greater impairment.

5.2.6.1.5 Trail Making Test (TMT) parts A & B

The trail making task is divided into two parts. In part A participants are asked to join numbered circles in sequence (1-25); this is a measure of attention and visuo-spatial domains and a score > 78 seconds indicates impairment. Part B is more complex and requires the participant to connect both lettered and numbered circles in a particular sequence (1-A-2-B-3-C etc.) and also measures the domains of task switching and working memory, with a score of >273 seconds indicating impairment. If the participant was unable to complete the task, the maximum time was allotted (Reitan, 1958).

One previously published study (Papandonatos et al., 2015) has suggested that a cut-off of >48 seconds has 63% sensitivity and 70% specificity to detect unsafe drivers for Trails A. The same study (Papandonatos et al., 2015) published a threshold of >108 for trails B that showed 88% sensitivity and 40% specificity.

5.2.6.1.6 Snellgrove maze

The Snellgrove maze is a short task designed to measure the domains of attention, visuo-constructional ability and planning and foresight (executive function). Participants are asked to complete a maze without crossing any lines or hitting any dead ends. Participants are timed and mistakes noted. A completion time of >61 seconds

with or without errors or <60 seconds with 2+ errors suggests that the person is not cognitively safe to drive; a time of <60 seconds with 0-1 errors indicates that the person is likely safe to drive (Snellgrove, 2005). This previously published threshold (Snellgrove, 2005) is reported to have 78% sensitivity and 82% specificity to detect unsafe drivers.

5.2.6.1.7 Ruler drop task

The ruler drop task is a basic measure of reaction time. Participants are asked to hold out their thumb and forefinger, and the ruler is placed between them. It is then dropped, without telling the participant, and the participant must catch it. A measurement is then taken of the drop distance. This is repeated three times and an average taken, this is then converted into a reaction time in milliseconds.

5.2.7 Participant assessments – Computerised tests of attention, concentration and visuo-spatial function

These tasks were carried out on a touch screen tablet, placed at a comfortable position for the participant. Participants had the opportunity to practice each task before the full task was administered.

5.2.7.1 Simple reaction time (SRT)

In this task, a white X is presented on a black background at random intervals for a maximum of 3000 milliseconds per trial, over thirty trials, taking a maximum of 90 seconds to complete. The participant must touch the screen as quickly as they can when the X is presented. The number of correct responses and mean reaction time in milliseconds time are recorded. A higher response time indicated slower response and so worse performance. This measured attention and reaction time (Elder et al., 2022).

5.2.7.2 Choice reaction time (CRT)

In this task, a white arrow pointing either left < or right > is presented on a black background at random intervals for a maximum of 3000 milliseconds per trial, for 30 trials, taking a maximum of 90 seconds to complete. Participants are asked to indicate the correct direction as quickly as possible by tapping the boxes on the left or right of the screen. The number of correct responses, errors and mean reaction time in milliseconds are recorded. A higher response time indicated slower response and so worse performance. This measured attention and cognitive processing time (Elder et al., 2022).

5.2.7.3 Digit vigilance task (DVT)

In this task a series of random numbers, white on a black background, are presented between zero and nine at a rate of two per second, for 360 trials and runs for 3 minutes. Participants are asked to tap the screen as quickly as possible whenever a number 9 appears in the sequence. A pale 9 is present on the screen at all times as a reminder for the participant. Number of correct responses, errors, false positives and mean response time is recorded. A higher response time indicates worse performance. This measured attention and concentration (Elder et al., 2022).

5.2.7.4 Line angle discrimination task

In this task four white lines appear on a black background, three are presented at the same angle, one at a different angle. Participants are asked to tap the line that is different to the other three. The difficulty is adjusted depending on correct or incorrect responses and there are 30 trials taking a maximum of 2 minutes to complete. The angle that the participant can discriminate is calculated, with a lower angle representing better discrimination. This measured visuo-spatial function (Wood et al., 2013).

5.2.7.5 Motion detection task

The participant is presented with four boxes, that each have moving cars. Three will be moving at the same speed, and one at a different speed. The participant is asked to tap the box with the cars moving at a different speed to the others. The difficulty is adjusted depending on correct or incorrect responses and there are 30 trials taking a maximum of 2 minutes to complete. Number of correct responses, errors and difference in speed discrimination is recorded. This measured attention and visuo-spatial function (Wood et al., 2013).

5.2.8 Participant assessments – Non-cognitive measures

5.2.8.1 Clinical history – Comorbidities and medications

The clinical history included a comprehensive medical history in order to gather information on any comorbidities the participant might have. This included weekly alcohol intake and a list of current medication and daily dosages. Comorbidities were assessed and recorded using the Charlston Comorbidity Index (Charlson et al., 1987) as previously described in chapter 4, and medications assessed and recorded using Medichec (Bishara et al., 2017) as previously described in chapter 4.

5.2.8.2 Driving history

Participants were asked about their driving history and current driving habits. The questionnaire was developed by the researcher and comprised two sections. The first recorded details of driving history and recent driving experience based upon possible predictors suggested by previous research (Piersma et al., 2016), the second section asked questions about specific driving behaviours and were adapted from previously published driving behaviour measures (Molnar et al., 2005; Winter et al., 2010). They were asked:

- Year driving test passed
- Number of years licence held
- Class of licence held
- Professional driver experience (if any)
- Endorsements (if any)
- How many times a week do you currently drive?
- How many miles per day do you drive?
- What would you estimate is the average distance per week you drive?
- How many of these miles are driven within 5 miles of home?
- How many of these miles are driven within 10 miles of home?
- How many unique destinations do you visit in a week?
- What is the longest trip you have taken in the last month?
- Compared to 5 years ago, how would you rate your driving now on a scale of 1 – 5 (1=much worse, 2=somewhat worse, 3=the same, 4=somewhat better, 5=much better)?

In the last year have you noticed that you:

1. Have you had any changes to your driving?
2. Felt a loss of confidence in your driving?
3. Restricted your driving e.g. not driving at night/in bad weather/at peak times?
4. Felt overwhelmed in everyday driving situations?
5. Felt overly hesitant at junctions or roundabouts?
6. Felt you have had a delayed reaction to events on the road?
7. Driven too close to another vehicle or strayed from the lane you were driving in?

8. Used excessive speed or driven too slowly?
9. Failed to respond appropriately to a hazard e.g. crossing or junction?
10. Felt unable to respond appropriately to changes on familiar routes e.g. lane closures or diversions?
11. Made any technical driving errors e.g. forgetting to release the handbrake/not checking for hazards before moving off?
12. Become lost on a familiar route?
13. Forgotten where you were driving to?
14. Had any accidents or near misses?
15. Had any minor accidents e.g. in car parks?
16. Had any parking problems e.g. hitting kerbs/scrapes?
17. Had other road users sound the horn or flash lights at you?
18. Had other road users need to adjust their movements to accommodate you?
19. Received any cautions or fines for minor driving offences e.g. speeding/failing to stop at a red light?
20. Noticed passengers giving you verbal prompts e.g. warning of hazards/gear changes (co-piloting)?
21. Noticed passengers giving you frequent cues or directions?
22. Have others criticized your driving or expressed reluctance to be a passenger?

5.2.8.3 Demographic data

The sex and age of the participant at the time of referral for on-road assessment were recorded.

5.2.8.4 Vision and hearing measures

Participants were asked to rate their vision as good, average or poor and whether they needed glasses. Visual acuity was recorded using a Snellen chart at a distance of 3 meters and were allowed to wear glasses where needed. Contrast sensitivity was measured using the Peli-Robson chart (Pelli et al., 1988).

Participants were asked to rate their hearing as good, average or poor and whether they used hearing aids.

5.2.8.5 Epworth Sleepiness Scale (ESS)

The Epworth sleepiness scale (ESS) was used to record incidences of daytime sleepiness. The participant is asked to rate on a scale of 0 to 3 how likely they are to fall asleep in certain situations e.g. in a meeting, while a passenger in a car, when talking to someone, when watching TV with 0 being never and 3 being highly likely. A higher total score indicated greater daytime sleepiness (Johns, 1991).

5.2.8.6 Geriatric Depression Scale (GDS)

The Geriatric Depression Scale assessed the presence of depression symptoms. This is a 15-item scale, with yes or no answers. Example questions include 'Do you often get bored?', 'Do you often feel helpless?'. A cut-off score of 5 or above indicates depressive symptoms (Yesavage et al., 1982).

5.2.9 Informant measures

The informant was asked to add any additional relevant information they may have had to the participant's medical, alcohol and medication history.

5.2.9.1 Informant driving history

The informant was asked the same driving related questions detailed above, but from their perspective.

5.2.9.2 Neuropsychiatric inventory with caregiver distress (NPI)

The NPI assessed the frequency and severity of ten neuropsychiatric symptoms. The informant was asked about the presence of symptoms for each one, and if present, asked to rate the frequency (1 occasionally to 4 very frequently) and severity (1 mild to 3 marked) of the phenomena. A total score for each domain was then calculated (severity x frequency). A caregiver distress scale allows for recording of the impact of these symptoms. The total overall NPI score and score of each symptom present were recorded (Cummings, 1997).

5.2.9.3 Dementia cognitive Fluctuation Scale (DCFS)

The DCFS provides a measure of cognitive fluctuations that may be being experienced by the participant. Functional variability, daytime sleepiness, daytime lethargy and overall level of consciousness were recorded and each item scored 1-5 with a higher score indicating greater impairment, a total score was also calculated (Lee et al., 2014).

5.2.9.4 Instrumental Activities of Daily Living (IADL)

The IADL asked the informant to rate the participant's present ability on a series of eight everyday tasks e.g. food preparation or mode of transportation, with a higher score indicating greater impairment. Individual item scores and total score were recorded (Cromwell et al., 2003; Lawton & Brody, 1969).

5.2.9.5 Bristol Activities of Daily Living scale (BADL)

The BADL assessed twenty everyday living activities e.g. eating, drinking, orientation, hygiene etc. Informant's are asked to rate their friend/relatives ability in each of the activities on a scale of 0 to 3 (0=no change in ability to do task – 3=marked change in ability to do task). A higher score indicates greater impairment, total score was recorded (Bucks et al., 1996).

5.2.10 Clinician rated scales

5.2.10.1 Clinical Dementia Rating (CDR)

The CDR rated the participant level of function on six domains (memory, orientation, judgement & problem solving, community affairs and personal care). This measure assesses the effect of cognitive impairment on daily functional activities and is rated on a 5-point scale (0=no impairment – 3= severe impairment) in each of the domains and indicates dementia severity. A higher score indicates greater impairment and individual item scores and sum of boxes (total of all scores) was recorded (Hughes et al., 1982).

5.2.10.2 Clinical Frailty Scale (CFS)

The scale measured the participant's frailty on a scale from 1 (very fit) to 9 (terminally ill) (Rockwood et al., 2005).

5.2.11 Driving assessment

The on-road driving assessment has previously been described in chapter 4.

5.2.12 Procedure

All assessments were carried out by the researcher in the participant's home, at least two weeks before the on-road assessment of driving took place. They took between 75 and 90 minutes to complete and were finished in one session.

5.2.13 Missing data

It was not possible to collect a full data set for all participants. For participant measures some were not completed due to time constraints, or because the participant was unable to complete the task. Not all participants had an informant available. Due to the small data set, data imputation was not used for missing data. For the trails A & B task failure to complete was recorded and used in analysis.

5.2.14 Data analysis plan

All data was analysed using IBM SPSS statistics version 29.0. In order to test the clinical tool developed in the previous chapter it was applied to this new cohort and the sensitivity and specificity to detect unsafe drivers determined.

The collected data was also analysed to determine which of the individual variables were predictive of the on-road assessment outcome. The discriminant ability of the variables was assessed to determine which of the advanced assessments demonstrated good discriminant ability to determine safe and unsafe drivers.

Stages of analysis were identical to steps 1-3 previously described in chapter 4 (page 102).

5.2.15 Comparison of significant results

The discriminant ability of measures that were significant were compared to those that were significant from the development cohort using AUROC in order to determine if any of the advanced assessments demonstrated stronger discriminant ability.

5.2.16 Comparison of previously published thresholds

Due to the poor discriminant ability of the tool developed in Chapter 4, previously published thresholds for cognitive tests were tested in this cohort where they are available, to assess whether they were useful as predictors of driving safety in this cohort.

5.3 Results – Investigation of advanced assessments

5.3.1 Participants

Twenty-seven participants were recruited into the study, with two excluded from the data analysis (both surrendered their licence voluntarily prior to on-road assessment).

Of the 25 participants included in the study the overall median age was 77, with 21 male and 4 female. Nine (36%) of the participants were prescribed anti-dementia medication and 8 had a diagnosis of MCI, 12 a diagnosis of Alzheimer's disease, 3 vascular dementia, 1 Lewy body dementia and 1 unspecified dementia. Fifteen were classified as safe (median age 76.0) and ten as unsafe (median age 77.5) in the on-road assessment.

5.3.2 Testing the clinical tool in an independent cohort

The clinical tool developed in chapter 4 was applied to an independent cohort of participants. Of those who scored 2 (n=1) and rated as high risk none were found to be safe and 1 were found to be unsafe in an on-road assessment giving a positive predictive value of 10%. Of those who scored 0 and rated as low risk, 7 were found to be safe and 5 were found to be unsafe in an on-road assessment giving a negative predictive value of 46.7%, and of those who scored 1 and rated as 'indeterminate risk', 8 were found to be safe and 4 unsafe in an on-road assessment.

The tool demonstrated poor sensitivity (10%) and specificity (47%) to predict unsafe drivers, p=0.42.

	Safe	**Unsafe**
Tool score 0	7 (47%)	5 (50%)
Tool score 1	8 (53%)	4 (40%)
Tool score 2	0 (0%)	1 (10%)

Table 24: Tool classifications of safe and unsafe drivers in prospective cohort, sensitivity & specificity using 1.5 cut-off

5.3.3 Participant assessments – Cognitive measures

5.3.3.1 Global cognitive measures – ACE III/MoCA/MMSE

None of the individual items, domains or total score were significantly different between the safe and unsafe groups for ACE III, MoCA or MMSE.

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
Age, median (IQR) n=25	76.0 (70-79)	77.5 (68.8-83.0)	0.64[a]	0.56 (0.31-0.81)	77.5	0.50	0.73
Sex Male	13 (86.7%)	8 (80%)	1[b]	0.53 (0.30-0.77)	0.5	0.20	0.87
Anti- dementia medication prescribed	6 (40%)	3 (30%)	0.69[b]	0.55 (0.32-0.78)	0.5	0.70	0.40
Ace III Attention sub score	16.0 (13.0-18.0)	15.0 (13.8-17.8)	1[a]	0.50 (0.27-0.74)	15.5	0.60	0.53
Ace III Memory sub score	16.0 (12.0-19.0)	13.5 (12.5-17.3)	0.94[a]	0.51 (0.28-0.74)	15.5	0.70	0.53
Ace III Fluency sub score	9.0 (8.0-12.0)	9.5 (5.0-11.0)	0.61[a]	0.57 (0.33-0.80)	11.5	0.90	0.33
Ace III Language sub score	24.0 (20.0-25.0)	23.0 (21.8-25.0)	0.85[a]	0.52 (0.29-0.75)	24.5	0.70	0.47
Ace III Visuo-spatial sub score	14.0 (11.0-16.0)	14.5 (10.5-16.0)	0.81[a]	0.47 (0.22-0.71)	-	-	-
Ace III Total score	78.0 (61.0-88.0)	76.5 (63.8-82.0)	0.68[a]	0.55 (0.32-0.78)	86	1.00	0.33
Ace III Drawing total	7.0 (4.0-8.0)	7.0 (3.25-8.0)	0.89[a]	0.48 (0.24-0.72)	-	-	-
MoCA Visuo & EF	4.0 (2.0-5.0)	4.0 (2.0-5.0)	0.89[a]	0.48 (0.25-0.71)	-	-	-
MoCA Attention	6.0 (4.0-6.0)	5.0 (3.5-6.0)	0.29[a]	0.63 (0.41-0.86)	5.5	0.7	0.67
MoCA Language	2.0 (1.0-2.0)	2.0 (0.75-2.0)	0.94[a]	0.51 (0.28-0.75)	2.5	0.9	0.2
MoCA Total Score	22.0 (15.0-25.0)	20.0 (16.8-23.3)	0.57[a]	0.57 (0.34-0.80)	24.5	1	0.27

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
MMSE Total Score	26.0 (21.0-28.0)	24.0 (23.0-27.3)	0.85a	0.53 (0.29-0.76)	24.5	0.6	0.6

Table 25: Demographics and global cognitive measures measure by on-road outcome group for the prospective cohort

Abbreviations: ACE III = Addenbrooke's Cognitive Examination, AUROC=Area under the curve, CI=Confidence Interval, EF=Executive Function, IQR=Inter Quartile range, MoCA=Montreal Cognitive Assessment, MMSE=Mini Mental State Examination, Visuo=Visuo-spatial.

a=Mann Whitney U test, b=Fisher's Exact test, c=Chi Square.

5.3.3.2 Snellgrove maze

Maze completion time did not reach statistical significance between safe and unsafe groups. Maze errors were significantly different between the safe (median score = 0(0-1) and unsafe (median score=1(0.75-2.25) groups (AUROC=0.77(0.57-0.97), p=0.02).

5.3.3.3 Other participant cognitive measures

Digit span, Trail Making Test A&B and the ruler drop task were not significantly different between safe and unsafe groups.

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
Digit Span Forwards	6.0 (5.0-9.0)	7.0 (5.75-9.0)	1[a]	0.50 (0.27-0.73)	9.5	1	0.2
Digit Span Backwards	5.0 (4.0-6.0)	4.0 (2.8-5.3)	0.18[a]	0.66 (0.45-0.88)	4.5	0.6	0.67
Digit Span Total	13.0 (9.0-15.0)	11.0 (9.0-14.0)	0.46[a]	0.59 (0.37-0.82)	14.5	0.9	0.4
Maze Completed, Yes	13 (86.7%)	8 (80%)	1[b]	0.53 (0.30-0.77)	0.5	0.2	0.87
Maze Time (Secs)	46.0 (36.0-74.0)	59.0 (35.0-147.8)	0.68[a]	0.55 (0.31-0.79)	70.5	0.5	0.73
Maze Errors	0.0 (0.0-1.0)	1.0 (0.8-2.3)	**0.02[a]**	0.77 (0.57-0.97)	0.5	0.8	0.73
Trails A	66.0 (40.0-78.0)	92.0 (35.5-111.0)	0.56[a]	0.58 (0.31-0.85)	85	0.56	0.8
Trails B	300.0 (127.0-300.0)	300.0 (300.0-300.0)	0.48[a]	0.59 (0.35-0.83)	224.5	0.89	0.33
Ruler drop reaction time (ms)	0.16 (0.15-0.17)	0.19 (0.16-0.23)	0.12[a]	0.70 (0.46-0.94)	0.17	0.67	0.73

Table 26: Further cognitive measures by on-road outcome group for the prospective cohort

1 participant was unable to complete Trails A and 18 were unable to complete Trails B and were allotted the maximum time, one person did not attempt the task. 4 participants were unable to complete the maze and allotted the maximum time, and 1 person was unable to complete the ruler task.

Abbreviations: AUROC=Area under the curve, CI=Confidence Interval, IQR=Inter Quartile range, MMSE=Mini Mental State Examination, MS-Milliseconds. a=Mann Whitney U test, b=Fisher's Exact test, c=Chi Square.

5.3.4 Participant assessments – Computerised tests of attention, concentration and visuo-spatial function

The difference between choice reaction time and simple reaction time was significantly different between the safe and unsafe groups (AUROC=0.81(0.63-0.98), p=0.01). For the DVT the mean reaction time and mean reaction time standard deviation were significantly different between safe and unsafe groups (AUROC=0.77(0.57-0.87), p=0.03 and AUROC=0.76(0.54-0.98), p=0.04 respectively).

None of these angle discrimination or motion task measures showed a significant difference between the safe and unsafe groups.

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
SRT MC (ms)	560.13 (459.670-871.27)	526.66 (474.23-690.16)	0.59[a]	0.43 (0.19-0.66)	-	-	-
SRT SD (ms)	234.07(88.32-363.22)	157.82(110.08-254.96)	0.51[a]	0.41 (0.17-0.66)	-	-	-
CRT MC (ms)	704.03 (611.78-931.46)	866.75 (709.02-1002.15)	0.15[a]	0.68 (0.46-0.90)	680.71	0.9	0.5
CRT SD (ms)	124.02 (106.51-273.29)	179.54 (111.17-620.63)	0.29[a]	0.64 (0.41-0.86)	159.10	0.6	0.71
CRT Errors	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.71[a]	0.55 (0.31-0.79)	14	0.1	1.0
CRT-SRT (ms)	128.31 (5.50-224.701)	257.88 (188.76-377.54)	**0.01[a]**	0.81 (0.63-0.98)	190.43	0.8	0.71
DVT No Correct	34.0 (30.5-36.0)	31.0 (25.5-35.5)	0.22[a]	0.66 (0.41-0.91)	32	0.67	0.71
DVT MT (ms)	576.57 (510.13-606.73)	630.30(570.84-715.53)	**0.03[a]**	0.77 (0.57-0.98)	628.45	0.56	0.93
DVT SD (ms)	89.88 (83.97-131.70)	155.40 (98.34-244.87)	**0.04[a]**	0.76 (0.54-0.98)	152.16	0.56	1.0
Angle Result (Degrees)	18.28 (10.96-28.88)	42.19 (18.58-81.13)	0.07[a]	0.74 (0.51-0.98)	47.68	0.5	1.0

Motion Result (Speed)	5.0 (2.5-4.98)	5.0 (1.8-5.0)	0.70[a]	0.56 (0.29-0.82)	4.98	0.44	0.85

Table 27: Computerised measures by on-road outcome group for the prospective cohort

SRT/CRT 1 participant did not attempt the task, DVT 2 participants did not attempt the task, angle & motion tasks 2 participants did not attempt and 1 was unable to understand the tasks.

Abbreviations: AUROC=Area under the curve, CI=Confidence Interval, CRT=Choice reaction time, DVT=Digit vigilance task, IQR=Inter Quartile range, MC=Mean Correct, MS=Milliseconds, MT=Mean Time, SD=Standard deviation, SRT=Simple reaction time.

a=Mann Whitney U test, b=Fisher's Exact test, c=Chi Square.

5.3.5 Participant assessments – Non cognitive measures

None of the non-cognitive measures were significantly different between the safe and unsafe groups. Despite being a significant predictor in the development cohort there were no significant differences between the age of the safe and unsafe groups in this cohort.

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
Drinks alcohol, yes	9 (60%)	3 (30%)	0.23[b]	0.35 (0.13-0.57)	-	-	-
Weekly alcohol units	4.0 (0.0-14.0)	0.0 (0.0-4.3)	0.13[a]	0.32 (0.11-0.53)	-	-	-
Wear glasses, yes	14 (93.3%)	10 (100%)	1[b]	0.53 (0.30-0.77)	0.5	1.0	0.07
Vision rating	0 (0-0)	0 (0-1)	0.29[a]	0.63 (0.40-0.87)	0.5	0.4	0.87
Wear hearing aid, Yes	7 (46.7%)	2 (20%)	0.23[b]	0.37 (0.14-0.59)	-	-	-
Hearing rating	0 (0-1)	0 (0-2)	0.57[a]	0.57 (0.33-0.81)	1.5	0.3	0.93
Visual Acuity (Left eye)	0.46 (0.32-0.65)	0.31(0.24-0.55)	0.19[a]	0.32 (0.08-0.57)	-	-	-
Visual Acuity (Right eye)	0.47 (0.40-0.64)	0.47(0.35-0.50)	0.51[a]	0.41 (0.16-0.66)	-	-	-
Contrast sensitivity	1.5 (1.2-1.65)	1.43 (1.31-1.5)	0.53[a]	0.58 (0.35-0.81)	1.58	0.9	0.4
AEC Total, (Median, IQR)	0.0 (0.0-0.0)	0.0 (0.0-1.5)	0.61[a]	0.57 (0.33-0.81)	2.5	0.2	1.0

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
Number of medications causing dizziness (Median, IQR)	3.0 (2.0-8.0)	4.5 (2.75-5.5)	0.57[a]	0.57 (0.37-0.80)	3.5	0.7	0.53
Number of medications causing drowsiness (Median, IQR)	1.0 (1.0-2.0)	2.5 (0.75-4.0)	0.29[a]	0.63 (0.40-0.87)	2.5	0.5	0.8
CCI Total score (Median, IQR)	1.0 (0.0-2.0)	1.0 (1.0-3.0)	0.26[a]	0.64 (0.42-0.86)	0.5	1	0.33
GDS	1.0 (0.0-6.0)	2.0 (1.5-5.0)	0.52[a]	0.59 (0.35-0.82)	1.5	0.78	0.53
ESS	7.0 (2.0-11.0)	4.5 (2.8-11.3)	1.0[a]	0.50 (0.27-0.74)	2.5	0.8	0.33
Years in Ed.	11.0 (11.0-16.0)	11.0 (10.0-11.5)	0.14[a]	0.67 (0.46-0.90)	10.5	0.3	0.93

Table 28: Non-cognitive measures by on-road outcome group for the prospective cohort

1 participant did not complete the GDS.

Abbreviations: AEC= Anticholinergic Effect on Cognition, AUROC=Area under the curve, CI=Confidence Interval, IQR=Inter Quartile range.

a=Mann Whitney U test, b=Fisher's Exact test, c=Chi Square. Vision/Hearing rating – 0=Good, 1=Average, 2=Poor

5.3.5.1 Driving history

None of the driving measures were significantly different between the safe and unsafe groups.

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
Years licence held	53.0 (49.0-62.0)	50.0 (47-56.25.0)	0.26[a]	0.64 (0.42-0.86)	57.5	0.9	0.47
Professional driving experience, yes	1 (6.7%)	3 (30%)	0.27[b]	0.38 (0.15-0.62)	-	-	-
Endorsements, yes	0 (0%)	1 (10%)	0.40[b]	0.55 (0.31-0.79)	0.5	0.1	1.0
No times drive per week (participant)	7.0 (5.0-7.0)	5.0 (2.5-7.5)	0.39[a]	0.61 (0.35-0.88)	4	0.44	0.85
Average miles per day (participant)	10.0 (4.0-20.0)	4.0 (1.0-27.5)	0.27[a]	0.69 (0.35-1.0)	5.5	0.8	0.73
Average distance per week (participant)	50.0 (20.0-70.0)	15.5 (11.3-96.3)	0.25[a]	0.68 (0.38-0.98)	18	0.67	0.83
How many miles within 5 miles of home (participant)	4.0 (0.0-25.0)	15.50 (11.3-61.3)	0.53[a]	0.61 (0.32-0.89)	9.5	0.83	0.55

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
How may miles within 10 miles of home (participant)	2.0 (0.0-70.0)	0.0 (0.0-35.0)	0.35[a]	0.36 (0.06-0.65)	-	-	-
No of Unique destinations per week (participant)	3.5 (2.3-3.5)	3.0 (2.0-4.0)	0.65[a]	0.56 (0.28-0.85)	2.5	0.43	0.75
Longest trip (participant)	7.0 (3.5-22.5)	13.0 (5.0-15.0)	0.70[a]	0.45 (0.18-0.71)	-	-	-
Driving rating (participant)	3 (3-3)	3 (2-3)	0.77[a]	0.54 (0.29-0.79)	2.5	0.33	0.8
Answered 'yes' to any question (participant)	11 (78.6%)	7 (77.8%)	1[b]	0.50 (0.25-0.74)	2	0.0	1.0
Total 'yes' Score (participant)	1.5 (0.8-4.5)	2.0 (0.5-4.5)	0.93[a]	0.52 (0.27-0.76)	3	0.44	0.64
Driving rating (informant)	2.0 (1.5-3.0)	2.0 (1.0-3.0)	0.80[a]	0.46 (0.13-0.78)	-	-	-
Answered 'yes' to any question (informant)	11 (84.6%)	6 (85.7%)	1b	0.51 (0.23-0.78)	0.5	0.86	0.15

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
Total 'yes' Score (informant)	3 (1-7)	3 (1-15)	0.64a	0.57 (0.27-0.87)	9.5	0.43	0.92

Table 29: Driving questions by on-road outcome group for prospective cohort

Response rates for participant driving history range between 17 and 25 as some participants responded 'unsure' to some of the questions. Four participants did not have an informant. Response rates for informant driving history range between 14 and 20 as some participants responded 'unsure' to some of the questions.

Abbreviations: AUROC=Area under the curve, CI=Confidence Interval, IQR=Inter Quartile range.

a=Mann Whitney U test, b=Fisher's Exact test, c=Chi Square.

5.3.6 Informant measures

None of the informant measures were significantly different between safe and unsafe groups.

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
NPI Overall Total Score	3.0 (0.0-11.8)	2.0 (0.0-22.0)	0.86[a]	0.54 (0.25-0.81)	21.5	0.29	1.0
DCFS Stare	1.0 (1.0-2.0)	1.0 (1.0-2.0)	0.54[a]	0.41 (0.16-0.66)	-	-	-
DCFS Logic	1.0 (1.0-2.0)	1.0 (1.0-2.0)	0.91[a]	0.49 (0.22-0.75)	-	-	-
DCFS Total Score	8.0 (5.5-11.3)	6.0 (6.0-9.0)	0.54[a]	0.41 (0.14-0.68)	-	-	-
IADL Total Score	11.0 (8.8-17.3)	13.0 (11.0-19.0)	0.59[a]	0.58 (0.31-0.84)	10.5	0.86	0.50
BADL Total Score	3.0 (0.8-4.3)	3.0 (2.0-10.0)	0.49[a]	0.60 (0.32-0.88)	9.5	0.29	1.0

Table 30: Informant measures by on-road outcome group for prospective cohort

4 participants did not have an informant, responses for measures ranged from 17-21 as informants answered 'unsure' to some questions.

Abbreviations: AUROC=Area under the curve, BADL=Bristol Activities of Daily Living, CI=Confidence Interval, DCFS=Dementia Cognitive Fluctuations Scale, IADL=Instrumental Activities of Daily Living, IQR=Inter Quartile range. NPI=Neuropsychiatric Inventory.

a=Mann Whitney U test, b=Fisher's Exact test, c=Chi Square.

5.3.7 Clinician rated scales – Clinical Dementia Rating (CDR) and clinical Frailty scale (CFS).

None of the clinician rated measures were significantly different between safe and unsafe groups.

	Safe (n=15)	Unsafe (n=10)	p	AUROC (95 %CI)	Threshold cut-off	Sensitivity	Specificity
CDR Memory	1.0 (1.0-1.0)	1.0 (0.5-1.0)	0.29[a]	0.37 (0.14-0.60)	-	-	-
CDR Orientation	0.0 (0.0-0.5)	0.0 (0.0-0.13)	0.43[a]	0.40 (0.17-0.63)	-	-	-
CDR Judgement & Problem solving	0.5 (0.0-0.5)	0.25 (0.0-0.5)	0.77[a]	0.46 (0.23-0.70)	-	-	-
CDR Community Affairs	0.5 (0.0-0.5)	0.5 (0.0-0.5)	0.50[a]	0.58 (0.35-0.81)	0.25	0.70	0.47
CDR Home and Hobbies	0.0 (0.0-0.5)	0.0 (0.0-0.5)	0.98[a]	0.51 (0.27-0.74)	0.25	0.30	0.73
CDR Personal Care	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.89[a]	0.52 (0.28-0.75)	0.25	0.10	0.93
CDR Overall Rating	0.5 (0.5-0.5)	0.5 (0.5-0.5)	0.68[a]	0.45 (0.21-0.69)	-	-	-
CDR Sum of Boxes	2.0 (1.0-3.0)	1.75 (0.5-2.25)	0.50[a]	0.42 (0.18-0.65)	-	-	-
CFS	2.0 (2.0-3.0)	3.0 (2.0-3.25)	0.24[a]	0.64 (0.42-0.87)	2.5	0.7	0.53

Table 31: Clinician measures by on-road outcome group for prospective cohort

Abbreviations: AUROC=Area under the curve, CDR=Clinical Dementia Rating Scale, CFS-Clinical Frailty Scale, CI=Confidence Interval, IQR=Inter Quartile range.

a=Mann Whitney U test, b=Fisher's Exact test, c=Chi Square.

5.3.8 Comparison of previously published thresholds

5.3.8.1 Montreal Cognitive Assessment (MoCA)

When applied to our prospective cohort the <12 cut-off demonstrated 10% sensitivity and 87% specificity to detect unsafe drivers (see Table 32).

	12 and Under	13-26	27 and over
Safe	2 (13.3%)	11 (73.3%)	2 (13.3%)
Unsafe	1 (10%)	9 (90%)	0 (0%)

Table 32: Esser (2016) published cut-off scores applied to prospective cohort for MoCA total

The majority of participants were classified as indeterminate using this cut-off score.

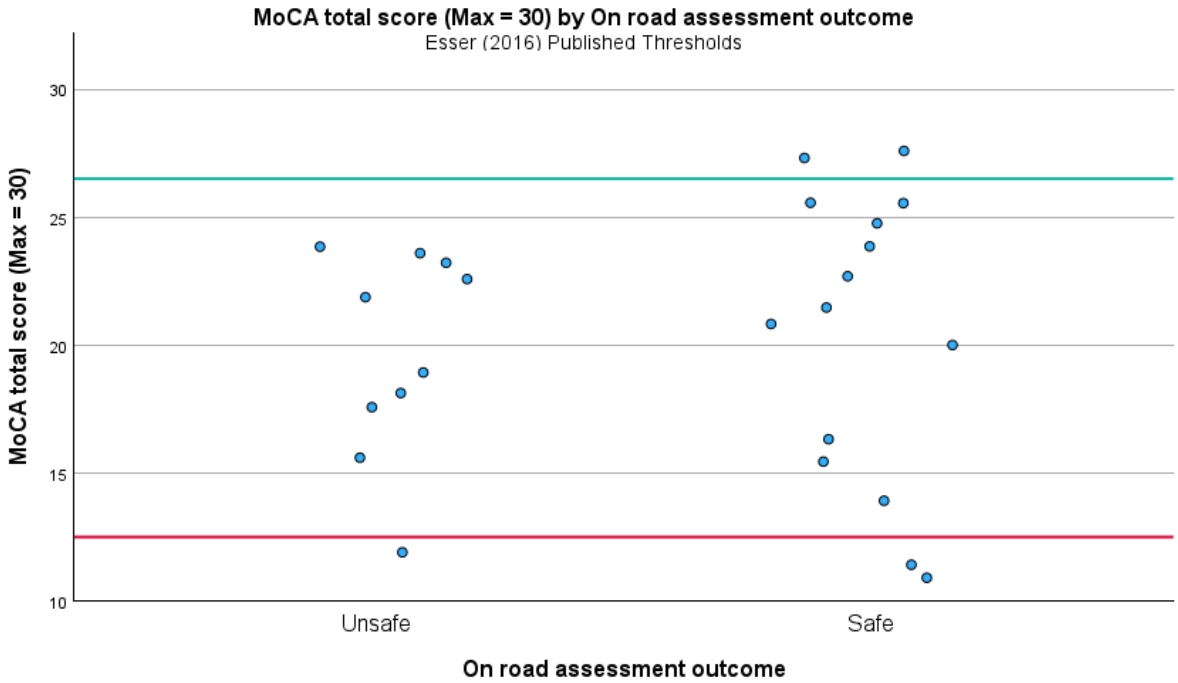

Figure 5: Scatterplot of Esser (2016) published thresholds for MoCA total score applied to our prospective cohort according to on-road assessment outcomes.

When applied to our cohort both of the MoCA domains (attention and attention & executive function/visuo-spatial combined) reported by M'au et al. demonstrated the same sensitivity and specificity. Sensitivity to detect unsafe drivers was lower at 40% and sensitivity was 67% (see figure 6).

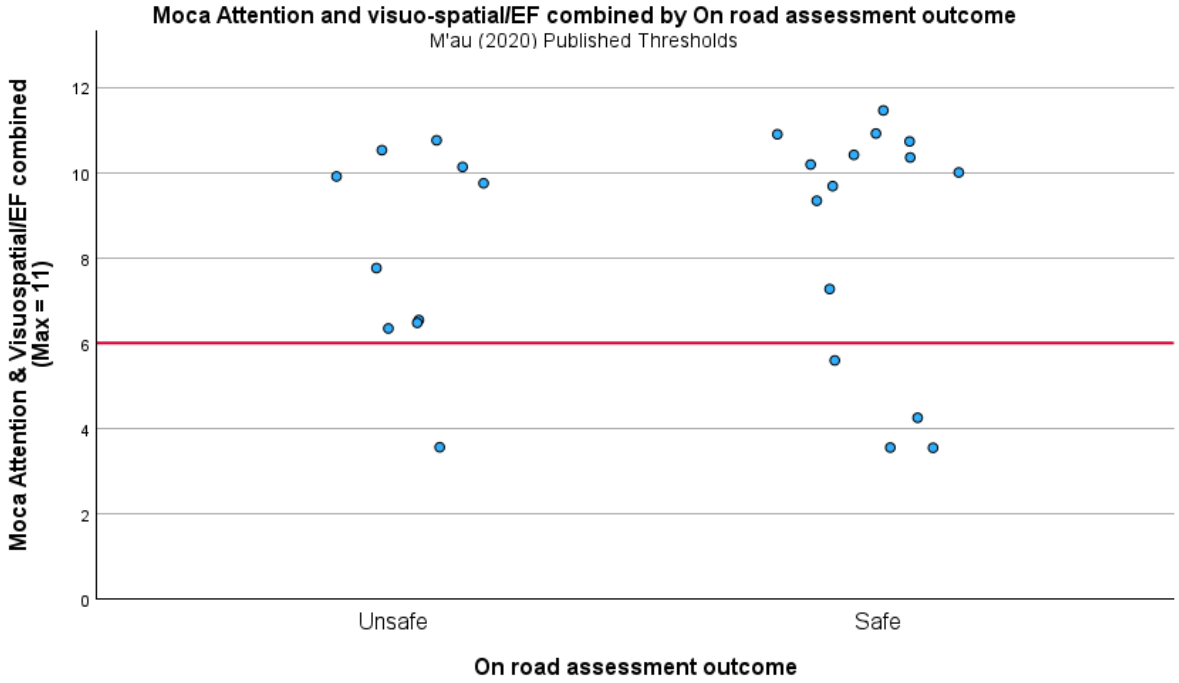

Figure 6: Scatterplot of M'au (2020) published thresholds for MoCA attention & visuo-spatial/executive function sub score combined applied to our prospective cohort according to on-road assessment outcomes.

5.3.8.2 Mini-Mental State Examination (MMSE)

Applied to our cohort sensitivity was 10% and specificity 87% for previously reported MMSE cut-off scores (see Table 33).

	19 and Under	20-24	25 and over
Safe	2 (13.3%)	4 (26.7%)	9 (60%)
Unsafe	1 (10%)	5 (50%)	4 (40%)

Table 33: Piersma (2018) published cut-off scores applied to prospective cohort for MMSE

For both of these published thresholds 9/25 participants were not classified (see Figure 7).

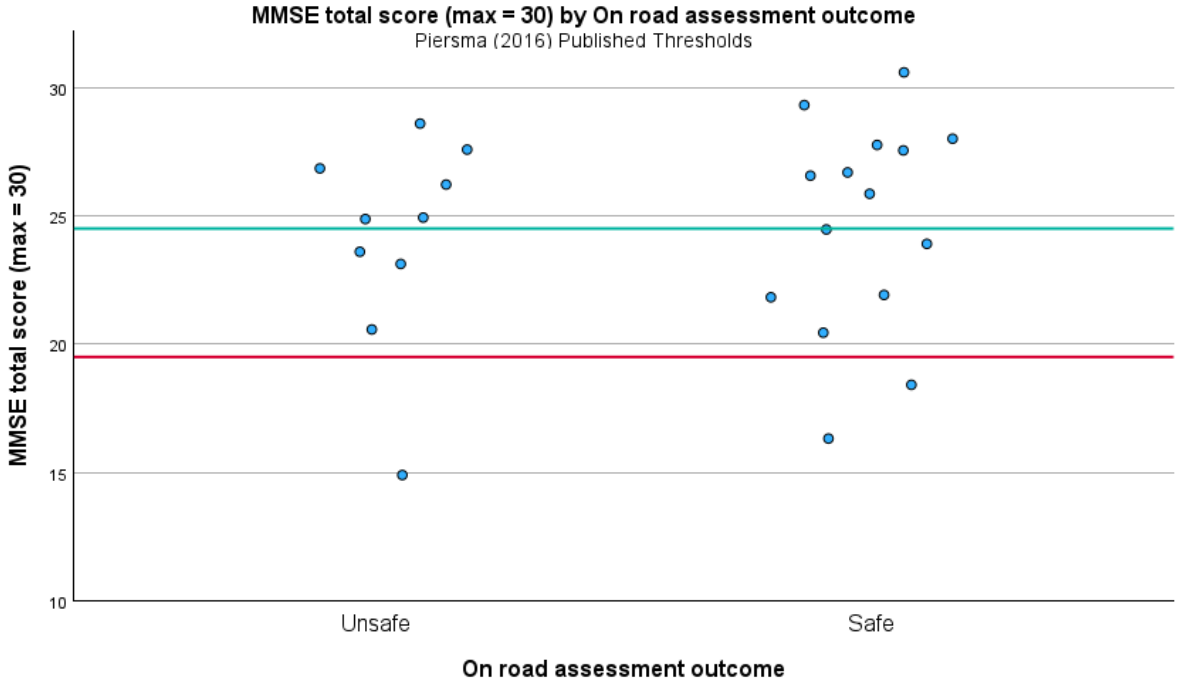

Figure 7: Scatterplot of Piersma (2018) published thresholds for MMSE applied to our prospective cohort according to on-road assessment outcomes.

5.3.8.3 Trail Making Test – Parts A&B

When thresholds published previously by (Papandonatos et al., 2015) applied to our cohort sensitivity was 67% and specificity 40% (see Figure 8) for Trails A.

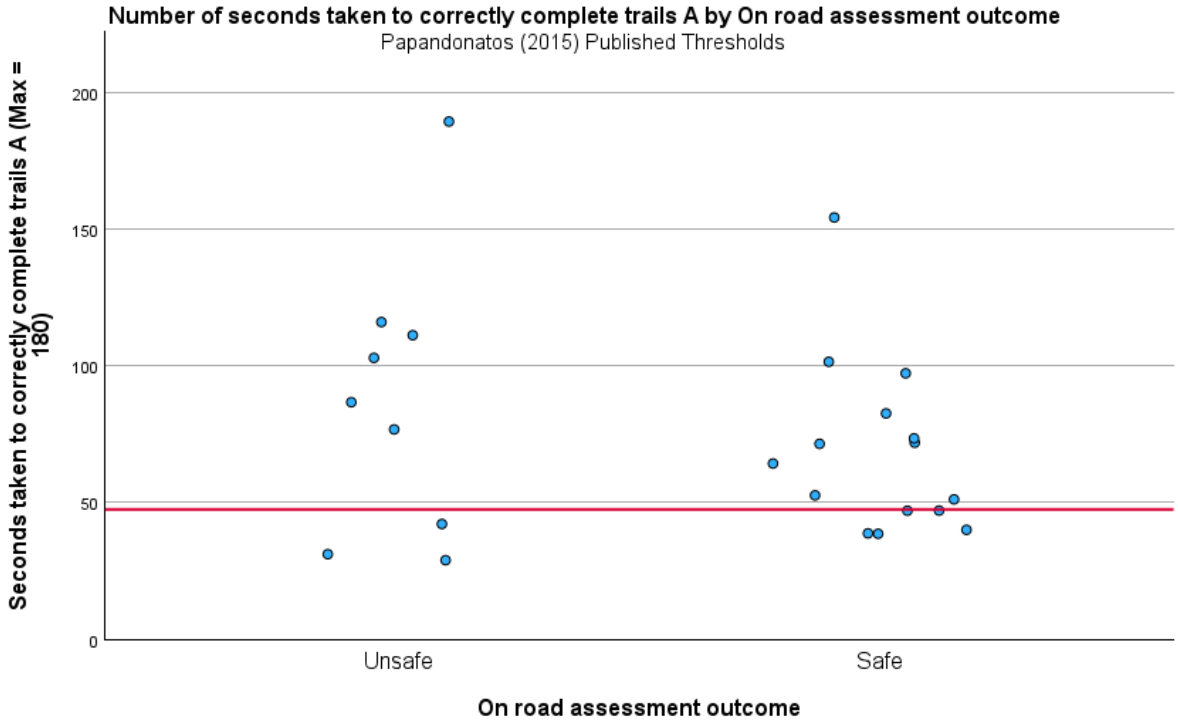

Figure 8: Scatterplot of Papandonatos (2015) published threshold for Trails A applied to our prospective cohort according to on-road assessment outcomes.

When Trails B threshold was applied to our cohort it demonstrated 89% sensitivity and 13% specificity (see Figure 9).

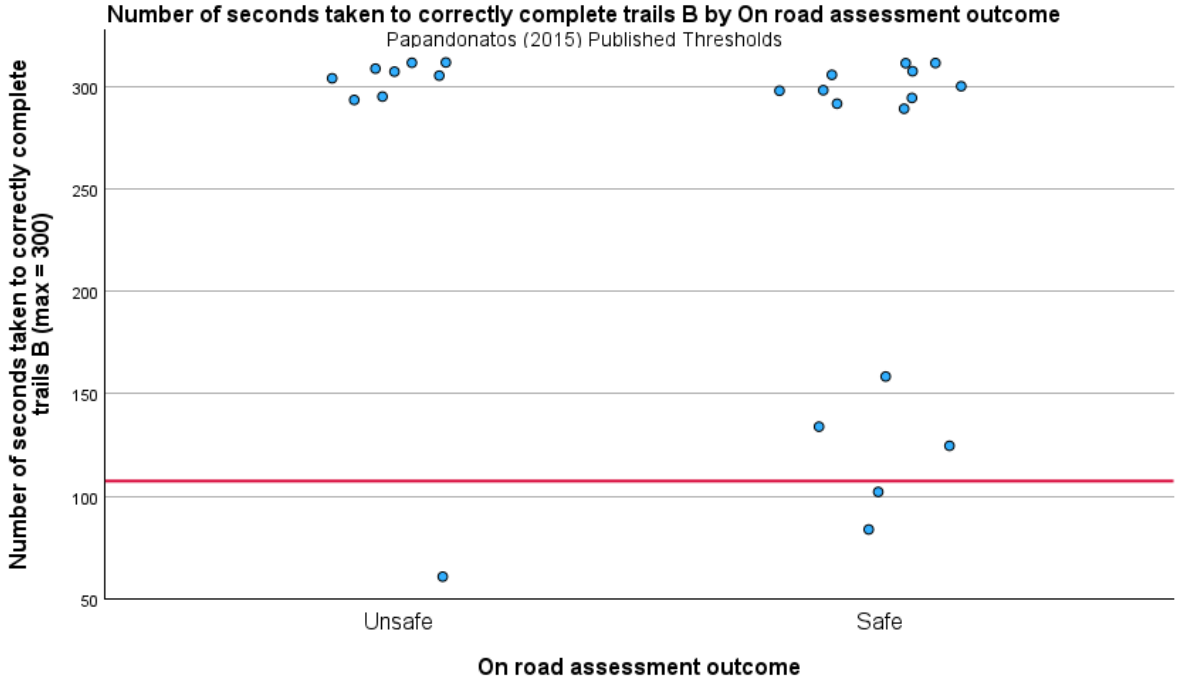

Figure 9: Scatterplot of Papandonatos (2015) published threshold for Trails B applied to our prospective cohort according to on-road assessment outcomes.

5.8.3.4 Snellgrove maze

Published thresholds (Snellgrove, 2005),applied to our cohort demonstrated 60% sensitivity and 53% specificity (see Table 34).

	Snellgrove score <60 (0-1 errors)	**Snellgrove score >61 or <60 2+ errors**
Safe (On-Road)	8 (53.3%)	7 (46.7%)
Unsafe (On-Road)	4 (40%)	6 (60%)

Table 34: Snellgrove maze scoring applied to prospective cohort by on-road outcome

5.4 Discussion – Investigation of advanced assessments

5.4.1 Brief summary of aim and results

The aim of this chapter was to test the driving decision aid tool developed in the previous stage (chapter 4) in an independent cohort to determine whether it could successfully predict those who would be determined to be safe or unsafe in an on-road assessment of driving. An additional aim was to investigate the discriminant ability of advanced assessments.

The driving decision aid tool demonstrated poor sensitivity to detect unsafe drivers. Advanced assessments that were determined to be significant predictors of on-road outcome were maze error score, reaction time difference (CRT-SRT), digit vigilance task (DVT) mean time and standard deviation and angle task result in degrees and number correct.

5.4.2 Testing the tool in an independent cohort

Despite the similarities in demographics, age and dementia severity to the development cohort, when tested in this independent cohort the sensitivity fell from 50% to 10% and the specificity from 95% to 47%, suggesting that the tool does not work well to predict drivers who might be found unsafe in an on-road assessment of driving. It is possible that this is due to the small numbers in both cohorts increasing the heterogeneity of the samples but follows the same pattern seen in previously published test batteries that either show a drop in sensitivity to detect unsafe drivers when tested in as independent cohort. The Nottingham Neurological Driving Assessment (Lincoln et al., 2006) demonstrated a reduction in sensitivity from 67% to 44%; the Rookwood test battery demonstrated a reduction in sensitivity when applied to a dementia cohort (46%) (McKenna & Bell, 2007) and the Piersma battery demonstrated a reduction in sensitivity when tested in a cohort of non-AD dementia (Piersma et al., 2018).

The developed driving decision aid tool in its present form is unlikely to work well in a clinical setting, and with such a poor sensitivity to detect unsafe drivers will not be acceptable to clinicians. In chapter 3, clinicians expressed a need for a research backed clinical tool that can not only be used to aid decision making about driving safety but also be utilised to help the patient understand why an assessment of their driving might be needed, demonstrating such a poor ability to predict unsafe driving when applied,

this clinical tool does not fulfil that important criterion. In addition, the cut-off score thresholds were calculated in the development cohort for visuo-spatial domain of 13.5 was vastly different from the one generated in this cohort of 9.5 despite similar median scores between the safe (14 vs 14) and unsafe (13 vs 14.5) groups suggesting that this is potentially not the optimal threshold.

5.4.3 Participant assessments – Cognitive measures

5.4.3.1 Global measures of cognition - ACE III/MoCA/MMSE

The data from this cohort allows for some evaluation of the predictive ability of the ACE III and its individual components with the novel data produced in the development cohort. These results demonstrated no predictive ability of any aspect of the ACE III to detect safe or unsafe drivers in contrast to the development cohort where visuo-spatial domain, clock drawing and drawing elements were significant, despite the cohort being similar in age and dementia severity. These findings contradict the results from the previous chapter which raises doubt about the usefulness of the visuo-spatial sub score in assessing potential driving safety in a clinical setting. However, this is limited data from two small cohorts, and there is no published data on the ACE III to compare these findings.

When results from both cohorts were combined (to give 56 total cases, data not shown), none of the individual items, domains or total score are significant (using Mann Whitney U) suggesting that it is not due to the small numbers in the cohort, but that the ACE III and its elements are not useful in predicting driving safety, this is perhaps not surprising given that the test has been developed to detect and diagnose a dementia (Hsieh et al., 2013), rather than assess driving safety.

No elements from the MoCA were significant predictors in this prospective cohort, despite the AUROC suggesting some discriminant ability in the development cohort. This is in agreement with (Ma'u & Cheung, 2020) who also found it to be non-significant.

As with the MoCA, the MMSE was not a significant predictor of on-road outcome in this prospective cohort, and few studies in the published literature have established thresholds for detecting safe and unsafe drivers (see Table 25 and Figure 7).

5.4.3.2 Previously published thresholds applied to prospective cohort – Global measures of cognition (MoCA/MMSE)

The main focus of our research was on sensitivity to detect unsafe drivers of clinical measures, and as such any previously published thresholds that were tested in our cohort that has a trichotomous outcome were made binary by calculating specificity as the percentage of people who scored above the sensitivity cut-off and were found to be safe in an on-road test.

Previous research investigating the MoCA and prediction of fitness to drive is extremely limited. When published thresholds for MoCA total score (Esser et al., 2016) were applied to this cohort they demonstrated poor sensitivity to detect unsafe drivers and the majority of the participants (n=20) fell into the uncertain area in-between these scores (see Figure 5). In a clinical setting most of the patients seen will likely fall into the uncertain range using these cut-off scores, given that at the diagnostic stage they are likely to be relatively unimpaired. The utility of the MoCA total score alone to assess driving safety is poor and suggests that this group of people is very difficult to classify.

While none of the individual items of the MoCA were found to be significant predictors in this prospective cohort, previously published research (Ma'u & Cheung, 2020) found MoCA attention score and attention & visuo-spatial/executive function scores combined to be significantly predictive of on-road outcomes. Both of these demonstrated the same sensitivity to predict unsafe drivers when applied to the prospective cohort. The combined score covers more cognitive domains, and the inclusion of the visuo-spatial domain would make it more acceptable to clinicians based upon the clinician comments described in chapter 3 placing importance on the visuo-spatial domain when making an assessment of driving safety. When applied to our prospective cohort these thresholds did not work well, missing 60% of unsafe drivers. The M'au et al. thresholds (Ma'u & Cheung, 2020) were developed in a more impaired cohort, as suggested by the difference in mean MoCA total scores (unsafe 19.6 vs 17.3 and safe 20.3 vs 19.2 respectively) and is possibly why they miss such a high proportion of unsafe drivers in a relatively unimpaired cohort. These elements of the MoCA would not be useful in a clinical setting where most people would be in the early stages of a dementia or MCI.

The Piersma et al. (Piersma et al., 2018) cut-off thresholds were chosen based on published guidelines (Versijpt et al., 2017), but missed a significant proportion of unsafe drivers (90% in our cohort) who are at the very mild to mild dementia stage. These cut-off scores also did not classify 9/25 participants, suggesting that as with the MoCA, driving safety is very difficult to classify in this group of people. MMSE score (Piersma et al., 2018) or MMSE as a measure of dementia severity (Berndt et al., 2008) is not sufficient to classify driving safety. Although regularly used in a clinical setting, these results suggest that the MMSE is not a useful measure in determining driving safety in early-stage dementia and is in agreement with consensus recommendations (Rapoport et al., 2018) and previous research (Bennett et al., 2016; Berndt et al., 2008; Fox et al., 1997; Iverson et al., 2010; Piersma et al., 2018).

5.4.3.3 Other tests of cognition - Digit span/ Trail Making Test – Parts A & B/ Ruler drop task

Digit span was not predictive of driving safety, despite previously being found to be correlated with failure of an on-road test (Carr et al., 2011); however, other similar tests of verbal and working memory have been found to have no association with on-road outcomes (Dawson et al., 2009; Fox et al., 1997; Lincoln et al., 2006). These findings add to the evidence that measures of working memory are not useful in assessment of driving safety in a clinical setting therefore are not recommended.

The Trail Making Test was also not a significant predictor of driving safety in this prospective cohort.

Reaction time calculated from the ruler drop task was not a significant predictor, and results for reaction time tasks in previous literature have been mixed finding significant correlation with on-road outcome (Piersma et al., 2016) and no correlation with on-road outcome (Bieliauskas et al., 1998). Reaction time for braking/hazards has been shown to be impaired in older drivers with MCI or mild dementia when compared to controls (Barco et al., 2015; Davis et al., 2018; Devlin et al., 2012; Pavlou et al., 2017), and poor reaction time would be expected to be predictive of unsafe driving, it is probable that this test is a poor measure to use in this population rather than reaction time not being associated with driving safety, as it is not a precise measure and finger dexterity is likely to be impaired in older populations.

5.4.3.4 Snellgrove maze

Error score of the Snellgrove maze was significantly predictive of driving safety in this prospective cohort. Maze completion time, but not errors, has previously been found to be correlated with on-road outcome (Carr et al., 2011; Ma'u & Cheung, 2020; Ott, Festa, et al., 2008; Piersma et al., 2016; Whelihan et al., 2005) so these findings are in contradiction to the established literature, however it should be noted that these were different mazes to the Snellgrove with the exception of Carr et al., (2011).

5.4.3.5 Previously published thresholds applied to the prospective cohort – Other cognitive tests – Trails A&B/Snellgrove maze

Previously published thresholds for Trails A&B (Papandonatos et al., 2015) applied to our prospective cohort appeared to have good sensitivity (particularly trails part B). However, 33% of unsafe drivers for trails A were still missed by this threshold. Additionally, 60% of those who scored over the threshold for trails A and 87% for trails B (see Figure 8 and Figure 9, pages 161-162) were found to be safe in the on-road assessment.

These cut-off thresholds were established in a cohort with a relatively high level of education (mean 15 years) compared to the mean level of education in our cohort (mean 12.6 years) and cognitive tests are sensitive to education (e.g. Tombaugh & McIntyre, (1992)) suggesting that even thresholds previously tested in an independent sample is not suitable for use in a clinical setting without controlling for education level and is not useful in assessment of driving safety.

Many participants struggled to complete part B with 18/24 who attempted it in the prospective cohort being assigned the maximum score of 300 seconds as they were unable to complete the test. It could be argued that this in itself can be indicative of an impairment that could impact driving safety, but 10 of the 15 participants found to be safe in this cohort had also been awarded the maximum score, indicating that the cut-off score is essentially meaningless, and this is simply not an effective measure of driving safety.

The Snellgrove maze published scoring by the developers (Snellgrove, 2005) uses both time in seconds and errors to predict driving safety, when applied to this cohort demonstrated poor sensitivity and missed 40% of unsafe drivers. Additionally, 47% of

those classified as unsafe by the scoring were found to be safe in the on-road assessment. This outcome once again highlights the problem with many established thresholds not showing the same predictive ability in an independent cohort.

5.4.3.6 Previously published cognitive test thresholds applied to the prospective cohort – Overall recommendations

None of the previously published thresholds applied to our cohort found good sensitivity to detect unsafe drivers. Of those tested, Trails A and the Snellgrove maze demonstrated the best sensitivity at 67% and 60% respectively and although this is poor, therefore appear to be the best tests that can be recommended using previously published thresholds applied to our cohort. However, when overall accuracy is considered, any usefulness is diminished. For MoCA and MMSE almost all of our prospective cohort were in the indeterminate range, which is essentially ineffectual in the clinical setting. For trails A&B the majority of the cohort were above the threshold, again making these scores ineffectual for determining driving safety,

This outcome is likely because these thresholds were being tested in a cohort of people who had been already referred for an on-road assessment of driving, and therefore there was already an uncertainty regarding their safety to drive, and that these thresholds are not adequate for this population. This highlights the importance of the availability of an on-road assessment for those with mild impairment, as this research suggests that there is nothing clinical that can replace this.

5.4.3.7 Clinician judgement and cognitive test thresholds

In the previous chapter it was described that clinician advice on whether a person should stop driving until an on-road assessment has taken place was recorded. Although there was no significant difference between groups, the classifier evaluation metrics gave a sensitivity of 50%. Clinician judgement alone showed better sensitivity than previously published thresholds applied to our cohort for MoCA, MoCA attention and visuo-spatial/executive function combined and MMSE.

5.4.4 Participant assessments – computerised tests of attention, concentration and visuo-spatial function

5.4.4.1 Simple and Choice reaction time tasks

Difference between the choice and simple time reaction times was a significant predictor of on-road outcome and agrees with previous research that a visual based reaction time task is significantly correlated with on-road outcome (Piersma et al., 2016). This research produces novel data in the use of the reaction time tasks in relation to driving, and the task has shown high levels of test-retest reliability (Elder et al., 2022). The data is suggestive of this being an effective test for predicting driving safety with adequate discriminant ability and is simple and quick to administer via touch screen tablet in a clinical setting taking 5 minutes to complete. Although further testing is needed in a larger population, it did demonstrate marginally better discriminant ability (AUROC = 0.80) than the best assessments from the development chapter (AUROC range = 0.73-0.75).

5.4.4.2 Digit vigilance task

This research produced novel data on the use of the computerised digit vigilance task to predict driving safety. The results show that this is an effective predictor of attention and concentration that is simple and quick to administer in a clinical setting taking 3 minutes to complete and can be easily administered on a touch screen tablet without any specialist knowledge required.

5.4.4.3 Line angle discrimination task

The result in degrees approached significance in predicting on-road outcome. This is novel data using this task for this purpose and indicates that it potentially could be an effective test when assessing driving safety. Interestingly this test of visuo-spatial perception approached significance in this cohort where others (ACE III domain, MoCA visuo-spatial/executive function/clock/drawings) administered on paper did not. This is likely to be because this is a more nuanced test of visuo-spatial skills, with the difference in degrees increasing or decreasing in difficulty depending on the participants performance. It has previously been found detect visuo-spatial deficits and be significantly related to cognitive impairment (Wood et al., 2013) in people with a

diagnosis of DLB and AD and so could be a relevant addition for use in a memory clinic setting, although cannot be recommended at this time on the strength of this data.

The tasks that found a significant difference between groups (CRT-SRT and DVT) could be grouped to form a computerised battery for the assessment of driving safety in a clinical setting. In total they would take around 8 minutes to administer and could easily be programmed to calculate and produce a single outcome result removing the need for clinicians to calculate or interpret the results in relation to driving safety meeting the expressed needs of clinicians described in chapter 3 by not adding undue burden to an already time pressured assessment. Further research would be required to assess the utility and validate these results in a larger cohort, but these initial results are promising.

5.4.5 Participant assessments – non-cognitive measures

5.4.5.1 Clinical history – Comorbidities and medications

The number of comorbidities was not found to be predictive of driving safety in this cohort. It is difficult to interpret this in the context of previous research as it has not previously been sufficiently investigated in a dementia cohort, although it was not found to be associated with unsafe driving in those with a cognitive impairment (Hotta et al., 2018) or in normal older adults (Carr et al., 2016). It is possible that the small numbers, and relatively healthy cohort, in this study were insufficient to detect an effect of comorbidities on driving, and that that if conditions are well controlled they may not affect driving (Falkenstein et al., 2020), although there is no information on the cumulative effect that comorbidities with a diagnosis of dementia may have on driving safety, and so this evidence is not sufficient to contradict consensus recommendations of the inclusion of comorbidities in a holistic assessment of driving safety (Driving & Dementia Working Group, 2018). Potentially the measure used was not the correct one to use in this research and a more detailed measure such as the Cumulative illness rating scale or Index of coexisting disease (De Groot et al., 2003) would have yielded different results. The CCI measure used in this research (Charlson et al., 1987) is relatively simplistic in that for many conditions it is a binary score (presence/absence) although additional weighting is given to the presence of some conditions (diabetes with complications, kidney disease, moderate/severe liver disease, cancer, hemi/paraplegia and AIDS), and an overall score calculated. In contrast the CIRS-G (Linn et al., 1968) is more detailed and accounts for levels of severity of disease (mild – extremely severe)

and gives five output scores (total number of categories, total score, severity index per category, number of categories at level 3 and 4). In addition, the CIRS-G includes a detailed assessment of vision, hearing, vertigo/dizziness, neurological disorders and musculoskeletal disorders that could be related to driving safety.

Similarly, medication was not predictive of driving safety despite previous association with elevated crash risk of psychoactive drugs and opioid analgesics being demonstrated in the literature in older adults (Fournier et al., 2015; Leveille et al., 1994; Meuleners et al., 2011; Ray et al., 1992). This cohort did not report high use of medications that can cause drowsiness or are associated with a high anticholinergic burden, but there was a high incidence of medications that can cause dizziness, and it is surprising that no effect was seen on driving. It is probable that this is due to this small cohort being relatively healthy and unimpaired and so medication use is not having a detectable effect at this early stage of dementia. Concordance with medication regime was not factored into the analysis in this research, and as older people on multiple medications are more likely to not adhere to the regimen (De Groot et al., 2003) it is possible that this was a factor in the non-significant result. In addition, it can be difficult to untangle the possible effect that medication may have on driving safety from the possible effect the medical condition it is being used to treat (De Groot et al., 2003) and so when assessing driving safety, they should be considered collectively.

5.4.5.2 Demographic data

The participants in this stage of the research were a convenience cohort and none had a severe cognitive impairment (mean ACE III = 74.7, mean MMSE = 24.2, mean MoCA = 20.0). The mean ACE III and MoCA total scores were comparable to those in the development cohort and were close in mean age (76.7 and 75.6). As with the development cohort the sample is representative of people who would typically be seen in a clinical setting and were referred for an on-road assessment of driving as part of the early diagnostic process, so would be expected to be at a mild stage of dementia at this point. The mean dementia severity of this cohort is CDR=0.5 and is similar to previously published studies who report participants with very mild, mild or probable dementia or a CDR score<2 (e.g. (Frittelli et al., 2009; Papandonatos et al., 2015; Piersma et al., 2016; Piersma et al., 2018; Whelihan et al., 2005)).

Despite being a significant predictor of driving safety in our clinical tool, age did not emerge as a significant predictor in this cohort. When both cohorts are combined (56 cases) and analysed (Mann Whitney U) age is significant (p=0.04), suggesting that age may be related to driving safety. This conclusion is supported by previous research that found age to be predictive of failure of an on-road test (Dawson et al., 2009; Ott, Heindel, et al., 2008) and associated with unsafe driving acts (Hotta et al., 2018).

5.4.5.3 Vision and hearing measures

In accordance with previous research (Carr et al., 2011; Dawson et al., 2009; Hotta et al., 2018; Ott et al., 2013; E. Y. , Uc et al., 2004; E. Y. Uc et al., 2005) visual acuity was not significantly predictive of on-road outcome in this cohort, this is likely to be due to those with vision poor enough to affect driving being filtered out before the on-road assessment of driving can take place, as this is tested prior to the on-road assessment which does not go ahead if vision is too poor. Additionally, 24/25 participants reported using glasses and acuity was tested with their glasses on, and so any visual deficit was corrected contributing to visual acuity being a poor predictor of driving safety.

Contrast sensitivity has been variously found to be significantly correlated with failing an on-road test (Carr et al., 2011), and with reduced identification of road signs and landmarks (E. Y. Uc et al., 2005). However, it is not predictive of driving errors in dementia (Dawson et al., 2009) and there were no significant differences between groups in this cohort. A score of 1.5 or lower indicates visual impairment (Parede et al., 2013), and although both safe and unsafe groups had a median score of 1.5 or below, the difference between the groups was negligible (0.07). These findings do not support the inclusion of contrast sensitivity in a clinical assessment of driving safety at this time, and it is likely that the prevalence of visual impairment expected to be found (both previously diagnosed and undetected) in this population make it a poor predictor.

The hearing measures were self-reported and not predictive of driving safety. To date the direct relationship between hearing impairment and driving safety in those with a diagnosis of dementia has not been investigated, however in older adults those with poor hearing have been found to have greater difficulty driving in the presence of distractors (Hickson et al., 2010). Auditory attention (reaction time to a tone) has been found to be a predictor of driving safety (Piersma et al., 2016), so it is probable that

hearing impairment could be an indicator of driving safety, but these results were not in agreement. In this research auditory, attention was not investigated specifically and self-rating of hearing is a poor substitute for that as it is not clear how any hearing impairment may be impacting driving ability.

5.4.5.4 Epworth Sleepiness Scale (ESS)

Daytime sleepiness was not found to be predictive of on-road driving safety. This is under-researched at present in the literature; however one study has found that sleep disordered breathing was associated with worse driving performance in those with MCI (Cross et al., 2017). Interestingly, in this cohort those found to be unsafe in the on-road assessment reported lower daytime sleepiness than those found to be safe (median scores 4.5 vs 7). Reported daytime sleepiness was relatively low in this cohort, with scores of 0-10 determined as the 'normal' range. The effects of daytime sleepiness may be picked up by the impact it has on other cognitive domains such as fluctuations in attention, concentration or reaction times and these more detailed measures are likely to be more sensitive to this than a self-report scale.

5.4.5.5 Geriatric Depression Scale (GDS)

An association has previously been found between depression and driving behaviour in an MCI cohort (Beratis et al., 2017), but was not found to be a predictor of on-road safety in our cohort. The incidence of depressive symptoms was relatively low in this cohort and the small sample size is possibly why it was not a significant predictor. As a diagnosis of MCI or dementia is associated with higher rates of depression than those with normal cognition (Snowden et al., 2015) more research is needed on the effect this might have on driving safety.

5.4.5.6 Driving history

Perhaps surprisingly, driving history in relation to prediction of driving safety is under researched in those with dementia. Recent driving experience and participants' judgement of their own driving safety has previously been found to be predictive of driving safety (Piersma et al., 2016). However none of the participant driving questions were significantly predictive of driving safety in this study. Previous research has found that people with dementia are very poor predictors of their own driving safety (Brown et al., 2005) and this is reflected in these results. None of the driving questions investigated

would enhance the predictive ability of the developed clinical tool, however a clinical assessment of driving safety should always include a conversation about recent driving as currently recommended by consensus guidelines (Driving & Dementia Working Group, 2018), and described as forming an important part of risk assessment by clinicians in chapter 3.

5.4.6 Informant measures

5.4.6.1 Informant driving history

The results from this cohort did not suggest that the inclusion of any of the informant driving questions in the driving decision aid tool would improve its predictive ability. This is in opposition to previous findings that informant rating of driving quality (Barco et al., 2021) and caregiver opinion of driving cessation (Piersma et al., 2016) were significantly predictive of driving safety, but in agreement with research that suggests caregivers are poor predictors of on-road outcome (Brown et al., 2005). In chapter 3 clinicians reported that this was one of the most important aspects in their assessment of driving safety in a clinical setting, and while these results do not support that in respect to predictive ability, a holistic assessment should still include a conversation with an informant where possible (Driving & Dementia working group, 2018).

5.4.6.2 Neuropsychiatric inventory with caregiver distress (NPI)

This research produces novel data in the investigation of the NPI to predict driving safety. None of the individual items or total score were significantly predictive of driving safety, and so at this time cannot be recommended for inclusion in an assessment of clinical driving safety. However, previous research in participants with a diagnosis of frontotemporal dementia in a driving simulator found significant correlations between the total score of a similar neuropsychiatric measure (the Neurobehavioral Rating Scale (NBS) (Levin et al., 1987; Sultzer et al., 1992) which contains several overlaps of neuropsychiatric symptoms with the NPI such as anxiety, disinhibition, agitation, depression, uncooperativeness, hallucinations, mood liability and apathy) and speeding/ignoring stop signs, and agitation with number of collisions (de Simone et al., 2007). Although FTD symptoms are very different to those of other dementias, there is some overlap suggesting that if severe enough these symptoms could be predictive of driving safety and further investigation is needed. The prospective cohort in this

research were relatively unimpaired and had low neuropsychiatric scores (see Table 30) so it is possible that this is why it did not emerge as a significant predictor.

5.4.6.3 Dementia cognitive Fluctuation Scale (DCFS)

This research produces novel data in the investigation of the DCFS to predict driving safety. The results were non-significant and so the inclusion of the DCFS in a clinical driving safety is not recommended at this stage. However, fluctuations are more prevalent in those with a diagnosis of Lewy Body Dementia (I. McKeith, 2004; I. G. McKeith et al., 2017), and only one person in this cohort had that diagnosis, meaning any effects were too small to detect in the overall sample.

5.4.6.4 Activities of daily living – Instrumental Activities of Daily Living (IADL) and Bristol Activities of Daily Living scale (BADL)

Predictive ability of functional ability in relation to driving safety is under-researched and this research presents novel data of the IADL and BADL. A similar functional assessment questionnaire (FAQ) has previously found a positive association with road test failure of financial ability, shopping, gameplaying and meal preparation and stove use (Barco et al., 2021), however, none of the measures investigated in this research were found to be significantly predictive of on-road outcome. The results from our prospective cohort do not recommend the inclusion of the IADL or BADL in the improvement of the predictive tool or a clinical assessment of driving safety at present, however it is possible that as participants (see Table 30) were only mildly impaired that the predictive value was too small to be detected. Future research should continue to investigate the utility of functional ability in the prediction of driving safety.

5.4.7 Clinician rated scales

5.4.7.1 Clinical Dementia Rating (CDR)

Previous research has demonstrated that those with a CDR score of 1 will have a faster median time to failure of an on-road test than those with a score of 0.5 (Ott, Heindel, et al., 2008) and a similar measure the AD8 significantly associated with road test failure (Barco et al., 2015; Carr et al., 2011). In addition, CDR memory, orientation, judgement and problem solving, community affairs and sum of boxes have been shown to be predictive of driving safety (Piersma et al., 2016), but were not found to be significant predictors in this research. The CDR scores in Table 31 (page 157) demonstrate no

differences between safe and unsafe groups in our cohort in median scores for any element of the CDR, and so in a mild cohort such as this is not likely to be a useful clinical predictor.

5.4.7.2 Clinical Frailty Scale

Clinical frailty has not been investigated previously in respect to driving safety in a dementia cohort and so this research produces novel data. The differences in frailty rating were negligible between the safe and unsafe groups (see Table 31, page 157) and so it is not surprising that it was not found to be a significant clinical predictor. Previous research has found that pre-frailty is significantly associated with crashes (Liu et al., 2022) and marginally associated with driver errors (Carr et al., 2016) in cognitively normal older people, however the results from this study do not justify the inclusion of a measure of frailty in the assessment of driving safety at this time.

5.4.8 Comparison of significant results

The AUROC of significant predictors in the development cohort (age, visuo-spatial domain, drawing combined score and clock drawing (AUROC ranges between 0.73-0.75)) were compared with the measures in the prospective cohort that found significant differences between the safe and unsafe groups (maze errors, RT difference, DVT mean time and standard deviation (AUROC ranges between 0.76-0.80)) to determine if the advanced assessments had better discriminant ability. Although the advanced assessments showed a marginally better AUROC, there was not a large difference.

5.4.9 Limitations and future directions

The small number of participants was a limitation in this research and therefore limited the range of scores that were available for analysis. In addition, the inability to collect a full data set for informant measures makes it possible that important potential predictors were unable to be detected due to the small the limited number of cases rather than the measure was not predictive. As with the development cohort, this also meant that the potentially important impact of dementia type on driving safety could not be investigated.

This cohort also contained a mixture of dementia diagnosis, replicating the limitations of the development cohort in that it increased the heterogeneity of the sample and in contrast to much of the research published in this field does not focus on Alzheimer's

disease. As with the development cohort, due to the small numbers it was not possible to include the effect of dementia type on driving safety.

In both the retrospective development and prospective cohort there was a higher proportion of male participants. As previously discussed, this is likely due to drivers in this age group being more likely to be male, and women are more likely to let their partners become the main driver as they get older (Department for Transport, 2022). However, with women twice as likely to receive a diagnosis of dementia (Alzheimer's Research UK, 2022) and older women more likely to be found unsafe to drive in an independent assessment of driving (Mitchell, 2018) this is a limitation in this research.

Some advanced assessments were found to be significantly potential predictors, however, it was not possible to test these in an independent cohort, and so it is not possible to conclusively report that they improve the sensitivity and specificity of the developed clinical tool to detect unsafe drivers or validate a new clinical tool that includes these measures. More research is needed to test an improved tool.

The results from this prospective cohort highlighted that meaningful cut-off thresholds are difficult to establish, with calculated thresholds for the ACE III and MoCA not only being different between our development and prospective cohorts, but also trails A & B and maze thresholds being different to previously published ones. Cut-off scores used need to be acceptable to both clinicians and patients and their families (see chapter 3) for a tool using these to be useful, and these findings suggest that this may not be possible.

A major limitation in this research was that the clinical tool that was developed simply did not work when tested in an independent cohort. Future research is needed to test the ability of promising predictors such as reaction times and mazes in enhancing predictive ability.

These findings cannot be applied to persons with moderate or severe dementia, and at this level reduced functional ability or low MMSE or MoCA scores may still predict unsafe driving.

Future research is needed with larger participant numbers to investigate the possible predictive ability of measures such as the functional measures and frailty that have

been found to have a significant association with on-road safety but were not found to be predictive in this research.

5.5 Conclusions

The developed clinical tool did not work well when applied to an independent cohort and this is reflective of results seen in other developed tests and batteries that seem to work well in the development cohort, but perform poorly when applied to an independent cohort (Lincoln et al., 2006; McKenna et al., 2004), suggesting that it may simply not be possible to predict on-road driving safety, particularly in those with a mild dementia using currently collected clinical data assessments.

Three advanced assessments demonstrated good discriminant ability to detect driving safety and show promise for enhancing the predictive ability of the developed clinical tool however it was not possible to test this in an independent cohort. Also, a number of non-cognitive measures such as comorbidities, medication, functional measures and frailty that were expected to be predictive of driving safety based on previous research findings were not, possibly due to the relatively unimpaired nature of the cohort, suggesting that both the cognitive and non-cognitive measures tested are not suitable or sensitive enough for prediction of driving safety in those with an MCI or mild dementia.

Most people who are assessed in a memory service are likely to be in an early stage of dementia, and so rather than prediction, the focus should be on screening measures to determine who may need referral for an on-road assessment of driving.

The findings of this research suggest that, at present, it is not possible to recommend the use of the predictive clinical tool over the current recommendations for a holistic assessment for driving safety (Driving & Dementia Working Group, 2018).

Chapter 6. Conclusions

6.1 Summary of research

This research aimed to develop a driving decision aid tool that could be used by a wide range of clinicians when making a decision about an individual's safety to drive with a diagnosis of a dementia or MCI. The driving decision aid tool was developed by retrospectively examining the clinical notes of people who had an independent on-road driving assessment in the preceding 12 months and identifying possible predictors of driving safety. The developed driving decision aid tool was then tested in an independent prospectively recruited cohort, where it performed poorly. The discriminant ability of advanced assessments, that may be possible clinical predictors but that were not available in the retrospective clinical notes were then examined, with Snellgrove maze errors, difference between choice and simple reaction time tasks and digit vigilance task result significantly different between safe and unsafe groups. Previously published cognitive thresholds tested in this cohort in order to determine what might be helpful to clinicians were not sensitive enough to detect unsafe drivers in those with mild dementia.

6.2 Implications for research

6.2.1 Research quality in the body of literature

In the previously published literature there is little that is clinically useful for clinicians who are expected to make an assessment of driving safety. There are very few high quality research studies in the body of literature (Martin et al., 2013). This was highlighted by the literature review in chapter 2, where only nine studies met the criteria for investigating the discriminant ability of cognitive assessments. A major problem in the body of research is that there has been huge variability in the variables and outcome measures used across studies. The relevant cognitive domains have been investigated, but the variety of different assessments that have been examined do not demonstrate consistent findings. It is difficult to extrapolate whether the measure itself is not sufficient to detect impairments that may affect driving safety, or whether that domain is not indicative of driving safety in the population being tested e.g. those with MCI or mild dementia. The findings in chapters 4 and 5 highlight this issue, where in similar populations the visuo-spatial sub-score of the ACE III was found to be predictive of on-

road outcome in the development cohort (described in chapter 4), but not in the prospective cohort (described in chapter 5).

Further issues identified were:

- Lack of validated cut-off scores and test re-test reliability
- Many of the studies used small cohorts
- There were differences in the severity of the dementia cohorts
- Majority emphasis on Alzheimer's disease
- Use of multiple variables with multiple outcome measures may result in false positives

These issues, along with the lack of validation means that the results cannot be reliably applied to a more diverse population, which would be more usual in a clinical setting.

The studies that were selected as relevant in this research (the nine studies that reported predictive data, see table 2 in chapter 2) that were assessed for quality all scored between 7-8 on the Newcastle-Ottawa scale (Wells et al., 2000) classifying them in the good to high quality range, however, six of these studies were relating to full test batteries that were not useful for application in a clinical memory service setting. This is due to the complex nature of the batteries (e.g. the need to calculate the potential outcome using equations) and the time they take to administer (between 30 and 60 minutes) that is not appropriate in an already busy assessment appointment. Additionally, one of these measures utilises assessment from using a driving simulator which is not available or practical in a clinical setting. There is a need for high quality studies that investigate measures that are tested in an independent cohort and are relevant for application in clinical services.

6.2.2 Misplaced emphasis in the body of literature

Previous research has placed too much emphasis on correlation between cognitive tests and driving safety. While it is undoubtedly important to understand the association between cognitive domains and possible unsafe driving behaviours it is difficult to translate this knowledge into clinically useful evidence. There needs to be a shift towards further investigation of possible clinically useful predictors of driving safety and their clinical applications, such as thresholds that have been derived from a more

diverse dementia cohort, that would be reflective of the clinical population, that are then tested in an independent cohort for validity.

In addition, a move away from the prominence of cognitive tests is needed to more fully investigate how functional assessments may be predictive of on-road driving safety. Input from a wider cross-section of clinicians (e.g. involvement of occupational therapists) would be constructive in informing what functional measures or assessments could be realistic for application as part of a larger assessment of memory in a clinical setting. Clinical utility needs to be the foremost consideration, another complex test battery, or tests that use for example driving simulators would not be useful to clinicians.

6.2.3 The challenge of Mild Cognitive Impairment

Little has been done to address the assessment of driving safety in those with a diagnosis of MCI. The DVLA guidance for clinicians requires clinicians to decide if there may be a 'possible driving impairment' in MCI. In the absence of 'possible driving impairment, the person with MCI does not need to inform the DVLA as they do with dementia (DVLA, 2024). This means that the decision whether to inform the DVLA of the diagnosis is solely for clinicians to make. In the body of literature only one group have tested the predictive ability of a test battery in this population (Fuermaier et al., 2017; Piersma et al., 2016). The clinical component of the battery was unable to predict driving safety in those with MCI. The neuropsychological component did, however, half of the assessments that are included in this element are arguably specific to driving (traffic theory test and hazard perception) and are not suitable for administration in a clinical assessment primarily focussed on determining the presence of a dementia. There is an urgent need for research to focus on MCI specifically, and what can be translated to help clinicians.

6.2.4 Application and translation of current evidence

The test batteries that have been developed to assess driving safety have been shown to mainly perform poorly when they are applied to an independent cohort, and more focus is needed on why this is the case and how this can be translated into more effective clinical predictive measures of driving safety.

6.2.5 Current gaps in previous research

Not enough research has been carried out in the different sub-types of dementia, and how these can differentially affect driving safety. There is an understanding of how the type of dementia can impact driving behaviours, but this needs to be interpreted for practical clinical use. Studies that have included dementias other than Alzheimer's disease have not included sub-type as part of the analysis (Camilleri & Whitehead, 2023), and predictive tests developed in an Alzheimer's cohort perform poorly when applied to other types of dementia (Piersma et al., 2018). Differing dementia aetiologies are likely to differentially affect driving safety, and more work is needed on a measure that encapsulates the wider range of cognitive or behavioural impairments that would be clinically useful in an assessment of driving safety when a dementia other than Alzheimer's is suspected.

Where it is reported in the research, participants in driving and dementia research have a high preponderance of male participants, and do not reflect the prevalence of women diagnosed with dementia in the wider population. In future more needs to be done to enhance the inclusion of women in these studies.

6.2.6 Investigation of novel assessments

This research revealed some promising advanced assessments (Snellgrove maze errors, difference between choice and simple reaction time tasks and digit vigilance task result) for clinical prediction of driving safety, but there is a need to test these in a larger and independent cohort to assess discriminative ability, and there is a need for further research to do this. However, researchers need to ensure that the clinical utility is at the forefront and need to be careful not to stray into developing another test battery with a lot of assessments and complex equations.

6.3 Clinical implications

6.3.1 Pathways and responsibilities

Research in this area needs to be more service inclusive, and there is a need for primary care input. The clinicians interviewed in chapter 3 expressed that more could be done prior to referral to the memory service. At present there is no collectively defined pathway for how driving should be addressed in primary care when a referral to secondary care for an assessment of memory is made, and there is a need for research

to understand what is happening currently and the reasons it is or is not being raised. Once this is established research needs to move on to assess what is practical for GPs around raising this issue, and include GP input, to determine a pathway of what course of action is acceptable to all involved in the referral process.

The lack of a defined clinical pathway or mechanism for follow-up is a gap in current clinical practice identified by this research, particularly for those with a diagnosis of MCI who will not have yearly reviews of their licence by the DVLA. There is a need to develop a simple pathway to facilitate this.

Clinician knowledge around the issue of clinical assessment of driving safety, within the services included in this research was highly likely due to the driving research carried out within the local area. In memory clinic services across the country it is possible that there is more variability in clinician knowledge, and there is a need for a defined standard clinical pathway and training that can be disseminated and adapted in local services to enhance consistency in service provision.

6.3.2 Making a determination of driving safety based on current and novel evidence

In chapter 3 clinicians stated that measures used to determine driving safety should be backed by empirical evidence. The literature review in chapter 2 and novel research described in chapters 4 and 5 determined that global measures of cognition are only useful as a measure of dementia severity that can help clinicians to screen out those who are obviously unsafe to drive i.e. a CDR score or 2 or above but have little other utility in a clinical setting. Similarly, previously published thresholds of measures of attention (Trails A, MoCA sub-score), executive function (MoCA sub-score and Trails B) and visuo-spatial (MoCA sub-score) investigated in chapter 5 were shown to be not useful clinically for a determination of driving safety in a mild dementia cohort. At present, clinicians should not make a determination of driving safety based on these measures alone and continue to follow current consensus guidelines of a holistic assessment.

The results from the development cohort in chapter 4 of this research found that the visuo-spatial sub-score of the ACE III could be suggestive of potential unsafe driving but were not strong enough to be useful as anything further than a screening tool. This could easily be adapted for use and application for use in clinical services where a full

cognitive assessment is not routinely carried out and could be suggestive of the need for a further on-road assessment of driving. However, results from chapter 5 reflected the overarching problem in this field of research, in that a measure found to be predictive in one cohort, was then not when applied to an independent cohort, and so cannot be strongly recommended at this time. Measures of attention, executive function and visuo-spatial skills may be helpful to clinicians when making a determination of driving safety, but cognitive assessments alone are not sensitive enough to be the only consideration.

Cognitive tests (both individual and batteries), clinical judgement and informant report have been demonstrated to be highly imperfect when making a judgement of driving safety (detailed in chapters 2,4 and 5). This highlights the importance of the availability of an independent on-road assessment of driving, but it is not practical or cost effective to simply refer everyone for this. Clinicians interviewed in chapter 3 expressed the need for a clinical driving decision aid tool, but the major findings in this research demonstrated that the data driven tool that was developed simply did not work when applied.

It is not possible to be fully confident in who may or may not be safe to drive from clinical assessment alone, although it can be reasonably supposed that those with a dementia severity of CDR 2 or higher will no longer be safe (Berndt et al., 2008; Camilleri & Whitehead, 2023). The difficulty is more evident at the other end of the scale, i.e. those with MCI or mild dementia. Clinicians may feel that many of those people might still be safe to drive but results in chapters 4 and 5 highlight this disparity by demonstrating that of the 22 (totalled from both retrospective and prospective cohorts) who had an MCI diagnosis 5 were found to be unsafe in the on-road assessment. Clinicians should refer those who fall into the 'indeterminate' range for an on-road assessment, as for those individuals there is no evidence that any other clinical measure/s are sensitive enough to determine this.

At present the best evidence is for a measured clinical judgement by clinicians in line with published consensus guidelines (Driving & Dementia Working Group, 2018). For a clinical determination of driving safety it may be advantageous to shift the focus from prediction to the development of useful screening tools to identify those who need referral for an on-road assessment.

6.3.3 Gaps in service delivery

At present, there is a large gap in service delivery of the need for a provision of advanced planning for eventual driving cessation in those living with dementia and an aftercare service for those who have been advised to stop driving. Opportunities for a possible partnership with relevant NHS services, such as Drive Mobility, to develop this should be explored.

6.4 Implications for future training

6.4.1 Gaps in clinician knowledge

Speaking to clinicians in chapter 3 revealed that knowledge from the literature is not 'trickling down' into clinical practice, highlighted by the emphasis that was placed on informant report that while useful is not supported by the research evidence, and this is likely to be surprising to many clinicians. This gap in current clinical knowledge needs to be addressed.

6.4.2 Scope of future training

The development of of a short training course, with a focus on clinical assessment of driving safety in those living with dementia, would address many of the gaps in knowledge and service provision outlined above. It would give consistency to clinician approaches and standardise service provision. It should include evidence from up-to-date research in the assessment of driving safety, as well as covering the legal requirements and implications for clinicians, and be adaptable for local use to include what complimentary services are available to clinicians in their locality such as the North East Drive Mobility Advice Service Hub (available at https://www.cntw.nhs.uk/services/north-east-drive-mobility-independent-assessment-advice-service-walkergate-park/north-east-and-cumbria-hubs-mobility-advice-service/). Ideally this would be accredited and involve input from relevant agencies such as the DVLA and Drive Mobility.

6.5 Future directions

No clinical assessment of driving safety will be as accurate as an on-road assessment, but there is a need to develop an evidence-based, useable screening tool for those with a mild dementia to determine who should be referred for these assessments as it is not

practical or cost effective to refer everyone who has this diagnosis. Presently this has not been possible, but this research investigated a number of advanced assessments that showed promise in this regard and should inform future research in this area. Additionally, a shift in emphasis from cognitive measures alone and greater inclusivity of functional measures may be a more positive direction.

In future an emphasis on improving training available to clinicians would help improve ability and confidence in using measured clinical judgement to make a determination of driving safety, and who would benefit from a referral to an independent assessment.

Ideally a combination of both of these would improve the clinical assessment of driving safety in the future.

Appendix A. Qualitative interview schedule

Self-guide prompts:

Hello, I'm Kirsty and I am the researcher working on this project, thank you for agreeing to take part.

This is part of the IMPASS project, which aims to develop a simple clinical tool that will help medical professionals identify safe and potentially unsafe drivers in the clinic. It would also help to identify those who would benefit from further assessment, such as a specialist driving assessment.

As part of this we would like to explore the experiences of clinicians discussing driving with a diagnosis of dementia with your patients and their families, as well as how you currently make any decisions about safety to drive, and what you think would help you do this in your day to day practice.

At this point I would like to ask you if you have any questions about either the project or how the interview will run. It should take no longer than an hour.

I would just like to remind you that this interview is being recorded, so it can be transcribed later, all discussion will be confidential and any names removed from the transcript, you will only be identifiable to the study team by a unique ID number. I am going to ask a series of 7 questions, although this is not structured – please feel free to talk about anything that comes to mind, even if it goes beyond the question asked. You can also feel free to give practical examples from your experience to supplement your answers.

Please be aware that you can stop the interview at any time.

If you are happy to proceed we can start with the first question – there are no right or wrong answers, we are just trying to capture your experiences.

<u>Questions:</u>

1. **In your experience when is the topic of driving raised with your patients (and their families)?**

(Is this at them initial referral appointment/diagnostic appointment/another time? Is this raised by yourself/another team member? Do you think this is an appropriate time? When do you think would be the most appropriate time to raise the issue? What is your experience of any follow up on this issue, is there any? Who does it? Who should be doing it?)

Further prompts: How do you find raising this topic? What kinds of response have you had and how do you feel about managing these?

2. **Please tell me about what factors you take into account when considering whether a patient is safe/unsafe to drive, or may need a referral for a driving assessment.**
   (Are these cognitive e.g. based on MMSE or other tests/based on 'red flags'/co-morbidities/medications/family or patient report/any current guidance that is available)
   Further prompts: Could you please tell me more about the weighting you place on any of the factors you consider.

3. **Who do you think should be responsible for addressing or raising this issue with patients and their families?**
   (Consultants/doctors/memory nurse/GP's etc.)

   Further prompts: Can you tell me more about why you think they are best placed to raise the issue?

4. **Do you have any tools/decision aids that you currently use in practice for driving that you find particularly useful?**
   (What format do you think would work well for you in a clinical setting? What would you like a driving decision aid/tool to look like/what should be the main features e.g. ease of use/time/decision tree/flowchart etc?)

   Further prompts: Do you have any examples of any other decision aids/tool you currently use that you particularly find easy to use/like to format of?

5. **Do you think a decision aid/tool would be enough?**
   (What else do you think would be helpful? Training to compliment the tool for example)

   Further prompts: Online training/course? Talks at meetings?

6. **Is there anything else you think you would find useful when tackling this difficult subject with patients and their families?**
   (Anything that would make it easier to raise the subject? Anything that would make your decision-making process easier?)

   Further prompts: Anything else that you currently do in practice that you think would be useful for other people to help with their decision process?

7. **Are you aware of the recent DVLA changes to law that allow more healthcare professionals to complete the DVLA medical questionnaire?**
   (How do you feel about this change? Would you be confident to complete the questionnaire?)

   Further prompts: Further needs? Training/talks/web course?

Appendix B. Patient and public involvement and engagement

This research involved a number of patient and public involvement and engagement activities.

Prior to the start of the PhD, feedback on the proposed project was sought from members of the public who had been involved in the development of the Driving and Dementia Consensus Guidelines for Clinicians and helped to shape the research. The application process also had patient and public involvement.

Throughout the span of the project the researcher met regularly with a team of lay research network monitors. These meetings were organised by the researcher and involved presentations about the progress and challenges of the project. They helped to shape the on-going direction of the project and provided valuable feedback on wording of patient information sheets and proposed additions to the research. These took place once to twice a year. A final presentation about the findings and outcomes of the research took place in August 2024.

In January 2020, the researcher attended a patient support group in Telford, and a carer support group in Church Stretton to explore their experiences and insight into navigating the process of an assessment of driving safety with a diagnosis of a dementia.

In September 2024, the research was presented at the Alzheimer's Research UK North East Network Public Meeting, which was attended by 62 people.

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