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## Driving with retinitis pigmentosa

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## REVIEW ARTICLE

# DriveSafe DriveAware: A systematic review

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**Abstract**

**Objectives:** Driving is an activity of daily living that significantly affects independence, and driving cessation is associated with poor health, lower quality of life, cognitive decline and early entry into care facilities. There is no consensus regarding the best off-road tool to assess driving safety. Therefore, this review explored the diagnostic accuracy, reliability and clinical utility of DriveSafe DriveAware (DSDA) compared with an on-road driving assessment.

**Methods:** This review adhered to the PRISMA guidelines. Electronic databases for all English language articles published prior to December 2021 were searched. Studies were assessed for methodological quality and results were synthesised using a narrative descriptive approach.

**Results:** Six studies were reviewed, consisting of 1332 participants. Four studies assessed diagnostic accuracy, two studies assessed reliability and three were relevant to clinical utility since they used DSDA as a standalone tool. Some studies demonstrated high levels of diagnostic accuracy, with specificity and sensitivity above 90% for those who fall into the safe and unsafe categories (50% of those assessed). Inter-rater reliability showed substantial agreement, and test-retest reliability was demonstrated for all age groups. DSDA was assessed as having high clinical utility (as a standalone tool) based on time taken to conduct, cost effectiveness and equipment required to complete the assessment.

**Conclusions:** DriveSafe DriveAware appears to be an ideal tool for the subacute setting; however, at present, inadequate evidence exists to support its use as a standalone tool for directing driving decisions. Further research is required.

**KEYWORDS**

aging, automobile driving, cognitive function, occupational therapy, patient safety

## 1 | INTRODUCTION

Driving is a daily living activity that significantly affects independence, community access and participation.<sup>1</sup> Driving enables individuals to participate in valuable roles, such as caring for the family, employment, volunteering

and leisure activities.<sup>1</sup> Furthermore, driving is symbolic of independence,<sup>2</sup> and ‘*the infringement on the patient’s autonomy and well-being*’ (p. 110) must be balanced against the risk posed to the community.<sup>3</sup> There is significant evidence that limiting transport access (i.e., by driving cessation) is associated with poor health, depression, loneliness,

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lower life satisfaction, lower activity levels, cognitive decline and early entry into care facilities.<sup>4,5</sup> Therefore, accurately identifying drivers who are safe to continue driving promotes healthy ageing by enabling those individuals to maintain their quality of life and independence.<sup>5,6</sup> Many people suffer from health conditions and disabilities that impair their ability to drive safely, particularly as they age.<sup>7</sup> For example, it is estimated that one-third of people of retirement age or older have some kind of disability.<sup>7</sup> In Australia, these individuals require medical clearance or an occupational therapy driving assessment to determine their fitness to drive.<sup>2,8</sup>

In the subacute hospital setting, medical staff are expected to make driving fitness decisions based on medical status alone.<sup>9</sup> Unsurprisingly, medical staff are reluctant to decide about driving suitability based on the limited information available to them. This reluctance is not without reason – relatively high fatality rates are reported for older drivers, and functional deficits in vision and cognition have been linked to increased crash involvement.<sup>5,10</sup> To make an informed decision, medical staff make referrals to private occupational therapy driving assessor services to elicit further information on driving fitness.<sup>8</sup> These driving assessor services complete a range of off-road and on-road tests as part of their assessment.<sup>8</sup> An on-road assessment is accepted as the gold standard for assessing driving,<sup>11</sup> and specialist training is required to become an occupational therapy driving assessor.<sup>12</sup> Unfortunately, driving assessment services come at a significant cost to clients. As a result, some clients elect to cease driving rather than pursue a test.

Although assessing fitness to drive is a recognised domain of occupational therapy,<sup>13</sup> hospital-based occupational therapists have not historically provided on-site support (to the medical team) for driving-related decisions because they do not have the appropriate postgraduate studies or access to dual-control vehicles. Ideally, a suitable off-road assessment would inform the medical team about driving capacity decisions, reduce unnecessary expense to clients by preventing inappropriate referrals to driving assessor services and reduce unnecessary driving cessation.

At first glance, DriveSafe DriveAware (DSDA)<sup>14</sup> is a short and simple tool to administer, and some studies have found<sup>11,15,16</sup> it has a high level of sensitivity and specificity. No previous systematic reviews have focused on DSDA. A previous systematic review of off-road tests identified DSDA and a battery of computerised sensory-motor and cognitive tests (SMCTests) as the highest performing off-road tests against the criteria of approaching 90% sensitivity and specificity.<sup>2</sup> Furthermore, other tests, including Useful Field of View (UFOV), DriveAble, multidomain tests, clock drawing and the Cognitive Behavioural Driver's

### Practice Impact

DriveSafe DriveAware is not currently recommended as a standalone tool for driving fitness decision-making. However, future research should include larger sample sizes, blinded assessors and a standardised route for comparison of on-road testing. Furthermore, collaboration with driving centres is recommended for retrospective analysis and stratification of the results into diagnostic groups.

Inventory, were identified as those that should only be utilised in conjunction with on-road testing.<sup>2</sup> A commentary suggested that the authors found strong evidence for construct validity and internal reliability of DriveSafe, and felt that DriveAware did not have the same strength.<sup>17</sup> The SMCTests were excluded from this investigation since they require a simulator set-up, which is impractical for the subacute hospital setting owing to financial and space constraints. No consensus exists regarding the best 'off-road' tool to provide information about driving capacity.<sup>2</sup> Therefore, the aim of this review was to examine the diagnostic accuracy, reliability and clinical utility of DSDA for older people with cognitive impairments compared with an on-road driving assessment.

## 2 | METHODS

### 2.1 | Research question

The research question informing this review was 'What is the diagnostic accuracy, reliability and clinical utility of DSDA for older people with cognitive impairments compared with an on-road driving assessment?'

### 2.2 | DriveSafe DriveAware tool

DriveSafe DriveAware is a screening tool, or measure of cognitive fitness, that predicts driving ability<sup>13</sup> and a validated clinical screening tool for driving safety.<sup>11,15</sup> It may be administered in around 10 min and provides automatic scoring and report generation.<sup>14</sup> The reports are designed to show how the client performed and help the health professional make a recommendation about driving, or decide on appropriate next steps if further testing is indicated.<sup>14</sup>

The DriveSafe DriveAware assessment tool is an application on an iPad (or similar device) that assesses two

areas critical for safe driving – global awareness of the driving environment and awareness of one's own abilities in direct relation to driving.<sup>14</sup> It has two components: DriveSafe and DriveAware. The test requires supervision by, and a short interview with, a health professional.<sup>14</sup>

The DriveSafe component presents 10 images of a four-way intersection.<sup>14</sup> Each intersection includes a number of people and vehicles (ranging from two to four objects in total).<sup>14</sup> These objects are presented for 4s and then removed from the screen. For each object presented, the client is prompted to recall three pieces of information:

1. type of object (e.g., car, pedestrian, couple walking together, truck or bicycle)
2. object location
3. direction of movement.

The DriveAware component consists of seven questions, which are delivered as a semi-formal interview. Two of these ask the client to rate his or her perceived performance on the DriveSafe component. The remaining five questions comprise the health professional interview.<sup>14</sup> Awareness is necessary for a driver to be able to monitor his or her own performance and employ compensatory strategies where necessary (e.g., avoid driving at night or on unfamiliar roads), and reduced awareness is associated with unsafe driving with a range of medical conditions.<sup>14,18</sup>

DriveSafe DriveAware is scored as 'likely to fail an on-road assessment' if the result is  $\leq 71$  on DriveSafe

and  $\leq 10$  on DriveAware, or  $\leq 57$  on DriveSafe and  $\leq 12$  on DriveAware. Drivers identified as 'likely to pass an on-road assessment' score  $\geq 72$  on DriveSafe and  $\geq 11$  on DriveAware, or between 58 and 71 on DriveSafe and between 13 and 17 on DriveAware. Further testing with an on-road assessment is recommended for all those scores falling in the middle range (see Figure 1).

## 2.3 | Search strategy

We conducted a systematic review of all English language research articles published prior to December 2021. Two searches were conducted: the first search focused on material up to January 2019; the second search, focusing on the period between January 2019 and December 2021, was performed to update the literature. Electronic databases were searched for current literature, including Medical Literature Analysis and Retrieval System Online (Medline), Emcare, PsycINFO, OT Seeker, Proquest Nursing, and Allied Health database, and Cochrane Database of Systematic Reviews. The search was performed with the aid of a professional librarian using a combination of search terms, including (but not limited to) aged, cognitive impairment, Alzheimer's, stroke, DriveSafe, and DriveAware. Inclusion criteria were informed using the PICO (participants, intervention, comparison outcome) framework. The search strategies can be found in Appendix S1.

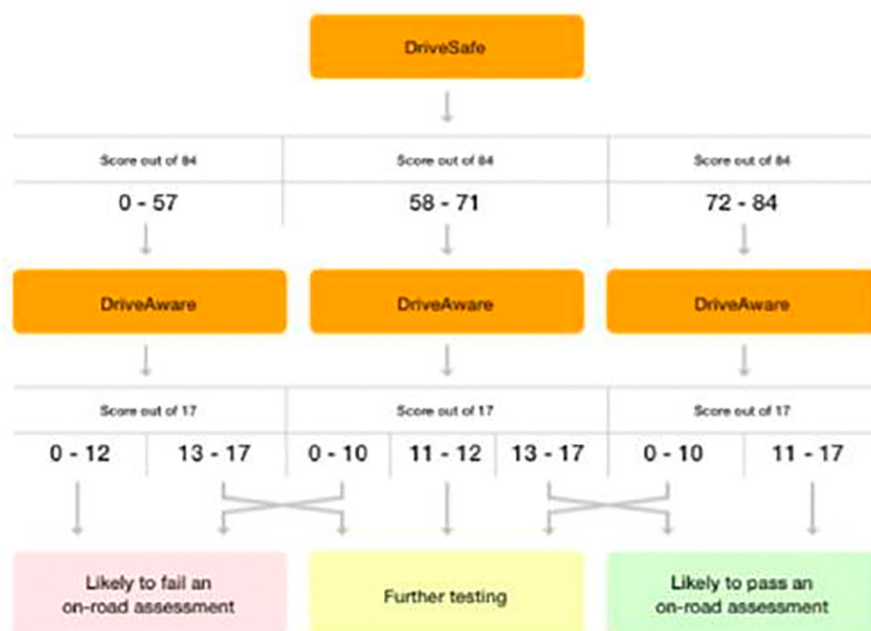


FIGURE 1 DriveSafe DriveAware categorisation flow chart. Note. Reprinted from *DriveSafe DriveAware for Touch Screen A Screening Tool for Cognitive Fitness to Drive Administration Manual* by B. Cheal & Haijiang, K., 2015, p. 32. Copyright 2015 by Pearson Australia Group Pty Ltd.

## 2.4 | Study selection

Two independent reviewers (the first and second authors) completed the screening and critical analysis of the articles retrieved. This systematic review included quantitative primary research studies focusing on DSDA (intervention) as a tool to assess driving skills against an on-road driving test (comparison). Articles from any date were included. The PICO framework<sup>19</sup> was used to develop the research question. The population of interest comprised people with diagnosed mild cognitive impairment (MCI), a cerebral vascular accident (CVA) or dementia. The intervention of interest was DSDA. The comparison of interest was an on-road driving assessment, and the outcomes of interest were diagnostic accuracy, reliability and clinical utility. Studies that assessed the reliability of DSDA were included even if they did not include an on-road assessment. This review excluded articles that were not research-based, including letters and commentaries on articles.

## 2.5 | Quality assessment

To assess the methodological quality of the selected articles, the data were extracted and appraised using the Joanna Briggs Institute critical appraisal tools<sup>20</sup> and the COSensus-based Standards for the selection of health Measurement INstruments (COSMIN) for reliability studies.<sup>21</sup> The critical appraisal information of these selected studies was then discussed and confirmed with the third author (LC) until consensus was achieved.

## 2.6 | Data extraction and analysis

The information extracted comprised the following: year of publication, country of origin, study design, sample size, gender, age, patient diagnosis, exposure, outcome and study results. Results were synthesised using a narrative descriptive approach.

## 3 | RESULTS

The study selection process identified 110 publications that resulted in the inclusion of six studies<sup>15,16,18,22–24</sup> in this review. See [Figure 2](#) for the PRISMA flow chart.

### 3.1 | Characteristics of included studies

Study details are summarised in [Table 1](#). The six studies reviewed were conducted in Australia and published

between 2009 and 2021. The study designs were either testing diagnostic accuracy,<sup>11,16,22</sup> cross-sectional<sup>15</sup> or reliability studies.<sup>18,23</sup> The ages of the participants varied (between 16 and 96 years), and most of the participants were male (40–78%). Patient diagnoses included a range of conditions, such as cognitively fit, MCI, CVA, dementia, Parkinson's disease (PD), Huntington's disease, traumatic brain injury and glioblastoma. In two studies, exposure was DSDA alone,<sup>11,16</sup> whereas in a third study, exposure was DriveAware alone.<sup>18</sup> Some studies<sup>15,22</sup> utilised a range of tests as the exposure, including DriveSafe, Useful Field of View (UFOV), Multi-D, a neurocognitive test battery, the Maze Navigation Test, Montreal Cognitive Assessment and Trail Making Tests A & B. For most studies, the comparison utilised was on-road assessment. One study<sup>18</sup> assessed the inter-rater reliability of awareness scores (intact, partial or absent) on the DriveAware questionnaire, and another study<sup>23</sup> assessed the test–retest reliability of DSDA four times in cognitively fit drivers.

### 3.2 | Diagnostic test accuracy

Two studies that assessed diagnostic accuracy<sup>11,16</sup> found high levels of accuracy for about 50% of drivers (those identified as 'likely to fail an on-road assessment' or 'likely to pass an on-road assessment'). The remaining 50% of people assessed could not be deemed to have either failed or passed but rather required 'further testing' on-road (see [Figure 1](#)). Regarding the 50% who could be categorised as pass or fail, DSDA was found to have 93%–96% sensitivity (pass DSDA and pass on-road testing), and 91%–97% specificity (fail DSDA and fail on-road testing). In contrast, a large blinded study<sup>22</sup> ( $N = 560$ ), which only assessed the DriveSafe component, found DriveSafe was not an accurate predictor of driving ability, having a sensitivity of 59% and specificity of 79%.

A large cross-sectional study<sup>15</sup> of community-dwelling adults 65 years and older with MCI ( $n = 57$ ) and no cognitive impairment ( $n = 245$ ) suggested that DSDA is more useful in combination with other test items. This study found that the variables of age, DriveSafe score and multi-D (a weighted composite of the Colour Choice Reaction Time test, Dot Motion and Sway) classified 90% of the sample correctly and were a significant predictor of on-road driving test results.

### 3.3 | Reliability

One study<sup>18</sup> ( $n = 60$ ) addressed the inter-rater reliability of the DriveAware component using a Kappa scale. Kappa with values  $\leq 0.20$  are interpreted as slight agreement,

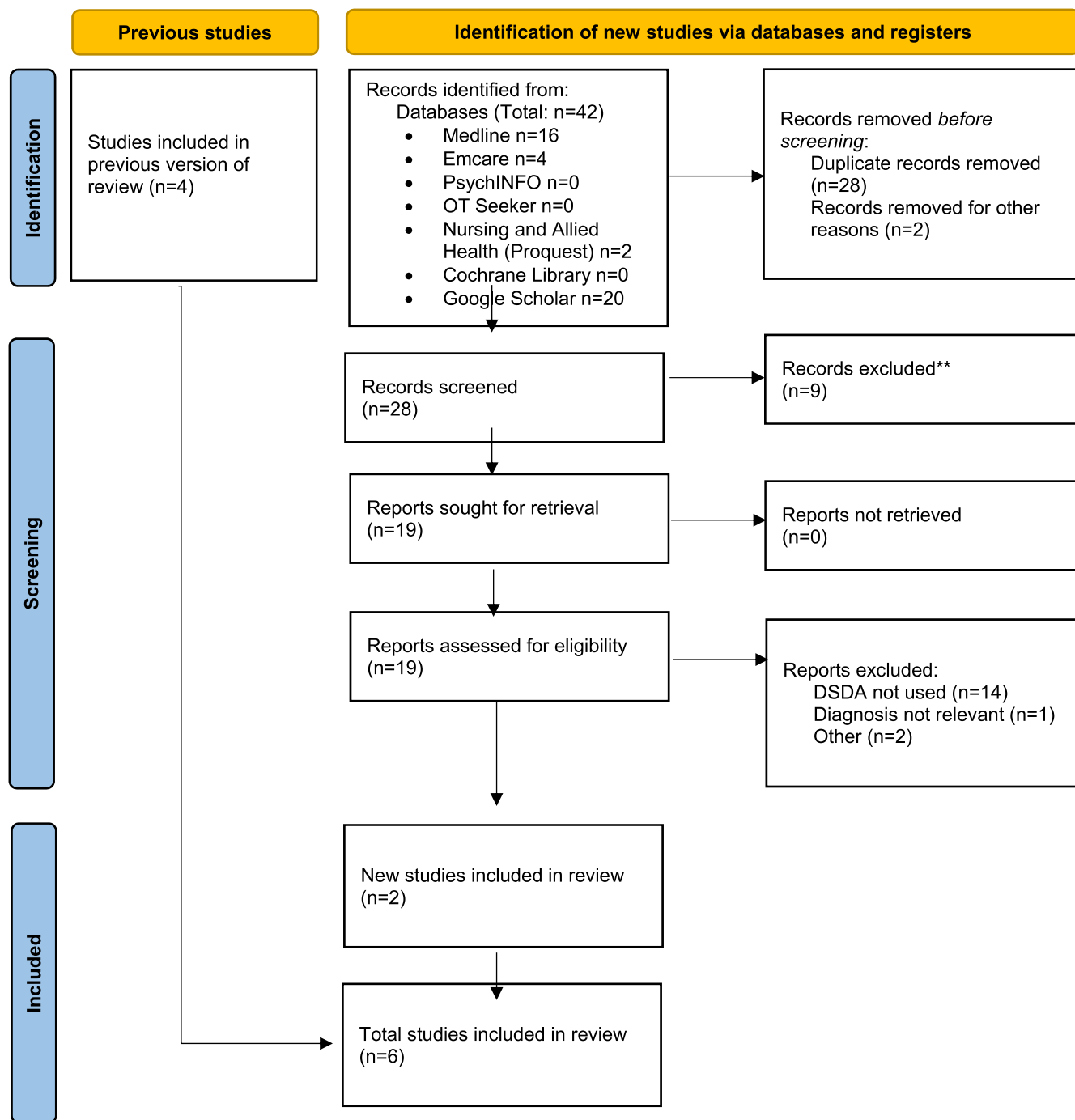


FIGURE 2 PRISMA flow chart. From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

0.21–0.40 as fair agreement, 0.41–0.60 as moderate agreement, 0.61–0.80 as substantial agreement and above 0.80 as almost perfect agreement.<sup>25</sup> The findings demonstrated substantial agreement (0.69 Kappa) among the assessors for the inter-rater reliability of DriveAware. In addition, no errors of agreement were noted if awareness was either intact or absent. However, errors of agreement were noted if awareness was deemed partial. Another study<sup>23</sup> assessed test–retest reliability and found DSDA classification and

DriveAware scores were consistent over repeated tests in cognitively fit drivers. DriveSafe scores increased between Tests 1 and 2, with no other changes from Tests 2 to 4.

### 3.4 | Quality assessment

Critical appraisal was conducted (see Table 2). Regarding diagnostic test accuracy, the studies' methodological

TABLE 1 Summary of study characteristics

Study (Year)	Design	Gender	Age range (years)	Sample size	Patient diagnosis	Intervention	Comparison	Outcome	Results
Anstey, et al., (2017) <sup>15</sup> Australia	Cross-sectional CI ( <i>n</i> = 57) NC ( <i>n</i> = 245)	Male	60% 65–96		Mild CI	DriveSafe (also UFOV; Multi-D; Neurocognitive test battery)	On-road test	Diagnostic accuracy	<ul style="list-style-type: none"> <li>Age, DriveSafe score and Multi-D were all identified as significant predictors of on-road driving test</li> <li>Accounted for 24% of the variance</li> <li>Correctly classified 90% of the sample</li> </ul>
Anstey, et al., (2020) <sup>22</sup> Australia	Diagnostic test accuracy ( <i>n</i> = 560)	Male	62%		Comparison group MCI group	DriveSafe (also Trail Making Test B; UFOV; DriveSafe Intersections; HPT; 14-item Road Rules and Road Craft test; Multi-D; Snellgrove Maze test)	On-road test	Diagnostic accuracy	Using safe driving as the reference value DriveSafe OR 0.95 (95% CI, 0.93–0.96); AUC 0.76 Sensitivity: 59% Specificity: 79%
Hines, & Bundy, (2014) <sup>16</sup> Australia	Diagnostic test accuracy ( <i>n</i> = 70)	Male	78%		Neurological conditions (CVA, Huntingtons, PD, GB, TBI, CI, Dementia, Spinal injuries)	DriveSafe DriveAware	On-road test	Diagnostic accuracy	<ul style="list-style-type: none"> <li>High level of accuracy for about half of the drivers</li> <li>The other half who scores fall between the upper and lower cut-offs, require on-road assessment</li> <li>Sensitivity: 96% (upper cut-off)</li> <li>Specificity: 91% (lower cut-off)</li> <li>High</li> </ul>
Johnston et al. (2021) <sup>23</sup> Australia	Reliability study ( <i>n</i> = 39)	Male	41% 20–91 (Median 58)		Cognitively fit to drive volunteers	DriveSafe DriveAware	No comparison as test of reliability	Clinical utility Clinical utility Test–retest Reliability	<ul style="list-style-type: none"> <li>Utility</li> <li>High</li> <li>Reliability</li> <li>Assessed test–retest reliability DSDA initial assessment, 6 weeks, 6 months &amp; 12 months</li> <li>DSDA classification and DriveAware scores was consistent over repeated tests</li> <li>DriveSafe scores increased between test 1 and 2, and thereafter no significant change from test 2 to 4.</li> <li>DriveSafe scores for older participants (70+ years) increased between test 1 and 2 more notably than younger participants scores</li> </ul>



TABLE 1 (Continued)

Study (Year)	Design	Gender	Age range (years)	Sample size	Patient diagnosis	Intervention	Comparison	Outcome	Results
Kay et al.(2009) <sup>11</sup> Australia	Diagnostic test accuracy 1: ( <i>n</i> = 52) 2: ( <i>n</i> = 44)		Male 79% 16–95		Neurological conditions (CVA, PD, MS); Dementia; Ortho or spinal injuries; Other (Cancer, Polio, Vision deficits, Psychiatric disorders) Acquired Brain Injury	DriveSafe DriveAware	On-road test	Diagnostic accuracy	<ul style="list-style-type: none"> <li>Unsafe drivers DriveSafe ≤76</li> <li>DriveAware &gt;17</li> <li>Safe driver DriveSafe &gt;95</li> <li>DriveAware &lt;15</li> <li>The other half who scores fall between the upper and lower cut-offs, require on-road assessment</li> </ul> Sensitivity: Group 1: 93% (upper cut-off) Group 2: 95% (upper cut-off) Specificity: Group 1: 97% (lower cut-off) Group 2: 96% (lower cut-off)
Kay et al. (2009) <sup>18</sup> Australia	Cross-sectional study ( <i>n</i> = 60)		Male 72% 61–86		MCI, Dementia, CVA, PD, other	DriveAware	On-road test	Inter-rater reliability	Utility <ul style="list-style-type: none"> <li>High</li> </ul> There were no errors of agreement if awareness was either intact or absent There were errors of agreement if awareness was deemed partial Reliability <ul style="list-style-type: none"> <li>69% substantial agreement beyond chance</li> </ul> Utility <ul style="list-style-type: none"> <li>High</li> </ul>

Abbreviations: CI, cognitive impairment; CVA, cerebrovascular accident; GB, Guillain Barré syndrome; HPT, Hazard Perception Test; MCI, mild cognitive impairment; MNT, Maze Navigation Test; MoCA, Montreal Cognitive Assessment; MS, multiple sclerosis; NC, normal cognition; PD, Parkinson's disease; TBI, traumatic brain injury; TMT A & B, Trail Making Tests; UFOV, Useful Field of View.

quality overall was moderate. The index test results were not interpreted without knowledge of the reference standard (Q4), the reference standard results were not interpreted without knowledge of the results of the index test (Q7), and not all patients were included in the analysis (Q10). The methodological quality of the cross-sectional studies overall was moderate. It was unclear whether objective, standard criteria were used for measurement of the condition (Q4). Regarding reliability, the studies' methodological quality was adequate. In one study (Q4), the intraclass correlation coefficient was not calculated for continuous scores, and in the other study (Q6 & 7), a weighted Kappa was not calculated.

## 4 | DISCUSSION

DriveSafe DriveAware is a short and simple tool to administer, and some studies found<sup>11,15,16</sup> it to have a high level of sensitivity and specificity for half of their participant drivers, that is, those identified as 'likely to fail an on-road

assessment' or 'likely to pass an on-road assessment'. The remaining half of the drivers assessed required 'further on-road testing'. One study demonstrated substantial inter-rater reliability agreement among assessors for DriveAware, and another study demonstrated consistent test-retest reliability among assessors for DSDA classification and DriveAware scores.

Clinical utility was assessed by the authors based on: (1) the time taken to conduct the assessment (requiring <30 mins to be high utility), (2) cost effectiveness and (3) practicability of the equipment required. DSDA has a high clinical utility based on these criteria. It is efficient, taking approximately 10–15 min to administer. It is cost-effective (AUD\$10 to AUD\$15 per report, depending on level of bulk purchase). Finally, the equipment required is practicable; it does not require specialised equipment (e.g., a simulator), but utilises technology already used in the subacute hospital setting (iPad/tablet/computer). The protocols described in two studies,<sup>15,22</sup> which comprised a battery of assessments, were deemed low utility as the process would exceed the stated time limit of 30 min.

TABLE 2 Critical appraisal of studies

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Include
Diagnostic test accuracy appraisal checklist <sup>a</sup>											
Anstey et al., 2020 <sup>22</sup>	Y	Y	Y	Y	Y	Y	Y	U	Y	Y	Y
Hines & Bundy, 2014 <sup>16</sup>	N	Y	Y	N	Y	Y	N	Y	Y	N	Y
Kay et al., 2009 <sup>11</sup>	Y	Y	Y	N	Y	Y	N	Y	Y	N	Y
Analytical cross-sectional study appraisal checklist <sup>b</sup>											
Anstey et al., 2017 <sup>15</sup>	Y	Y	Y	Y	Y	Y	Y	Y			Y
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9		
Reliability <sup>c</sup>											
Johnston et al. 2021 <sup>23</sup>	VG	VG	VG	D	D	VG	NA	NA	NA	NA	NA
Kay et al., 2009 <sup>18</sup>	VG	VG	VG	VG	D	VG	NA	VG	VG	D	D

Abbreviations: A, Adequate; D, Doubtful; I, Inadequate; N, No; NA, Not applicable; U, unclear; VG, Very good; Y, Yes.

<sup>a</sup>Diagnostic test accuracy appraisal checklist: Q1. Was a consecutive or random sample of patients enrolled? Q2. Was a case control design avoided? Q3. Did the study avoid inappropriate exclusions? Q4. Were the index test results interpreted without knowledge of the results of the reference standard? Q5. If a threshold was used, was it prespecified? Q6. Is the reference standard likely to correctly classify the target condition? Q7. Were the reference standard results interpreted without knowledge of the results of the index test? Q8. Was there an appropriate interval between index test and reference standard? Q9. Did all patients receive the same reference standard? Q10. Were all patients included in the analysis?

<sup>b</sup>Analytical Cross-sectional study appraisal checklist: Q1. Were the criteria for inclusion in the sample clearly defined? Q2. Were the study subjects and the setting described in detail? Q3. Was the exposure measured in a valid and reliable way? Q4. Were objective, standard criteria used for measurement of the condition? Q5. Were confounding factors identified? Q6. Were strategies to deal with confounding factors stated? Q7. Were the outcomes measured in a valid and reliable way? Q8. Was appropriate statistical analysis used?

<sup>c</sup>COSMIN appraisal checklist for reliability: Q1. Were patients stable in the time between the repeated measurements on the construct to be measured? Q2. Was the time interval between the repeated measurements appropriate? Q3. Were the measurement conditions similar for the repeated measurements – except for the condition being evaluated as a source of variation? Q4. Did the professional(s) administer the measurement without knowledge of scores or values of other repeated measurement(s) in the same patients? Q5. Did the professional(s) assign scores or determine values without knowledge of the scores or values of other repeated measurement(s) in the same patient? Q6. Were there any other important flaws in the design or statistical methods of the study? Q7. For continuous scores: Was an intraclass correlation coefficient (ICC) calculated? Q8. For ordinal scores: Was a (weighted) kappa calculated? Q9. For dichotomous/ordinal scores: Was a kappa calculated for each category against the other categories combined?<sup>21</sup>

Although there are a number of off-road tests (including DSDA) that purport to assess driving ability, an inadequate number of studies exist to select the most accurate and cost-effective test. Instead, on-road driving assessment remains the accepted gold standard for driving ability.

#### 4.1 | Implications for clinical practice

In the subacute hospital environment, the associated risks of driving decisions are held by medical professionals alone. Although we acknowledge that DSDA would provide additional information to medical professionals, the completion of DSDA by occupational therapists would transfer some of the risk associated with the decision to them. We would, in short, be endorsing DSDA as a decision-making tool. That additional risk is undesirable, and the research is inadequate to support such a change. However, we acknowledge the existing clinical gap and the potential opportunity for occupational therapists to contribute to decisions about driving.

#### 4.2 | Implications for research

Further research into DSDA is indicated because it is a clinically promising tool. Future studies should include larger sample sizes. COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) is an initiative consisting of international multidisciplinary researchers who have expertise in the development and evaluation of instruments.<sup>26</sup> For studies assessing reliability, sensitivity and specificity, the COSMIN study design checklist recommends that the sample size should be greater than 100.<sup>27</sup> The sample size for studies assessing DSDA should be sufficient for differing medical conditions. The articles reviewed ranged in participant numbers from 60 to 302. However, they all used consecutive convenience sampling; consequently, the number and relevance of diagnoses were mixed (e.g., of 90 participants in the 2014 study by Hines and Bundy,<sup>16</sup> 23% had traumatic brain injury). Therefore, even with larger sample sizes, the studies did not necessarily follow the COSMIN guidelines for sample size.

Furthermore, ensuring that on-road assessors are blinded to the results of the off-road test is essential for future research. In addition, a standardised route for the on-road test would also improve inter-rater reliability. Moreover, the authors of this review recommend a collaboration with driving centres that currently utilise DSDA to (1) retrospectively review the data and compare DSDA

results with on-road results and (2) stratify the data into primary diagnosis groups. Additionally, researchers may consider performing a longitudinal study with a view to linking crash statistics with the outcome of DSDA.

#### 4.3 | Strengths and limitations

The strengths of our systematic review are threefold: (1) we followed a rigorous process using the PRISMA guidelines; (2) we posed a clearly defined research question; and (3) we searched multiple databases without date limits up to December 2021. All parts of the review, namely selection of studies, critical appraisal and data extraction, were conducted by two independent authors. However, we do need to acknowledge some limitations of the review that affect the generalisability of the findings.

Generalisability, also called external validity, is the extent to which the results of a review can be extrapolated to different settings.<sup>28</sup> The studies included in this systematic review used small sample sizes, and patients with different medical conditions (e.g., traumatic brain injury) were not adequately represented. Some of the studies used convenience sampling, whereby participants signed up for the study rather than being randomly sampled; consequently, a risk of participation bias was present, in that the patients who were assessed with DSDA may not have represented patients in the wider community.

The results of this study have low internal validity. Internal validity is the extent to which a review reduces its own systematic error and the degree of confidence evident that the causal link being assessed is trustworthy and not influenced by other variables.<sup>28</sup> The confounding factors identified were (1) only English language studies were included (however, we did search all the major electronic databases); and (2) owing to the small number of studies included in this review, we were unable to conduct meta-analysis.

### 5 | CONCLUSIONS

DriveSafe DriveAware appears to be an ideal tool for the subacute setting; however, at present DSDA is not appropriate for implementation because it has been examined by only a few studies, the sample sizes of which were small and disease conditions varied. The studies reviewed found that DSDA has high levels of accuracy for half of the drivers who used it, the drivers likely to pass and those likely to fail. Regarding the remaining half whose scores fall between the upper and lower cut-offs, the studies recommended further testing (by on-road driving assessment).

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## CONFLICTS OF INTEREST

No conflicts of interest declared.

## DATA AVAILABILITY STATEMENT

Data sharing is not applicable as no datasets were generated or analysed.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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