Subject: Submission to National Transport Commission. Rail Workers Safety Review

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Background:

Medmont International Pty Ltd manufactures a number of instruments used in the ophthalmic industry, including an automated computerised static perimeter, model M700, used to assess visual fields. The M700 is widely used in Australia by optometrists and ophthalmologists.

There are a number of other computerised perimeters available, such as Humphrey Visual Field Analayser (Carl Zeiss Pty Ltd), Octopus perimeter and Optimed. The Humphrey HFVA and Medmont M700 are the most common automated perimeters used in Australia. Most automated perimeters produce visual field tests based on controlled viewing conditions using validated testing algorithms and results obtained are comparable for a given patient. In particular, there is good data comparing the Humphrey HFVA and the Medmont M700.

The author is a clinical optometrist in practice for 45 years, has provided clinical advice and general consultant opinion to Medmont in the past. He has an interest in visual ergonomics and has been used as a consultant to the CASA Aviation Medical Unit.

The Current Problem:

Aust Roads and the National Transport Commission publish the guideline document “Assessing Fitness To Drive For Commercial And Private Vehicle Drivers” (March 2012) which is endorsed and used by Australian driving regulatory authorities.1 Section 10 describes vision and eye disorders.

Section 10.2.3 Visual Fields provides a definition of visual fields and discusses assessment methods.

In the second paragraph the last 2 sentences are as follows:

“If the automated perimetry suggests that the requirements for an unconditional licence are not met, then the field test should be performed. While opinions on fitness to drive can be based on testing fields for each eye separately the Esterman binocular field is the preferred method of assessment.”

Section 10.3 defines normal fields Driving licences as follows:

Private Unconditional

- Binocular: 110° horizontal ± 10° vertical above and below the horizontal midline
- Monocular: Any significant loss (scotoma) within a central radius of 20° from the foveal fixation or other scotoma likely to impede driving performance
Private Conditional

- Licence may be granted subject to a report from treating optometrist or ophthalmologist and subject to annual review
- Monocular persons adapted to their condition as above but subject to two year review

Commercial Unconditional

- No visual field defect

Commercial Conditional

- Binocular: 140˚horizontal ± 10˚vertical above and below the horizontal midline
- Monocular: Any significant loss (scotoma, hemianopia, quadrantopia) likely to impede driving performance
- Licence may be granted subject to a report from treating optometrist or ophthalmologist and subject to annual review.

The specific reference to Esterman binocular visual field as a preferred or superior test is anecdotal, has poor supporting evidence, devalues better tests and implies a potential bias to some perimeter manufacturers.

Comment:

Measurement of Normal Visual Fields:

The extent of a normal visual field is approximately 180˚ horizontal x 120˚ vertical.

Commonly accepted standards of visual fields considered safe for driving refer to normal within 110˚horizontal ± 10˚vertical and no significant central losses. ¹

Automated static perimetry is regarded clinically as the best technique available to measure visual fields.

Most automated perimeters produce visual field tests based on controlled viewing conditions using validated testing algorithms and results obtained are comparable for a given patient. The extent and sensitivity of the patients measured visual field can be used to diagnose and monitor conditions that affect the complete visual pathway.

Clinically useful visual fields are typically measured using

- monocular viewing over the central 50 to 100˚ field
- thresholding methods sensitive to patient responses
- an assessment of patient reliability by recording fixation or response errors
- comparison to previous results or inbuilt age normal reference databases
- analysis of rate of progression and/or prediction of future losses

Most perimeters use a central fixation point and test to ±50˚ from fixation or 100˚ overall field. ² The area tested can be extended by moving the fixation point during the test.

Ancillary tests include binocular threshold and supra threshold screening tests, or in the case of a binocular dysfunction, the proportion of the field in which the subject can maintain single vision.
Results can also be exported for further analysis using specialised software to combine monocular results and simulate the extent of a combined or integrated binocular field.

Visual fields measured on well designed and validated automated perimeters are comparable. In particular there is good data comparing the Humphrey HFVA and the Medmont M700.

An expanded description of perimetry methods is described in Appendix 1.

**Visual Fields and Driving**

The evidence linking visual field losses and driving capacity is controversial. There are a number of studies linking both monocular and binocular visual field assessment and driving ability. Many rely on the results of an Esterman binocular visual field and often fail to demonstrate a link between results and driving capacity.

**Esteman Suprathreshold Field Parameters**

The Esterman test was first developed using visual fields determined by manual kinetic perimeters. It was used to describe the effect of visual field loss on general mobility and the testing protocol tested sensitivity over a wide horizontal field with a bias to the inferior field but effectively ignored the central 20°.

The Esterman visual field test (EVFT) was adapted to static automated perimetry particularly the HFVA. Other perimeters have similar test protocols incorporated into their software. A similar pattern of test targets are presented binocularly to the patient at suprathreshold high contrast levels with limited or no control of initial fixation. Medmont for instance has included the Medmont Binocular Driving Test which has equivalent test coverage, stimulus density and sensitivity as the EVFT.

The test is of limited clinical use, but has been adopted as an approximation of the patients “real field of view” and advocated to be more relevant in terms of functional ability. The test is relatively quick and has been commonly applied to assess occupational or driving capacity.

The early availability of the EVFT on the HFVA perimeter has created an impression that this perimeter is the only one capable of doing the test.

The HFVA EVFT test parameters are as follows:

- Bright suprathreshold (10 dB) targets are presented at 120 points in the predominantly horizontal field.
- There are few targets in the central ±20°, with 12 locations examined above the midline and 22 below, and no stimuli within ±7.5° of fixation.
- The patient is free to move both eyes and can anticipate where the next target may be located.
- Responses are recorded as seen or not seen and there is no thresholding of any targets.
- There is no capacity to record fixation losses.
- The Esterman Efficiency Score (EES) is the percentage of stimuli seen and biased towards the inferior visual field due to the greater density of stimuli within this area.
Scores are typically clustered at high levels (>80%) and it is difficult to fail as central field losses are often missed.

Esterman Suprathreshold Test Limitations

Despite the limitations of the evidence linking Esterman test results and driving capacity, it has persisted as a default test for determining driving and occupational capacity. Specific features and limitations with the test include:

- Use of suprathreshold targets and free fixation from both eyes simultaneously
- Fast test speed and convenience, fewer opportunities to fail patients
- Poor measures of patient reliability
- Poor sensitivity and clustering of high pass scores
- Passes patients with recognised significant monocular field defects including dense arcuate and hemifield losses
- Controversial and varied acceptance of the test as a predictor of driving capacity.
- Perception that the test can only be performed on the Humphrey Visual Field Analyser. (The Esterman title for the test may be copyrighted and commercially limited to the HFVA manufacturer)
- Similar test protocols are available on other perimeters but less well recognised by regulators conditioned to accept Esterman test results only.

The most significant and obvious concern is the disparity between obvious poor monocular test results and the overly optimistic Esterman result.

Regulators have been in the past forced to decide on specific cases where ophthalmic consultants have provided reports that considered a good result on Esterman as superior to a poor result from the monocular threshold field and recommended patients as operationally safe to perform specific tasks such as flying or driving.

Such conflicting opinions are often anecdotal and not supported by good evidence.

The gold standard of care to determine visual field changes requires regular monocular thresholded tests.

Clinical use of an Esterman Field test only to detect or monitor progression of visual field losses without also using monocular threshold tests would be unlikely and be regarded as negligent.
NTC Visual Field Guidelines

The existing NTC guidelines perpetuate an impression that the Esterman test is a superior visual field test when assessing driving capacity. There is minimal evidence available to support this view.

Guidelines should be evidence-based. New studies have recognised the limitation of Esterman test and suggest that integrated monocular threshold field tests may be more sensitive predictors of driving capacity.⁴

Some commercial software is available and utilises existing monocular test results to create simulated binocular threshold tests.⁴

New perimeters are now capable of threshold testing of binocular fields with various controls of fixation and the results may be more useful in predicting the effect of visual field loss on operational task capacity.

The Civil Aviation Safety Authority of Australia has recently recognised the limitations of opinions based on Esterman test results.¹ Adequate field testing is defined in their guidelines as “50+ degree monocular visual field testing. (Esterman binocular field not acceptable) Medmont binocular field test with fixation is acceptable”. Normal field test results require “no overlapping field defect, no defect within 20 degrees of the visual axis and total field loss less than one quadrant”

Suggested Solution

The new guidelines should continue to describe visual fields, assessment methods and continue to recommend automated visual field analysis using currently commercially available and tested perimeters.

References to specific perimeters or testing protocols should be generic and inclusive. An examining professional will form an opinion based on a number of tests regarding a licence applicant’s ability to operate safely. The guidelines should direct the examiner to determine which tests are regarded as providing acceptable evidence to support such an opinion.

The current guidelines can be easily modified by replacing specific references to Esterman binocular field tests with generic statements to read as follows:

Monocular automated perimetry is the best method to measure field loss significant enough to establish if the requirements for an unconditional licence are met.

If a significant monocular loss is found, then a binocular threshold field test should be performed or simulated by integrating existing monocular threshold results.

Fixed intensity suprathreshold binocular field tests (eg Esterman Visual Field Test and Medmont Binocular Driving Test) may provide a general indication of peripheral perception but will not be considered alone as a valid test of capacity to drive

Impact of Suggested Solution

The NTC guidelines will be upgraded to reflect evidence based opinion and be consistent with those recommended by other regulators such as CASA

The removal of the Esterman reference should overcome the limitations listed in this report
Appropriate Visual Field reports from all commercially available perimeters should be accepted as valid.

More comprehensive testing and reports will be required to justify conditional licencing.

Applicants seeking testing and reports to support a case for conditional licencing should be advised that they may be charged appropriate fees for this service.

Manufacturers may be stimulated to provide suitable software changes or hardware upgrades to either provide practical binocular threshold testing or allow existing monocular tests to be integrated into a binocular result.
Appendix 1 PERIMETRY METHODS. 2,3,4,5.

Kinetic Perimeters

Visual fields were measured in the past kinetically with an observer presenting moving fixed size and brightness targets from a non-seen to seen area.

A simple confrontation test was used with various targets presented monocularly to a patient seated opposite the teter who presented various targets in the four quadrants of the patient's vision. A small target could be used to elicit the blindspot.

Bjerrum Fields used a black background screen at 1 m from the observer with a darkened observer presenting white targets of various sizes using a small wand. While the test may have been sensitive for a given patient and observer technique inter test comparisons were not reliable.

Hemispherical perimeters were used to test peripheral fields. The Goldmann perimeter was the best developed of these and presented projected targets of known size and contrast against a standard background. The observer viewed the patient through a small telescope and recorded when the patient reported seeing a target moved from a non-seeing to seeing area. Points were plotted on paper and represented topographically as zones of equal vision.

Some observer skill was required to record field losses reliably. Kinetic visual fields are rarely used now other than for preliminary screening.

Automated Perimeters

Automated static perimeters present small lit targets in a testing bowl with controlled viewing conditions and computerised control of the target location, contrast and size. Most perimeters use a central fixation point and test to ±50° from fixation or 100° overall field. The subject’s results can be analysed for changes over time and compared to an age matched normal range of responses.

The subject is required to fixate a central target in a uniformly lit bowl field. Other targets are presented briefly, one at a time, at random and at a variety of locations in a pre-selected grid. The subject is instructed to press a response button when the targets are seen. The software then reduces the target contrast until there is no response, i.e. they are not seen. The target brightness is adjusted in a staircase mode according to patient response. A 50% threshold brightness is recorded when the response oscillates between targets seen and not seen.

This value represents the target contrast at a given point which the subject might see on 50% of occasions and is measured in decibel (dB) units.

The task is a sensitive psychophysical test and requires an alert co-operative subject to respond appropriately.

Subject reliability is measured by:

- fixation losses (the number of times they were measured not looking at the aiming target);
- false positives (the number of times the response button was pressed when a target was not present);
- false negatives (the number of times they did not respond to target already seen at a lower contrast).

A patient database is established to allow repeated field tests over time to determine if there is any progressive change. Sophisticated software presents targets in a random pattern with standard viewing conditions and provides the ability to match aged based norms. Printouts show field losses using numerical and grey scales; the darker areas representing more extensive field loss and lighter areas indicating points seen, graded by sensitivity.

Each perimeter has its own presentation and software designs and have undergone validation and reliability testing. Well controlled studies have shown that results from different perimeters are directly comparable and convertible to establish and reliably document visual field changes.

The development of computer controlled static perimeters improved the reliability of measurement of visual fields and has been clinically accepted for many years as the clinical “gold standard” for detecting and monitoring changes in visual field loss.
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