



# THE USE OF A TOOL TO DETECT THE PRESENCE OF VISION DEFECTS IN PATIENTS DIAGNOSED WITH STROKE

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## Phase 1 Validation of the Tool

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This report to the Agency for Clinical Innovation (ACI), sets out the findings from the first phase of validation of the vision screening tool for eye conditions in patients with stroke. This was a strategy proposed in a previous report to State wide Ophthalmology service (SOS) and the greater metropolitan clinical task force (GMCT) 2008. The following document discussed the outcomes of this validation process

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## PROJECT SUMMARY

In response to the 2008 report to the Statewide Ophthalmology Service (SOS) of the Greater Metropolitan Clinical Taskforce (GMCT) <sup>1,2</sup>, a vision screening tool was developed to be used by non-eye care practitioners to assist in the identification of pre-existing and recently acquired vision problems in patients who had recently had a stroke. The need for such a tool had been previously identified, with many patients failing to have eye conditions detected and therefore managed during the early stages of their recovery.

The vision screening tool comprises a mini questionnaire with a vision screening test designed to be conducted at the bedside. The questionnaire determined current and newly acquired ocular conditions in response to some straightforward questions and guided observations by the non-eye care practitioners. It was determined that before this screening tool could be implemented, it required validation.

Ethical approval for the validation project was sought from both the University of Sydney and the Northern Sydney Local Health District (appendix 3), as the project included recruitment of patients and clinical staff from two hospitals. Additional site specific ethics applications were made for Hornsby Ku-ring-gai and Manly Hospitals. Human Research Ethics Committee (HREC) approval LNR/14/HAWKE/199, SSA reference LNRSSA/14/HAWKE/280 (Hornsby Ku-ring-gai) and LNRSSA/14/HAWKE/281 (Manly), were granted in September 2014. Data collection commenced in October 2014 and was completed by August 2015.

A total of 100 hundred patients, along with the stroke unit clinical staff were recruited from the two selected hospitals. All patients recruited were admitted to a stroke ward and diagnosed as having had a recent stroke. The study had 2 arms that were run simultaneously. Each arm examined the use of the vision screening tool but each compared it to a different measure. To complete validation of the vision screening tool the two comparisons undertaken were:

1. The information obtained by the screening tool administered by the stroke (non-eye care) clinician compared to outcomes from the same tool administered by an orthoptist as the eye care professional
2. The information obtained by the screening tool administered by the stroke clinician was compared to a 'gold standard' orthoptic eye examination, including a complete patient history, observation and tests of ocular motility and visual acuity.

Both arms are looking at measures of validity, including the delivery and accuracy of the questions and tests incorporated in the vision screening tool. It is the intention that once the tool has been validated, it will be used by non-eye care practitioners in stroke wards as part of the routine investigation protocol for patients diagnosed with stroke.

To date progress and preliminary analysis for validation of the vision screening tool has been presented at two scientific conferences:

- Stroke 2015, Melbourne
- Orthoptics Australia Annual Scientific Conference, Wellington 2015.

## Methodology

Two public hospitals; Hornsby Kur-ring-gai and Manly participated in the study. Both hospitals were identified as having stroke units and no current access to on-site eye care professionals. Patients with a diagnosis of stroke and who had been admitted to these stroke units for a minimum of three days were eligible for recruitment. Any patients unable to provide comprehensible responses or to indicate through actions, such as matching or tracing letters when performing a vision assessment, were excluded. Potential patients were identified by the lead clinic nurse consultant (CNC) at each of the hospital sites. The patients identified by the CNC were verbally informed of the study purpose and patient burden. Initial verbal consent to participate was followed by written consent obtained immediately before testing commenced. If a patient was unable to give consent, either written or verbal on their own, then guardians or carers were asked to give consent on the patient's behalf.

The study comprised of two arms run in parallel. Allocation of patients into either of the arms was random. In both arms the vision screening tool was administered by a non-eye care practitioner. The first arm (Sample 1) involved a sample of 50 patients for whom the tool was administered twice, once by the orthoptist and again by the stroke practitioner in the unit. In the second arm comprising a further 50 patients in whom the tool administered by the stroke clinician was compared to a complete visual assessment by an orthoptist, as an experienced eye care practitioner. The Tool was then administered by a health practitioner from the stroke unit to the same patient (Sample 2). The order in which the assessments were conducted was interchangeable and somewhat dependant on patient and assessor availability.

The vision screening tool has 3 primary sections, section 1 composed of targeted questions about current eye health, section 2 recorded observations and section 3 comprising patient responses to a few simple but informative eye tests. For each of the tasks there was a tick box for recording an answer of yes or no in response to the question asked, or to the observation made and to the test results. Beside each section there is guide as to whether further action or no action is required should there be a patient response indicating an eye condition (see Appendix 1).

The comprehensive visual assessment as performed by the orthoptist consisted in part of an ocular history including questioning about the presence of existing eye disease and on its ongoing management. In order to test sensory and motor eye function the following tests were performed:

**Near and distance visual acuity** was tested, using a 3m LogMAR EDTRS chart with the patient wearing glasses for distance and/or near vision if they had them. A pinhole test was performed on those patients found to have reduced distance vision. When assessing near vision, if the patients prescribed reading glasses were not present, then a substitute pair of +2.00 DS reading glasses were provided. While for most of the patients in this age group, this level of near correction was not entirely adequate to provide optimal assistance with reading, it did allow the orthoptist to gauge if near vision was improved with their use. This testing is relevant for these patients as any decrease in vision may decrease the patient's ability to perform vision based tasks including activities related to their rehabilitation.

**Cover test for detection of strabismus, ocular motility** were conducted and **convergence near point** was measured, particularly looking for the presence of cranial nerve palsy affecting ocular motility and eye lid function or saccade and pursuit eye movement abnormalities. Any disturbance in the eyes ability to coordinate together can affects the patient's ability to perform even the simplest of tasks such as reading and eating.

**Pupil responses** to light were assessed on all patients. This simple but important test required little patient involvement yet abnormal responses can be indicative of pathology occurring within the visual pathway.

Confrontational **visual fields** were performed to illicit the presence of any gross visual field abnormalities, one of the most common defect as a result of stroke is hemianopia. Visual **neglect** was assessed by simultaneously holding 2 separate objects in front of the patient and ascertaining simultaneous recognition. Facial asymmetry and eye lid abnormalities were also considered.

The full orthoptic assessment was non-invasive and did not include an examination of the fundus which would have required the use of mydriatic eye drops to dilate the pupil. If the orthoptist felt information from patient history or test results were indicative of ocular pathology, patients not already under the care of an ophthalmologist were referred on.

## Results and Discussion

For the purpose of validating the vision screening tool, we looked at the level of agreement for each of the questions, observation and vision testing tasks on the tool when used by both a non-eye care practitioner and the orthoptist. Consideration of the results in table 1 below, show that in the majority of questions, observations and tests there are high levels of agreement between results obtained using the tool by the two different practitioners.

Table 1: copy of questions, observations and tasks on the screening tool

Question:	% of Agreement		% of Agreement
<b>Ask if the patient</b>		<b>OBSERVE for</b>	
<ul style="list-style-type: none"> <li>Has ever had their eyes tested?</li> </ul>	100%	<ul style="list-style-type: none"> <li>Droopy upper or lower eyelid</li> </ul>	72%
<ul style="list-style-type: none"> <li>Had an eye problem before the stroke?</li> </ul>	66%	<ul style="list-style-type: none"> <li>Shutting of an eye(s)</li> </ul>	86%
<ul style="list-style-type: none"> <li>Routinely uses eye drops?</li> </ul>	88%	<ul style="list-style-type: none"> <li>Nystagmus</li> </ul>	93%
<ul style="list-style-type: none"> <li>Wears glasses (<i>or contact lenses</i>)? If so what for?               <ul style="list-style-type: none"> <li>Near e.g. reading</li> <li>Distance eg. driving/TV</li> </ul> </li> </ul>	94% 96% 88%	<ul style="list-style-type: none"> <li>Patient missing or bumping into things</li> </ul>	93%
<ul style="list-style-type: none"> <li>Are glasses with the patient?</li> </ul>	83%	<b>CAN the patient without moving their head:</b>	
<b>Does the patient SAY that they have:</b>		<ul style="list-style-type: none"> <li>Look at an object with both eyes at the same time</li> </ul>	98%
<ul style="list-style-type: none"> <li>Had any change in their vision since they had the stroke?</li> </ul>	78%	<ul style="list-style-type: none"> <li>Look from one object to another</li> </ul>	98%
<ul style="list-style-type: none"> <li>Is the vision problem overcome by wearing glasses</li> </ul>	83%	<ul style="list-style-type: none"> <li>Follow an object smoothly from one side to the other</li> </ul>	98%
<ul style="list-style-type: none"> <li>Double vision?</li> </ul>	92%	Follow an object smoothly up and down	100%
<ul style="list-style-type: none"> <li>Uncomfortable eyes i.e. sore, itchy, dry, watery, red, crusty?</li> </ul>	74%	<b>CAN the patient see:</b>	
		<ul style="list-style-type: none"> <li>Near Print – test over the page</li> </ul>	86%
		<ul style="list-style-type: none"> <li>Distance Print – test over the page</li> </ul>	87%

Any areas where agreement fell below 80% were identified as requiring further analysis and determination of possible causes. This occurred on four occasions as indicated below (Table 2)

1. Had an eye problem before the stroke?	66%	3. Uncomfortable eyes i.e. sore, itchy, dry, watery, red, crusty?	74%
2. Had any change in their vision since they had the stroke?	78%	4. Droopy upper or lower eyelid	72%

For each of the patients recruited into sample 1, responses to these particular questions and observations, as well as the timing of the screening, was re-examined to determine if the order of delivery of the tool influenced the patient's responses. It was found that for 2 of the questions (1 & 2 in Table 2), responses were particularly influenced by order of delivery, with the first administration of the tool prompting a positive response on second questioning, no matter which clinician administered the vision screening tool initially. It is highly probable that amending these questions to include additional minor prompts for the patient about previous eye problems or vision changes would increase levels of agreement. It is recommended that such changes are applied before the implementation of the screening tool. In the third instance, it appeared that the word uncomfortable was open to variable interpretation and just a simple listing of the symptoms would suffice. The remaining (4<sup>th</sup>) item was an observation and appeared to be variably judged by both practitioners underperforming sections of the screening tool can be considered transient in nature and it is not surprising that variations in patient responses are documented.

Comparing the responses gained by the screening tool to the more comprehensive visual assessment could not be done on an item by item basis as they were not precisely matched. However, the following three key outcomes could be compared with the gold standard orthoptic assessment for validation purposes. They are:

1. Whether the tool detected a pre-existing ocular problem
2. Whether the tool identified any newly acquired ocular problem
3. Whether any ocular condition found requiring further management was referred

Measures of sensitivity and specificity of the tool were used to conduct this analysis.

For sample 2 comparison with the gold standard orthoptic assessment found that the vision screening tool correctly identified the existence of a pre-existing ocular condition in 100% (sensitivity and specificity) of the patients. This clearly shows that the screening tool is very capable of identifying pre-existing ocular conditions in patients admitted to hospital for stroke. This is important to ensure continuation of current management of patient's ocular conditions such as using drops for the control of glaucoma or the use of spectacles so that best corrected vision is achieved for daily activities and implementation of rehabilitation strategies unhindered by poor vision.

When identifying newly acquired visual problems, the vision screening tool was able to correctly identify new visual condition, the sensitivity and specificity was 66.67% when compared to the gold standard orthoptic assessment. In this analysis, false positives occurred in 33% of cases. This may be a consequence of the design of the vision screening tool which aims to detect obvious and gross

ocular or visual changes. More subtle conditions that a trained eye care professional will detect are therefore more likely to be missed in these circumstances.

In the third comparison regarding referral rate it was found for the patients identified as needing referral for further assessment sensitivity of the tool was 90% and specificity 50%. While onward referral for patients who were identified with visual problems is high, the false positive value is 50% indicating over-referral of patients by responses obtained using the vision screening tool.

**Table 3**

	Sensitivity	95% C.I.	Specificity	95% C.I.
Tool detected pre-existing ocular problems	<b>100</b>	<b>92.73 to 100</b>	<b>100</b>	<b>20.65 to 100</b>
Tool identified any newly acquired ocular problems	<b>66.67</b>	<b>41.71 to 84.82</b>	<b>66.67</b>	<b>49.61 to 80.25</b>
Any ocular condition found requiring further management was referred	<b>90</b>	<b>69.90 to 97.21</b>	<b>50</b>	<b>32.63 to 67.37</b>

### **Summary: Future Directions**

The results show that the vision screening tool is suitable and a valid instrument for achieving its designated purpose, that is, the ability to identify pre-existing and newly acquired visual problems in patients with a diagnosis of stroke in the majority of cases. The tool was highly successful in ascertaining pre-existing conditions. It is suggested that the sensitivity of the tool for detecting newly acquired conditions could be refined by minor changes to the existing questionnaire (see Appendix 2). In consultation with the Orthoptic Standing Committee within SOS, it is suggested that only those questions and observations with agreement levels below 80% be targeted for these minor modifications. These modifications are to remove any likelihood of ambiguity and misinterpretation and to provide appropriate prompts in the question that may improve the delivery of the vision screening tool. These recommended modifications have been highlighted within the vision screening tool in Appendix 2.

To further enhance the ability of the vision screening tool, it is suggested that additional support for the delivery of the tool be developed in the form of an accompanying education package designed to train those non-eye care practitioners who are to use the vision screening tool. The aim of the education package would be to improve knowledge of common age and stroke related visual conditions and how they might present, particularly by observation. It is expected that such an educational package would improve accuracy of observations and determination of the significance of patient's responses to questions. This has the potential to reduce over-referral of patients (50% during validation) to ophthalmological services, so that these services are not over-stretched. This is crucial for stroke practitioners in regional areas where services are limited and access to continued education in visual health may be limited.

## References

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[http://www.aci.health.nsw.gov.au/\\_data/assets/pdf\\_file/0019/155035/stroke\\_report\\_2008\\_07\\_08.pdf](http://www.aci.health.nsw.gov.au/_data/assets/pdf_file/0019/155035/stroke_report_2008_07_08.pdf) (date accessed 2nd Feb, 2016)

**Checklist for Vision Problems Post Stroke (original)**

Please complete pages 1 & 2 by direct communication with the patient/ their carer and/or observation of the patient & document findings in the Action column

Completed by: .....

Date: .....

QUESTION	Yes	No	ACTION	
<b>ASK if the patient:</b>				
• Has ever had their eyes tested?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Date of last eye test: _____ with: _____
• Had an eye problem before the stroke?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	List known eye conditions:
• Routinely uses eye drops?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	List eye drops & use on medical record:
• Wears glasses (or contact lenses)? If so what for?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Use appropriate glasses
o Near e.g. reading	<input type="checkbox"/>	<input type="checkbox"/>		
o Distance eg. driving/TV	<input type="checkbox"/>	<input type="checkbox"/>		
• Are glasses with the patient?	<input type="checkbox"/>	<input type="checkbox"/>	No	Ask carer to bring glasses in
<b>Does the patient SAY that they have:</b>				
• Had any change in their vision since they had the stroke?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Refer for detailed eye examination
• Is the vision problem overcome by wearing glasses	<input type="checkbox"/>	<input type="checkbox"/>	Yes No	Use appropriate glasses for activities Refer for detailed eye examination
• Double vision?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Refer for detailed eye examination
• Uncomfortable eyes i.e. sore, itchy, dry, watery, red, crusty?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Use appropriate prescribed eye drops. If this fails refer for eye examination
<b>OBSERVE for</b>				
• Droopy upper or lower eyelid	<input type="checkbox"/>	<input type="checkbox"/>		Refer for detailed eye examination if the answer is <b>Yes</b> for any observation.
• Shutting of an eye(s)	<input type="checkbox"/>	<input type="checkbox"/>		<b>Note observation</b>
• Nystagmus	<input type="checkbox"/>	<input type="checkbox"/>		
• Patient missing or bumping into things	<input type="checkbox"/>	<input type="checkbox"/>		
<b>CAN the patient without moving their head:</b>				
• Look at an object with both eyes at the same time	<input type="checkbox"/>	<input type="checkbox"/>		Refer for detailed eye examination if the answer is <b>No</b> for any action
• Look from one object to another	<input type="checkbox"/>	<input type="checkbox"/>		
• Follow an object smoothly from one side to the other	<input type="checkbox"/>	<input type="checkbox"/>		
• Follow an object smoothly up and down	<input type="checkbox"/>	<input type="checkbox"/>		
<b>CAN the patient see:</b>				
• Near Print – test over the page	<input type="checkbox"/>	<input type="checkbox"/>		Refer for detailed eye examination if the answer is <b>No</b> for either test
• Distance Print – test over the page	<input type="checkbox"/>	<input type="checkbox"/>		
<b>ACTIONS</b>			No Action	<input type="checkbox"/> Eye Drops <input type="checkbox"/>
			Glasses	<input type="checkbox"/> Onward Referral <input type="checkbox"/>

PLEASE TURNOVER →

## NEAR PRINT TEST

- TEST IN GLASSES IF USUALLY WORN BY THE PATIENT
- HOLD THE PAGE AT ELBOW LENGTH FROM THE PATIENT
- ASK THE PATIENT TO READ THE LETTERS BELOW AT ELBOW LENGTH FROM THE EYES

N E R X 1 4 3 5

## DISTANCE PRINT TEST

- TEST IN GLASSES IF USUALLY WORN BY THE PATIENT
- HOLD THE PAGE AT 2 METRES FROM THE PATIENT
- ASK THE PATIENT TO READ THE LETTERS BELOW AT 2 METRES FROM THE PATIENT

A T O V 5 7 4 3

**Checklist for Vision Problems Post Stroke (amended)**

Please complete pages 1 & 2 by direct communication with the patient/ their carer and/or observation of the patient & document findings in the Action column

Completed by: .....

Date: .....

QUESTION	Yes	No	ACTION	
<b>ASK if the patient:</b>				
Have ever had their eyes tested?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Date of last eye test: _____ with: _____
Had an eye problem before the stroke? (Such as: glaucoma, cataracts, macular degeneration or eye changes due to diabetes)	<input type="checkbox"/>	<input type="checkbox"/>	Yes	list known eye conditions:
Routinely uses eye drops?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	List eye drops & use. Record in medical record:
Wears glasses (or contact lenses)?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Use appropriate glasses
If so what for? (tick one or both)				
o Near e.g. reading <input type="checkbox"/>				
o Distance eg. driving/TV <input type="checkbox"/>				
Are glasses with the patient?	<input type="checkbox"/>	<input type="checkbox"/>	No	Ask carer to bring glasses in
Had any problem or change in their vision since being admitted to hospital with this stroke?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Refer for detailed eye examination
Does your vision problem improve by wearing glasses	<input type="checkbox"/>	<input type="checkbox"/>	Yes No	Use appropriate glasses for activities Refer for detailed eye examination
Do you have double vision?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Refer for detailed eye examination
Do you ever have sore, itchy, dry, watery, red or crusty eyes?	<input type="checkbox"/>	<input type="checkbox"/>	Yes	Use appropriate eye drops. If this fails refer for eye examination
<b>OBSERVE for</b>				
Droopy upper or lower eyelid	<input type="checkbox"/>	<input type="checkbox"/>		Refer for detailed eye examination if the answer is <b>Yes</b> for any observation.
Shutting of an eye(s)	<input type="checkbox"/>	<input type="checkbox"/>		<b>Note observation</b>
Nystagmus (wobbling eyes)	<input type="checkbox"/>	<input type="checkbox"/>		
Patient missing seeing things or is bumping into things	<input type="checkbox"/>	<input type="checkbox"/>		
<b>CAN</b> the patient without moving their head:				
Look at an object with both eyes at the same time	<input type="checkbox"/>	<input type="checkbox"/>		Refer for detailed eye examination if the answer is <b>No</b> for any action
Look from one object to another	<input type="checkbox"/>	<input type="checkbox"/>		
Follow an object smoothly from one side to the other	<input type="checkbox"/>	<input type="checkbox"/>		
Follow an object smoothly up and down	<input type="checkbox"/>	<input type="checkbox"/>		
<b>CAN</b> the patient see:				
Near Print – test over the page	<input type="checkbox"/>	<input type="checkbox"/>		Refer for detailed eye examination if the answer is <b>No</b> for either test
Distance Print – test over the page	<input type="checkbox"/>	<input type="checkbox"/>		
<b>ACTIONS</b>				
			No Action <input type="checkbox"/>	Eye Drops <input type="checkbox"/>
			Glasses <input type="checkbox"/>	Onward Referral <input type="checkbox"/>

PLEASE TURNOVER →

## NEAR PRINT TEST

- **TEST IN GLASSES IF USUALLY WORN BY THE PATIENT**
- HOLD THE PAGE AT ELBOW LENGTH FROM THE PATIENT
- ASK THE PATIENT TO READ THE LETTERS BELOW AT ELBOW LENGTH FROM THE EYES

N E R X 1 4 3 5

## DISTANCE PRINT TEST

- **TEST IN GLASSES IF USUALLY WORN BY THE PATIENT**
- HOLD THE PAGE AT 2 METRES FROM THE PATIENT
- ASK THE PATIENT TO READ THE LETTERS BELOW AT 2 METRES FROM THE PATIENT (if patient sitting in bed 2m is at end of bed)

A T O V 5 7 4 3

# THE USE OF A TOOL TO DETECT THE PRESENCE OF VISION DEFECTS IN PATIENTS DIAGNOSED WITH STROKE

## Phase 1 Validation of the Tool

### Stroke and vision screening tool - phase 1 validation

**VERSION 7, DATE 7.7.14**

#### **CONFIDENTIAL**

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#### **STATEMENT OF COMPLIANCE**

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

**PROTOCOL SYNOPSIS**

Title	THE USE OF A TOOL TO DETECT THE PRESENCE OF VISION DEFECTS IN PATIENTS DIAGNOSED WITH STROKE - Phase 1 Validation of the Tool
Objectives Primary: Secondary:	Validate the vision screening tool
Study Design	2 cohort study
Planned Sample Size	100 patients 20 Health Care Practitioners
Selection Criteria	Patients who have suffered a stroke will be examined to detect the presence of vision defects. Health Care Practitioners working on the stroke ward (Stroke Clinicians) will be invited to examine the patient using a tool to detect the presence of vision defects.
Study Procedures	The study has two 2 components which will be run simultaneously. Both components involve the use of the vision screening tool on 100 patients diagnosed with stroke. All of the recruited patient cohort will have the vision screening tool delivered by a health care practitioner working on the stroke ward (stroke clinician) in one of the selected hospitals. Half of the recruited patient cohort will complete the screening tool a second time as delivered by the research Orthoptist or complete a full vision assessment.
Statistical Procedures Sample Size Calculation: Analysis Plan:	The main outcome measure will be the total number of relevant vision conditions identified by each examination. Analysis will summarise concordance between these totals, using intra class correlation coefficients. Power for this statistic is calculated using a 'within-subjects ANOVA'. With alpha set at 0.05 and power at 80% an n of 50 would allow detection of a moderate effect size, equating to a d of approximately 0.4.
Duration of the study	<b>6- 8 months</b>

**GLOSSARY OF ABBREVIATIONS**

<b>ABBREVIATION</b>	<b>TERM</b>
CN	Clinic Nurse
OT	Occupational therapist
PT	Physiotherapist
MP	Medical Practitioner
SP	Speech Pathologist

## 1. INVESTIGATORS AND FACILITIES

### 1.1 Study Location/s

#### 1.1.1 Hornsby Ku-ring-gah Hospital and Manly Hospital

### 1.2 Study Management

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NSW Health Agency for Clinical Innovation (ACI)

### 1.5 Funding and resources

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## 2. INTRODUCTION AND BACKGROUND

### 2.1 Background Information

**Literature Review:**

Stroke increases with every decade after the age of 55 years [1]. In patients diagnosed with stroke, vision is affected due to pathology and normal age related changes. The vision problems can be directly caused by the stroke and include peripheral and central field loss [2, 3], visual neglect [2, 4], double vision from eye muscle defects, gaze palsy and nystagmus.[3, 5-7] The age related vision conditions which may have occurred before the onset of the stroke include glaucoma, age-related macular degeneration (AMD) and cataract [3] and these like stroke, occur with a greater frequency as age increases. Additionally, many of these patients have refractive error [6] which has been corrected by spectacles. Because of the acute onset of the stroke, which requires emergency transport for hospital care, the patient's required spectacles can be left at home or other people's spectacles can be retrieved in error, resulting in decreased vision from lack of appropriate optical correction. Patients may also have old or inappropriate spectacles or have lost their spectacles resulting in poor vision. Stroke related health conditions such as diabetes and hypertension can also produce new vision problems such as diabetic and hypertensive retinopathy

Vision defects in patients have been shown to affect spontaneous recovery and rehabilitation in a variety of ways. Decreased visual acuity can affect the patient's ability to see details which in turn affects reading skills and colour based tasks [3]. Patients can also have problems in reduced light level which affects perception of facial features, negotiation of stairs, curbs, glass doors and water based activities such as washing [3]. Loss of depth judgment through eye muscle defects can affect the ability of a patient to locate and place objects and position their limbs, especially when undertaking mobility tasks [8]. Vision defects that affect object and spatial awareness can impact on a patient's general awareness, object location, personal positioning and awareness of their surroundings [6]. All of these factors can affect the patient's interaction with the staff who are involved in the care and recovery of the patient.

There are many designated stroke units across Australia but limited availability of direct eye care services in the inpatient setting of these units. In NSW there may be no hospital based eye care, access to eye care in hospitals through an outpatient eye clinic or an orthoptist may provide ward based assessment and care.

**Investigators experience:**

In 2007 [9] a study into the most effective way to provide eye care for stroke patients was undertaken with a cohort of 150 patients across three sites. It revealed that 86% of the patients admitted to hospital following a stroke had a vision problem that either occurred as a consequence of the stroke or was present prior to the stroke. It also showed that the most effective option for the detection of vision problems was the provision of an orthoptist on the ward.

The overall recommendation of this earlier study was that *"Increased attention is paid to the detection of ocular conditions - both pre existing and acquired - as part of the acute stroke management process"*. As there are very few orthoptists employed in stroke units, this recommendation was addressed by developing a vision screening tool for use by non-ophthalmic clinicians.

**Development of the Vision Screening Tool (the Tool)**

The Tool was developed by the Stroke and Vision Defect Working Group of the Statewide Ophthalmology Service (SOS), now the Ophthalmology Network of the Agency for Clinical

Innovation (ACI) to enhance detection of ocular conditions. The initial Tool was developed and trialed informally with the working group, patients, and amendments were made.

Following initial development the Tool reached a standard that appeared effective and so it was tested against the results [10] of 100 case studies of patients admitted to hospital with a stroke who had had a full orthoptic eye assessment. Information from the full orthoptic assessment was used to complete a second Tool record. The outcomes from the two tools and the full orthoptic assessment were compared and revealed:

- 498 ocular conditions and vision defects were detected by orthoptists in the inpatient setting
- 309 (62%) of the 498 conditions were identified by the Tool when used by an orthoptist
- 85 (17%) of the 498 conditions were identified by all other health care professionals caring for stroke patients who did not use the Tool

Overall the Tool was more effective than non orthoptic assessors. It was particularly effective in detecting symptoms, observations, ocular history, ocular medication, use of and need for spectacles, spectacles left at home, face and lid droop and ocular deviation. The Tool missed some factors, including decreased visual acuity, and the actual level of any vision loss, pupil defects, eye movement defects, decreased convergence, field loss, visual neglect and nystagmus.

Following analysis of the research data, the Tool was modified to address the deficiencies including the incorporation of a near and distance vision test to be assessed on a pass/ fail basis.

### **Presentations and Publications**

The Stroke and Vision Defects Study (2007) and the development of the Tool has been written up for publication and has been presented in Australia and internationally:

- *'Stroke & the Eyes: the presence of decreased visual acuity'* was an invited presentation at the Asia Pacific Ophthalmology Conference, Sydney, 2011
- The presentation *'Towards gaining the best information about vision to assist the recovery of a patient with stroke'*, was awarded the International Research Prize at the International Orthoptics Conference Vancouver Canada, July 2012
- *'Towards gaining the best information about vision to assist the recovery of a patient with stroke'* was presented at Smart Stokes 2012 Sydney, and the Australian Orthoptic Conference, Melbourne, 2012
- *'Stroke and the eyes: the presence of decreased visual acuity'* was presented at Smart Strokes 2012 Sydney, and the Australian Orthoptic Conference, Melbourne 2012
- Jolly N, Macfarlane A, Heard R *Towards the development of a tool for the assessment of vision defects in patients with stroke Strabismus* June 2013, vol. 21, No.2:145-149.

## **2.2 Research Question**

Aim- to validate the vision screening tool, when used by clinicians on the stroke ward who have no vision testing expertise, as an effective method to identify eye and vision problems in patients diagnosed with stroke.

Research questions-

1. Is the tool, when used by any clinician caring for patients who have suffered a stroke, an effective device for detecting eye conditions compared to a full eye assessment by an orthoptist?
2. Is the tool effective in detecting vision defects in patients in the stroke ward, when used by staff, who have limited eye health knowledge, as effective as the tool being used by an orthoptist?

### **2.3 Rationale for Current Study**

Many hospitals which care for patients who have been diagnosed with stroke do not have access to eye services and specialised eye care practitioners such as an Orthoptist or Ophthalmologist. A study of 150 patients admitted to hospital with a diagnosis of stroke showed that 86% had vision problems (9). To assist with the detection of ocular defects in patients recently diagnosed with stroke, a team of vision care experts have devised a quick and easy to use vision screening tool for health care practitioners located on the stroke ward to be used as part of regular stroke assessment. The screening tool will detect pre-stroke eye conditions and new visual problems that may have occurred as a result of stroke. It is important that pre-stroke ocular conditions are acknowledged and their on-going management maintained, while new stroke-related ocular defects are identified and referred for further assessment and communicated and managed appropriately so as not to hinder recovery and rehabilitation. It is the intention that once the tool has been validated it can be used by non-eye care practitioners and implemented as part of the routine investigation protocol for patients diagnosed with stroke.

## **3. STUDY OBJECTIVES**

### **3.1 Primary Objective**

This new study outlined in the following pages will progress the use of the Tool to detect the presence of vision defects in patients diagnosed with stroke with the overarching goal to facilitate rehabilitation and recovery.

Phase 1: To validate the Tool

Phase 2:

- a. To introduce the Tool to multiple stroke units and evaluate its effectiveness once validated
- b. To identify clinical decisions taken or recommended by non-orthoptic clinicians who have used the Tool. Both short term (e.g. use of spectacles) and long term (e.g. visit to a clinic as recommended) actions are include

## 4. STUDY DESIGN

### 4.1 Type of Study

Two cohort study

### 4.2 Study Design

The study has two 2 components which will be run simultaneously. Both components involve the use of the vision screening tool on 100 patients diagnosed with stroke. All of the recruited patient cohort will have the vision screening tool delivered by a health care practitioner working on the stroke ward (stroke clinician) in one of the selected hospitals. Half of the recruited patient cohort will complete the screening tool a second time as delivered by the research Orthoptist or complete a full vision assessment.

The vision screening tool has 3 sections including questions to be asked and tasks to be performed by the examiner:

- Section 1. Asks the patient about their ocular history and use of spectacles
- Section 2. Observes the patient for eye defects and
- Section 3. Asks the patient to perform ocular tasks

For each task there is a tick box and where appropriate a column with guidance for action by the clinician that includes asking the patient to use their spectacles, have their spectacles brought in from home or have the patient referred for a full ocular assessment. There are instances where no action is recommended following examination using the Tool and the patient continues as they are.

The full vision assessment is performed by the research Orthoptist consisting of ocular history including the presence of eye disease and ongoing management, this would include looking at the patient's medical record to ascertain site of stroke lesion and related medical conditions. Tests for sensory and motor eye function i.e. visual acuity, peripheral vision, pupils, deviation detection and neglect assessment are also performed. No medication routinely used in Ophthalmic investigation such as dilating drops will be used in this study.

Patients on average are located on the stroke ward for approximately 3-4 days before into moving onto rehabilitation or discharged. This of course will depend on the severity of the stroke. Because of this tight time frame and to ensure that patients recruited complete both components of the study any assessments by stroke clinicians using the vision screening tool will only be undertaken 1 to 2 days prior too or after the scheduled visit of the research Orthoptist. These scheduled visits will be coordinated through the clinic nurse supervisor at each site.

The recruitment phase will take place over a 6 -9 month period. A previous feasibility study determined that this would be sufficient time to gather the required sample numbers. Overall 100 admitted stroke patients will be recruited across both components of the study, 50 from each chosen hospital.

The primary analysis is the same for both parts of the study: the Tool used by a stroke clinician compared to the Tool used by the research orthoptist; and the Tool used by the

stroke clinician compared to a criterion standard orthoptic examination. Sample size is calculated based on this analysis.

The main outcome measure will be the total number of relevant vision conditions identified by each examination. Analysis will summarise concordance between these totals, using intra class correlation coefficients. Power for this statistic is calculated using a 'within-subjects ANOVA'. With alpha set at 0.05 and power at 80% an n of 50 would allow detection of a moderate effect size, equating to a d of approximately 0.4.

#### **4.3 Number of Participants**

100 patients, 20 clinicians

#### **4.4 Number of centres**

Stroke units in two hospitals, Hornsby Kur-ring-gah and Manly have been approached to participate in the study. This was based on their ability to service the cohort number required for the study and that they do not currently have access to on-site eye care professionals

#### **4.5 Expected Duration of Study**

Based on the projected number of stroke patients to be admitted to either of the two selected hospitals data collection should be completed in 6 - 8 months. A further 4 months will be dedicated to analysing and publication of the results. Data collection will commence immediately after ethics application is approved

Expected start date 30th May 2014

#### **4.6 Primary and Secondary Outcome Measures**

Primary outcome of this study is the validation of the vision screening tool. For validation to occur the vision screening tool must be able to demonstrate that when used by a non-eye care professionals it is able to detect the presence of vision defects. Vision loss or poor visual acuity whether pre-existing or acquired can impact rehabilitation outcomes in patients diagnosed with stroke. Among other ocular defects the vision screening tool is able to quantify a patient's vision. This information will enable health care workers on the stroke unit make adaptation of strategies used in patient care. Once validation of the vision screening tool is completed the tool will be circulated to be used in the assessment of stroke patients in NSW health hospitals.

## **5. PARTICIPANT ENROLLMENT AND RANDOMISATION**

### **5.1 Recruitment**

All Patients admitted to the general stroke ward with a diagnosis of stroke and who meet the eligibility criteria and all health care practitioners within the stroke unit to which these patients have been admitted, will be invited to participate in the study. Patients and health care practitioners will initially be identified by the Clinic Nurse Supervisor and given a copy of the Participant Information Statement. If expressing a verbal interest in participating in the study, participants will be required to give written consent by signing the patient information statement and consent form. Any further queries the participants may have will be directed to the research orthoptist. These patients will not undergo screening until they are satisfied their questions have been addressed.

Participation in the study will be voluntary, and participants may refuse to participate or withdraw at any stage.

## **5.2 Eligibility Criteria**

### **5.2.1 Inclusion Criteria**

Any patient with a diagnosis of a stroke admitted to a study site who is capable of responding to an assessment using the screening tool and full eye assessment by an orthoptist will be invited to participate in the study. In those patients identified with reduced capacity, meaning they are unable to fully understand the purpose and consequences of participating in the study, additional informed consent may be sought from a family member or guardian on their behalf.

### **5.2.2 Exclusion Criteria**

Any patient who is unable to perform a visual acuity assessment ie: cannot name or match the letters and numbers on the chart or who cannot provide a comprehensible verbal response to questions will be excluded.

## **5.3 Informed Consent Process**

Each participant will be required to read the information and consent document. For the purpose of this research audience we have used the patient information sheet template provided by NSLHD in order to provide the relevant information that the participants require in order to make an informed decision about enrolling in the study. There are three separate information sheets needed for this study. One is required for the health care practitioner who will be administering the vision screening tool and the other two are for the enrolment of patients who have had a stroke. The reason behind the 2 different consent forms for patients is that some of the patients will have their visual function assessed twice by the vision screening tool administered by two different clinicians (a stroke clinician and an orthoptist) and other patients will have an assessment using the vision screening tool conducted by a stroke clinician, as well as a complete eye assessment conducted by an orthoptist.

## **5.4 Enrolment and Randomisation Procedures**

Participant diagnosed with stroke will be enrolled into the study after the informed consent process has been completed and the participant has met all inclusion criteria and none of the exclusion criteria. The participant will receive a study enrolment number and this will be documented in the participant's medical record and on all study documents. Health care practitioners recruited to administer the vision screening tool to stroke patients will only be identified by their profession. I.e CN, OT, SP, MP or PT.

When a patient has been identified they will be then undergo vision assessment by using the vision screening tool or complete eye assessment this may be in no particular order and will depend on staff or orthoptist availability.

## 5.5 Subject Withdrawal

### 5.5.1 Reasons for withdrawal

Patient termination from the study would include: discharge of the patient before they are able to undergo two vision assessments; complications that arose from the stroke that means that no longer meet the inclusion criteria. Any patients that are terminated from the study will have any information already collected destroyed.

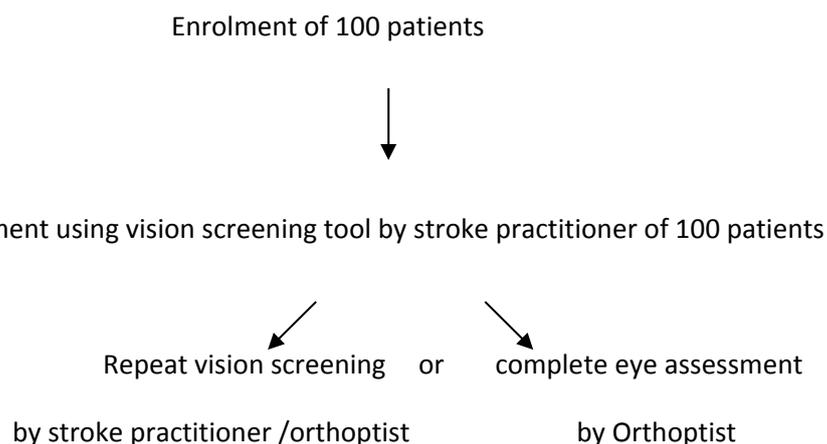
## 5.6 Trial Closure

Feedback of patient's vision results will be written up in patient charts by the orthoptist. Results from the data collected about the efficiency of the vision screening tool will offered to the health care practitioners in the formal presentation or newsletter.

## 6. STUDY VISITS AND PROCEDURES SCHEDULE

### Study Flow Charts

Diagram of the study design (examples below)



List Interventions	Enrolment Visit	Visit 1	Visit 2	Visit 3	Final Study Visit
Informed Consent	✓	Vision assessment by screening tool performed by stroke clinician	Vision assessment by orthoptist using either the tool or by doing a full vision test.		
Inclusion / Exclusion criteria	✓	Diagnosed with stroke and capable of responding to tool.	Diagnosed with stroke and capable of responding to tool or full vision test.		
Physical examination		Of eye function	Of eye function		
CXR	✓				✓
Adverse Event & Serious Adverse Event Assessment		✓	✓	✓	✓

**7. ADVERSE EVENT REPORTING-** please note that this is not a clinical trial and does not involve the use of medication or any invasive methods. The remainder of section 9 and 10 that refer to “adverse events, devices events, serious adverse events and radiation toxicity” is not applicable to the study being submitted for consideration. There is a possibility of minor injury during the testing procedure by accidental bumping of the face. Any such injury will be instantly reported to the supervising stroke clinician.

## 8. STATISTICAL METHODS

### 8.1 Sample Size Estimation

100 patients, 20 clinicians

### 8.2 Population to be analysed

The population to be studied has a diagnosis of stroke and this is the only criteria required for selection.

### **8.3 Statistical Analysis Plan**

The main outcome measure will be the total number of relevant vision conditions identified by each examination. Analysis will summarise concordance between these totals, using intra class correlation coefficients. Power for this statistic is calculated using a 'within-subjects ANOVA'. With alpha set at 0.05 and power at 80% an n of 50 would allow detection of a moderate effect size, equating to a d of approximately 0.4.

## **9. DATA MANAGEMENT**

### **9.1 Data Collection**

The study has two 2 components which will be run simultaneously. Both components involve the use of the vision screening tool on 100 patients diagnosed with stroke. All of the recruited patient cohort will have the vision screening tool delivered by a health care practitioner working on the stroke ward (stroke clinician) in one of the selected hospitals. Half of the recruited patient cohort will complete the screening tool a second time as delivered by the research Orthoptist or complete a full vision assessment. The information will be recorded on the tool.

The full vision assessment is performed by the research Orthoptist. The results will be recorded on a separate recording sheet. The data includes extracting from the medical file information about the site of the stroke lesion and any relevant medical conditions, determining the ocular history and management.

### **9.2 Data Storage**

Hard copies of consent letters will be stored at each of the sites participating in the study, for the Manly site this will be in the CNC office CTD level 1 building 20. At Hornsby Ku-rin-gai they will be located in CNC office next to the nurse's administration office ground floor Lumby Unit. The screening tool and the visual assessment results will be de-identified and stored in a locked filing cabinet located on University premises T320 building C42. . All written test results and responses will be scanned as a PDF file and digitally stored on a password protected computer in the same locked office. The files containing study data will be located on a password protected computer. There will be key access to the office by the researchers.

## **10. ADMINISTRATIVE ASPECTS**

### **10.1 Confidentiality**

When a patient has agreed to participate in the study, they will be allocated a code number. This number will be used for all future analysis and presentation of information. The identity of the participant will only be known to the researchers. Similarly, when any Stroke Clinician agrees to participate in the study their name will be removed and a code used for the purposes of the study.

Using the Australian code for responsible conduct as a guide collected data associated with this project will be retained for 5 years after publication. After which data will then be destroyed.

**10.2 Independent HREC Approval**

This project is being submitted to the Northern Sydney Local Area Health District HREC for approval

**10.3 Amendments to the protocol/project**

Any proposed amendment to the study protocol will be submitted to the Northern Sydney Local Area Health District HREC for review prior to implementation.

**10.4 Protocol Deviations**

It is anticipated that protocol deviation could include minor administrative changes, such as increasing the recruitment number at one of the hospitals because admissions of patients diagnosed with stroke at the other site is not sufficient to meet the data collection end date. These changes will not affect the scientific soundness of validating the vision screening tool.

**10.5 Participant Reimbursement**

There is no reimbursement for participants

**10.6 Financial Disclosure and Conflicts of Interest**

None of the researchers stand to gain any financial or other benefits from this study.

**11. USE OF DATA AND PUBLICATIONS POLICY**

The following methods are proposed for the distribution and publication of the results gained in this study to validate the vision screening tool. Lead investigator Neryla Jolly and Student Researcher will be primary authors on all publications.

1. Thesis to meet the course requirements of the MAppsci via research
2. Report to ACI& NSW Health
3. Publication in the Appropriate Scientific Journals
4. Conference Presentations at Stroke Australia, Orthoptics Australia

## 12. REFERENCES

- 1 **Stroke statistics** [[www.theuniversityhospital.com/stroke/stats.htm](http://www.theuniversityhospital.com/stroke/stats.htm)]
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3. Wolter M, Preda S: **Visual Deficits Following Stroke: Maximising Participation in Rehabilitation.** *Topics in Stroke Rehabilitation* 2006, **13**(3):12-21.
4. George S, Hayes A, Chen C, Crotty M: **are Vision Specific Quality of Life Questionnaires Important in Assessing Rehabilitation for Patients with Hemianopia Post Stroke?** *Topics in Stroke Rehabilitation* 2011, **18**(4):394-401.
5. Clisby C: **Visual assessment of patients with cerebrovascular accident on the elderly care wards.** *British Orthoptic Journal* 1995, **52**:38-40.
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8. Rowe F, Vg: **Visual impairment following stroke. Do stroke patients require vision assessment?** *Age and Ageing* 2009, **38**:188-193.
9. Jolly N, Macfarlane A, Thompson K: **Report to The Statewide Ophthalmology Service of The Greater Metropolitan Clinical Taskforce.** In. Sydney; 2008.
- 10 Jolly N, Macfarlane A, Heard R **Towards the development of a tool for the assessment of vision defects in patients with stroke** *Strabismus* June 2013, vol. 21, No.2:145-149.

### **13.APPENDICES**

List all appendices i.e:

1. Information and consent forms
  - I. Stroke clinician information sheet
  - II. Patient information sheet (1)
  - III. Patient information sheet (2)
  - IV. Guardian Consent and information sheet (1)
  - V. Guardian Consent and information sheet (2)
2. Vision screening tool
3. Data collection sheet - Orthoptic investigation
4. Letter of participation ACI
5. Code of Conduct for researchers at Sydney University as followed for this research project

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30 September 2014

Neryla Jolly  
Discipline of Orthoptics  
Sydney University Faculty of Health Sciences  
75 East St  
Lidcombe NSW 2141

Dear Neryla

**NSLHD reference: RESP/14/126**

**Title: The use of a tool to detect the presence of vision defects in patients diagnosed with stroke – Phase 1 Validation of the tool**

**HREC reference: LNR/14/HAWKE/199**

**SSA reference: LNRSSA/14/HAWKE/280 (Hornsby Ku-ring-gai Hospital), LNRSSA/14/HAWKE/281 (Manly)**

Thank you for submitting an application for authorisation for a Low and Negligible Risk Research Site Specific Assessment (LNR SSA) project. I am pleased to advise that the delegate of the Chief Executive for Northern Sydney Local Health District has granted authorisation on **28 September 2014** for the above project to commence at **Hornsby Ku-ring-gai Hospital and Manly Hospital**.

The version of the LNR SSA reviewed by NSLHD RGO was **AU/7/C728116 (Manly Hospital)** and **AU/7/D72814 (Hornsby Ku-ring-gai Hospital)**.

Ethical approval for this study was granted by the **Northern Sydney Local Health District HREC** at a meeting of the Executive Committee held on **23 July 2014**.

The documents authorised for use at this site are:

Document	Version	Date
Protocol	7	07 July 2014
Participant Information Sheet and Consent Form – Screening tool vs Full vision Assessment	6	25 June 2014
Participant Information Sheet and Consent Form – Screening tool evaluation used by Stroke Clinician and Orthoptist	6	25 June 2014
Stroke Clinician Information Sheet and Consent Form	-	25 June 2014
Guardian Information Sheet and Consent Form – Screening tool vs Full vision Assessment	1	07 July 2014
Guardian Information Sheet and Consent Form - Screening tool evaluation used by Stroke Clinician and Orthoptist	1	07 July 2014
Recording Sheet	-	-
Checklist for Vision Problems Post Stroke	-	-

Site authorisation will cease on the date of HREC expiry **23 July 2019**.

You are reminded that, in order to comply with the Guidelines for Good Clinical Research Practice (GCRP) in Australia, and in accordance with additional requirements of NSLHD, the Chief Investigator is responsible for ensuring the following:

1. The HREC is notified of anything that might warrant review of the ethical approval of the project, including unforeseen events that might affect the ethical acceptability of the project.
2. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and are submitted to the HREC for review, are copied to the Research Governance Officer.