

## **TAGS - SUPPLEMENTARY MATERIAL 1**

# Patient paperwork, Case Report Forms and Participant Questionnaires

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#### **Participant Information Sheet**

Version 2.0 23-02-2016

Treatment of Advanced Glaucoma Study (TAGS): A multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma.

#### PART 1

#### 1. Invitation

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

PART 1 tells you the purpose of this study and what will happen to you if you take part.

PART 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

#### **BACKGROUND TO THE CONDITION**

Glaucoma is a disease of the eye that occurs when the pressure of the fluid inside the eye is too high. It usually affects both eyes, although one may be more severely affected than the other. Glaucoma is very common; around 2% of the UK population over the age of 40 have the condition. This rate increases as people get older and as many as 10% of those in their 80s are affected. Glaucoma is the second most common reason for registering people as visually impaired in the UK. People with



advanced glaucoma (those who have more severe visual field loss) have an increased risk of further progression and blindness.

Glaucoma is treated by using eye drops (medical) or by an operation (surgery) to lower eye pressure.

The two methods of lowering eye pressure that we will investigate in the TAGS study are:

 An operation called a trabeculectomy which allows the fluid to leave the eye more easily.

#### and

 Medical care which may require up to four different eye drops to be used.

#### 2. What is the purpose of the study?

Reducing pressure is currently the only effective treatment for glaucoma. Both the treatments described above are commonly and successfully used in the NHS to reduce pressure but we do not know which treatment is better to prevent patients with advanced glaucoma from losing further vision. In the TAGS study we aim to find out which option is best. We will recruit 440 participants from NHS hospitals throughout the UK. The study will help us to find the best treatment of patients with advanced glaucoma in the future.

#### 3. Why have I been invited to take part?

You have been chosen because you have been diagnosed with advanced glaucoma in at least one of your eyes and treatment is required to lower your eye pressure to prevent further visual loss.

#### 4. Do I have to take part?

No. It is up to you to decide whether or not to take part.

If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to show that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason.

If you leave the study, we will still keep records about the treatment given to you, unless you object, as these are valuable to the study. If you decide to leave the study at any time, or decide not to take part, the quality of care you receive will not be affected.

#### 5. What will happen if I take part?

Patients who agree to take part in TAGS will be given either medical (eye drops) or surgical (trabeculectomy) treatment. The particular treatment given to each person in the study will be decided by a computer system. This is called randomisation. Randomisation is similar to tossing a coin to decide which group you are entered into and is important to make sure that the results of the study are accurate.

If you decide to take part, neither you nor your doctor can decide which treatment you will receive. There is an equal chance you will be placed into either treatment group.

If you are happy to take part in the TAGS study you will be asked some questions to make sure that your circumstances mean you are suitable to take part in the study. If you are suitable, you will be asked to sign a consent form and complete the first questionnaire. Your details will be entered into a computer system and you will be allocated to receive one of the two treatment procedures. The doctors and nurses treating you will not be involved in your procedure allocation and have no control over what group you are put in. Both procedures are suitable for the treatment of your glaucoma and are currently used in the NHS.

You can find further information about the two treatments in section 7.

#### 6. What do I have to do?

To collect the information we need, everyone in the study will be sent questionnaires by post approximately 1, 3, 6, 18 and 27 months after you join the study. The questionnaires ask about your vision and general health.

We will send you up to two reminders and will aim to contact you by post, email and/or telephone, taking into account which communication method is best for you. If you are in the surgery group we will ask you to complete another questionnaire before your operation.

After your treatment you will be asked to come back to an outpatient clinic at your hospital to check how you are getting on. We will ask you to complete questionnaires about your vision while you are in the clinic at around 4, 12 and 24 months after you join the study; we will also collect information about your treatment at these visits. Participating in this clinical trial will not affect the care you receive for your glaucoma

All the clinical care that you receive during the study will be the same as the standard care that is usually given within the NHS.

In addition to collecting information about your clinical condition we will also collect information about your income and what you spend in relation to your glaucoma care. This information is important as it will allow researchers to determine which treatments are best value for money. You may decline to provide this information if you wish

The study nurse and/or doctor involved in the study will also collect information from your NHS records during the time you are in the study.

Glaucoma is a lifelong condition and we want to make sure that the treatments we give have a long-term benefit. To this end, we aim to apply for funding to extend this study so we can look at longer-term outcomes (up to 10 years from when you started participating in the study). If this extension is funded we would like to continue to include you in the study for this longer period. We will use the same questionnaires that are currently used in this study, which we will ask you to complete every couple of years at most. We would also collect information from your medical records about your eye health and your glaucoma treatment. This will not require any extra visits to hospital clinics for you as your glaucoma will continue to be treated in the NHS for the rest of your life and the information we will be collecting will be part of your routine care.

Data for all participants in the study, including those who withdraw, will be kept securely for a minimum of 15 years.

#### 7. What are the treatments being tested?

Group name	Procedure
Eye drops	<ul> <li>You will be started on one or more medication(s) at your first hospital visit. Your doctor will decide what type(s) of eye drops you need.</li> <li>The medications you receive may later change if your doctor thinks you need more treatment for your glaucoma</li> <li>If eye drops do not control your eye pressure it is normal for surgery (trabeculectomy) to be undertaken</li> </ul>
Trabeculectomy	<ul> <li>This will happen within 3 months</li> <li>Involves making a small hole in your eye</li> <li>Day case procedure (but may require hospital admission)</li> <li>Can be done under either a local or a general anaesthetic</li> <li>Surgery normally takes about 40-60 minutes to complete</li> <li>If both your eyes need surgery, there will usually be a wait of around two to three months between your first and second operations.</li> <li>While waiting for surgery you will be treated with eye drops to lower the pressure</li> </ul>

Waiting times for treatment will reflect current care in the NHS and we expect the procedure will be carried out in around three months of you agreeing to take part. Individual patient needs will be taken into consideration.

#### 8. What are the alternatives for diagnosis or treatment?

Eye drops or trabeculectomy are the two most common treatments for people with advanced glaucoma. Laser treatment can also be used to treat glaucoma but is not often used to treat patients with advanced glaucoma.

## 9. What are the side effects of any treatment received when taking part?

If you do decide to take part in the study, you must report any problems you have to your study nurse or doctor. There is also a contact number

given at the end of this information sheet for you to phone if you become worried at any time.

There are no expected risks or disadvantages to participating in TAGS. Whichever group you are allocated to, your care will be overseen by an experienced consultant ophthalmologist (eye doctor) and any surgery performed will be done by a trained and experienced glaucoma specialist. Steps are always taken to make sure that any possible risks are minimised. As part of routine care, you will be well informed of potential risks.

#### The reported side effects of eye drops include:-

#### Common (greater than 1 in 10)

Redness\*
Stinging\*
Itching\*
Transient blurred vision
Eyes watering\*
Ocular discomfort\*

#### Occasional (between 1 in 10 and 1 in 50)

Allergy\*
Eyelash growth
Change in skin colour around eye
Change in iris colour
Shortness of breath
Unpleasant taste in mouth
Dry mouth

#### Uncommon (less than 1 in 50)

Fatigue
Kidney stones
Skin rash
Cataract formation
Retinal detachment

<sup>\*</sup> In some case these symptoms may be due to preservatives in the drops – if this is the case preservative free drops can be used.

#### Reported trabeculectomy side effects include:-

#### Common (greater than 1 in 10)

Discomfort
Blurred vision
Cataract formation within 5 years

#### Occasional (between 1 in 10 and 1 in 50)

Pressure too low Leak from operation site

#### Uncommon (less than 1 in 50)

Infection Severe loss of vision (less than 1 in 500) Bleeding in the eye

Both surgery and medical treatments are often used in the NHS for treating glaucoma patients. Although all these complications are well-recognised, many patients do not suffer any problems and most of the side effects are mild.

## 10. What are other possible disadvantages and risks of taking part? *For Women:*

The eye drops might harm an unborn child; therefore you should not take part in this study if you are pregnant, breast-feeding or you intend to become pregnant during the study. If you are a woman who could become pregnant, you will be asked to have a pregnancy test (urine) before taking part.

To take part in TAGS you must agree to use a reliable form of contraception during the trial (if taking eye drops). This should be continued for at least three months after the treatment has finished.

#### 11. What are the possible benefits of taking part?

We cannot promise the study will help you but by taking part in this study you will be directly helping us to inform the treatment of future patients diagnosed with glaucoma. The results of the study will help plan effective services offered by the NHS.

You will receive the same health care from your doctors whether you choose to participate in the study or not.

#### 12. What happens when the research study stops?

Your doctor will continue your care and treatment as standard. If the study is stopped earlier than expected for any reason, you will be told and your continuing care will be arranged

#### 13. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details are available from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

#### 14. Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. Details are included in Part 2.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read Part 2 before making any decision.

#### PART 2

#### 15. What if new information becomes available?

Sometimes during the course of a clinical trial, new, relevant information becomes available on the treatments that are being studied. If this happens, we will tell you about it and discuss with you whether you want to or should continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign a new consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

#### 16. What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, but you will need to continue attending appointments with your ophthalmologist and/or optometrist to have your glaucoma monitored as part of your standard care. It is normal that your glaucoma will be monitored for the rest of your life.

#### 17. Will my part in this study be kept confidential?

If you consent to take part in this study, your records will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital and the registered clinical trials unit (CHaRT) managing this research under the provisions of the 1998 Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

Information will be transferred from your hospital site to the clinical trial centre (CHaRT) organizing the research, to enable questionnaires to be sent to you and analysis of the study results. This will be done by mail and electronically. Personal details like your name and address will be sent separately to any clinical results collected for the trial. All other records will have your name removed and will only feature your unique study number and date of birth.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the course of the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

If you withdraw consent from further study treatment, unless you object, your data will remain on file and will be included in the final study analysis.



## National Institute for Health Research

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study.

Other researchers may wish to access data from this study in the future (this will not include names, addresses or dates of birth, and it is not possible to identify participants from the data). If this is the case, the consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

#### 18. Informing your General Practitioner (GP)

If you participate in the study we will tell your GP you are taking part, but only with your permission. We will also ask your GP to contact us if you visit them with any problems that may relate to your glaucoma treatment.

#### 19. What will happen to any samples I give?

We are not taking any samples as part of this study

#### 20. Will any genetic testing be done?

No, there is no plan to undertake genetic testing

#### 21. What will happen to the results of this clinical trial?

The results of the study will be used to make recommendations on treatments for patients with advanced glaucoma. The results of this study will also be published in scientific journals and presented at scientific meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

#### 22. Who is organising and funding this clinical trial?

The study has been designed by UK ophthalmology medical doctors and researchers. Patients will be recruited at different hospitals throughout the UK. The Nottingham University Hospitals NHS Trust will act as sponsor for the research.

The study is being funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme. It

is being co-ordinated by The Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered clinical trials unit, at the University of Aberdeen.

#### 23. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the NHS by Derby 1 Research Ethics Committee.

The study has also been reviewed and approved by the Research & Innovation department of Nottingham University Hospitals NHS Trust and of your local Research and Development Office.

#### 24. Contact for further information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the drug(s)/procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact the local study team whose contact information is given at the end of this Patient Information Leaflet.

For further information about trabeculectomy surgery the International Glaucoma Association provides a "glaucoma buddy" service where it is possible to speak to a patient who has previously undergone trabeculectomy and will discuss the surgery with you. This service can be accessed through the IGA Sightline Service at 01233 648170.

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and for considering this study.

If you have any questions or would like any more information, please contact:

#### Study Office contact details:

#### TAGS Study Office

Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen AB25 2ZD

Telephone: +44 (0)1224 438196

Email:tags@abdn.ac.uk

Website:http://www.tagsstudy.co.uk

Local contact details:

<<Insert contact details of local Pl
and/or Research Nurse>>

<<Insert contact details of local patient advice and liaison service>>

## TREATMENT OF ADVANCED GLAUCOMA STUDY (TAGS)

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	_	_	_	_	_				

#### **Consent Form**

Treatment of Advanced Glaucoma Study

			Glaucoma Study
Paı	ticipant Initials: P	rincipal Investigator:	Study
		Please INITIA	<b>AL</b> each box
		d understand the information leaflet dated 23-02-2016 (Version had the opportunity to ask questions.	
2.	I understand that my particip without my medical care or leg	ation is voluntary and that I am free to withdraw at any time pal rights being affected.	
3.	and NHS records, including Relevant information may be le	relevant to the TAGS study may be collected from my hospita Office of National Statistics (ONS) and NHS central registers coked at by authorised individuals from the Sponsor for the study ity in order to check that the study is being carried out correctly.	.
4.		ntact details will be kept confidentially and securely by the study at the study coordinators can use my contact details to send meantact me by post.	
5.		hdraw from the above study, the data collected from me will be f the trial, unless I specifically withdraw consent for this.	
6.	study. I understand that any in	ding electronic, of personal information for the purposes of this information that could identify me will be kept strictly confidentia on will be included in the study report or other publication.	
7.	I agree that my GP, or any ot study.	her doctor treating me, will be notified of my participation in this	6
8.		ate in a long-term follow-up of TAGS should funding to extend the reed (please delete to indicate).	yes / no
9.	I am willing to be asked in the (please delete to indicate).	future if I would be willing to take part in other relevant research	yes / no
10	. I agree to take part in the stud	dy.	
	Your signature (participant)		
	Your name in block capitals  Date		
	To be completed by the 1	al tague mambay taking a secont.	
	•	eal team member taking consent: ed to the person named above, the nature and purpose of the st	udy and
	Signature		
	Name in block capitals  Date		

Original to be retained and filed in the site file, 1 copy to patient, 1 copy to be filed in patient's notes, 1 copy to trial office.

National Institute for Health Research

TAGS Trial Office, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, University of Aberdeen, Scotland, AB25 2ZD Tel 01224 438196; Fax 01224 438165; Email: <a href="mailto:tags@abdn.ac.uk">tags@abdn.ac.uk</a>

Version: 3.0 Date: 15/01/2016



## **Contents**

Form	Version	Date
Eligibility checklist	1.3	27 Nov 2014
Personal Details	1.1	19 May 2014
Baseline visit and randomisation	1.3	7 August 2014
Surgery details	1.0	7 March 2014
4-month visit	1.3	7 August 2014
12-month visit	1.3	7 August 2014
24-month visit	2.0	5 April 2014
Serious adverse event report form	1.1	13 May 2014
Change of status form	2.0	5 August 2014
	Eligibility checklist Personal Details Baseline visit and randomisation Surgery details 4-month visit 12-month visit 24-month visit Serious adverse event report form	Eligibility checklist Personal Details 1.1 Baseline visit and randomisation Surgery details 1.0 4-month visit 1.3 12-month visit 1.3 24-month visit 2.0 Serious adverse event report form 1.1

#### <u>Erratum</u>

- 1. <u>Need for cataract surgery</u>: implemented on 1.6.2015, a label was added to revise Section 1 of the follow-up CRFs (4-, 12- and 24-months) to capture information about whether the patient had had cataract surgery.
- 2. <u>12- and 24-month CRFs</u>: In Section 2 when documenting Hospital Outpatient Visits and medication changes to avoid duplicating data you have already collected please look at events <u>since the last study</u> <u>visit NOT</u> since the baseline visit.
- 3. <u>24-month CRF</u>: implemented on 9.5.2016, a label was added to revise page 10 to repeat the baseline CRF

### TAGS: Eligibility Checklist



	Treatment of Advanced Glaucoma Study		
	Patient Name:		
To b	e eligible for the study the following criteria must be met:		
4)	Occupation of the control of the con	Yes	No
1)	Severe glaucomatous visual field loss (Hodapp classification) in one or both eyes at presentation.		
Но	dapp classification of glaucoma severity [has any of the following]:  1. MD < -12.00dB,  2. More than 50% of points defective in the pattern deviation probability plot at the 5% level,  3. More than 20 points defective at the 1% level,  4. A point in the central 5 degrees has a sensitivity of 0-dB,  5. Points within 5 degrees of fixation under 15 dB sensitivity in both upper and lower hemi-fields.		
2)	Open angle glaucoma including pigment dispersion glaucoma, pseudoexfoliative glaucoma and normal tension glaucoma.		
3)	Willingness to participate in the trial.		
4)	Ability to provide informed consent.		
5)	Over 18 years of age.		
6)	Females of child-bearing potential must have a negative urine test for pregnancy and agree to use a reliable method of contraception for the duration of her inclusion in the trial and three months thereafter.		
	A female is considered to be of childbearing potential unless she is without a uterus or is post-menopausal and has been amenorrheic for at least 12 consecutive months.		
7)	<ul> <li>None of the following conditions apply:</li> <li>a. Inability to undergo incisional surgery due to inability to lie flat or unsuitable for anaesthetic.</li> <li>b. High-risk of trabeculectomy failure such as previous conjunctival surgery, complicated cataract surgery.</li> <li>c. Secondary glaucomas, and primary angle-closure glaucoma.</li> <li>d. Females who are: <ul> <li>i. pregnant,</li> <li>ii. nursing,</li> <li>iii. planning a pregnancy,</li> <li>iv. of childbearing potential not using a reliable method of contraception.</li> </ul> </li> </ul>		
Nar	ne: Signature: Dat	e:	



# TAGS PERSONAL DETAILS CRF (Store securely and separately from baseline CRF).

		) (Sto	ore s	ecure	eiy ar	ıa se	para	ately	/ Tro	m b	ase	iine	CR	KF).			
	Treatment of Advanced Glaucoma Study	f						St	tudy	nur	mbe	er [					
PATIEN	IT DET	AILS	(S	tick	er m	nay	<u>be</u>	us	<u>ed</u>	bel	low	<u>/)</u>					
Title:	Mr		Mrs	s	N	Miss		N	Иs			Oth	er				
First name:																	
Surname	:																
Date of b	irth	D D	/	M	/ /	Υ	Υ	Υ	Υ					Male	Fer	nale	
Address		Postcoo	de:									7					
Contact telephone Number	e [																
CONSUL	FANT DE	TAILS			-1												_
Initials						S	urna	me									
GP DETA	ILS				7												_
Initials						S	urna	me									
Address																	
<u>Pregn</u>	<u>ancy</u>	Fem	ale o	of child	d-bea	ring p	oote	ntial	?	Υe	es		N	lo			
		If YE	S, n	egativ	e pre	egnar	ıcy t	est r	eco	rded	l?	<u> </u>	_				
Ethnic	ity													<u>L</u>			
	aucasian	1							Asia	an -	Orie	ental					
Afro-C	Caribbean	1		,	Asian	– Inc	dia/F	Pakis	stan/	Ban <sub>1</sub>	glad	desh					
Other	(specify)	)							Mix	xed I	heri	tage	!				



## **Baseline visit and randomisation**

Please use the following list in conjunction with the comprehensive guide to procedures in the TAGS Study Guide and the TAGS Standard Operation Manual.

Ch	necklist - Please initial when completed	Initials
1	Eligibility checklist completed and signed by doctor	
2	Consent form completed	
3	Baseline Questionnaire completed	
4	Personal Details CRF completed	
5	Patient randomised, informed of randomisation group and next step	
6	Patient study number added to CRF and Questionnaire	
7	Surgery appointment booked (if applicable)	
8	4-month appointment booked	
9	Study database updated with all information in CRFs and Questionnaire	

Ph	ysical Examinations - Please initial when completed	Initials
1	Medical History (including current glaucoma medication)	
2	ETDRS-Visual Acuity (Right, Left, and Binocular)	
3	Central Corneal Thickness	
4	Intraocular pressure	
5	Lens status	
6	Humphrey Visual Fields (upload files to study website. Print out a hard copy for the CRF).	
7	Esterman Visual Field	
8	Glaucoma Diagnosis	

	TAGS BASEI	INE CRF							
Treatment o		Study number							
Glaucoma Study	Date of Baseline Assessment		/ Y Y Y Y						
	Date of Diagnosis of glaucoma	DD1MM	1 Y Y Y Y						
Section 1 -	Medical History								
Is the patient on any glaucoma medication? (include any holding treatment issued when diagnosed. <i>Please indicate medication below</i> ).  Please indicate current medications and date of initiation									
	Right Eye	L	eft Eye						
Pg analogue	D D M M Y Y Y	D D M M Y	YYY						
β-blocker	D D M M Y Y Y	D D M M Y	Y Y Y						
CA inhibitor	D D M M Y Y Y	D D M M Y	YYY						
α-agonist	D D M M Y Y Y	D D M M Y	YYY						
Pilocarpine	D D M M Y Y Y	D D M M Y	YYY						
Diamox	D D M M Y Y Y	D D M M Y	YYY						
Co-morbidity	,	Right	Left						
AMD Vascular occ Diabetic Reti Cataract Other (please	nopathy								

#### **Section 2 - Visual Acuity**

#### 1. ETDRS distance visual acuity for RIGHT eye

Circle each letter/ number the patient correctly identifies at 4 metres and record the total number of letters read correctly in the column to the right. If the patient reads less than 20 letters, then move the patient to 1 metre (Note: Add +0.75 sphere if tested at 1 metre) and record the number of letters read correctly. If the patient is unable to read letters correctly at both 4 metres and 1 metre, then the visual Acuity Score is recorded as 0 and patient should be tested for HM, CF, LP and NLP.

4 - me	etre distance:			1 – me	tre distance:					
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Letters	3		Number correct at 1 metre	
1	20/200	N C K Z O		1	20/800	N C	K Z	0		
2	20/160	RHSDK		2	20/640	RH	Z D	K		
3	20/125	DOVHR		3	20/500	D O	V H	R		
4	20/100	C Z R H S		4	20/400	C Z	R H	S		
5	20/80	ONHRC	- <u> </u>	5	20/320	O N	H R	С		
6	20/63	D K S N V	- <u> </u>	6	20/250	D K	S N	V		
7	20/50	Z S O K N								
8	20/40	CKDNR								
9	20/32	SRZKD		If zero	letters are rea	d correc	tly at	4M or 1N	1	
10	20/25	H Z O V C		indicate	e best visual a	cuity for	RIGH	IT eye:		
11	20/20	N V D O K		Co	unt Fingers	ì				
12	20/16	V H C N O		На	nd Motion	J	@			
13	20/12.5	S V H C Z		Lig	ht Perception				(distance)	
14	20/10	O Z D V K		No	Light Percept	ion/ Artif	ficial E	ye		
Calcu	late Visual Acu	ity Score – RIGHT e	ye:							
A. T	otal number co	orrect at 4 metres:								
B. If	A ≥ 20, enter	30, otherwise enter a	a zero (0):							
C. T	otal number co	orrect at 1 metre (if no	ot tested, enter a z	zero):						
RIGH	RIGHT EYE: Sum of A, B and C above:									

N.B. Letter (or numbers) may vary according to charts used

Page 2

## 2. ETDRS distance visual acuity for <u>LEFT</u> eye

4 - me	etre distance:			1 – me	etre distance:			
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Letters		Number correct at 1 metre
1	20/200	DSRKN		1	20/800	DSR	R K N	
2	20/160	СКZОН		2	20/640	СКΖ	ОН	
3	20/125	ONRKD		3	20/500	O N F	RKD	
4	20/100	K Z V D C		4	20/400	ΚZ\	/ D C	
5	20/80	V S H Z O		5	20/320	V S F	H Z O	
6	20/63	HDKCR		6	20/250	H D K	CR	
7	20/50	CSRHN						
8	20/40	S V Z D K						
9	20/32	N C V O Z		If zero	letters are rea	ad correctly	y at 4M or	1M
10	20/25	R H S D V		indicat	te best visual a	acuity for L	EFT eye:	
11	20/20	SNROH		Co	ount Fingers	}		
12	20/16	ODHKR		Ha	and Motion	J	@	
13	20/12.5	ZKCSN		Li	ght Perception			(distance)
14	20/10	CRHDV		No.	o Light Percep	tion/ Artific	cial Eye	
Calcul	late Visual Acu	uity Score – LEFT ey	e:					
А. Т	otal number co	orrect at 4 metres:						
B. If	A ≥ 20, enter	30, otherwise enter	a zero (0):					
		orrect at 1 metre (if n		zero):				
		•		-				

N.B. Letter (or numbers) may vary according to charts used

LEFT EYE: Sum of A, B and C above:

## 3. ETDRS distance visual acuity for <u>BOTH</u> eyes

4 - me	etre distance:			1 – me	etre distance:		
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent		umber correct t 1 metre
1	20/200	NCKZO		1	20/800	N C K Z O	
2	20/160	RHSDK		2	20/640	R H Z D K	
3	20/125	D O V H R		3	20/500	D O V H R	
4	20/100	CZRHS		4	20/400	CZRHS	
5	20/80	ONHRC		5	20/320	O N H R C	
6	20/63	DKSNV		6	20/250	D K S N V	
7	20/50	ZSOKN					
8	20/40	CKDNR					
9	20/32	SRZKD		If zero	letters are rea	ad correctly at 4M or 1M	
10	20/25	H Z O V C		indica	te best visual a	acuity for BOTH eyes:	
11	20/20	N V D O K		Co	ount Fingers	ì	
12	20/16	VHCNO		Ha	and Motion	<b>,</b> @	
13	20/12.5	SVHCZ		Li	ght Perception		(distance)
14	20/10	O Z D V K		No	Light Percep	tion/ Artificial Eye	
Calcul	late Visual Acu	uity Score – BOTH e	/es:				
A. T	otal number co	orrect at 4 metres:					
B. If	A ≥ 20, enter	30, otherwise enter	a zero (0):				
C. T	otal number co	orrect at 1 metre (if r	ot tested, enter a	zero):			
вотн	EYES: Sum o	of A, B and C above:					

N.B. Letter (or numbers) may vary according to charts used

## **Section 3 - Central Corneal Thickness**

Central Corneal Thickness:	Ri	ight eye	е	-			Left	eye	
				μm					μr
Section 4 - Intraocul	lar Press	ure							
IOP – at <b>DIAGNOSIS</b> , UNTRI	EATED, 2 rea	adings	(if withi	n 3 mr	n Hg –	if not take	e third	meası	rement)
		Right	t Eye			Left E	ye		
1 <sup>st</sup> reading (Goldmann Appla	nation):			mm H	g			mm H	g
2 <sup>nd</sup> reading (Goldmann Appla	nation):			mm H	g			mm H	g
3 <sup>rd</sup> reading (Goldmann Appla	nation):			mm H	g			mm H	g
Mean									
10D -41- 11 11 11 11 11			: `			•	<u>'</u>		
IOP at baseline evaluation (if		•	,						
IOP– 2 readings (if within 3 m	m Hg – if not	take th	hird me	asurer	ment)				
		Right	t Eye			Left E	ye		
1 <sup>st</sup> reading (Goldmann Appla	nation):			mm H	g			mm H	g
2 <sup>nd</sup> reading (Goldmann Appla	nation):			mm H	g			mm H	g
3 <sup>rd</sup> reading (Goldmann Appla	nation):			mm H	g			mm H	g
Mean									
Mires equilibrated by									
IOP recorded by									
Target IOP as per Canadian	Consensus	Guida	nce	Righ	t Eye		Left	Eye	
	Target	IOP es	stimate			mm Hg			mm Hg
Lens Status									
Eye		Pha	akic		Pseud	dophaki	<u> </u>	Aph	akic
RIGHT eye			<u></u>						<u></u>
LEFT eye					_ <del></del>				

### Section 5 - Visual fields (Humphrey 24.2 SITA standard)

### Visual Fields unreliable if false positive > 15%

### Baseline 1

<u>Date:</u>								
Right Eye:	Reliable		Unreliable		Not	done		
Left Eye:	Reliable		Unreliable		Not	done		
<b>If visual fields reliabl</b> Right Eye:	e, please enter MI	) in dE	B of the VF +/- MD PSD	dE	3			
Left Eye:			+/- MD PSD	dE	3			
If perimetry undertaker file	າ, has a copy for ea	ach ey	e been added to th	e CRF	Yes		No	
If No, why?								
Has an electronic reco	rd of the VF been	saved	to disc		Yes		No	
If No, why?								
Baseline 2								
Date:								
Right Eye:	Reliable		Unreliable		Not	done		
Left Eye:	Reliable		Unreliable		Not	done		
<b>If visual fields reliabl</b> Right Eye:	e, please enter MI	) in dE	B of the second V +/- MD PSD	<b>F</b> dE	3			
Left Eye:			+/- MD PSD PSD	dE	3			
If perimetry undertaker file	າ, has a copy for ea	ach ey	e been added to th	e CRF	Yes		No	
If No, why?								
Has an electronic reco If No, why?	rd of the VF been s	saved t	to disc		Yes		No	
Esterman VF tes	<u>t:</u>							
Has an electronic reco	rd of the Esterman	VF be	een saved to disc		Yes		No	
If No, why?								

## **Glaucoma Diagnosis**

Primary Open Angle Glaucoma Pigment Dispersion Syndrome Pseudoexfoliation Syndrome Other: -		uding NTG)				
DIAGNOSIS for <b>RIGHT</b> eye		Advanced glaucoma		Non-advanced glaucoma		Neither
DIAGNOSIS for <b>LEFT</b> eye		Advanced glaucoma		Non-advanced glaucoma		Neither
Is the patient eligible to be registe	ered as	s sight impaired (SI)?		No SI Severe SI		
Has participant completed the TA If No, why?	.GS Pa	articipant Baseline Qı	uestio	onnaire? Yes 🔲	٨	lo 🔲

## **RANDOMISATION INFORMATION**

Telephone Randomisation Service Numb	er		0800	2802 307	
Web Address			www.tagss	tudy.co.uk	
Gender	Male	;	Female		
Are both eyes eligible?	Yes	;	No		
Which is the nominated index eye	Right	t	Left		
If both eyes are eligible the participant with the <u>least severe</u> (better MD) disease will lisease severity or IOP then the participar the <b>index eye</b> the fellow eye is treated as i	II be the <b>index eye</b> . nt will nominate the <b>ir</b>	If both eye	es are equiva	lent in teri	ns of
Study number					
Please indicate what group the patient has been randomised to	Surgical		Medica	al	



## **Surgery**

Please use the following list in conjunction with the comprehensive guide to procedures in the TAGS Study Guide and the TAGS Standard Operation Manual.

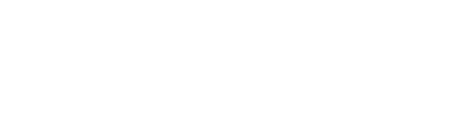
Inc	Index Eye Checklist - Please initial when completed					
1	Pre-trabeculectomy Questionnaire completed					
2	Surgery CRF completed					
3	Study database updated with all information in CRF and Questionnaire					

Fe	llow Eye Checklist –Please initial when completed (if needed)	Initials
1	Pre-trabeculectomy Questionnaire completed	
2	Surgery CRF completed	
3	Study database updated with all information in CRF	



## TAGS - Surgery CRF

Glaucoma Study					
20 1		St	udy number		
Date of visit		D		M / Y	YYY
PATIENT DETAILS (Sticker m	ay be used below	<b>'</b> )			
CONSULTANT DETAILS					
Date of surgery:			_		
Reason for surgery					
Study allocation					
Uncontrolled IOP					
Visual Field progression					
Drop intolerance/allergy					
Patient preference					
Other:					
Section 1 - Medica	al History	Systemic m	edications	Stopped be	fore surgery
Is the patient on:	Warfarin	☐ Yes	☐ No	☐ Yes	☐ No
	Aspirin	Yes	☐ No	Yes	☐ No
	NSAID	Yes	☐ No	Yes	☐ No
	Dabigatran	Yes	☐ No	Yes	☐ No
	Clopidogrel	Yes	■ No	Yes	☐ No
	Gingko Biloba	— □ Yes	— П No	□ □ Yes	— П No



<del>章</del>

Anaesthetist	Consultant Fellow Other Grade:			Other Theatre Staff	Scrub no Nurse ru ODA G	unner	 
Surgery Tec	hnique/ Dis	posable	s/Equip	<u>oment</u>			
Traction suture	•			Corneal Superior rec	ctus	_ _	
Conjunctival FI	ар			Fornix Limbal		_ _	
ММС	Do	se		0.2mg/ml 0.4mg/ml other			
	Du	ration		3 minutes other			
Scleral flap sut	Re	errupted leasable justable		_ _ _			er er
A/C maintainer	Ye: □	S		No □			
Preop Iopidine Per-operative M Peroperative Vis Subconjunctival	scoelastic			_ _ _			
Subconjunctival	steroid						

	Suture types	Silk	
		Nylon	
		Vicryl	
		Other	
ications?			
	ications?	 	Suture types Silk Nylon Vicryl Other



## TAGS - Surgery CRF

Glaucoma Study					
20 1		St	udy number		
Date of visit		D		M / Y	YYY
PATIENT DETAILS (Sticker m	ay be used below	<b>'</b> )			
CONSULTANT DETAILS					
Date of surgery:			_		
Reason for surgery					
Study allocation					
Uncontrolled IOP					
Visual Field progression					
Drop intolerance/allergy					
Patient preference					
Other:					
Section 1 - Medica	al History	Systemic m	edications	Stopped be	fore surgery
Is the patient on:	Warfarin	☐ Yes	☐ No	☐ Yes	☐ No
	Aspirin	Yes	☐ No	Yes	☐ No
	NSAID	Yes	☐ No	Yes	☐ No
	Dabigatran	Yes	☐ No	Yes	☐ No
	Clopidogrel	Yes	■ No	Yes	☐ No
	Gingko Biloba	— □ Yes	— П No	□ □ Yes	— П No

Preop o	<u>lrops</u>			<u>Right</u>			<u>Left</u>	
Pg anal	ogue							
B-block	er							
CA inhib	oitor							
A-agoni	st							
Parasyr	npathomimetic							
				<u>Yes</u>			<u>No</u>	
Diamox								
Preop I	<u>OP</u>			<u>Right</u>			<u>Left</u>	
					-	_		
Side of	surgery							
<u>General</u>								
Anaesthetic	Regional	block	<b></b>	Admissio	n type	Day Ca	ase	
	General					Overni	ght stay	
	Time into	OR	Time out of C	DR				
<u>Staffing</u>			Number					Nivershau
Surgeon	Consultant		Number	Surgeon	Consi	ultant		Numbe
Julyeon	Fellow			Assistant	Fellov			
	Other			-	Traine			
	Grade	:			Scrub	nurse		

Anaesthetist	Consultant Fellow Other Grade:			Other Theatre Staff	Scrub no Nurse ru ODA G		  
Surgery Tec	hnique/ Dis	posable	s/Equip	<u>oment</u>			
Traction suture	•			Corneal Superior rec	etus	_ _	
Conjunctival FI	ар			Fornix Limbal		_ _	
ММС	Do	se		0.2mg/ml 0.4mg/ml other		_ _ 	
	Du	ration		3 minutes other		_ 	
Scleral flap sut	Re	errupted leasable justable		_ _ _			er er
A/C maintainer	Ye: □	S		No □			
Preop Iopidine Per-operative M Peroperative Vis Subconjunctival	scoelastic			_ _ _			
Subconjunctival	steroid						

	Suture types	Silk	
		Nylon	
		Vicryl	
		Other	
ications?			
		 	Suture types Silk Nylon Vicryl Other



## 4-month clinic visit

Please use the following list in conjunction with the comprehensive guide to procedures in the TAGS Study Guide and the TAGS Standard Operation Manual.

Checklist - Please initial when completed			
1	4-month Questionnaire completed		
2	Patient study number added to CRF and Questionnaire		
3	12-month appointment booked		
4	Study database updated with all information in CRF and Questionnaire		

Ph	ysical Examinations - Please initial when completed	Initials
1	Adverse events recorded (check medical notes and ask patient).	
2	Hospital visits recorded (overnight, day case and outpatient)	
3	Further interventions recorded (if any)	
4	Current glaucoma medication recorded.	
5	Medication changes recorded	
6	ETDRS-Visual Acuity (Right, Left, and Binocular)	
7	Intraocular pressure	
8	Humphrey Visual Fields (upload files to study website. Print out a hard copy for the CRF).	



## **TAGS - 4 MONTH CRF**

Treatment of Advanced Glaucoma Study		Study numb	per
Date of visit	D	D/M	M / Y Y Y
Section 1			
Since the last study visit:			
Has the patient had cataract surgery?			
Intervention Undertaken Phaco + IOL	Right □	Left	Date  d d m m y y
Phaco + IOL			
Has the patient had a trabeculectomy? (	lf <u>not</u> please	skip to <u>Sect</u>	<u>ion 2)</u>
Intervention Undertaken Trabeculectomy	Right □	Left	Date  d d m m y y
Trabeculectomy			
Since the last study visit (baseline	) have any	y of the fo	llowing occurred?

If Yes, what (please tick all that are appropriate and include the date)?

Event	Right	Left	Date
Irreversible loss of ≥10 ETDRS letter			d d m m y y
Shallow anterior chamber			d d m m y y
Early Bleb leak			
Corneal Epithelial defect			
Persistent Uveitis			d d m m y y
Conjunctival button hole			d d m m y y
Malignant glaucoma			d d m m y y
Macular oedema			
Hyphema			
Choroidal effusion			
Suprachoroidal haemorrhage			
Iris incarceration			
Hypotony requiring intervention			
Retinal detachment	_	_	
Corneal decompensation	_		
Late Bleb Leak			
Blebitis			
Endophthalmitis			d d m m y y
Ptosis			

# Since the last study visit (baseline) have any of the following interventions been undertaken?

If Yes, what (please tick all that are appropriate and include the date)?

Intervention	Right	Left	Date
Massage			
Releasable release (please circle)	_	_	
Adjustment / suturelysis / releasable release Adjustment / suturelysis / releasable release			
Adjustment / suturelysis / releasable release			
Adjustment / suturelysis / releasable release			
Adjustment / suturelysis / releasable release			
5-FU injection			
o . ogoodo			
	ь	ь	
Steroid injection			d d m m y y
	Ц	Ц	
Needling + 5-FU injection			
		_	
Bleb resuturing			
AC reformation			
Bleb revision			
Phaco + IOL			
Other			d d m m y y

Was <b>overnight</b> a	dmission required for any of the above?	Yes	No 🔲
If Yes, please pro	ovide admission and discharge date(s)		
	Date of Admission	Date of Discharge	
Admission 1	D D M M Y Y Y	D D M M Y Y	YY
Admission 2	D D M M Y Y Y	D D M M Y Y	YY
Admission 3	D D M M Y Y Y	D D M M Y Y	YY
Was a day case	admission required for any of the above?	Yes	No 🔲
If Yes, please pro	ovide admission date(s)		
	Date of Admission		
Admission 1	D D M M Y Y Y		
Admission 2	D D M M Y Y Y		
Admission 3	D D M M Y Y Y		

### Section 2

### **Hospital Outpatient Visits**

Please record the dates and reason of any hospital visits related to glaucoma care since the baseline visit.

Number
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16

Date										
0	0	m	S	y	У					
0	0	m		y	y					
0	O	m	M	y	y					
0	6	m	M	y	y					
0	O	m	M	y	y					
0	Q	m	m	y	y					
0	0	M	E	Ŋ	y					
0	Q	M	M	y	y					
0	0	m	M	y	y					
(	0	m	ß	y	y					
0	0	m	M	y	y					
0	O	M	M	y	y					
0	0	m	m	y	y					
0	0	M	S	y	y					
0	O	M	S	y	y					
0	0	m	m	y	y					

Reason							

•	any anti-glaucoma		100000 :	Yes [			No		
Yes, please in	dicate medication a	and date (DD/MIM	I/YYYY) in	itiated					
	R	ight Eye		Left Eye					
g analogue	D D M	M Y Y Y	Y	D D	M	Y	Y	Y	
-blocker		M Y Y Y	Y	D D	M	Y	Y	Y	
A inhibitor	D D M	M Y Y Y	Y	D D	M M	1 Y	Y	YY	
-agonist	D D M	M Y Y Y	Y	D D	M N	1 Y	Y	YY	
ilocarpine	D D M	M Y Y Y	Y	D D	M	1 Y	Y	Y	
Diamox	D D M	M Y Y Y	Y	D D	M	1 Y	Y	Y	
	D D M	M Y Y Y M Y Y Y	Y	D D	M M		Y	YY	
low many diffe	erent bottles of me	edication are the	ey current	ly using	(please	e circle	e)		
1	2	3	>3						
nedication ch	Changes study visit (base anges have bee	eline) please in n made	ndicate h	ow man	y <u>glau</u>	<u>coma</u>	relate	d	
Medication	Stop		Eye	Reaso	n for st	oppin	g		
		m y y							
	0 0	m y y							
		m y y							
<b>ledication</b>	Start	date	Eye	Reaso	n for st	arting			
	d d m	m y y							
	d d m	m y y		1					
	6 6 m								

Has the patient had any adverse events to the <b>either</b> eye including medication intolerence?	Yes	No	
If "Yes", please give details*			

\*If there are any serious adverse events (meaning death, or unexpected adverse events not listed above but deemed related to participation in TAGS which involve or prolong hospitalisation), please complete a Serious Adverse Event form.

#### **Section 3**

#### **Vision and Ocular Examination**

# Visual Acuity Assessment (1=RIGHT EYE. 2=LEFT EYE. 3=BOTH EYES)

#### 1. ETDRS DISTANCE VISUAL ACUITY/RIGHT EYE

Circle each letter/ number the patient correctly identifies at 4 metres and record the total number of letters read correctly in the column to the right. If the patient reads less than 20 letters, then move the patient to 1 metre (Note: Add +0.75 sphere if tested at 1 metre) and record the number of letters read correctly. If the patient is unable to read letters correctly at both 4 metres and 1 metre, then the visual Acuity Score is recorded as 0 and patient should be tested for HM, CF, LP and NLP.

4 - me	etre distance:			1 – me	tre distance:						
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Let	tters	3			Number correct at 1 metre
1	20/200	N C K Z O		1	20/800	N	С	K	Z	0	
2	20/160	RHSDK		2	20/640	R	Н	Z	D	K	
3	20/125	D O V H R		3	20/500	D	0	٧	Н	R	
4	20/100	C Z R H S		4	20/400	С	Z	R	Н	S	
5	20/80	ONHRC		5	20/320	0	Ν	Н	R	С	
6	20/63	DKSNV		6	20/250	D	K	S	Ν	V	
7	20/50	ZSOKN									
8	20/40	CKDNR									
9	20/32	SRZKD		If zero	letters are read	d co	rrec	tly	at 4	M or 1M	
10	20/25	H Z O V C		indicate	e best visual a	cuity	/ for	RIG	GH <sup>-</sup>	T eye:	
11	20/20	N V D O K		Co	unt Fingers	ι					
12	20/16	VHCNO		На	nd Motion	J		(	@		
13	20/12.5	S V H C Z		Lig	ht Perception						(distance)
14	20/10	O Z D V K		No	Light Percepti	ion/	Arti	ficia	al E	ye	
Calcul	ate Visual Acui	ity Score – RIGHT e	ye:								
A. T	otal number co	orrect at 4 metres:									
B. If	A ≥ 20, enter	30, otherwise enter a	a zero (0):								
C. T	otal number co	orrect at 1 metre (if n	ot tested, enter a ze	ero):					•		
DICH.	T EVE: Qum of	A P and C above:									

# 2. ETDRS DISTANCE VISUAL ACUITY/<u>LEFT</u> EYE

4 - me	etre distance:			1 – me	etre distance:		
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Letters	Number correct at 1 metre
1	20/200	DSRKN		1	20/800	DSRKN	
2	20/160	СКZОН		2	20/640	СКZОН	
3	20/125	ONRKD		3	20/500	ONRKD	
4	20/100	K Z V D C		4	20/400	K Z V D C	
5	20/80	V S H Z O		5	20/320	V S H Z O	
6	20/63	HDKCR		6	20/250	HDKCR	
7	20/50	C S R H N					
8	20/40	S V Z D K					
9	20/32	N C V O Z		If zero	letters are rea	ad correctly at 4M or 1	M
10	20/25	R H S D V		indicat	te best visual a	acuity for LEFT eye:	
11	20/20	S N R O H		Co	ount Fingers	}	
12	20/16	ODHKR		Ha	and Motion	@	
13	20/12.5	Z K C S N		Li	ght Perception		(distance)
14	20/10	CRHDV		No	Light Percep	tion/ Artificial Eye	
Calcul	ate Visual Acu	uity Score – LEFT ey	e:				
A. T	otal number co	orrect at 4 metres:					
B. If	A ≥ 20, enter	30, otherwise enter	a zero (0):				
C. T	otal number co	orrect at 1 metre (if r	ot tested, enter a	zero):			
LEFT	EYE: Sum of A	A, B and C above:					

# 3. ETDRS DISTANCE VISUAL ACUITY/BOTH EYES

4 - me	tre distance:			1 – m	etre distance:			
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Letters	3	Number correct at 1 metre
1	20/200	N C K Z O		1	20/800	N C	K Z O	
2	20/160	RHSDK		2	20/640	RH	Z D K	
3	20/125	D O V H R		3	20/500	D O	V H R	
4	20/100	C Z R H S		4	20/400	C Z	RHS	
5	20/80	ONHRC		5	20/320	O N	H R C	
6	20/63	DKSNV		6	20/250	D K	S N V	
7	20/50	Z S O K N						
8	20/40	CKDNR						
9	20/32	S R Z K D		If zero	letters are rea	ad correc	tly at 4M o	r 1M
10	20/25	H Z O V C		indica	te best visual a	acuity for	BOTH eye	es:
11	20/20	N V D O K		C	ount Fingers	ì		
12	20/16	V H C N O		H	and Motion	,	@	
13	20/12.5	S V H C Z		Li	ght Perception	l		(distance)
14	20/10	OZDVK		N	o Light Percep	tion/ Artif	ficial Eye	
Calcul	ate Visual Acu	nity Score – BOTH e	yes:					
A. To	otal number co	orrect at 4 metres:						
B. If	A ≥ 20, enter	30, otherwise enter	a zero (0):					
C. To	otal number co	orrect at 1 metre (if r	ot tested, enter a	zero):				
вотн	EYES: Sum o	of A, B and C above:						
	·	rs) may vary accord versible loss of ≥1			nt):			

### IOP evaluation

IOP – 2 readings (if within 3 mm Hg – if not take third measurement )							
	Right Eye			Left Eye			
1 <sup>st</sup> reading (Goldmann Applanation):			mm Hg			mm Hg	
2 <sup>nd</sup> reading (Goldmann Applanation):			mm Hg			mm Hg	
3 <sup>rd</sup> reading (Goldmann Applanation):			mm Hg			mm Hg	
Mean							

Mires equilibrated by	
IOP recorded by	

# Visual fields (Humphrey 24.2 SITA standard)

VF1 - Date	D D M M 7	YYY	Y					
Right Eye:	Reliable		Unreliable		Not	done		
Left Eye:	Reliable		Unreliable		Not	done		
If visual fields relia	ıble, please enter Mi	o in dB of th	e VF					
Right Eye:		+/-	MD PSD	dE	3			
Left Eye:		+/-	MD PSD	dE	3			
If perimetry undertal file	ken, has a copy for ea	ach eye bee	n added to t	he CRF	Yes		No	
If No, why?								
Has an electronic re	cord of the VF been s	saved to disc	:		Yes		No	
If No, why?								
VF2 - Date	D D M M 7	YYY	Y					
Right Eye:	Reliable		Unreliable		Not	done		
Left Eye:	Reliable		Unreliable		Not	done		
If visual fields relia	ble, please enter MI	o in dB of th	e second V	F				
Right Eye:		+/-	MD PSD	dE	3			
Left Eye:		+/-	MD PSD	dE	3			
file	ken, has a copy for ea	ach eye bee	n added to t	he CRF	Yes		No	
If No, why?								
Has an electronic re	cord of the VF been s	saved to disc	;		Yes		No	
If No, why?								
-	mpleted the study q	uestionnaire	?	Yes	]		No	
If No, why?								



# 12-month clinic visit

Please use the following list in conjunction with the comprehensive guide to procedures in the TAGS Study Guide and the TAGS Standard Operation Manual.

Ch	necklist - Please initial when completed	Initials
1	12-month Questionnaire completed	
2	Patient study number added to CRF and Questionnaire	
3	24-month appointment booked	
4	Study database updated with all information in CRF and Questionnaire	

Ph	ysical Examinations - Please initial when completed	Initials
1	Adverse events recorded (check medical notes and ask patient).	
2	Hospital visits recorded (overnight, day case and outpatient)	
3	Further interventions recorded (if any)	
4	Current glaucoma medication recorded.	
5	Medication changes recorded	
6	ETDRS-Visual Acuity (Right, Left, and Binocular)	
7	Intraocular pressure	
8	Humphrey Visual Fields (upload files to study website. Print out a hard copy for the CRF).	

#### TAGS - 12 MONTH CRF

Treatment of Advanced Glaucoma Study			
		Study num	ber
Date of visit	D	D / N	1 M / Y Y Y Y
Section 1			
Since the last study visit:			
Has the patient had cataract surgery?			
Intervention Undertaken Phaco + IOL	Right □	Left	Date d d m m y y
Phaco + IOL			d d m m y y
Has the patient had a trabeculectomy? (	(If <u>not</u> please	skip to <u>Sec</u>	tion 2)
Intervention Undertaken Trabeculectomy	Right □	Left	Date
Trabeculectomy			

### Since the last study visit (4 month) have any of the following occurred?

If Yes, what (please tick all that are appropriate and include the date)?

Event	Right	Left	Date	
Irreversible loss of ≥10 ETDRS letter				377
Shallow anterior chamber			d d m m y ;	37
Early Bleb leak			d d m m y ;	37
Corneal Epithelial defect			d d m m y ;	37
Persistent Uveitis			d d m m y g	37
Conjunctival button hole			d d m m y	37
Malignant glaucoma			d d m m y g	<i>y</i>
Macular oedema			d d m m y g	y
Hyphema			d d m m y g	y
Choroidal effusion			d d m m y g	y
Suprachoroidal haemorrhage			d d m m y g	y
Iris incarceration				y
Hypotony requiring intervention	п	П		777
Retinal detachment	H	H		3 <i>)</i> /
Corneal decompensation	H	H		3 <i>)</i> /
Late Bleb Leak	H	H		3/
Blebitis	H	H		3 <i>/</i>
Endophthalmitis	ä	ī		<i>V</i> 7
Ptosis				y

# Since the last study visit (4 month) have any of the following interventions been undertaken?

If Yes, what (please tick all that are appropriate and include the date)?

Intervention	Right	Left	Date
Massage		_ _ _ _	
Releasable release (please circle) Adjustment / suturelysis / releasable release	_ _ _ _	_ _ _ _	
5-FU injection	_ _ _ _	_ _ _ _	d d m m y y d d m m y y d d m m y y d d m m y y d d m m y y
Steroid injection	_ _ _	_ _ _	d d m m y y d d m m y y d d m m y y d d m m y y
Needling + 5-FU injection	_ _ _	_ _ _	d d m m y y d d m m y y d d m m y y d d m m y y
Bleb resuturing			
AC reformation			
Bleb revision			
Phaco + IOL			
Other			d d m m y y

Was <b>overni</b>	ight a	adm	issic	n re	quire	ed fo	r any	of the above?	Yes No No
If Yes, pleas	se pro	ovid	le ac	lmiss	sion	and	disch	narge date(s)	
						Dat	e of	Admission	Date of Discharge
Admission	1		D	D	M	M	Υ	YYY	D D M M Y Y Y
Admission	2		D	D	M	M	Υ	YYY	
Admission	3		D	D	M	M	Y	YYY	D D M M Y Y Y Y
Was a <b>day</b>	case	adr	niss	ion r	equi	red f	or an	ny of the above?	Yes No No
If Yes, pleas	se pro	ovid	le ac	lmiss	sion	date	(s)		
	·							Admission	
						Dat	e or A	Admission	
Admission	1		D	D	M	M	Υ	YYY	
Adminaion	•								
Admission	2		D	D	W	IVI	Y	YYY	
Admission	3		D	D	M	M	Υ	YYY	
Section 2	<u>2</u>								
Hospital	Out	tpa	tie	nt V	'isit	S			
Please rec				tes a	and	reas	son (	of any hospita	al visits related to glaucoma care sinc
Number	Γ			Da	ate				Reason
1	Ī	0	0	M	M	y	Ŋ		
2		0	0	M	m	y	Ŋ		
3		6	6	M	m	Ŋ	y		
4	-	0	0	M	M	y	У		
5	-	0	0	M	m	Ŋ	y		
7	-	0	0	M	m	Ŋ	y		
		0	0	m	m	У	У		
8		6	6	M	M	У	У		
9		0	0	m m	m m	λ λ	λ λ		
9		0 0	0 0 0	m m	m m	λ λ λ	y y		
9 10 11	-	0 0 0	0 0 0	m m m		λ λ λ λ	А А А А		
9	-	0 0	0 0 0	m m	m m	λ λ λ	y y		

15 16

Current anti-glaucoma medication (prior to clinical assessment)								
Is the patient on	any anti-glaucoma medication?	Yes No						
If Yes, please in	dicate medication and date (DD/MM/YY)	YY) initiated						
	Right Eye	Left Eye						
Pg analogue	D D M M Y Y Y	D D M M Y Y Y						
β-blocker	D D M M Y Y Y	D D M M Y Y Y						
CA inhibitor	D D M M Y Y Y	D D M M Y Y Y						
α-agonist	D D M M Y Y Y	D D M M Y Y Y						
Pilocarpine	D D M M Y Y Y	D D M M Y Y Y						
Diamox	D D M M Y Y Y	D D M M Y Y Y						
Other (please spec	cify medication(s))  DDMMYYYYY  DDMMMYYYYY							
How many diffe	erent bottles of medication are they cu	rrently using (please circle)						
0 1	2 3	>3						
Medication Changes Since the last study visit (baseline) please indicate how many glaucoma related medication changes have been made								
Medication	Stop date Eye	Reason for stopping						
Medication	Start date Eye	Reason for starting						
	d d m m y y							

Has the patient had any adverse events to the <b>either</b> eye including medication intolerence?	Yes		No	
If "Yes", please give details*				
*If there are any serious adverse events (meaning death, or unexp	ected a	advers	se events not	listed

# **Vision and Ocular Examination**

# Refraction

	+/-	Sphere	+/-	Cyl		Axis
Right eye				-	x	
	+/-	Sphere	+/-	Cyl		Axis
Left eye			1	-	х	

Page 5

<sup>\*</sup>If there are any serious adverse events (meaning death, or unexpected adverse events not listed above but deemed related to participation in TAGS which involve or prolong hospitalisation), please complete a Serious Adverse Event form.

#### **Section 3**

### **Vision and Ocular Examination**

# Visual Acuity Assessment (1=RIGHT EYE. 2=LEFT EYE. 3=BOTH EYES)

#### 1. ETDRS DISTANCE VISUAL ACUITY/RIGHT EYE

Circle each letter/ number the patient correctly identifies at 4 metres and record the total number of letters read correctly in the column to the right. If the patient reads less than 20 letters, then move the patient to 1 metre (Note: Add +0.75 sphere if tested at 1 metre) and record the number of letters read correctly. If the patient is unable to read letters correctly at both 4 metres and 1 metre, then the visual Acuity Score is recorded as 0 and patient should be tested for HM, CF, LP and NLP.

4 - me	tre distance:			1 – me	tre distance:						
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Le	tters	3			Number correct at 1 metre
1	20/200	N C K Z O		1	20/800	N	С	K	Z	0	
2	20/160	RHSDK		2	20/640	R	Н	Z	D	K	
3	20/125	D O V H R		3	20/500	D	0	٧	Н	R	
4	20/100	C Z R H S		4	20/400	С	Z	R	Н	S	
5	20/80	ONHRC		5	20/320	0	N	Н	R	С	
6	20/63	D K S N V		6	20/250	D	K	S	N	٧	
7	20/50	Z S O K N									
8	20/40	CKDNR									
9	20/32	S R Z K D		If zero	etters are read	d co	rrec	tly a	at 4	M or 1M	I
10	20/25	H Z O V C		indicate	e best visual a	cuity	/ for	RIC	GH"	T eye:	
11	20/20	N V D O K		Co	unt Fingers	ι					
12	20/16	VHCNO		Ha	nd Motion	}		(	0		
13	20/12.5	S V H C Z		Lig	ht Perception						(distance)
14	20/10	O Z D V K		No	Light Percepti	ion/	Arti	ficia	ΙE	ye	
Calcula	ate Visual Acui	ity Score – RIGHT e	/e:								
A. To	otal number co	rrect at 4 metres:									
B. If	A ≥ 20, enter 3	30, otherwise enter a	zero (0):								
C. To	otal number co	rrect at 1 metre (if no	ot tested, enter a z	ero):							
RIGHT	EYE: Sum of	A, B and C above:									

## 2. ETDRS DISTANCE VISUAL ACUITY/<u>LEFT</u> EYE

4 - me	etre distance:			1 – me	etre distance:		
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Letters	Number correct at 1 metre
1	20/200	DSRKN		1	20/800	DSRKN	
2	20/160	C K Z O H		2	20/640	C K Z O H	
3	20/125	ONRKD		3	20/500	ONRKD	
4	20/100	K Z V D C		4	20/400	K Z V D C	
5	20/80	V S H Z O		5	20/320	V S H Z O	
6	20/63	HDKCR		6	20/250	H D K C R	
7	20/50	CSRHN					
8	20/40	S V Z D K					
9	20/32	N $C$ $V$ $O$ $Z$		If zero	letters are rea	ad correctly at 4M o	r 1M
10	20/25	R H S D V		indica	te best visual a	acuity for LEFT eye	:
11	20/20	SNROH		Co	ount Fingers	}	
12	20/16	ODHKR		Ha	and Motion	@ 	
13	20/12.5	ZKCSN		Li	ght Perception		(distance)
14	20/10	CRHDV		No	o Light Percep	tion/ Artificial Eye	
0		:: 0 ! ===					
Calcul	ate Visual Acu	ity Score – LEFT ey	e: 				
A. T	otal number co	orrect at 4 metres:					
B. If	A ≥ 20, enter	30, otherwise enter	a zero (0):				
C. T	otal number co	orrect at 1 metre (if n	ot tested, enter a	zero):			
LEFT	EYE: Sum of A	A, B and C above:					

# 3. ETDRS DISTANCE VISUAL ACUITY/BOTH EYES

4 - me	tre distance:			1 – m	etre distance:			
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Letters		Number correct at 1 metre
1	20/200	NCKZO		1	20/800	N C	K Z O	
2	20/160	RHSDK		2	20/640	R H	Z D K	
3	20/125	D O V H R		3	20/500	D O	V H R	
4	20/100	C Z R H S		4	20/400	C Z	RHS	
5	20/80	ONHRC		5	20/320	O N	H R C	
6	20/63	D K S N V		6	20/250	D K	S N V	
7	20/50	ZSOKN						
8	20/40	CKDNR						
9	20/32	S R Z K D		If zero	letters are rea	ad correc	tly at 4M or 1	M
10	20/25	H Z O V C		indica	te best visual a	acuity for	BOTH eyes:	
11	20/20	N V D O K		C	ount Fingers	J		
12	20/16	V H C N O		H	and Motion	J	@	
13	20/12.5	S V H C Z		Li	ght Perception			(distance)
14	20/10	OZDVK		N	o Light Percep	tion/ Artif	icial Eye	
Calcul	ata Visual Aqu	ity Score – BOTH ey	(OC)					
			/es.					
		orrect at 4 metres:						
		30, otherwise enter						
		orrect at 1 metre (if n	ot tested, enter a	a zero):				
вотн	EYES: Sum o	of A, B and C above:						
N.B. Le	tter (or numbe	rs) may vary accordi	ng to charts used	d				
Por	scope for Irro	versible loss of ≥10	CTDDS lotter	(if proces	ot):			
Red	350115 101 1116	versible loss of 210		(ii prese				

### **IOP** evaluation

IOP – 2 readings (if within 3mm Hg – if not	take t	nird me	easurement)			
	Righ	t Eye		Left	Eye	
1 <sup>st</sup> reading (Goldmann Applanation):			mm Hg			mm Hg
2 <sup>nd</sup> reading (Goldmann Applanation):			mm Hg			mm Hg
3 <sup>rd</sup> reading (Goldmann Applanation):			mm Hg			mm Hg
Mean						

Mires equilibrated by	
IOP recorded by	

# Visual fields (Humphrey 24.2 SITA standard)

VF1 - Date	D D M M S	YYY	Y					
Right Eye:	Reliable		Unreliable		Not	done		
Left Eye:	Reliable		Unreliable		Not	done		
If visual fields reliated Right Eye:  Left Eye:	able, please enter MI	) in dB of tl +/- [ +/- [	he VF  MD  PSD  MD		iB iB			
<b></b>		. [	PSD					
file	ken, has a copy for ea	ach eye bee	en added to t	he CRF	Yes		No	
If No, why?								
Has an electronic re	ecord of the VF been s	saved to disc	С		Yes		No	
If No, why?								
VF2 - Date	D D M M Y	YYY	Y					
Right Eye:	Reliable		Unreliable		Not	done		
Loft Ever		П	Unreliable	П	Not	done	П	
Left Eye:	Reliable			ш			_	
•	Reliable able, please enter MI	D in dB of ti +/- [			iВ		_	
If visual fields relia			he second V	(				
If visual fields reliated Right Eye:  Left Eye:		+/- [ +/- [	he second V  MD  PSD  MD  PSD  PSD		lΒ		No	
If visual fields reliated Right Eye:  Left Eye:  If perimetry underta	able, please enter MC	+/- [ +/- [	he second V  MD  PSD  MD  PSD  PSD  en added to t		dB dB		No	
If visual fields reliated Right Eye:  Left Eye:  If perimetry undertated file  If No, why?	able, please enter MC	<b>+/-</b> [ <b>+/-</b> [	he second V  MD  PSD  MD  PSD  PSD  en added to t		dB dB		No No	
If visual fields reliated Right Eye:  Left Eye:  If perimetry undertated file  If No, why?	able, please enter MC	<b>+/-</b> [ <b>+/-</b> [	he second V  MD  PSD  MD  PSD  PSD  en added to t		dB dB Yes			
If visual fields reliance Right Eye:  Left Eye:  If perimetry undertaine If No, why?  Has an electronic reliance If No, why?	able, please enter MC	+/- [ +/- [ ach eye been	he second V  MD PSD  MD PSD  en added to to		dB dB Yes			



# 24-month clinic visit

Please use the following list in conjunction with the comprehensive guide to procedures in the TAGS Study Guide and the TAGS Standard Operation Manual.

Checklist - Please initial when completed					
1	24-month Questionnaire completed				
2	Patient study number added to CRF and Questionnaire				
3	Study database updated with all information in CRF and Questionnaire				

Ph	ysical Examinations - Please initial when completed	Initials
1	Adverse events recorded (check medical notes and ask patient).	
2	Hospital visits recorded (overnight, day case and outpatient)	
3	Further interventions recorded (if any)	
4	Current glaucoma medication recorded.	
5	Medication changes recorded	
6	Formal refraction recorded	
6	ETDRS-Visual Acuity (Right, Left, and Binocular)	
7	Intraocular pressure	
8	Humphrey Visual Fields (upload files to study website. Print out a hard copy for the CRF).	
9	Esterman Visual Field	

#### TAGS - 24 MONTH CRF

Treatment of Advanced Glaucoma Study  Date of visit	D	Study numl	per M / Y Y Y Y
Section 1			
Since the last study visit:			
Has the patient had cataract surgery?			
Intervention Undertaken Phaco + IOL	Right □	Left	Date  d d m m y y
Phaco + IOL			
Has the patient had a trabeculectomy?	(If <u>not</u> please	skip to <u>Sect</u>	tion 2)
Intervention Undertaken Trabeculectomy Trabeculectomy	Right	Left □	Date         6       0       m       m       y       y         6       0       m       m       y       y
Since the last study visit (12 mont	:h) have an	y of the f	ollowing occurred?
If Yes, what (please tick all that are appropriat	e and include	the date)?	
Event	Right	Left	Date
Irreversible loss of ≥10 ETDRS letter Shallow anterior chamber Early Bleb leak Corneal Epithelial defect Persistent Uveitis Conjunctival button hole Malignant glaucoma Macular oedema Hyphema Choroidal effusion	00000000	00000000	

Suprachoroidal haemorrhage

Hypotony requiring intervention

Iris incarceration

Retinal detachment

Late Bleb Leak

Endophthalmitis

Blebitis

**Ptosis** 

Corneal decompensation

# Since the last study visit (12 month) have any of the following interventions been undertaken?

If Yes, what (please tick all that are appropriate and include the date)

Intervention	Right	Left	Date
Massage	_ _ _ _		
Releasable release (please circle) Adjustment / suturelysis / releasable release	_ _ _ _	_ _ _ _	
5-FU injection	_ _ _ _	_ _ _ _	
Steroid injection	_ _ _	_ _ _	
Needling + 5-FU injection	_ _ _	_ _ _	
Bleb resuturing			
AC reformation			
Bleb revision			
Phaco + IOL			
Other			

Was <b>overnight</b> a	admission required for any of the above?	Yes	No 🔲
If Yes, please pro	ovide admission and discharge date(s)		
	Date of Admission	Date of Discharg	е
Admission 1	D D M M Y Y Y	D D M M Y	YYY
Admission 2	D D M M Y Y Y	D D M M Y	YYY
Admission 3	D D M M Y Y Y	D D M M Y	YYY
Was a day case	admission required for any of the above?	Yes	No 🔲
If Yes, please pro	ovide admission date(s)		
	Date of Admission		
Admission 1	D D M M Y Y Y		
Admission 2	D D M M Y Y Y		
Admission 3	D D M M Y Y Y		

### Section 2

## **Hospital Outpatient Visits**

Please record the dates and reason of any hospital visits related to glaucoma care since the last study follow-up visit.

Number
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16

		Da	ite		
0	0	m	m	À	y
0	0	M		y	У
0	<b>6</b>	m	E	À	y
0	0	m		y	y
0	0	m	S	y	y
0	0	m	M	Ŋ	y
0	6	m		У	y
0	<b>6</b>	m	E	À	y
0	0	M	S	У	y
0	70	m	S	Ŋ	y
0	0	m	S	Ŋ	y
0	0	M		y	У
0	0	m	M	y	y
0	Ó	m	M	y	y
0	0	m	E	Ŋ	y
0	0	m	M	y	y

Reason	

Current anti-g	laucoma medication (pri	or to clin	nical assessment)	
Is the patient on an	y anti-glaucoma medication?		Yes	No 🔲
If Yes, please indic	ate medication and date (DD/MN	1/YYYY) in	itiated	
	Right Eye		Left E	ye
Pg analogue	D D M M Y Y Y	Y	D D M M 7	Y Y Y
β-blocker	D D M M Y Y	Y	D D M M 7	Y Y Y
CA inhibitor	D D M M Y Y	Y	D D M M 7	Y Y Y
α-agonist	D D M M Y Y	Y	D D M M 7	Y Y Y
Pilocarpine	D D M M Y Y	Y	D D M M 7	y y y
Diamox	D D M M Y Y	Y	D D M M 7	Y Y Y
Other (please specify	medication(s))  D D M M Y Y Y  D D M M Y Y Y	Y		Y Y Y Y Y
How many differe	nt bottles of medication are the	ey current	tly using (please cir	cle)
0 1	2 3	>3		
	nanges udy visit (baseline) please ir iges have been made	ndicate h	ow many <u>glaucom</u>	<u>a</u> related
Medication	Stop date	Eye	Reason for stopp	ing
	d d m m y y			
Medication	Start date	Eye	Reason for starting	ng
	d d m m y y			
	d d m m y y			
	d d m m y y			
	d d m m y y			

medication intolerend		ts to the <b>either</b>	eye includin	<sup>g</sup> Yes □	N	• <b></b>
If "Yes", please give	details*					
*If there are any ser above but deemed r complete a Serious A	elated to participa	ation in TAGS v				
Section 3						
Has the patient be	een listed for tra	abeculectom	y?	Yes 🔲	N	• <b></b>
Vision and O	cular Exami	<u>ination</u>				
A formal refraction		erformed at	the final 2	4-month vis	sit <b>before</b> th	າe 24-
Refraction						
Right eye		Sphere .		Cyl .	x	
Left eye	+/-	Sphere		Cyl	x Ax	IS

#### **Section 3**

### **Vision and Ocular Examination**

# Visual Acuity Assessment (1=RIGHT EYE. 2=LEFT EYE. 3=BOTH EYES)

### 1. ETDRS DISTANCE VISUAL ACUITY/RIGHT EYE

Circle each letter/ number the patient correctly identifies at 4 metres and record the total number of letters read correctly in the column to the right. If the patient reads less than 20 letters, then move the patient to 1 metre (Note: Add +0.75 sphere if tested at 1 metre) and record the number of letters read correctly. If the patient is unable to read letters correctly at both 4 metres and 1 metre, then the visual Acuity Score is recorded as 0 and patient should be tested for HM, CF, LP and NLP.

4 - me	re distance:		1 – metre distance:								
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Le	tters	3			Number correct at 1 metre
1	20/200	N C K Z O		1	20/800	N	С	K	Z	0	
2	20/160	RHSDK		2	20/640	R	Н	Z	D	K	
3	20/125	D O V H R		3	20/500	D	0	٧	Н	R	
4	20/100	C Z R H S		4	20/400	С	Z	R	Н	S	
5	20/80	ONHRC		5	20/320	0	N	Н	R	С	
6	20/63	D K S N V		6	20/250	D	K	S	N	٧	
7	20/50	Z S O K N									
8	20/40	CKDNR									
9	20/32	S R Z K D		If zero	etters are read	d co	rrec	tly a	at 4	M or 1M	I
10	20/25	H Z O V C		indicate	e best visual a	cuity	/ for	RIC	GH"	T eye:	
11	20/20	N V D O K		Co	unt Fingers	ι					
12	20/16	VHCNO		Ha	nd Motion	5		(	0		
13	20/12.5	S V H C Z		Lig	ht Perception						(distance)
14	20/10	O Z D V K		No	Light Percepti	ion/	Arti	ficia	ΙE	ye	
Calcula	ate Visual Acui	ity Score – RIGHT ey	/e:								
A. To	otal number co										
B. If A $\geq$ 20, enter 30, otherwise enter a zero (0):											
C. To	otal number co	ero):									
RIGHT	RIGHT EYE: Sum of A, B and C above:										

# 2. ETDRS DISTANCE VISUAL ACUITY/<u>LEFT</u> EYE

4 - metre distance:				1 – metre distance:							
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Le	Letters			Number correct at 1 metre	
1	20/200	DSRKN		1	20/800	D	S	R	K	N	
2	20/160	СКZОН		2	20/640	С	K	Z	0	Н	
3	20/125	ONRKD		3	20/500	0	Ν	R	K	D	
4	20/100	K Z V D C		4	20/400	K	Z	٧	D	С	
5	20/80	V S H Z O		5	20/320	٧	s	Н	Z	0	
6	20/63	HDKCR		6	20/250	Н	D	K	С	R	
7	20/50	CSRHN									
8	20/40	S V Z D K									
9	20/32	N C V O Z		If zero	letters are rea	ad co	orre	ctly	at 4	IM or 1	М
10	20/25	RHSDV		indicat	e best visual a	acuit	y fo	r LE	FT	eye:	
11	20/20	SNROH		Co	ount Fingers	١	L				
12	20/16	ODHKR		Ha	and Motion	ا	ſ		@		
13	20/12.5	Z K C S N		Liç	ght Perception	1					(distance)
14	20/10	C R H D V		No	Light Percep	tion/	Art	ificia	al E	ye	
Calcul	ate Visual Acu	uity Score – LEFT ey	e:								
А. Т	otal number co	orrect at 4 metres:									
B. If	A ≥ 20, enter										
C. T	otal number co	orrect at 1 metre (if r	ot tested, enter a	a zero):							
LEFT	EYE: Sum of A	A, B and C above:									

# 3. ETDRS DISTANCE VISUAL ACUITY/BOTH EYES

4 - me	tre distance:			1 – me	etre distance:				
Row	Acuity Equivalent	Letters	Number correct at 4 metres	Row	Acuity Equivalent	Letters			Number correct at 1 metre
1	20/200	N C K Z O		1	20/800	N C	K Z C	) _	
2	20/160	RHSDK		2	20/640	RH	Z D K	< _	
3	20/125	DOVHR		3	20/500	D O	V H F	R _	
4	20/100	C Z R H S		4	20/400	C Z	RHS	S _	
5	20/80	ONHRC		5	20/320	O N	HRO	С _	
6	20/63	D K S N V		6	20/250	D K	SNV	<b>/</b>	
7	20/50	ZSOKN							
8	20/40	CKDNR							
9	20/32	S R Z K D		If zero	letters are rea	d correct	tly at 4N	or 1M	
10	20/25	H Z O V C		indicat	e best visual a	acuity for	вотн е	eyes:	
11	20/20	N V D O K		Co	ount Fingers	ì			
12	20/16	V H C N O		Ha	and Motion	J	@ _		
13	20/12.5	S V H C Z		Lig	ght Perception				(distance)
14	20/10	OZDVK		No	Light Percept	tion/ Artif	icial Eye	е	
Calcul	ate Visual Acu	ity Score – BOTH ey	es:						
A. To	otal number co	orrect at 4 metres:					_		
B. If	A ≥ 20, enter	30, otherwise enter a	a zero (0):				_		
C. To	otal number co	orrect at 1 metre (if n	ot tested, enter a	zero):			_		
вотн	EYES: Sum o	of A, B and C above:					_		
N.B. Le	tter (or numbe	rs) may vary accordi	ng to charts used	l					
Rea	sons for Irre	versible loss of ≥10	ETDRS letter	(if preser	nt):				

#### **IOP** evaluation

	R	ight Eye	Left	Eye		
1 <sup>st</sup> reading (Goldmann App	planation):	mm Hg			mm Hg	
2 <sup>nd</sup> reading (Goldmann Ap	planation):	mm Hg			mm Hg	
3 <sup>rd</sup> reading (Goldmann App	planation):	mm Hg			mm Hg	
Mean						
Mires equilibrated by IOP recorded by						
Visual fields <i>(Hum</i>	nphrey 24.2 SI	ΓA standard)				
	D M M Y Y	YYY				
VF1 - Date		Unreliable		Not d	lone $\square$	
VF1 - Date  Right Eye:	D M M Y Y	YYY		Not d		
VF1 - Date  Right Eye:  Left Eye:  If visual fields reliable, ple  Right Eye:	Reliable Reliable	Unreliable Unreliable  Unreliable  Unreliable  Unreliable	□ dB			
VF1 - Date  Right Eye:  Left Eye:  If visual fields reliable, ple	Reliable Reliable	Unreliable Unreliable  Unreliable  HB of the VF  +/- MD				
VF1 - Date  Right Eye:  Left Eye:  If visual fields reliable, ple  Right Eye:  Left Eye:  If perimetry undertaken, ha file	Reliable Reliable Bease enter MD in Co	Unreliable Unreliable  Unreliable  Unreliable  HB of the VF  +/-	dB dB			
VF1 - Date  Right Eye:  Left Eye:  If visual fields reliable, ple  Right Eye:	Reliable Reliable Reliable Reliable Reliable Reliable Reliable Researcher MD in consistency of the second Reliable Relia	Unreliable Unreliable  Unreliable  Unreliable  HB of the VF  +/-	dB dB	Not d	one	

VF2 - Date	D D M M Y Y	YYY				
Right Eye:	Reliable	Unreliable		Not done		
Left Eye:	Reliable	Unreliable		Not done		
If visual fields reliabl Right Eye: Left Eye:	le, please enter MD in d	B of the second V +/- MD PSD +/- MD PSD	F dB			
If perimetry undertake file If No, why?	n, has a copy for each e	ye been added to tl	he CRF γ	∕es □	No 🔲	
·	ord of the VF been saved	to disc	١	∕es □	No 🔲	_ 
If No, why?						
Esterman VF tes	<u>st:</u>					
Has an electronic reco	ord of the Esterman VF b	een saved to disc	١	∕es □	No 🔲	
If No, why?						
Is the patient <b>ELIGIE</b>	<b>BLE</b> to be registered as	s sight impaired (S	SI	ere SI		
Has the patient beer	n <b>REGISTERED</b> as sig	ht impaired (SI)?	No SI Sev	ere SI		
		Date of Registr	ation:			
Has the patient comp	oleted the study questi	onnaire?	Yes		No 🗖	
If No, why?						



# Serious Adverse Event and Death report form

(More available from the TAGS Trial Office and on the study website at www.tagsstudy.co.uk)



# Serious Adverse Event/Death Report Form

			1	• •.			. •	· — -		_	<b>.</b>		<b>-</b> P -		••••	•
	Treatmo															
	Glauco		Stuc	dy Num	shar		Τ				٦					
	Study		Stud	ly Num	ibei.											
Record h	' oenits	siv اد	ite (pl:	anned	or unn	lanne	d) ac	encia	ted w	ith f	_ iirthe	r alau	coma	treati	ment/	
nterventi										/ILII .	u:	i giaa	٠٠٠٠٠	u out.	IIGIIG	
This form • An∖				<b>pietea</b> i or unexp		ut rela	ated to	o the p	articip	ant's	adva	nced al	aucon	na trea	tment t	hat are
not	further	rinter	vention	ns (e.g. i	f a partion										-	
• AL	L deat	ihs (t	or any	y reaso	n).											
Date (	of repo	rt _	D	D	M	IV	1	Υ	Υ		Υ	Υ	$\neg$			
Date .	Ji iepo	" <u> </u>			191	141	<u></u>	·			-	l l				
Initia	al Repo	ort			Follow	Up R	eport	t T								
	-					-	•		ļ							
Subject D	etails:															
Initials			Date	of Birth	D D	M	M Y	′ Y	YY	Ge	ender:	Male		Fema	le	7
			]			<u> </u>		_ <del></del>					L			_
NHS/CHI N	Number	<u>:                                    </u>														
Serious A	dverse	Even	t													
Seriousnes	ss criter	ia (Ch	eck all t	that appl	y):											
	Por	ltad i	- dooth			l :fo the	atani		1,	loonite	-liaatio	- /Dralana	tion of	: baanita	"action [	$\neg$
	Res	uitea ii	in death			Life-thr	eateriii	ng		10Spi	alisatioi	n/Prolong	jauon o	ПОЅрна	IISalion	
			gnificant capacity		Congenita	al anom	aly/ Bir defe		]		Oth	er medic	ally imp	ortant co	ondition	
		III III III III III III III III III II	араску			<del>                                     </del>	ueic	T							L	
Date of Ev	ent:	D	D	M N	ΙΥ	Y	Υ	Υ								
Brief detai	ls of a	dvers	se ever	nt:												

Was the event of the second se	related to ion 8.2.2)	a proce	dure req	uired by	the proto	col?		Yes		No	0	]
Is this an "expe (see protocol sect	ected" se ion 8.1.3 f	erious adv	verse eve tential exp	ent? Dected eve	ents)			Yes		No	0	]
Other relevant	t history	(e.g. dia	gnostic	s, allerg	jies, etc	)						
Place where ad	verse ev	ent took	nlace or	was dete	ected:							
Tidos Wiloto da	110100 01	one took	piaco oi	1140 4010	<del>Jotoui</del>							
Details of any i	ntom/ont		a du									
Details of any i	nterventi	on requir	eu.									
To be signed by	the Princ	ipal Invest	igator or	designee								
I am the Principa	al Investi	gator		Yes	s	1	No					
		e designa	tion									
I confirm that the			uoi i									
Name: (PRINT)	ino 15 d 3	AE										
Signature:												
	 	<u> </u>		İ	1	<u> </u>	<u> </u>	1		1		
Date:	D	D	M	M	Y	Y		Υ	Υ			



# **Change of Status**

(More available from the TAGS Trial Office and on the study website at www.tagsstudy.co.uk)



### **CHANGE OF STATUS**

Study number
Date of change DD / MM / YYYY
Q1. Is this a post-randomisation exclusion?  (i.e. the participant was not eligible for the study)  If Yes, please state reason for the post-randomisation exclusion in the box below
Tres, pieuse state reason for the post-fundomisation exclusion in the box below
Q2. Is this change of status as a result of:  Loss to follow-up  *Include if not collected or reported elsewhere
If necessary, please add further details for the change of status in the box below
Q3. Who has requested the change of status?
Participant Clinician Other Please specify
Q4. What does the change of status relate to? (tick as many boxes as required)
Having treatment/taking medication
Attending follow-up clinics
Completing further questionnaires
Contact by telephone from a member of the TAGS team?
Relevant outcome data being collected via hospital and GP records  (only complete if participant explicitly requests this)

ISRCTN 56878850 Version 2, 05/08/2014



### **CHANGE OF STATUS**

Study number
Date of change DD / MM / YYYY
Q1. Is this a post-randomisation exclusion?  (i.e. the participant was not eligible for the study)  If Yes, please state reason for the post-randomisation exclusion in the box below
Tres, pieuse state reason for the post-fundomisation exclusion in the box below
Q2. Is this change of status as a result of:  Loss to follow-up  *Include if not collected or reported elsewhere
If necessary, please add further details for the change of status in the box below
Q3. Who has requested the change of status?
Participant Clinician Other Please specify
Q4. What does the change of status relate to? (tick as many boxes as required)
Having treatment/taking medication
Attending follow-up clinics
Completing further questionnaires
Contact by telephone from a member of the TAGS team?
Relevant outcome data being collected via hospital and GP records  (only complete if participant explicitly requests this)

ISRCTN 56878850 Version 2, 05/08/2014

# INELIGIBLE/DECLINED FORM



Outline data on patients who are ineligible or who decline participation	
Q1 Date of attempted recruitment DD / MM / YYYY	
Q2 Year of Birth Gender (please tick) Male Female	
Q3 Reasons for non-inclusion (PLEASE ANSWER FROM A, B or C & tick all reasons that app	ly):
A) PATIENT DECLINED: Patient declined to give a reason  Does not want surgery  Does not wish to be randomised  Does not wish to participate in a trial  Details:  Preference for medical treatment or for surgery  Lifestyle factors e.g. work or family commitments.  Other Reason (please give details below):	
B) INELIGIBLE – CLINICAL REASON:  Visual fields did not meet criteria (e.g. deficit not severe enough or fields improved)  Unable to undergo incisional surgery  High risk of trabeculectomy failure  Secondary glaucomas and Primary Angle-Closure Glaucoma (PACG)  Female who is pregnant, nursing, planning a pregnancy or not using reliable contraception  Patient unable to provide informed consent (or understand/complete trial documentation)  Other clinical reason (please give details):	
Details:	<u> </u>
C) INELIGIBLE – OTHER REASON: Could not be randomised within 3 months of diagnosis  Patient did not attend appointments Other non-clinical reason (please give details):  Details:	
Signature: Print Name:	



FOR TRIAL OFFICE USE ONLY	Contro ID		
R&D reference 1 3 7 8 4 0	Centre ID		
Eudract No.		Subject ID	Subject initials
2 0 1 3 0 0	4 0 2 0 1 1		

DO NOT SEND IDENTIFIABLE DATA OR SOURCE DOCUMENTS WITH THIS REPORT						
<b>1</b> .	MATERNAL II Date o		Date of last menstru		Expected D D M	date of delivery
M	lethods of contrac	ception	Contrace	ption used as ins	tructed	
			Yes	N	o 🗌	Uncertain
		STORY (include informatio e pregnancy. If none mar		rders, known ri	sk factors or cond	ditions that may affect
3.	PREVIOUS O	BSTETRIC HISTORY				
	Gestation week	Outcome including any abnorr	malities			
1						
2						
3						
4						
	+					

4. DRUG INFORMATION (list all therapies taken prior to and during pregnancy)

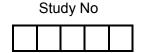
Name of drug	Daily dose	Route	Date Started	Date Stopped	Treatment Start (week of pregnancy)	Treatment Stop (week of pregnancy)
			D D M M Y Y	D D M M Y Y	D D	<u></u> D D
			D D M M Y Y	D D M M Y Y	D D	D D
			D D M M Y Y	D D M M Y Y	D D	0
			D D M M Y Y	D D M M Y Y	D D	םם
			D D M M Y Y	D D M M Y Y	D D	ОО
			D D M M Y Y	D D M M Y Y	D D	D D
			D D M M Y Y	D D M M Y Y	D D	<u></u> D D

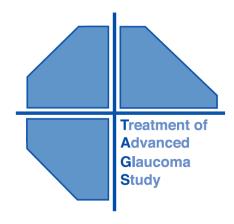
	ENATAL INFORMATION			
	any specific tests e.g. amniocente ancy so far?	sis, ultrasound, maternal serur	n AFP, been per	formed during the
Yes	□ No □ Uncertain □			
If yes	please specify test date and result	is:		
	Test	Date		Result
1		D D M M Y Y		
2		D D M M Y Y		
3		D D M M Y Y		
6. PR	EGNANCY OUTCOME			
(a)Ab	ortion Yes Date:	D D M M Y	Y	Y <b>No</b> ☐ (go to 6b)
Pleas	Therapeutic ☐ Planders Plande	·		
(b) De	elivery Yes Date:	D M M Y	Y	Y No 🗆
If yes:	Normal ☐ Forcep	s/Ventouse  Caesarea ted to birth:	n 🗆	
If the n	TERNAL PREGNANCY ASSOCIA nother experiences an SAE during ete a SAE form and submit it to the	the pregnancy, please indicate	e here.	

### **Pregnancy Notification Form**

Page 4

8. CHILD OUTC	OWE		Ab	onormal				Stillb	oirth		
If any abnormalities please specify and provide dates:											
	,000	<b>.</b> .	· · · · · · ·								
Sex		Heigh		Weight			ircumfere	nce	Agpar Scores	S:	
Male Fema		(cm):		(kg):		(cm):			1 min:	5 mins:	10 mins:
iviale — Fema	ie 🗀										
9. ASSESSMEN									o in norsistant	or oignificant	
Non-serious		oived spitalis		nged inp ı	alle	HI IL			s in persistent ity/incapacity	oi significant	
Life Threatening		•		omaly/bi	rth	defect			significant med	lical events	
Mother died		, ,					Stillbirth	neona	ate died 🗆		
Date of death	D	D	M	MY	Υ	YY	Date of	death	D	M M Y	YYY
10. ASSESSME								ΛE)			
Please indicate the	ne relatio	nship	betw	een pre	gna	ncy outc	ome:				
Unrelated Possibly* Probably* Definitely*											
If any of the fields management of t					ed,	the outc	ome is co	nsidere	ed RELATED t	o medication u	sed in the
11. ADDITIONA	L INFOR	RMAT	ION								
12. INFORMATI	ON SOU	IRCE									
Name											
Position											
Address											
Signature							 	ate of	report D	D M M Y	Y





# **TAGS**

### Treatment of Advanced Glaucoma Study

A multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma.

### **PARTICIPANT QUESTIONNAIRE**

Thank you for helping us with our research. We would be very grateful if you could complete this questionnaire.

### **CONFIDENTIAL**

BASELINE

ISRCTN - 56878850

Version 1.3, 19 June 2015

TAGS is funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (12/35/38).



The following questionnaire is broken down into five sections (Section A - Section E as detailed below). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

If you have any difficulties reading the text or understanding the meaning of any questions, then please ask a TAGS member of staff or contact the central office in Aberdeen.

The sections covered in this questionnaire are as follows:

Section A: All about you

**Section B:** Visual Functioning Questionnaire (split into 3 parts):

Part 1 - General Health and Vision

Part 2 - Difficulty with activities

Part 3 - Response to vision problems

**Section C:** Describing your own health today

Section D: Health Utility Index

**Section E:** Describing your experience of Glaucoma

#### SECTION A - ALL ABOUT YOU

Before you fill in our main questionnaire it will help us to understand your answers better if we have a little background data from you first as covered in the following questions. PLEASE TICK THE APPROPRIATE BOXES. Please remember that the answers from all TAGS questionnaires are strictly confidential.

Please try to complete all the questions. Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

We would like to send you questionnaires in a text size that best suits your needs. In future would you like to receive questionnaires	
In future I would like to receive questionnaires in this text size	
OR in future I would like to receive questionnaires in this text size	

□ In employment or self-employment □ Housework □ Retired □ Student □ Seeking work □ Other (please specify)  A2. Did your education continue after the minimum school leaving age? □ Yes □ No  A3. Do you have a family history of glaucoma? □ Yes □ No  A4. How many times have you visited the optician in the last 10 years? times	A1. Which of the following best describes your ma	in activity?
□ Yes □ No  A3. Do you have a family history of glaucoma? □ Yes □ No  A4. How many times have you visited the optician in the last 10 years?	☐ Retired ☐ Seeking work	
□ Yes □ No  A3. Do you have a family history of glaucoma? □ Yes □ No  A4. How many times have you visited the optician in the last 10 years?		
A3. Do you have a family history of glaucoma?  ☐ Yes ☐ No  A4. How many times have you visited the optician in the last 10 years?	A2. Did your education continue after the minimum	n school leaving age?
☐ Yes ☐ No  A4. How many times have you visited the optician in the last 10 years?	□ Yes	□ No
A4. How many times have you visited the optician in the last 10 years?	A3. Do you have a family history of glaucoma?	
	□ Yes	□ No
times	A4. How many times have you visited the optician	in the last 10 years?
		times

#### SECTION B - VISUAL FUNCTIONING QUESTIONNAIRE (NEI-VFQ-25)

The following section is a survey with statements about problems, which involve your vision, or feelings that you have about your eye condition. After each question please choose the response that best describes your situation. Please take as much time as you need to answer each question. All your answers are confidential. In order for this survey to improve our knowledge about eye problems and how they affect your quality of life, your answers must be as accurate as possible. Remember, if you wear glasses or contact lenses, please answer all of the following questions as though you were wearing them.

#### **INSTRUCTIONS:**

- 1. In general we would like to have people try to complete these forms on their own. If you find that you need assistance, please feel free to ask the project staff and they will assist you.
- 2. Please answer every question (unless you are asked to skip questions because they don't apply to you).
- 3. Answer the questions by circling the appropriate number.
- 4. If you are unsure of how to answer a question, please give the best answer you can and make a comment in the left margin.
- 5. If you have any questions, please feel free to ask a member of the project staff, and they will be glad to help you.

#### STATEMENT OF CONFIDENTIALITY:

All information that would permit identification of any person who completed this questionnaire will be regarded as strictly confidential. Such information will be used only for the purposes of this study and will not be disclosed or released for any other purposes without prior consent, except as required by law.

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### SECTION B - PART 1 GENERAL HEALTH AND VISION (NEI-VFQ-25)

B1: In general, would you say your overall health is:	
	(Circle One)

Excellent	1
Very Good	2
Good	3
Fair	4
Poor	5

B2: At the present time, would you say your eyesight using both eyes (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor or are you completely blind?

	(Circle One)
Excellent	1
Good	2
Fair	3
Poor	4
Very Poor	5
Completely Blind	6

B3: How much of the time do you worry about your eyesight?

	(Circle One)
None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

B4: How much pain or discomfort have you had in and around your eyes (for example, burning, itching, or aching)? Would you say it is:

	(Circle One
None	1
Mild	2
Moderate	3
Severe, or	4
Very severe	5

#### **SECTION B - PART 2 DIFFICULTY WITH ACTIVITIES**

The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses if you use them for that activity.

B5: How much difficulty do you have reading ordinary print in newspapers? Would you say you have:

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

B6: How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say:

(Circle One)

No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

B7: Because of your eyesight, how much difficulty do you have finding something on a crowded shelf?

1
2
3
4
5
6

(Circle One)

B8: How much difficulty do you have reading street signs or the names of stores? (Circle One)

No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# B9: Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night? (Circle One)

	(Oncie One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# B10: Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along?

objects on to the side wille you are walking along.	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# B11: Because of your eyesight, how much difficulty do you have seeing how people react to things you say?

3. 3	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# B12: Because of your eyesight, how much difficulty do you have picking out and matching your own clothes?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

### B13: Because of your eyesight, how much difficulty do you have visiting with people in their homes, at parties, or in restaurants?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

## B14: Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

#### B15: Are you currently driving, at least once in a while?

(Circle One)

Yes	1	Skip To Question B15c (page 7)
No	2	Go to Question B15a

#### B15a: If NO: Have you never driven a car or have you given up driving?

(Circle One)

Never drove	1	Skip To Section B, Part 3, Question B17 (page 8)
Gave up	2	Go to Question B15b

# B15b: IF YOU GAVE UP DRIVING: Was that mainly because of your eyesight, mainly for some other reason, or because of both your eyesight and other reasons?

(Circle One)

Mainly eyesight	1	Skip To Section B, Part 3, Question B17 (page 8)
Mainly other reasons	2	Skip To Section B, Part 3, Question B17 (page 8)
Both eyesight and other reasons	3	Skip To Section B, Part 3, Question B17 (page 8)

## B15c: IF CURRENTLY DRIVING: How much difficulty do you have driving during the daytime in familiar places? Would you say you have:

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4

### B16: How much difficulty do you have driving at night? Would you say you have:

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# B16a: How much difficulty do you have driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic? Would you say you have: (Circle One)

	(00.0
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

#### **SECTION B PART 3 – RESPONSES TO VISION PROBLEMS**

The next questions are about how things you do may be affected by your vision. For each one, please circle the number to indicate whether for you the statement is true for you <u>all</u>, <u>most</u>, <u>some</u>, <u>a little</u>, or <u>none</u> of the time.

(Circle One On Each Line)

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
B17:	Do you accomplish less than you would like because of your vision?	1	2	3	4	5
B18:	Are you limited in how long you can work or do other activities because of your vision?	1	2	3	4	5
B19:	How much does pain or discomfort in or around your eyes, for example, burning, itching, or aching, keep you from doing what you'd like to be doing? Would you say:	1	2	3	4	5

For each of the following statements, please circle the number to indicate whether for you the statement is definitely <u>true</u>, <u>mostly true</u>, <u>mostly false</u>, or <u>definitely false</u> for you or you are <u>not sure</u>.

(Circle One On Each Line)

		Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
B20:	I stay home most of the time because of my eyesight.	1	2	3	4	5
B21:	I feel frustrated a lot of the time because of my eyesight.	1	2	3	4	5
B22:	I have much less control over what I do, because of my eyesight.	1	2	3	4	5
B23:	Because of my eyesight, I have to rely too much on what other people tell me.	1	2	3	4	5
B24:	I need a lot of help from others because of my eyesight.	1	2	3	4	5
B25:	I worry about doing things that will embarrass myself or others, because of my eyesight.	1	2	3	4	5

#### **SECTION C – DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)**

The first section of the questionnaire is about your general health today.

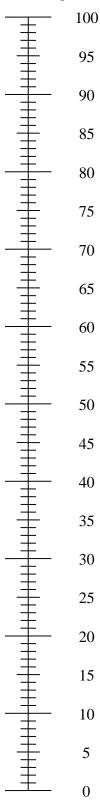
By placing a **tick** ( $\checkmark$ ) in one box in each group below, please indicate which statements best describe your own health state **today**.

MOBILITY	
I have no problems in walking about	
I have slight problems in walking about	
I have moderate problems in walking about	
I have severe problems in walking about	
I am unable to walk about	
SELF-CARE	
I have no problems washing or dressing myself	
I have slight problems washing or dressing myself	
I have moderate problems washing or dressing myself	
I have severe problems washing or dressing myself	
I am unable to wash or dress myself	
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	
I have slight problems doing my usual activities	
I have moderate problems doing my usual activities	
I have severe problems doing my usual activities	
I am unable to do my usual activities	
PAIN / DISCOMFORT	
I have no pain or discomfort	
I have slight pain or discomfort	
I have moderate pain or discomfort	
I have severe pain or discomfort	
I have extreme pain or discomfort	
ANXIETY / DEPRESSION	
I am not anxious or depressed	
I am slightly anxious or depressed	
I am moderately anxious or depressed	
I am severely anxious or depressed	
I am extremely anxious or depressed	

# The best health you can imagine

- We would like to know how good or bad your health is TODAY.
  This scale is numbered from 0 to 100.
  100 means the best health you can imagine.
- Too means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =	



The worst health you can imagine

This set of questions asks about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, <u>during the past week</u>. Please select <u>one</u> answer that <u>best describes</u> your level of ability or disability <u>during the past week</u>. Please indicate the selected answer by <u>circling</u> the number (e.g. 1, 2, 3, etc.) beside the answer.

#### Vision:

- Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, without glasses or contact lenses.
- Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, but with glasses.
- Able to read ordinary newsprint with or without glasses but unable to recognize a friend on the other side of the street, even with glasses.
- Able to recognize a friend on the other side of the street with or without glasses but unable to read ordinary newsprint, even with glasses.
- 5 Unable to read ordinary newsprint and unable to recognize a friend on the other side of the street, even with glasses.
- 6 Unable to see at all.

#### **Hearing:**

- Able to hear what is said in a group conversation with at least three other people, without a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but requires a hearing aid to hear what is said in a group conversation with at least three other people.
- Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people, with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, without a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, with a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- 6 Unable to hear at all.

#### Speech:

- 1 Able to be understood completely when speaking with strangers or friends.
- Able to be understood partially when speaking with strangers but able to be understood completely when speaking with people who know me well.
- Able to be understood partially when speaking with strangers or people who know me well.
- 4 Unable to be understood when speaking with strangers but able to be understood partially by people who know me well.
- 5 Unable to be understood when speaking to other people (or unable to speak at all).

#### **Ambulation:**

- 1 Able to walk around the neighbourhood without difficulty, and without walking equipment
- Able to walk around the neighbourhood with difficulty; but does not require walking equipment or the help of another person.
- Able to walk around the neighbourhood with walking equipment, but without the help of another person
- Able to walk only short distances with walking equipment, and requires a wheelchair to get around the neighbourhood.
- 5 Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood.
- 6 Cannot walk at all.

#### **Dexterity:**

- 1 Full use of two hands and ten fingers.
- 2 Limitations in the use of hands or fingers, but does not require special tools or help of another person.
- Limitations in the use of hands or fingers, is independent with use of special tools (does not require the help of another person).
- 4 Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with use of special tools).
- 5 Limitations in use of hands or fingers, requires the help of another person for most tasks (not independent even with use of special tools).
- 6 Limitations in use of hands or fingers, requires the help of another person for all tasks (not independent even with use of special tools).

**Emotion:** 1 Happy and interested in life.

2 Somewhat happy.

3 Somewhat unhappy.

4 Very unhappy.

5 So unhappy that life is not worthwhile.

#### Cognition:

- 1 Able to remember most things, think clearly and solve day to day problems.
- Able to remember most things, but have a little difficulty when trying to think and solve day to day problems.
- 3 Somewhat forgetful, but able to think clearly and solve day to day problems.
- 4 Somewhat forgetful, and have a little difficulty when trying to think or solve day to day problems.
- Very forgetful, and have great difficulty when trying to think or solve day to day problems.
- 6 Unable to remember anything at all, and unable to think or solve day to day problems.

#### Pain:

- 1 Free of pain and discomfort.
- 2 Mild to moderate pain that prevents no activities.
- 3 Moderate pain that prevents a few activities.
- 4 Moderate to severe pain that prevents some activities.
- 5 Severe pain that prevents most activities.

<sup>©</sup> Health Utilities Inc. (HUInc), 1998.

#### SECTION E - DESCRIBING YOUR EXPERIENCE OF GLAUCOMA^

In this section of the questionnaire we are interested in the importance you place on the different characteristics of glaucoma and its treatment effects.

Some of these statements may seem similar to earlier questions in the booklet. However, they are an important measurement tool for valuing how glaucoma and its treatment affect you.

Please tick one box (✓), for each of the **categories E1-E6**, which best describes any difficulties you have had in the **last month** with yourself, or your eyes or vision. **Remember**, if you wear glasses or contact lenses please answer all of the following questions as though you were wearing them.

As a guide about what is meant by the questions please look at the booklet 'Guide to the Questionnaire Sections'.

#### E1: Central and near vision

For example, do you have any difficulties with reading, writing, watching TV, sewing, card games, computer work, reading dials on cookers on clocks or any activities similar to these?

No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	

#### E2: Lighting and glare

For example, do you have any difficulties adjusting from light to dark and viceversa), dazzle from bright lights, or difficulties seeing in dim light?

No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	

#### E3: Mobility

For example, **because of your eyesight,** do you have any difficulties crossing roads, walking along busy pavements, negotiating steps and kerbs, tripping over low objects (for example children in pushchairs or dogs) or difficulties driving (or stopping driving) because of your vision?

No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	

E4: Activities of daily living For example, because of your eyesight, do you have any difficulties domestic, DIY or self-care tasks around the home? This category inc difficulties pouring liquid into containers (e.g. water into a glass), problems ju shelf height leading to difficulties putting objects into or retrieving them cupboards, being unaware of open cupboard doors and similar problems.	ludes dging
No No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	
E5: Eye discomfort  For example, any difficulties because of one or both eyes feeling gritty, so tired?	re, or
No 🗔	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	
E6: Other possible effects of glaucoma or its treatment For example, do you experience a dry mouth or a bitter after taste, fa shortness of breath or difficulties with sexual functioning?	tigue,
No No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	
^ Glaucoma Profile Index, GPI Burr JM, Kilonzo M, Vale L, Ryan M. Developing a Preference based Glaucoma Utility Inde a Discrete Choice Experiment. <i>Optom Vis Sci. 2007 Aug; 84(8):797-808</i>	x using
Do you think your glaucoma is getting worse?  Yes	
(Somner, 2012- IOVS)	
Date you filled in this questionnaire DD / M M / Y Y Y	
Have you asked for any help to fill this questionnaire today?	
No	

#### **THANK YOU**

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful in helping us carry out our research into treatments for Glaucoma.

It will be treated with the strictest confidence and kept securely.

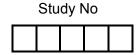
#### Thank you again for your help.

If you would like any further information or have any queries about the study, please contact:

TAGS Study Office
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
UK

Telephone: 01224 438196
Email: tags@abdn.ac.uk
Website: www.tagsstudy.co.uk

The questionnaires are processed in Aberdeen at the Centre for Health Care Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD, UK.





# **TAGS**

### Treatment of Advanced Glaucoma Study

A multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma

### **PARTICIPANT QUESTIONNAIRE**

Thank you for helping us with our research. We would be very grateful if you could complete this questionnaire.

#### CONFIDENTIAL

1 MONTH

ISRCTN - 56878850

Version 1.3 19 June 2015

TAGS is funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (12/35/38).



The following questionnaire is broken down into three sections (Section A - Section C as detailed below). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

If you have any difficulties reading the text or understanding the meaning of any questions, then please ask a TAGS member of staff or contact the central office in Aberdeen.

The sections covered in this questionnaire are as follows:

**Section A:** Describing your own health today

Section B: Health Utility Index

**Section C:** Describing your experience of Glaucoma

## PLEASE TICK THE APPROPRIATE BOXES. Please remember that the answers from all TAGS questionnaires are strictly confidential.

Please try to complete all the questions. Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

#### **INSTRUCTIONS:**

- 1. In general we would like to have people try to complete these forms on their own. If you find that you need assistance, please feel free to ask the project staff and they will assist you.
- 2. Please answer every question (unless you are asked to skip questions because they don't apply to you).
- 3. Answer the questions by circling the appropriate number.
- 4. If you are unsure of how to answer a question, please give the best answer you can and make a comment in the left margin.
- 5. If you have any questions, please feel free to ask a member of the project staff, and they will be glad to help you.

#### STATEMENT OF CONFIDENTIALITY:

All information that would permit identification of any person who completed this questionnaire will be regarded as strictly confidential. Such information will be used only for the purposes of this study and will not be disclosed or released for any other purposes without prior consent, except as required by law.

© R 1996

#### SECTION A - DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

The first section of the questionnaire is about your general health today.

By placing a tick ( $\checkmark$ ) in one box in each group below, please indicate which statements best describe your own health state today.

MOBILITY	
I have no problems in walking about	
I have slight problems in walking about	
I have moderate problems in walking about	
I have severe problems in walking about	
I am unable to walk about	
SELF-CARE	
I have no problems washing or dressing myself	
I have slight problems washing or dressing myself	
I have moderate problems washing or dressing myself	
I have severe problems washing or dressing myself	
I am unable to wash or dress myself	
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	
I have slight problems doing my usual activities	
I have moderate problems doing my usual activities	
I have severe problems doing my usual activities	
I am unable to do my usual activities	
PAIN / DISCOMFORT	
I have no pain or discomfort	
I have slight pain or discomfort	
I have moderate pain or discomfort	
I have severe pain or discomfort	
I have extreme pain or discomfort	
ANXIETY / DEPRESSION	
I am not anxious or depressed	
I am slightly anxious or depressed	
I am moderately anxious or depressed	
I am severely anxious or depressed	
I am extremely anxious or depressed	

The best health you can imagine

- We would like to know how good or bad your health is TODAY.
  This scale is numbered from 0 to 100.
  100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =	

The worst health you can imagine

This set of questions asks about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, <u>during the past week</u>. Please select <u>one</u> answer that <u>best describes</u> your level of ability or disability <u>during the past week</u>. Please indicate the selected answer by <u>circling</u> the number (e.g. 1, 2, 3, etc.) beside the answer.

#### Vision:

- Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, without glasses or contact lenses.
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- Able to read ordinary newsprint with or without glasses but unable to recognize a friend on the other side of the street, even with glasses.
- Able to recognize a friend on the other side of the street with or without glasses but unable to read ordinary newsprint, even with glasses.
- 5 Unable to read ordinary newsprint and unable to recognize a friend on the other side of the street, even with glasses.
- 6 Unable to see at all.

#### Hearing:

- Able to hear what is said in a group conversation with at least three other people, without a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but requires a hearing aid to hear what is said in a group conversation with at least three other people.
- Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people, with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, without a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, with a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- 6 Unable to hear at all.

#### Speech:

- 1 Able to be understood completely when speaking with strangers or friends.
- Able to be understood partially when speaking with strangers but able to be understood completely when speaking with people who know me well.
- Able to be understood partially when speaking with strangers or people who know me well.
- 4 Unable to be understood when speaking with strangers but able to be understood partially by people who know me well.
- 5 Unable to be understood when speaking to other people (or unable to speak at all).

#### **Ambulation:**

- 1 Able to walk around the neighbourhood without difficulty, and without walking equipment
- Able to walk around the neighbourhood with difficulty; but does not require walking equipment or the help of another person.
- Able to walk around the neighbourhood with walking equipment, but without the help of another person
- Able to walk only short distances with walking equipment, and requires a wheelchair to get around the neighbourhood.
- 5 Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood.
- 6 Cannot walk at all.

#### **Dexterity:**

- 1 Full use of two hands and ten fingers.
- 2 Limitations in the use of hands or fingers, but does not require special tools or help of another person.
- Limitations in the use of hands or fingers, is independent with use of special tools (does not require the help of another person).
- 4 Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with use of special tools).
- 5 Limitations in use of hands or fingers, requires the help of another person for most tasks (not independent even with use of special tools).
- 6 Limitations in use of hands or fingers, requires the help of another person for all tasks (not independent even with use of special tools).

**Emotion:** 1 Happy and interested in life.

2 Somewhat happy.

3 Somewhat unhappy.

4 Very unhappy.

5 So unhappy that life is not worthwhile.

#### Cognition:

- 1 Able to remember most things, think clearly and solve day to day problems.
- Able to remember most things, but have a little difficulty when trying to think and solve day to day problems.
- 3 Somewhat forgetful, but able to think clearly and solve day to day problems.
- 4 Somewhat forgetful, and have a little difficulty when trying to think or solve day to day problems.
- Very forgetful, and have great difficulty when trying to think or solve day to day problems.
- 6 Unable to remember anything at all, and unable to think or solve day to day problems.

#### Pain:

- 1 Free of pain and discomfort.
- 2 Mild to moderate pain that prevents no activities.
- 3 Moderate pain that prevents a few activities.
- 4 Moderate to severe pain that prevents some activities.
- 5 Severe pain that prevents most activities.

<sup>©</sup> Health Utilities Inc. (HUInc), 1998.

#### SECTION C - DESCRIBING YOUR EXPERIENCE OF GLAUCOMA^

In this section of the questionnaire we are interested in the importance you place on the different characteristics of glaucoma and its treatment effects.

Some of these statements may seem similar to earlier questions in the booklet. However, they are an important measurement tool for valuing how glaucoma and its treatment affect you.

Please tick one box (✓), for each of the **categories 1-6**, which best describes any difficulties you have had in the **last month** with yourself, or your eyes or vision. **Remember,** if you wear glasses or contact lenses please answer all of the following questions as though you were wearing them.

As a guide about what is meant by the questions please look at the booklet 'Guide to the Questionnaire Sections'.

#### C1: Central and near vision

For example, do you have any difficulties with reading, writing, watching TV, sewing, card games, computer work, reading dials on cookers on clocks or any activities similar to these?

No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	

#### C2: Lighting and glare

For example, do you have any difficulties adjusting from light to dark and viceversa), dazzle from bright lights, or difficulties seeing in dim light?

No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	

#### C3: Mobility

For example, **because of your eyesight,** do you have any difficulties crossing roads, walking along busy pavements, negotiating steps and kerbs, tripping over low objects (for example children in pushchairs or dogs) or difficulties driving (or stopping driving) because of your vision?

No		
Some difficulty		
Quite a lot of difficulty		
Severe difficulty		

C4: Activities of daily living For example, because of your eyesight, do you have any difficulties with domestic, DIY or self-care tasks around the home? This category includes difficulties pouring liquid into containers (e.g. water into a glass), problems judging shelf height leading to difficulties putting objects into or retrieving them from cupboards, being unaware of open cupboard doors and similar problems.				
No No				
Some difficulty				
Quite a lot of difficulty				
Severe difficulty				
C5: Eye discomfort  For example, have any difficulties because of one or both eyes feeling gritty or tired?	, sore,			
No No				
Some difficulty				
Quite a lot of difficulty				
Severe difficulty				
Severe difficulty				
C6: Other possible effects of glaucoma or its treatment  For example, do you experience a dry mouth or a bitter after taste, fa shortness of breath or difficulties with sexual functioning?	atigue,			
No No				
Some difficulty				
Quite a lot of difficulty				
Severe difficulty				
^ Glaucoma Profile Index, GPI Burr JM, Kilonzo M, Vale L, Ryan M. Developing a Preference based Glaucoma Utility Ind a Discrete Choice Experiment. <i>Optom Vis Sci. 2007 Aug; 84(8):797-808</i>	ex using			
Do you think your glaucoma is getting worse?  Yes				
(Somner, 2012- IOVS)				
No _				
Date you filled in this questionnaire  D    M   M   / Y   Y   Y	Y			
Have you asked for any help to fill this questionnaire today?				
No				

#### **THANK YOU**

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful in helping us carry out our research into treatments for Glaucoma.

It will be treated with the strictest confidence and kept securely.

#### Thank you again for your help

If you would like any further information or have any queries about the study, please contact:

TAGS Study Office
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
UK

Telephone: 01224 438196 Email: tags@abdn.ac.uk Website: www.tagsstudy.co.uk

The questionnaires are processed in Aberdeen at the Centre for Health Care Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD, UK.

Study No					



# **TAGS**

### Treatment of Advanced Glaucoma Study

A multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma.

### **PARTICIPANT QUESTIONNAIRE**

Thank you for helping us with our research. We would be very grateful if you could complete this questionnaire.

#### CONFIDENTIAL

PRE-TRABECULECTOMY

ISRCTN - 56878850

Version 1.3 19 June 2015

TAGS is funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (12/35/38).



The following questionnaire is broken down into three sections (Section A - Section C as detailed below). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

If you have any difficulties reading the text or understanding the meaning of any questions, then please ask a TAGS member of staff or contact the central office in Aberdeen.

The sections covered in this questionnaire are as follows:

**Section A:** Describing your own health today

Section B: Health Utility Index

**Section C:** Describing your experience of Glaucoma

# PLEASE TICK THE APPROPRIATE BOXES. Please remember that the answers from all TAGS questionnaires are strictly confidential.

Please try to complete all the questions. Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

#### **INSTRUCTIONS:**

- 1. In general we would like to have people try to complete these forms on their own. If you find that you need assistance, please feel free to ask the project staff and they will assist you.
- 2. Please answer every question (unless you are asked to skip questions because they don't apply to you).
- 3. Answer the questions by circling the appropriate number.
- 4. If you are unsure of how to answer a question, please give the best answer you can and make a comment in the left margin.
- 5. If you have any questions, please feel free to ask a member of the project staff, and they will be glad to help you.

#### STATEMENT OF CONFIDENTIALITY:

All information that would permit identification of any person who completed this questionnaire will be regarded as strictly confidential. Such information will be used only for the purposes of this study and will not be disclosed or released for any other purposes without prior consent, except as required by law.

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# SECTION A - DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

The first section of the questionnaire is about your general health today.

By placing a tick ( $\checkmark$ ) in one box in each group below, please indicate which statements best describe your own health state today.

MOBILITY	
I have no problems in walking about	
I have slight problems in walking about	
I have moderate problems in walking about	
I have severe problems in walking about	
I am unable to walk about	
SELF-CARE	
I have no problems washing or dressing myself	
I have slight problems washing or dressing myself	
I have moderate problems washing or dressing myself	
I have severe problems washing or dressing myself	
I am unable to wash or dress myself	
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	
I have slight problems doing my usual activities	
I have moderate problems doing my usual activities	
I have severe problems doing my usual activities	
I am unable to do my usual activities	
PAIN / DISCOMFORT	
I have no pain or discomfort	
I have slight pain or discomfort	
I have moderate pain or discomfort	
I have severe pain or discomfort	
I have extreme pain or discomfort	
ANXIETY / DEPRESSION	
I am not anxious or depressed	
I am slightly anxious or depressed	
I am moderately anxious or depressed	
I am severely anxious or depressed	
I am extremely anxious or depressed	

The best health you can imagine

We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The worst health you can imagine

This set of questions asks about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, <u>during the past week</u>. Please select <u>one</u> answer that <u>best describes</u> your level of ability or disability <u>during the past week</u>. Please indicate the selected answer by <u>circling</u> the number (e.g. 1, 2, 3, etc.) beside the answer.

#### Vision:

- Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, without glasses or contact lenses.
- Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, but with glasses.
- Able to read ordinary newsprint with or without glasses but unable to recognize a friend on the other side of the street, even with glasses.
- Able to recognize a friend on the other side of the street with or without glasses but unable to read ordinary newsprint, even with glasses.
- 5 Unable to read ordinary newsprint and unable to recognize a friend on the other side of the street, even with glasses.
- 6 Unable to see at all.

### Hearing:

- Able to hear what is said in a group conversation with at least three other people, without a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but requires a hearing aid to hear what is said in a group conversation with at least three other people.
- Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people, with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, without a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, with a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- 6 Unable to hear at all.

## Speech:

- 1 Able to be understood completely when speaking with strangers or friends.
- Able to be understood partially when speaking with strangers but able to be understood completely when speaking with people who know me well.
- Able to be understood partially when speaking with strangers or people who know me well.
- 4 Unable to be understood when speaking with strangers but able to be understood partially by people who know me well.
- 5 Unable to be understood when speaking to other people (or unable to speak at all).

## **Ambulation:**

- 1 Able to walk around the neighbourhood without difficulty, and without walking equipment
- Able to walk around the neighbourhood with difficulty; but does not require walking equipment or the help of another person.
- Able to walk around the neighbourhood with walking equipment, but without the help of another person
- Able to walk only short distances with walking equipment, and requires a wheelchair to get around the neighbourhood.
- 5 Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood.
- 6 Cannot walk at all.

## **Dexterity:**

- 1 Full use of two hands and ten fingers.
- 2 Limitations in the use of hands or fingers, but does not require special tools or help of another person.
- Limitations in the use of hands or fingers, is independent with use of special tools (does not require the help of another person).
- 4 Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with use of special tools).
- 5 Limitations in use of hands or fingers, requires the help of another person for most tasks (not independent even with use of special tools).
- 6 Limitations in use of hands or fingers, requires the help of another person for all tasks (not independent even with use of special tools).

**Emotion:** 1 Happy and interested in life.

2 Somewhat happy.

3 Somewhat unhappy.

4 Very unhappy.

5 So unhappy that life is not worthwhile.

## Cognition:

- 1 Able to remember most things, think clearly and solve day to day problems.
- Able to remember most things, but have a little difficulty when trying to think and solve day to day problems.
- 3 Somewhat forgetful, but able to think clearly and solve day to day problems.
- 4 Somewhat forgetful, and have a little difficulty when trying to think or solve day to day problems.
- Very forgetful, and have great difficulty when trying to think or solve day to day problems.
- 6 Unable to remember anything at all, and unable to think or solve day to day problems.

#### Pain:

- 1 Free of pain and discomfort.
- 2 Mild to moderate pain that prevents no activities.
- 3 Moderate pain that prevents a few activities.
- 4 Moderate to severe pain that prevents some activities.
- 5 Severe pain that prevents most activities.

<sup>©</sup> Health Utilities Inc. (HUInc), 1998.

## SECTION C - DESCRIBING YOUR EXPERIENCE OF GLAUCOMA^

In this section of the questionnaire we are interested in the importance you place on the different characteristics of glaucoma and its treatment effects.

Some of these statements may seem similar to earlier questions in the booklet. However, they are an important measurement tool for valuing how glaucoma and its treatment affect you.

Please tick one box ( $\checkmark$ ), for each of the **categories 1-6**, which best describes any difficulties you have had in the **last month** with yourself, or your eyes or vision. **Remember**, if you wear glasses or contact lenses please answer all of the following questions as though you were wearing them.

As a guide about what is meant by the questions please look at the booklet 'Guide to the Questionnaire Sections'.

### C1: Central and near vision

For example, do you have any difficulties with reading, writing, watching TV, sewing, card games, computer work, reading dials on cookers on clocks or any activities similar to these?

No
Some difficulty
Quite a lot of difficulty
Severe difficulty

### C2: Lighting and glare

For example, do you have any difficulties adjusting from light to dark and viceversa), dazzle from bright lights, or difficulties seeing in dim light?

No
Some difficulty
Quite a lot of difficulty
Severe difficulty

## C3: Mobility

For example, **because of your eyesight,** do you have any difficulties crossing roads, walking along busy pavements, negotiating steps and kerbs, tripping over low objects (for example children in pushchairs or dogs) or difficulties driving (or stopping driving) because of your vision?

No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	

C4: Activities of daily living  For example, because of your eyesight, do you have any difficulties domestic, DIY or self-care tasks around the home? This category includifficulties pouring liquid into containers (e.g. water into a glass), problems just shelf height leading to difficulties putting objects into or retrieving them cupboards, being unaware of open cupboard doors and similar problems.	udes Iging
No No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	
C5: Eye discomfort For example, have any difficulties because of one or both eyes feeling gritty, or tired?	sore,
No No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	
<b>C6: Other possible effects of glaucoma or its treatment</b> For example, do you experience a dry mouth or a bitter after taste, fatishortness of breath or difficulties with sexual functioning?	gue,
No No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	
^ Glaucoma Profile Index, GPI Burr JM, Kilonzo M, Vale L, Ryan M. Developing a Preference based Glaucoma Utility Index a Discrete Choice Experiment. <i>Optom Vis Sci. 2007 Aug; 84(8):797-808</i>	using
Do you think your glaucoma is getting worse?  Yes	
(Somner, 2012- IOVS)	
Date you filled in this questionnaire DD / M M / Y Y Y	
Have you asked for any help to fill this questionnaire today?	
No	

## **THANK YOU**

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful in helping us carry out our research into treatments for Glaucoma.

It will be treated with the strictest confidence and kept securely.

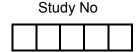
## Thank you again for your help

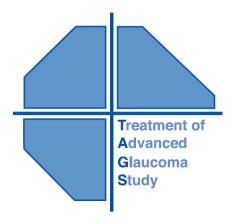
If you would like any further information or have any queries about the study, please contact:

TAGS Study Office
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
UK

Telephone: 01224 438196 Email: tags@abdn.ac.uk Website: www.tagsstudy.co.uk

The questionnaires are processed in Aberdeen at the Centre for Health Care Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD, UK.





# **TAGS**

# <u>Treatment of Advanced Glaucoma Study</u>

A multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma.

# PARTICIPANT QUESTIONNAIRE

Thank you for helping us with our research. We would be very grateful if you could complete this questionnaire.

# **CONFIDENTIAL**

4 MONTH

ISRCTN - 56878850

Version 1.2 19 June 2015

TAGS is funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (12/35/38).



The following questionnaire is broken down into two sections (Section A and Section B as detailed below). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

If you have any difficulties reading the text or understanding the meaning of any questions, then please ask a TAGS member of staff or contact the central office in Aberdeen.

The sections covered in this questionnaire are as follows:

**Section A:** Visual Functioning Questionnaire (split into 3 parts):

Part 1 - General Health and Vision

Part 2 - Difficulty with activities

Part 3 - Response to vision problems

Section B: Health Care Utilisation

Please try to complete all the questions. Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

## SECTION A - VISUAL FUNCTIONING QUESTIONNAIRE (NEI-VFQ-25)

The following section is a survey with statements about problems, which involve your vision, or feelings that you have about your eye condition. After each question please choose the response that best describes your situation. Please take as much time as you need to answer each question. All your answers are confidential. In order for this survey to improve our knowledge about eye problems and how they affect your quality of life, your answers must be as accurate as possible. Remember, if you wear glasses or contact lenses, please answer all of the following questions as though you were wearing them.

### **INSTRUCTIONS:**

- 1. In general we would like to have people try to complete these forms on their own. If you find that you need assistance, please feel free to ask the project staff and they will assist you.
- 2. Please answer every question (unless you are asked to skip questions because they don't apply to you).
- 3. Answer the questions by circling the appropriate number.
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## SECTION A - PART 1 GENERAL HEALTH AND VISION (NEI-VFQ-25)

A1:	In	general,	would you	say your	overall	health is:
-----	----	----------	-----------	----------	---------	------------

	(Circle One)
Excellent	1
Very Good	2
Good	3
Fair	4
Poor	5

A2: At the present time, would you say your eyesight using both eyes (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor or are you completely blind?

	(Circle One)
Excellent	1
Good	2
Fair	3
Poor	4
Very Poor	5
Completely Blind	6

A3: How much of the time do you worry about your eyesight?

year eyee.g	(Circle One)
None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

A4: How much pain or discomfort have you had in and around your eyes (for example, burning, itching, or aching)? Would you say it is:

	(Circle One)
None	1
Mild	2
Moderate	3
Severe, or	4
Very severe	5

## **SECTION A - PART 2 DIFFICULTY WITH ACTIVITIES**

The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses if you use them for that activity.

A5:	How much difficulty do you have reading ordinary print in newspapers?
	Would you say you have:

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A6: How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say:

No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

(Circle One)

# A7: Because of your eyesight, how much difficulty do you have finding something on a crowded shelf? (Circle One)

No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A8: How much difficulty do you have reading street signs or the names of stores? (Circle One)

No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A9: Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night? (Circle One)

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A10: Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A11: Because of your eyesight, how much difficulty do you have seeing how people react to things you say?

3.3	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A12: Because of your eyesight, how much difficulty do you have picking out and matching your own clothes?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A13: Because of your eyesight, how much difficulty do you have visiting with people in their homes, at parties, or in restaurants?

• •	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A14: Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events?

, , , , ,	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

## A15: Are you currently driving, at least once in a while?

(Circle One)

Yes 1 Skip To Question A15c (page 6)

No 2 Go to Question 15a

## A15a: If NO: Have you never driven a car or have you given up driving?

(Circle One)

Never drove 1 Skip To Section A, Part 3, Question A17 (page 7)

Gave up 2 Go to Question 15b

# A15b: IF YOU GAVE UP DRIVING: Was that mainly because of your eyesight, mainly for some other reason, or because of both your eyesight and other reasons?

(Circle One)

Mainly eyesight	1	Skip To Section A, Part 3, Question A17 (page 7)
Mainly other reasons	2	Skip To Section A, Part 3, Question A17 (page 7)
Both eyesight and	3	Skip To Section A, Part 3, Question A17 (page 7)
other reasons		

# A15c: IF CURRENTLY DRIVING: How much difficulty do you have driving during the daytime in familiar places? Would you say you have:

and anything in the second process are any year mane.	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4

# A16: How much difficulty do you have driving at night? Would you say you have:

(Circie One)
1
2
3
4
5
6

# A16a: How much difficulty do you have driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic? Would you say you have: (Circle One)

	(
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

## SECTION A PART 3 – RESPONSES TO VISION PROBLEMS

The next questions are about how things you do may be affected by your vision. For each one, please circle the number to indicate whether for you the statement is true for you <u>all</u>, <u>most</u>, <u>some</u>, <u>a little</u>, or <u>none</u> of the time.

(Circle One On Each Line)

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
A17:	Do you accomplish less than you would like because of your vision?	1	2	3	4	5
A18:	Are you limited in how long you can work or do other activities because of your vision?	1	2	3	4	5
A19:	How much does pain or discomfort in or around your eyes, for example, burning, itching, or aching, keep you from doing what you'd like to be doing? Would you say:	1	2	3	4	5

For each of the following statements, please circle the number to indicate whether for you the statement is definitely <u>true</u>, <u>mostly true</u>, <u>mostly false</u>, or <u>definitely false</u> for you or you are <u>not sure</u>.

(Circle One On Each Line)

		Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
A20:	I stay home most of the time because of my eyesight.	1	2	3	4	5
A21:	I feel frustrated a lot of the time because of my eyesight.	1	2	3	4	5
A22:	I have much less control over what I do, because of my eyesight.	1	2	3	4	5
A23:	Because of my eyesight, I have to rely too much on what other people tell me.	1	2	3	4	5
A24:	I need a lot of help from others because of my eyesight.	1	2	3	4	5
A25:	I worry about doing things that will embarrass myself or others, because of my eyesight.	1	2	3	4	5

# SECTION B – HEALTH CARE UTILISATION

Please print carefully within the boxes like this 2 7 or li	ke this	✓
B1: Have you been to see a GP because of your eyes during the last a months?	4 Yes	
	No	
If Yes, please give details:		
B2: How many appointments did you attend with a GP? (at GP surger	ry)	
P2: How many times did a CD visit you at home?		
B3: How many times did a GP visit you at home?		
B4: How many times did you have a telephone conversation with a G	P?	
B5: Have you had any appointments with a community	Yes	
	Go to B6)	
	No	
(Sk	tip to B7)	
B6: How many appointments with a community optician or optometri	st	
did you attend?		
B7: During the last 4 months have you had new spectacles or contact lenses?	t Yes	
	No	
	INU	
B7a: If Yes (to B7 above), how much did you pay?	£	
brain res (to br above), now much did you pay!	~	

This next question is about any appointments you may have had with <u>other health care</u> workers in the past 4 months

# B8: During the last 4 months have you had an appointment with: A District Nurse? If Yes, how many appointments did you have? Yes No A Practice Nurse? If Yes, how many appointments did you have? Yes No Other? Please specify Yes No How many appointments did you have? How many appointments did you have? This set of questions is about any private health care you may have had in the past 4 months B9: During the last 4 months have you paid for any private health care? If Yes please go to B9a, then B9b (below) if no please skip to B10 No B9a: If Yes, what sort of care did you pay for? B9b: If Yes, how much did it cost? B10: During the last 4 months have you had Yes If Yes; how many days? any days off work or your usual activities

No

because of your eyes?

B11: During the last 4 months, have you utilised any information or services related to your sensory impairment?	Yes No
e.g. Low Vision Clinic,	
Services offered by the Royal National Institute of Blind People, etc.	
If another, could you please specify in the space provided:	
B12: Are you currently in receipt of any form of travel allowance/concession as a result of your sensory impairment?	Yes No
e.g. Disabled person's railcard Dial-a-ride	
Companion's permit	
If another, could you please specify in the space provided:	
B13: Are you currently in receipt of any welfare benefits as a	Yes
result of your sensory impairment?	No
e.g. Disability living allowance Incapacity benefit	
Carer's allowance	
If another, could you please specify in the space provided:	

Date you filled in this questionnaire	D	D	1	M	M	1	Y	Y	Y	Y	
Have you asked for any help to fill this	s que	estio	nn	aire	toda	у?	•	,	Yes		
									No		

# **THANK YOU**

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful in helping us carry out our research into treatments for Glaucoma.

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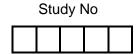
## Thank you again for your help

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Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
UK

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# **TAGS**

# Treatment of Advanced Glaucoma Study

A multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma.

# **PARTICIPANT QUESTIONNAIRE**

Thank you for helping us with our research. We would be very grateful if you could complete this questionnaire.

# **CONFIDENTIAL**

12 MONTHS



The following questionnaire is broken down into four sections (Section A - Section D as detailed below). Please work through all the sections as best you can from start to finish.

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The sections covered in this questionnaire are as follows:

**Section A:** Visual Functioning Questionnaire (split into 3 parts)

Part 1 - General Health and Vision

Part 2 - Difficulty with activities

Part 3 - Response to vision problems

**Section B:** Describing your own health today

**Section C:** Health Utility Index

**Section D:** Describing your experience of Glaucoma

Section E: Health Care Utilisation

Please try to complete all the questions. Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

## SECTION A - VISUAL FUNCTIONING QUESTIONNAIRE (NEI-VFQ-25)

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# SECTION A – PART 1 GENERAL HEALTH AND VISION (NEI-VFQ-25)

A1:	In general	, would v	vou sav	vour c	overall	health	is:
-----	------------	-----------	---------	--------	---------	--------	-----

	(Circle One
Excellent	1
Very Good	2
Good	3
Fair	4
Poor	5

A2: At the present time, would you say your eyesight using both eyes (with glasses or contact lenses, if you wear them) is excellent, good, fair, poor, or very poor or are you completely blind?

	(Circle One)
Excellent	1
Good	2
Fair	3
Poor	4
Very Poor	5
Completely Blind	6

A3: How much of the time do you worry about your eyesight?

	(Circle One)
None of the time	1
A little of the time	2
Some of the time	3
Most of the time	4
All of the time	5

A4: How much pain or discomfort have you had in and around your eyes (for example, burning, itching, or aching)? Would you say it is:

	(Circle One,
None	1
Mild	2
Moderate	3
Severe, or	4
Very severe	5

## **SECTION A - PART 2 DIFFICULTY WITH ACTIVITIES**

The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses if you use them for that activity.

A5:	How much difficulty do you have reading ordinary print in newspapers?	•
	Would you say you have:	

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A6: How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say: (Circle One)

No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A7: Because of your eyesight, how much difficulty do you have finding something on a crowded shelf?

•		
No difficulty at all	1	
A little difficulty	2	
Moderate difficulty	3	
Extreme difficulty	4	
Stopped doing this because of your eyesight	5	
Stopped doing this for other reasons or not interested in doing this	6	

(Circle One)

# A8: How much difficulty do you have reading street signs or the names of stores? (Circle One)

No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	

# A9: Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A10: Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A11: Because of your eyesight, how much difficulty do you have seeing how people react to things you say?

3. 3	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A12: Because of your eyesight, how much difficulty do you have picking out and matching your own clothes?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A13: Because of your eyesight, how much difficulty do you have visiting with people in their homes, at parties, or in restaurants?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A14: Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

## A15: Are you currently driving, at least once in a while?

(Circle One)

Yes	1	Skip To Question A15c (page 7)
No	2	Go to Question A15a

## A15a: If NO: Have you never driven a car or have you given up driving?

(Circle One)

Never drove 1 Skip To Section A, Part 3, Question A17 (page 8)
Gave up 2 Go to Question A15b

# A15b: IF YOU GAVE UP DRIVING: Was that mainly because of your eyesight, mainly for some other reason, or because of both your eyesight and other reasons?

(Circle One)

Mainly eyesight	1	Skip To Section A, Part 3, Question A17 (page 8)
Mainly other reasons	2	Skip To Section A, Part 3, Question A17 (page 8)
Both eyesight and	3	Skip To Section A, Part 3, Question A17 (page 8)
other reasons		

# A15c: IF CURRENTLY DRIVING: How much difficulty do you have driving during the daytime in familiar places? Would you say you have:

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4

# A16: How much difficulty do you have driving at night? Would you say you have:

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	s 6

# A16a: How much difficulty do you have driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic? Would you say you have:

you cay you mate.	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

## SECTION A PART 3 - RESPONSES TO VISION PROBLEMS

The next questions are about how things you do may be affected by your vision. For each one, please circle the number to indicate whether for you the statement is true for you all, most, some, a little, or none of the time.

(Circle One On Each Line)

		All of the time		Some of the time	A little of the time	None of the time
A17:	Do you accomplish less than you would like because of your vision?	1	2	3	4	5
A18:	Are you limited in how long you can work or do other activities because of your vision?	1	2	3	4	5
A19:	How much does pain or discomfort in or around your eyes, for example, burning, itching, or aching, keep you from doing what you'd like to be doing? Would you say:	1	2	3	4	5

For each of the following statements, please circle the number to indicate whether for you the statement is definitely <u>true</u>, <u>mostly true</u>, <u>mostly false</u>, or <u>definitely false</u> for you or you are <u>not sure</u>.

(Circle One On Each Line)

		Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
A20:	I stay home most of the time because of my eyesight.	1	2	3	4	5
A21:	I feel frustrated a lot of the time because of my eyesight.	1	2	3	4	5
A22:	I have much less control over what I do, because of my eyesight.	1	2	3	4	5
A23:	Because of my eyesight, I have to rely too much on what other people tell me.	1	2	3	4	5
A24:	I need a lot of help from others because of my eyesight.	1	2	3	4	5
A25:	I worry about doing things that will embarrass myself or others, because of my eyesight.	1	2	3	4	5

# SECTION B – DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

The first section of the questionnaire is about your general health today.

By placing a **tick** ( $\checkmark$ ) in one box in each group below, please indicate which statements best describe your own health state **today**.

MOBILITY	
I have no problems in walking about	
I have slight problems in walking about	
I have moderate problems in walking about	
I have severe problems in walking about	
I am unable to walk about	
SELF-CARE	
I have no problems washing or dressing myself	
I have slight problems washing or dressing myself	
I have moderate problems washing or dressing myself	
I have severe problems washing or dressing myself	
I am unable to wash or dress myself	
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	
I have slight problems doing my usual activities	
I have moderate problems doing my usual activities	
I have severe problems doing my usual activities	
I am unable to do my usual activities	
PAIN / DISCOMFORT	
I have no pain or discomfort	
I have slight pain or discomfort	
I have moderate pain or discomfort	
I have severe pain or discomfort	
I have extreme pain or discomfort	
ANXIETY / DEPRESSION	
I am not anxious or depressed	
I am slightly anxious or depressed	
I am moderately anxious or depressed	
I am severely anxious or depressed	
I am extremely anxious or depressed	

The best health you can imagine

The worst health you can imagine

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =	

## SECTION C – HEALTH UTILITY INDEX QUESTIONNAIRE (HUI3)

This set of questions asks about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, <u>during the past week</u>. Please select <u>one</u> answer that <u>best describes</u> your level of ability or disability <u>during the past week</u>. Please indicate the selected answer by <u>circling</u> the number (e.g. 1, 2, 3, etc.) beside the answer.

#### Vision:

- 1 Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, without glasses or contact lenses.
- Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, but with glasses.
- Able to read ordinary newsprint with or without glasses but unable to recognize a friend on the other side of the street, even with glasses.
- Able to recognize a friend on the other side of the street with or without glasses but unable to read ordinary newsprint, even with glasses.
- 5 Unable to read ordinary newsprint and unable to recognize a friend on the other side of the street, even with glasses.
- 6 Unable to see at all.

### Hearing:

- Able to hear what is said in a group conversation with at least three other people, without a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but requires a hearing aid to hear what is said in a group conversation with at least three other people.
- Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people, with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, without a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, with a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- 6 Unable to hear at all.

## Speech:

- 1 Able to be understood completely when speaking with strangers or friends.
- Able to be understood partially when speaking with strangers but able to be understood completely when speaking with people who know me well.
- Able to be understood partially when speaking with strangers or people who know me well.
- 4 Unable to be understood when speaking with strangers but able to be understood partially by people who know me well.
- 5 Unable to be understood when speaking to other people (or unable to speak at all).

## Ambulation:

- 1 Able to walk around the neighbourhood without difficulty, and without walking equipment
- Able to walk around the neighbourhood with difficulty; but does not require walking equipment or the help of another person.
- Able to walk around the neighbourhood with walking equipment, but without the help of another person
- Able to walk only short distances with walking equipment, and requires a wheelchair to get around the neighbourhood.
- 5 Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood.
- 6 Cannot walk at all.

#### **Dexterity:**

- 1 Full use of two hands and ten fingers.
- 2 Limitations in the use of hands or fingers, but does not require special tools or help of another person.
- 3 Limitations in the use of hands or fingers, is independent with use of special tools (does not require the help of another person).
- 4 Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with use of special tools).
- 5 Limitations in use of hands or fingers, requires the help of another person for most tasks (not independent even with use of special tools).
- 6 Limitations in use of hands or fingers, requires the help of another person for all tasks (not independent even with use of special tools).

## **Emotion:** 1 Happy and interested in life.

- 2 Somewhat happy.
- 3 Somewhat unhappy.
- 4 Very unhappy.
- 5 So unhappy that life is not worthwhile.

## Cognition:

- 1 Able to remember most things, think clearly and solve day to day problems.
- Able to remember most things, but have a little difficulty when trying to think and solve day to day problems.
- 3 Somewhat forgetful, but able to think clearly and solve day to day problems.
- 4 Somewhat forgetful, and have a little difficulty when trying to think or solve day to day problems.
- Very forgetful, and have great difficulty when trying to think or solve day to day problems.
- 6 Unable to remember anything at all, and unable to think or solve day to day problems.

#### Pain:

- 1 Free of pain and discomfort.
- 2 Mild to moderate pain that prevents no activities.
- 3 Moderate pain that prevents a few activities.
- 4 Moderate to severe pain that prevents some activities.
- 5 Severe pain that prevents most activities.

<sup>©</sup> Health Utilities Inc. (HUInc), 1998.

### SECTION D - DESCRIBING YOUR EXPERIENCE OF GLAUCOMA^

In this section of the questionnaire we are interested in the importance you place on the different characteristics of glaucoma and its treatment effects.

Some of these statements may seem similar to earlier questions in the booklet. However, they are an important measurement tool for valuing how glaucoma and its treatment affect you.

Please tick one box ( $\checkmark$ ), for each of the **categories D1-D6**, which best describes any difficulties you have had in the **last month** with yourself, or your eyes or vision. **Remember**, if you wear glasses or contact lenses please answer all of the following questions as though you were wearing them.

As a guide about what is meant by the questions please look at the booklet 'Guide to the Questionnaire Sections'.

#### D1: Central and near vision

For example, do you have any difficulties with reading, writing, watching TV, sewing, card games, computer work, reading dials on cookers on clocks or any activities similar to these?

No		
Some difficulty		
Quite a lot of difficulty		
Severe difficulty		

#### D2: Lighting and glare

For example, do you have any difficulties adjusting from light to dark and viceversa), dazzle from bright lights, or difficulties seeing in dim light?

No		
Some difficulty		
Quite a lot of difficulty		
Severe difficulty		

	For example, <b>because of your eyesight</b> , do you have any difficulties crossing roads, walking along busy pavements, negotiating steps and kerbs, tripping over low objects (for example children in pushchairs or dogs) or difficulties driving (or stopping driving) because of your vision?
	No No
	Some difficulty
	Quite a lot of difficulty
	Severe difficulty
	. <u></u>
D4:	Activities of daily living For example, because of your eyesight, do you have any difficulties with domestic, DIY or self-care tasks around the home? This category includes difficulties pouring liquid into containers (e.g. water into a glass), problems judging shelf height leading to difficulties putting objects into or retrieving them from cupboards, being unaware of open cupboard doors and similar problems.
	No No
	Some difficulty
	Quite a lot of difficulty
	Severe difficulty
D5:	Eye discomfort For example, have any difficulties because of one or both eyes feeling gritty, sore, or tired?
	No No
	Some difficulty
	Quite a lot of difficulty
	Severe difficulty
D6:	Other possible effects of glaucoma or its treatment For example, do you experience a dry mouth or a bitter after-taste, fatigue, shortness of breath or difficulties with sexual functioning?
	No
	Some difficulty
	Quite a lot of difficulty
	Severe difficulty

D3: Mobility

<sup>^</sup> Glaucoma Profile Index, GPI Burr JM, Kilonzo M, Vale L, Ryan M. Developing a Preference based Glaucoma Utility Index using a Discrete Choice Experiment. *Optom Vis Sci. 2007 Aug; 84(8):797-808* 

### **SECTION E - HEALTH CARE UTILISATION**

Please print carefully within the boxes like this 2 7 or like	xe this ✓
E1: Have you been to see a GP because of your eyes during the last 8 months?	Yes
	No
If Yes, please give details:	
E2: How many appointments did you attend with a GP? (at GP surgery	y)
E3: How many times did a GP visit you at home?	
E4: How many times did you have a telephone conversation with a GF	9?
E5: Have you had any appointments with a community	Yes
optician or optometrist in the last 8 months? (G	o to E6)
(Ski	No p to E7)
E6: How many appointments with a community optician or optometris did you attend?	st
E7: During the last 8 months have you had new spectacles or contact lenses?	Yes
	No
E7a: If Yes (to E7 above), how much did you pay?	£

This next question is about any appointments you may have had with <u>other health care</u> <u>workers</u> in the past 8 months

### E8: During the last 8 months have you had an appointment with:

A District Nurse?	Yes	If Yes, how	many ap	pointments did you h	nave?	
	No					
A Practice Nurse?	Yes	If Yes, how	many ap	pointments did you h	nave?	
	No					
Other? Please specify	Yes					
	No					
		How many a	appointm	ents did you have?		
		How many a	appointm	ents did you have?		
This set of questions is a months	about any	<u>private</u> health o	care you	may have had in the	past 8	
E9: During the last 8 m	onths ha	ve you <u>paid fo</u>	r any pri	ivate health care?	Yes	
If Yes please go to	E9a, the	n E9b (below)	if no ple	ase skip to E10	No [	
E9a: If Yes, what sort of care did you pay for?						
E9b: If Yes, how much	did it cos	t? £				
E10: During the last 8 any days off work of	or your u		Yes	If Yes; how m	nany day	ys?
because of your ey	es?		No			

E11: During the last 8 months, have you utilised any information or services related to your sensory impairment?	Yes No
e.g. Low Vision Clinic,	
Services offered by the Royal National Institute of Blind People, etc.	
If another, could you please specify in the space provided:	
E12: Are you currently in receipt of any form of travel allowance/concession as a result of your sensory impairment?	Yes No
e.g. Disabled person's railcard Dial-a-ride	
Companion's permit	
If another, could you please specify in the space provided:	
E13: Are you currently in receipt of any welfare benefits as a result of your sensory impairment?	Yes
	No
e.g. Disability living allowance Incapacity benefit	
Carer's allowance	
If another, could you please specify in the space provided:	

Do you think your glaucoma is getting worse?	5
(Somner, 2012- IOVS)	<b>&gt;</b>
Date you filled in this questionnaire DD / MM / Y Y Y	Y
Have you asked for any help to fill this questionnaire today?	<b>S</b>
N	<b>O</b>
THANK YOU	
Thank you very much for your time and patience in filling in this question	naire.
The information you have given us will be extremely useful in helping us car research into treatments for Glaucoma.	ry out oui

It will be treated with the strictest confidence and kept securely.

Thank you again for your help.

If you would like any further information or have any queries about the study, please contact:

TAGS Study Office
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
UK

Telephone: 01224 438196 Email: tags@abdn.ac.uk Website: www.tagsstudy.co.uk

Study Number			



# **TAGS**

Treatment of Advanced Glaucoma Study

### **Travel and time Questionnaire**

We would be very grateful if you could complete this questionnaire.

Thank you very much for helping us with our research.

### **CONFIDENTIAL**

This questionnaire will help us to find out how much it costs you to use health services. We will ask about your most recent admission to hospital, your most recent outpatient appointment, your most recent appointment with a GP and finally, your most recent visit to specialist. We wish to know how much money and time were spent by you and any companion in attending these appointments and as a result of any hospital admission you may have had.

### PART 1 - YOUR MOST RECENT ADMISSION TO HOSPITAL

If, in the last 12 mont and go to <b>Part 2</b> .	hs, you were no	ot admitted to hospita	al, please tick box	
			lled. If you used more than one e <u>main</u> (longest in terms of dista	
Bus	Н	ospital car		
Train	A	mbulance		
Taxi	_	ther blease specify)		
Private car				
	e the cost in the	box below. Please	s the total cost of the (one-way) put zero if you did not travel by t	ous,
Cost of (or	ne-way) fare (£)	per	nce	
	•	_	did you travel one-way? Please of the second if you did not travel by private c	
Number of	miles one-way			
	•		anion had to pay a parking fee elow. Please put zero if you dic	
Expenditure on	parking fee (£)	per	nce	

5. When you went to hospital, how lo hours and minutes in the box below.	ng did it take to travel there? Please write the number of
Number of hours	_ minutes
6. When you were admitted to the ho number of days in the box below.	spital, how long did you spend there? Please write the
Number of days	
7. What would you otherwise have be admitted to hospital? Please tick the	een doing as your <u>main</u> activity if you had not had to be box that best applies to you.
Housework	Paid work
Childcare	.Voluntary work
Caring for a relative or friend	Leisure activities
Unemployed	Other (please specify)
8. When you were admitted to hospit appropriate response.	al, did anyone come with you? Please tick the
	Yes Go to Question 9
	No Go to Part 2
9. Please tick the box(es) that best do hospital. You may tick more than one	escribe the person(s) who accompanied you to the e response if appropriate.
.Partner/spouse	Paid caregiver
Other relative	Other (please specify)
Friend	

they pay (one-way) in fa	ion travelled with you by bus or train approximately how much did res? Please write the approximate cost in the box below. Please put nion did not travel by bus or train at all.
Cost of (one-way	) fare (£) pence
	that best describes what your main companion would otherwise have n activity if they had not gone with you to the hospital.
Housework	Paid work
Childcare	.Voluntary work
Caring for a relative or f	riend Leisure activities
Unemployed	Other (please specify)
-	npanion take time off from paid work (or business activity if self- the appropriate response.
	Yes Go to Question 13
	No Go to Part 2
activity if self-employed	imber of hours your companion took off from paid work (or business) in the box below. Please put zero if your main companion did not work (or business activity if self-employed) to accompany you to the
N	lumber of hours
14. Whilst you were in come to visit you?	hospital, approximately how many times did your main companion
, ,	Number of times

### **PART 2 - YOUR MOST RECENT OUTPATIENT VISIT**

and go to <b>Part 3</b>	ioritris, you did	Thot have all outpatient ap	ppointinent, please tick box	
	se indicate the	-	ed. If you used more than one to main (longest in terms of dista	
Bus		Hospital car		
Train		Ambulance		
Taxi		Other (please specify)		
Private car				
of the (one-way) not travel by bus	journey? Plea	se write the cost in the bo	appointment what was the total of below. Please put zero if you fare.	
the number of mall.	• •	pelow. Please put zero if	d you travel one-way? Please v you did not travel by private car	
	st? Please writ		on had to pay a parking fee how w. Please put zero if you did no	
Expenditure	on parking fee	(£)	pence	

5. When you went to your outpatient appointment, how long did it take to travel there? Please write the number of hours and minutes in the box below.			
Number of hours	_ minutes		
6. When you had your outpatient a the number hours and minutes in t	ppointment, how long did you spend there? Please write he box below.		
Number of hours	_ minutes		
7. Please tick the box that best des main activity if you had not been vi	cribes what you otherwise would have been doing as your siting outpatients?		
Housework	Paid work		
Childcare	.Voluntary work		
Caring for a relative or friend	Leisure activities		
Unemployed	Other (please specify)		
8. When you visited outpatients did	anyone come with you? Please tick the appropriate box.		
Yes	Go to Question 9		
No	Go to Part 3		
9. Please tick the box(es) that best describe the person(s) who accompanied you to outpatients. You may tick more than one response if appropriate.			
.Partner/spouse	Paid caregiver		
Other relative	Other (please specify)		
Friend			

10. If your main companion travelled with you by bus or train approximately how much did

they pay (one-way) in fares? Please values if your main companion did not tra		in the box below. Please put
Cost of (one-way) fare (£)	_ pence	
11. Please tick the box that best descr been doing as their main activity if the	•	
Housework	Paid work	
Childcare	Voluntary work	
Caring for a relative or friend	Leisure activities	
Unemployed	Other (please specify)	
PART 3 - YOUR MOST RECENT GP APPOINTMENT  If, in the last 12 months, you did not have a GP appointment, please tick box and go to Part 4		
Please tick the box that best describe appointment. If you used more than o travelled for the main (longest in terms).	ne form of transport please	e indicate the way you
.Walked	Bus	
Cycled	.Taxi	
Private car	Other (please specify)	
2. If you travelled by bus or taxi, what cost in the box below. Please put zero the fare.	o if you did not travel by bu	• /
Cost of (one-way) fare (£)	_ pence	

• • • • • • • • • • • • • • • • • • • •	ow many miles did you travel one-way? Please write Please put zero if you did not travel by private car at
Number of miles one-way	
• • • • • • • • • • • • • • • • • • • •	u or a companion had to pay a parking fee how much he box below. Please put zero if you did not pay for
Expenditure on parking fee (£)	_ Pence
5. When you visited the GP, how long di minutes in the box below.	d it take to travel there? Please write the number of
Number of minutes	
•	d you spend there? Please write the number le in your answer the time spent waiting and also the
Number of minutes	
7. Please tick the box that best describe main activity if you had not visited the G	s what you otherwise would have been doing as your P.
.Housework	Paid work
Childcare	Voluntary work
Caring for a relative or friend	Leisure activities
Unemployed	Other (please specify)

8. When you visited the GP did anyone come with you? Please tick the appropriate response.			
Yes	Go to Question 9		
No	Go to Part 4		
9. Please tick the box(es) that best desc surgery. You may tick more than one re	. ,	ccompanied you to the GP's	
Partner/spouse	Paid caregiver		
Other relative	Other (please specify)		
Friend			
10. If your main companion travelled with you by bus how much approximately did they pay (one-way) in fares (if anything)? Please write the cost in the box below. Please put zero if your main companion did not travel by bus at all.			
Cost of (one-way) fare (£)	- Pence		
11. Please tick the box that best describes what your main companion would otherwise have been doing as their main activity if they had not gone with you to the GP's surgery.			
.Housework	Paid work		
Childcare	.Voluntary work		
Caring for a relative or friend	Leisure activities		
Unemployed	Other (please specify)		

### PART 4 - YOUR MOST RECENT VISIT TO A COMMUNITY OPTICIAN OR OPTOMETRIST

	se indicate the v		travelled. If you used more than one form or the main (longest in terms of distance)
Bus		Hospital car	
Train		Ambulance	
Taxi		Other (please specify)	
Private car			
the (one-way) jo	urney? Please		an or optometrist what was the total cost of e box below. Please put zero if you did not a fare.
Cost of (on	e-way) fare (£)	-	pence
			es did you travel one-way? Please write the ou did not travel by private car at all.
Numb	er of miles one-	way	
•	st? Please writ		ompanion had to pay a parking fee how ox below. Please put zero if you did not
Expenditure on	parking fee (£)	-	pence
5. When you visi write the number			w long did it take to travel there? Please
	Number of min	utes	

6. When you visited the optician or optometrist how long did you spend there? Please write the number hours and minutes in the box below.			
Number of hours	_ minutes		
7. What would you otherwise have the Specialist? Please tick the box	e been doing as your <u>main</u> activity if you had not had visit that best applies to you.		
Housework	Paid work		
Childcare	Voluntary work		
Caring for a relative or friend	Leisure activities		
Unemployed	Other (please specify)		
8. When you went to the optician of appropriate response.	or optometrist, did anyone come with you? Please tick the		
Y	es Go to <b>Question 9</b>		
ı	No Thank-you for completing this questionnaire		
9. Please tick the box(es) that best describe the person(s) who accompanied you to the optician or optometrist. You may tick more than one response if appropriate.			
.Partner/spouse	Paid caregiver		
Other relative	Other (please specify)		
Friend			

10. If your main companion travelled with you by bus how much approximately did they pay (one-way) in fares (if anything)? Please write the cost in the box below. Please put zero if your main companion did not travel by bus at all.			
Cost of (one-way) fare (£)	- pence		
	ribes what your main companion would otherwise if they had not gone with you to the Specialist.		
Housework	Paid work		
Childcare	Voluntary work		
Caring for a relative or friend	Leisure activities		
Unemployed	Other (please specify)		

### **THANK YOU**

Thank you very much for your time and patience in filling in this questionnaire. Please hand the questionnaire back to the research nurse or return it in the enclosed reply-paid envelope to the Trial Office in Aberdeen.

The information you have given us will be extremely useful in helping us carry out research. It will be treated with the strictest confidence and kept securely.

If you would like any further information or have any queries about the study, please contact:

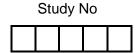
TAGS Office
Centre for Healthcare Randomised Trials
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD

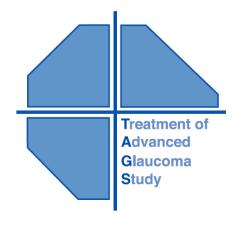
Telephone: 01224 438196

Email: tags@abdn.ac.uk

Website: www.tagsstudy.co.uk

The questionnaires are processed in Aberdeen at the Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, ABERDEEN, AB25 2ZD.





# **TAGS**

### Treatment of Advanced Glaucoma Study

A multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma.

### **PARTICIPANT QUESTIONNAIRE**

Thank you for helping us with our research. We would be very grateful if you could complete this questionnaire.

### CONFIDENTIAL

24 MONTH



The following questionnaire is broken down into five sections (Section A - Section E as detailed below). Please work through all the sections as best you can from start to finish.

Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

If you have any difficulties reading the text or understanding the meaning of any questions, then please ask a TAGS member of staff or contact the central office in Aberdeen.

The sections covered in this questionnaire are as follows:

**Section A:** Visual Functioning Questionnaire (split into 3 parts)

Part 1 - General Health and Vision

Part 2 - Difficulty with activities

Part 3 - Response to vision problems

**Section B:** Describing your own health today

Section C: Health Utility Index

Section D: Describing your experience of Glaucoma

Section E: Health Care Utilisation

Please try to complete all the questions. Some of the sections ask you to indicate your answers to the questions by placing a tick  $(\checkmark)$  in the appropriate box, and other sections ask you to circle your answer out of a list that is provided. Please read the questions carefully and answer each one as accurately as you can.

The following section is a survey with statements about problems, which involve your vision, or feelings that you have about your eye condition. After each question please choose the response that best describes your situation. Please take as much time as you need to answer each question. All your answers are confidential. In order for this survey to improve our knowledge about eye problems and how they affect your quality of life, your answers must be as accurate as possible. Remember, if you wear glasses or contact lenses, please answer all of the following questions as though you were wearing them.

#### **INSTRUCTIONS:**

- 1. In general we would like to have people try to complete these forms on their own. If you find that you need assistance, please feel free to ask the project staff and they will assist you.
- 2. Please answer every question (unless you are asked to skip questions because they don't apply to you).
- 3. Answer the questions by circling the appropriate number.
- 4. If you are unsure of how to answer a question, please give the best answer you can and make a comment in the left margin.
- 5. If you have any questions, please feel free to ask a member of the project staff, and they will be glad to help you.

#### STATEMENT OF CONFIDENTIALITY:

All information that would permit identification of any person who completed this questionnaire will be regarded as strictly confidential. Such information will be used only for the purposes of this study and will not be disclosed or released for any other purposes without prior consent, except as required by law.

© R 1996

### SECTION A – PART 1 GENERAL HEALTH AND VISION (NEI-VFQ-25)

A1: In general, would you say your ove	erali nealth is:	(Circle One)
	Excellent	1
	Very Good	2
	Good	3
	Fair	4
	Poor	5
A2: At the present time, would you s glasses or contact lenses, if you w very poor or are you completely bl	ear them) is excellent, good	d, fair, poor, or
		(Circle One)
	Excellent	1
	Good	2
	Fair	3
	Poor	4
	Very Poor	5
	Completely Blind	6
A3: How much of the time do you worr	y about your eyesight?	
		(Circle One)
	None of the time	1
	A little of the time	2
	Some of the time	3
	Most of the time	4
	All of the time	5
A4: How much pain or discomfort have		ur eyes (for
example, burning, itching, or achir	ig) r would you say it is:	(Circle One)

None Mild

Moderate

Severe, or

Very severe

1

2

3

4

5

### **SECTION A - PART 2 DIFFICULTY WITH ACTIVITIES**

The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses if you use them for that activity.

A5:	How much difficulty do you have reading ordinary print in newspapers?	•
	Would you say you have:	

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A6: How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say: (Circle One)

No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

## A7: Because of your eyesight, how much difficulty do you have finding something on a crowded shelf?

•		
No difficulty at all	1	
A little difficulty	2	
Moderate difficulty	3	
Extreme difficulty	4	
Stopped doing this because of your eyesight	5	
Stopped doing this for other reasons or not interested in doing this	6	

(Circle One)

### A8: How much difficulty do you have reading street signs or the names of stores? (Circle One)

No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A9: Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A10: Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A11: Because of your eyesight, how much difficulty do you have seeing how people react to things you say?

3. 3	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A12: Because of your eyesight, how much difficulty do you have picking out and matching your own clothes?

	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

## A13: Because of your eyesight, how much difficulty do you have visiting with people in their homes, at parties, or in restaurants?

• • •	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

## A14: Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events?

, , , , ,	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

### A15: Are you currently driving, at least once in a while?

(Circle One)

Yes	1	Skip To Question A15c (page 7)
No	2	Go to Question A15a

### A15a: If NO: Have you never driven a car or have you given up driving?

(Circle One)

Never drove	1	Skip To Section A, Part 3, Question A17 (page 8)
Gave up	2	Go to Question A15b

# A15b: IF YOU GAVE UP DRIVING: Was that mainly because of your eyesight, mainly for some other reason, or because of both your eyesight and other reasons?

(Circle One)

Mainly eyesight	1	Skip To Section A, Part 3, Question A17 (page 8)
Mainly other reasons	2	Skip To Section A, Part 3, Question A17 (page 8)
Both eyesight and	3	Skip To Section A, Part 3, Question A17 (page 8)
other reasons		

# A15c: IF CURRENTLY DRIVING: How much difficulty do you have driving during the daytime in familiar places? Would you say you have:

•	•	,	, ,	(Circle One)
No difficulty at all				1
A little difficulty				2
Moderate difficulty				3
Extreme difficulty				4

## A16: How much difficulty do you have driving at night? Would you say you have:

	(Circle One
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

# A16a: How much difficulty do you have driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic? Would you say you have:

you only you mate.	(Circle One)
No difficulty at all	1
A little difficulty	2
Moderate difficulty	3
Extreme difficulty	4
Stopped doing this because of your eyesight	5
Stopped doing this for other reasons or not interested in doing this	6

### SECTION A PART 3 - RESPONSES TO VISION PROBLEMS

The next questions are about how things you do may be affected by your vision. For each one, please circle the number to indicate whether for you the statement is true for you all, most, some, a little, or none of the time.

(Circle One On Each Line)

		All of the time		Some of the time	A little of the time	None of the time
A17:	Do you accomplish less than you would like because of your vision?	1	2	3	4	5
A18:	Are you limited in how long you can work or do other activities because of your vision?	1	2	3	4	5
A19:	How much does pain or discomfort in or around your eyes, for example, burning, itching, or aching, keep you from doing what you'd like to be doing? Would you say:	1	2	3	4	5

For each of the following statements, please circle the number to indicate whether for you the statement is definitely <u>true</u>, <u>mostly true</u>, <u>mostly false</u>, or <u>definitely false</u> for you or you are <u>not sure</u>.

(Circle One On Each Line)

		Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
A20:	I stay home most of the time because of my eyesight.	1	2	3	4	5
A21:	I feel frustrated a lot of the time because of my eyesight.	1	2	3	4	5
A22:	I have much less control over what I do, because of my eyesight.	1	2	3	4	5
A23:	Because of my eyesight, I have to rely too much on what other people tell me.	1	2	3	4	5
A24:	I need a lot of help from others because of my eyesight.	1	2	3	4	5
A25:	I worry about doing things that will embarrass myself or others, because of my eyesight.	1	2	3	4	5

### SECTION B – DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D)

The first section of the questionnaire is about your general health today.

By placing a **tick** ( $\checkmark$ ) in one box in each group below, please indicate which statements best describe your own health state **today**.

MOBILITY	
I have no problems in walking about	
I have slight problems in walking about	
I have moderate problems in walking about	
I have severe problems in walking about	
I am unable to walk about	
SELF-CARE	
I have no problems washing or dressing myself	
I have slight problems washing or dressing myself	
I have moderate problems washing or dressing myself	
I have severe problems washing or dressing myself	
I am unable to wash or dress myself	
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	
I have slight problems doing my usual activities	
I have moderate problems doing my usual activities	
I have severe problems doing my usual activities	
I am unable to do my usual activities	
PAIN / DISCOMFORT	
I have no pain or discomfort	
I have slight pain or discomfort	
I have moderate pain or discomfort	
I have severe pain or discomfort	
I have extreme pain or discomfort	
ANXIETY / DEPRESSION	
I am not anxious or depressed	
I am slightly anxious or depressed	
I am moderately anxious or depressed	
I am severely anxious or depressed	
I am extremely anxious or depressed	

The best health you can imagine

- The worst health you can imagine

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
- 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =	

This set of questions asks about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, <u>during the past week</u>. Please select <u>one</u> answer that <u>best describes</u> your level of ability or disability <u>during the past week</u>. Please indicate the selected answer by <u>circling</u> the number (e.g. 1, 2, 3, etc.) beside the answer.

#### Vision:

- 1 Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, without glasses or contact lenses.
- Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, but with glasses.
- Able to read ordinary newsprint with or without glasses but unable to recognize a friend on the other side of the street, even with glasses.
- Able to recognize a friend on the other side of the street with or without glasses but unable to read ordinary newsprint, even with glasses.
- 5 Unable to read ordinary newsprint and unable to recognize a friend on the other side of the street, even with glasses.
- 6 Unable to see at all.

#### Hearing:

- Able to hear what is said in a group conversation with at least three other people, without a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but requires a hearing aid to hear what is said in a group conversation with at least three other people.
- Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people, with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, without a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- Able to hear what is said in a conversation with one other person in a quiet room, with a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
- 6 Unable to hear at all.

#### Speech:

- 1 Able to be understood completely when speaking with strangers or friends.
- Able to be understood partially when speaking with strangers but able to be understood completely when speaking with people who know me well.
- Able to be understood partially when speaking with strangers or people who know me well.
- 4 Unable to be understood when speaking with strangers but able to be understood partially by people who know me well.
- 5 Unable to be understood when speaking to other people (or unable to speak at all).

#### Ambulation:

- 1 Able to walk around the neighbourhood without difficulty, and without walking equipment
- Able to walk around the neighbourhood with difficulty; but does not require walking equipment or the help of another person.
- Able to walk around the neighbourhood with walking equipment, but without the help of another person
- Able to walk only short distances with walking equipment, and requires a wheelchair to get around the neighbourhood.
- 5 Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood.
- 6 Cannot walk at all.

#### **Dexterity:**

- 1 Full use of two hands and ten fingers.
- 2 Limitations in the use of hands or fingers, but does not require special tools or help of another person.
- 3 Limitations in the use of hands or fingers, is independent with use of special tools (does not require the help of another person).
- 4 Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with use of special tools).
- 5 Limitations in use of hands or fingers, requires the help of another person for most tasks (not independent even with use of special tools).
- 6 Limitations in use of hands or fingers, requires the help of another person for all tasks (not independent even with use of special tools).

### **Emotion:** 1 Happy and interested in life.

- 2 Somewhat happy.
- 3 Somewhat unhappy.
- 4 Very unhappy.
- 5 So unhappy that life is not worthwhile.

### Cognition:

- 1 Able to remember most things, think clearly and solve day to day problems.
- Able to remember most things, but have a little difficulty when trying to think and solve day to day problems.
- 3 Somewhat forgetful, but able to think clearly and solve day to day problems.
- 4 Somewhat forgetful, and have a little difficulty when trying to think or solve day to day problems.
- Very forgetful, and have great difficulty when trying to think or solve day to day problems.
- 6 Unable to remember anything at all, and unable to think or solve day to day problems.

#### Pain:

- 1 Free of pain and discomfort.
- 2 Mild to moderate pain that prevents no activities.
- 3 Moderate pain that prevents a few activities.
- 4 Moderate to severe pain that prevents some activities.
- 5 Severe pain that prevents most activities.

<sup>©</sup> Health Utilities Inc. (HUInc), 1998.

### SECTION D - DESCRIBING YOUR EXPERIENCE OF GLAUCOMA^

In this section of the questionnaire we are interested in the importance you place on the different characteristics of glaucoma and its treatment effects.

Some of these statements may seem similar to earlier questions in the booklet. However, they are an important measurement tool for valuing how glaucoma and its treatment affect you.

Please tick one box ( $\checkmark$ ), for each of the **categories D1-D6**, which best describes any difficulties you have had in the **last month** with yourself, or your eyes or vision. **Remember**, if you wear glasses or contact lenses please answer all of the following questions as though you were wearing them.

As a guide about what is meant by the questions please look at the booklet 'Guide to the Questionnaire Sections'.

#### D1: Central and near vision

For example, do you have any difficulties with reading, writing, watching TV, sewing, card games, computer work, reading dials on cookers on clocks or any activities similar to these?

No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	

#### D2: Lighting and glare

For example, do you have any difficulties adjusting from light to dark and viceversa), dazzle from bright lights, or difficulties seeing in dim light?

No	
Some difficulty	
Quite a lot of difficulty	
Severe difficulty	

For example, <b>because of your eyesight,</b> do you have any difficulties crossing roads, walking along busy pavements, negotiating steps and kerbs, tripping over low objects (for example children in pushchairs or dogs) or difficulties driving (or stopping driving) because of your vision?
No No
Some difficulty
Quite a lot of difficulty
Severe difficulty
Activities of daily living For example, because of your eyesight, do you have any difficulties with domestic, DIY or self-care tasks around the home? This category includes difficulties pouring liquid into containers (e.g. water into a glass), problems judging shelf height leading to difficulties putting objects into or retrieving them from cupboards, being unaware of open cupboard doors and similar problems.
No No
Some difficulty
Quite a lot of difficulty
Severe difficulty
Eye discomfort For example, have any difficulties because of one or both eyes feeling gritty, sore, or tired?
No No
Some difficulty
Quite a lot of difficulty
Severe difficulty
Other possible effects of glaucoma or its treatment For example, do you experience a dry mouth or a bitter after taste, fatigue, shortness of breath or difficulties with sexual functioning?
No No
Some difficulty
Quite a lot of difficulty
Severe difficulty

D3: Mobility

<sup>^</sup> Glaucoma Profile Index, GPI Burr JM, Kilonzo M, Vale L, Ryan M. Developing a Preference based Glaucoma Utility Index using a Discrete Choice Experiment. *Optom Vis Sci. 2007 Aug; 84(8):797-808.* 

## **SECTION E - HEALTH CARE UTILISATION**

Please print carefully within the boxes like this 2 7 or like	e this
E1: Have you been to see a GP because of your eyes during the last 1 months?	2 Yes No
If Yes, please give details:	
E2: How many appointments did you attend with a GP? (at GP surgery	y)
E3: How many times did a GP visit you at home?	
E4: How many times did you have a telephone conversation with a GF	P? .
E5: Have you had any appointments with a community optician or optometrist in the last 12 months? (G	Yes o to E6)
	No
(Ski	p to E7)
E6: How many appointments with a community optician or optometris did you attend?	t
E7: During the last 12 months have you had new spectacles or contac lenses?	t Yes
	No
E7a: If Yes (to E7 above), how much did you pay?	£

This next question is about any appointments you may have had with <u>other health care</u> <u>workers</u> in the past 12 months.

## E8: During the last 12 months have you had an appointment with:

A District Nurse?	Yes		f Yes, how r	many a	ppoin	tments did you h	ıave?	
	No							
A Practice Nurse?	Yes		f Yes, how r	many a	ppoin	tments did you h	ave?	
	No							
Other? Please specify	Yes No							
		I	How many a	ppoint	ments	did you have?		
		I	How many a	ppoint	ments	did you have?		
This set of questions is a months.	about an	ny <u>priv</u>	<u>⁄ate</u> health d	are yo	u may	have had in the	past	12
E9: During the last 12 care?	months	have	you <u>paid f</u>	or any	priva	<u>te health</u>	Yes	
If Yes please go to	E9a, the	en Es	9b (below) i	f no pl	ease	skip to E10	No	
E9a: If Yes, what sort of care did you pay f								
E9b: If Yes, how much	did it co	ost?	£					
E10: During the last 12 any days off work of	or your		•	Yes		If Yes; how m	nany d	ays?
because of your ey	es (			No				

E11: During the last 12 months, have you utilised any information or services related to your sensory impairment?	Yes No
e.g. Low Vision Clinic,	
Services offered by the Royal National Institute of Blind People, etc.	
If another, could you please specify in the space provided:	
E12: Are you currently in receipt of any form of travel allowance/concession as a result of your sensory impairment?	Yes No
e.g. Disabled person's railcard Dial-a-ride	
Companion's permit	
If another, could you please specify in the space provided:	
E13: Are you currently in receipt of any welfare benefits as a result of your sensory impairment?	Yes
	No
e.g. Disability living allowance Incapacity benefit	
Carer's allowance	
If another, could you please specify in the space provided:	

Do you think your glaucoma is getting worse?	Yes	
(Somner, 2012- IOVS)	No	
Date you filled in this questionnaire DD / MM / Y Y	Υ	Υ
Have you asked for any help to fill this questionnaire today?	Yes	
	No	

### **THANK YOU**

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful in helping us carry out our research into treatments for Glaucoma.

It will be treated with the strictest confidence and kept securely.

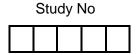
### Thank you again for your help.

If you would like any further information or have any queries about the study, please contact:

TAGS Study Office
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
UK

Telephone: 01224 438196 Email: tags@abdn.ac.uk Website: www.tagsstudy.co.uk

The questionnaires are processed in Aberdeen at the Centre for Health Care Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD, UK.





# **TAGS**

## Treatment of Advanced Glaucoma Study

A multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma

## PARTICIPANT QUESTIONNAIRE

Discrete Choice Experiment

Thank you for helping us with our research. We would be very grateful if you could complete this questionnaire.

### **CONFIDENTIAL**

Discrete Choice Experiment

### **QUESTIONNAIRE**

Before answering the questions please read the 'Guide to the Discrete Choice Experiment'.

Please complete all of the questions. If you make a mistake when answering a question, please draw a line through the undesired response and then record your desired response.

After answering all of the questions, please return it in the Freepost envelope supplied.

### Section 1 - Making choices

In this section you are presented with choices, each describing two health state situations: Situation A and B. We would like you to imagine that you have these difficulties and ask you to pick the scenario you think is worse. You may not like either situation but please choose the one that is less preferable to you by putting a tick in the appropriate box. Please tick just ONE box for every question. Again, **please choose one situation only.** 

To help you make your choices please refer to the Guide about aspects of quality of life that may be affected in glaucoma and associated levels of difficulty (Guide to the Discrete Choice Experiment).

Please see the following EXAMPLE QUESTION to help you fill out the following questions.

Example Question: Which situation is worse for you?		
SITUATION A	SITUATION B	
No difficulty with:	No difficulty with:	
Central and near vision	<ul> <li>Central and near vision</li> </ul>	
Lighting and glare	Some difficulty with:	
Mobility	Lighting and glare	
Some difficulty with:	Quite a lot of difficulty with:	
Activities of daily living	Activities of daily living	
Local eye discomfort	The effects of glaucoma and its treatment	
The effects of glaucoma and it	Severe difficulty with:	
treatment	Mobility	
	Local eye discomfort	
	(Tiple and house who)	
(Tick one box only)		
Situation A	Situation B ✓	

## In this case the person answering this question thought that the worse option was Situation B:

- Having no difficulty with central and near vision.
- Some difficulty with lighting and glare.
- Quite a lot of difficulty with activities of daily living and the effects of glaucoma and its treatment.
- Severe difficulty with mobility and local eye discomfort.

#### This is compared with **Situation A**:

- Having no difficulty with central and near vision, lighting and glare and mobility.
- Some difficulty with activities of daily living, local eye discomfort and the effects of glaucoma and its treatment.

## **Start making your choices**

Question 1 Which situation is worse for you?	
SITUATION A	SITUATION B
No difficulty with:	Some difficulty with:
Central and near vision	Lighting and glare
Local eye discomfort	Mobility
Some difficulty with:	Quite a lot of difficulty with:
Activities of daily living	Activities of daily living
The effects glaucoma and its treatment	Local eye discomfort
Severe difficulty with:	Severe difficulty with:
Mobility	Central and near vision
Lighting and glare	The effects glaucoma and its treatment
(Tick one box only)	
Situation A	Situation B

Question 2 Which situation is worse for you?	
SITUATION A	SITUATION B
No difficulty with:	No difficulty with:
Activities of daily living	Lighting and glare
Some difficulty with:	Mobility
Central and near vision	Local eye discomfort
Local eye discomfort	Quite a lot of difficulty with:
The effects of glaucoma and its	Central and near vision
treatments	Severe difficulty with:
Quite a lot of difficulty with:	Activities of daily living
Lighting and glare	The effects of glaucoma and its
Severe difficulty with:	treatments
Mobility	
(Tick one box only)	
Situation A	Situation B

Question 3 Which situation is worse for you?	
SITUATION A	SITUATION B
No difficulty with:	No difficulty with:
Central and near vision	Lighting and glare
Some difficulty with:	Activities of daily living
The effects of glaucoma and its	The effects of glaucoma and its
treatments	treatments
Quite a lot of difficulty with:	Some difficulty with:
Lighting and glare	Central and near vision
Mobility	Quite a lot of difficulty with:
Activities of daily living	Local eye discomfort
Severe difficulty with:	Severe difficulty with:
Local eye discomfort	Mobility
(Tick one box only)	
Situation A	Situation B

Question 4 Which situation is worse for you?	
SITUATION A	SITUATION B
No difficulty with:	No difficulty with:
The effects of glaucoma and its	Local eye discomfort
treatment	Some difficulty with:
Quite a lot of difficulty with:	Central and near vision
Central and near vision	Mobility
Mobility	Activities of daily living
Activities of daily living	Quite a lot of difficulty with:
Local eye discomfort	Lighting and glare
Severe difficulty with:	Severe difficulty with:
Lighting and glare	The effects of glaucoma and its
	treatments
(Tick one box only)	
Situation A	Situation B

Question 5 Which situation is worse for you?	
SITUATION A	SITUATION B
No difficulty with:	Some difficulty with:
Central and near vision	Central and near vision
Mobility	Local eye discomfort
Quite a lot of difficulty with:	The effects of glaucoma and its
Lighting and glare	treatments
Activities of daily living	Quite a lot of difficulty with:
Severe difficulty with:	Mobility
Local eye discomfort	Severe difficulty with:
The effects of glaucoma and its	Lighting and glare
treatments	Activities of daily living
(Tick on	e box only)
Situation A	Situation B

Question 6 Which situation is worse for you?		
SITUATION A	SITUATION B	
No difficulty with:	No difficulty with:	
Lighting and glare	Mobility	
Some difficulty with:	Some difficulty with:	
Mobility	Local eye discomfort	
The effects of glaucoma and its	Quite a lot of difficulty with:	
treatments	Lighting and glare	
Quite a lot of difficulty with:	The effects of glaucoma and its	
Central and near vision	treatments	
Activities of daily living	Severe difficulty with:	
Severe difficulty with:	Central and near vision	
Local eye discomfort	Activities of daily living	
(Tick one box only)		
Situation A	Situation B	

Question 7 Which situation is worse for you?			
SITUATION A	SITUATION B		
Some difficulty with:	No difficulty with:		
Central and near vision	Central and near vision		
Activities of daily living	Lighting and glare		
Local eye discomfort	Local eye discomfort		
The effects of glaucoma and its	Some difficulty with:		
treatments	Mobility		
Severe difficulty with:	Quite a lot of difficulty with:		
Lighting and glare	Activities of daily living		
Mobility	Severe difficulty with:		
	The effects of glaucoma and its		
	treatments		
(Tick one box only)			
Situation A	Situation B		

Question 8 Which situation is worse for you?			
SITUATION A	SITUATION B		
No difficulty with:	No difficulty with:		
<ul> <li>Central and near vision</li> </ul>	Local eye discomfort		
• Mobility	The effects of glaucoma and its		
Activities of daily living	treatments		
Some difficulty with:	Some difficulty with:		
Lighting and glare	Mobility		
Quite a lot of difficulty with:	Activities of daily living		
The effects of glaucoma and its	Severe difficulty with:		
treatments	Central and near vision		
Severe difficulty with:	Lighting and glare		
Local eye discomfort			
	ne box only)		
Situation A	Situation B		
Oituation A	Oituation D		

Question 9 Which situation is worse for you?				
SITUATION A	SITUATION B			
No difficulty with:	Some difficulty with:			
Lighting and glare	Central and near vision			
Mobility	Mobility			
Local eye discomfort	Activities of daily living			
Some difficulty with:	Quite a lot of difficulty with:			
The effects of glaucoma and its	Lighting and glare			
treatments	Severe difficulty with:			
Severe difficulty with:	Local eye discomfort			
Central and near vision	The effects of glaucoma and its			
Activities of daily living	treatments			
(Tick one box only)				
Situation A	Situation B			

Question 10 Which situation is worse for you?			
SITUATION A	SITUATION B		
No difficulty with:	Some difficulty with:		
Lighting and glare	Lighting and glare		
Activities of daily living	Mobility		
Local eye discomfort	Local eye discomfort		
Quite a lot of difficulty with:	The effects of glaucoma and its		
Central and near vision	treatments		
Severe difficulty with:	Quite a lot of difficulty with:		
Mobility	Activities of daily living		
The effects of glaucoma and its	Severe difficulty with:		
treatments	Central and near vision		
(Tick one box only)			
Situation A	Situation B		

Question 11 Which situation is worse for you?		
SITUATION A	SITUATION B	
Quite a lot of difficulty with:	No difficulty with:	
Central and near vision	Central and near vision	
Lighting and glare	Lighting and glare	
• Mobility	The effects of glaucoma and its	
Local eye discomfort	treatments	
Severe difficulty with:	Some difficulty with:	
Activities of daily living	Activities of daily living	
The effects of glaucoma and its	Severe difficulty with:	
treatments	Mobility	
	Local eye discomfort	
(Tick one box only)		
Situation A	Situation B	

Question 12 Which situation is worse for you?			
SITUATION A	SITUATION B		
No difficulty with:	No difficulty with:		
Mobility	Central and near vision		
Local eye discomfort	Activities of daily living		
Some difficulty with:	Some difficulty with:		
Central and near vision	The effects of glaucoma and its		
Activities of daily living	treatments		
Severe difficulty with:	Quite a lot of difficulty with:		
Lighting and glare	Lighting and glare		
The effects of glaucoma and its	Severe difficulty with:		
treatments	Mobility		
	Local eye discomfort		
(Tick one box only)			
Situation A	Situation B		

Question 13 Which situation is worse for you?			
SITUATION A	SITUATION B		
Some difficulty with:	No difficulty with:		
Lighting and glare	Activities of daily living		
Activities of daily living	Some difficulty with:		
The effects of glaucoma and its	Mobility		
treatments	Quite a lot of difficulty with:		
Quite a lot of difficulty with:	Central and near vision		
Local eye discomfort	Lighting and glare		
Severe difficulty with:	Severe difficulty with:		
Central and near vision	Local eye discomfort		
Mobility	The effects of glaucoma and its		
	treatments		
(Tick one box only)			
Situation A	Situation B		

Question 14 Which situation is worse for you?			
SITUATION A	SITUATION B		
No difficulty with:	No difficulty with:		
Activities of daily living	Lighting and glare		
The effects of glaucoma and its	Mobility		
treatments	Some difficulty with:		
Quite a lot of difficulty with:	The effects of glaucoma and its		
Mobility	treatments		
Local eye discomfort	Quite a lot of difficulty with:		
Severe difficulty with:	Central and near vision		
Central and near vision	Severe difficulty with:		
Lighting and glare	Activities of daily living		
	Local eye discomfort		
(Tick one box only)			
Situation A Situation B			

Question 15 Which situation is worse for you?			
SITUATION A	SITUATION B		
No difficulty with:	No difficulty with:		
Mobility	Central and near vision		
The effects of glaucoma and its	Some difficulty with:		
treatments	Lighting and glare		
Some difficulty with:	Activities of daily living		
Local eye discomfort	Quite a lot of difficulty with:		
Quite a lot of difficulty with:	Local eye discomfort		
Activities of daily living	The effects of glaucoma and its		
Severe difficulty with:	treatments		
Central and near vision	Severe difficulty with:		
Lighting and glare	Mobility		
(Tick one box only)			
Situation A	Situation B		

### Section 2 - About You

Finally, could you please provide a few details about yourself, to help us understand the results? **Again, all answers are completely confidential.** 

### 1. What is the highest level of education completed?

(Please tick one box)

Secondary school	
College	
University	
None	
Other (please specify)	
·	

2. Could you please provide an estimate of your annual house sources (before tax and including your partner/spouse)?	ehold income from all
	tick one box)
Less than £6,000	
£6,000 to £10,000	
£10,001 to £15,000	
£15,001 to £20,000	
£20,001 to £25,000	
£25,001 to £30,000	
£30,001 to £35,000	
£35,001 and greater	
Are there any comments that you would like to make reg questionnaire?	jarding the
Would you please say about how long it took you complete the whole questionnaire	to

Thank you for taking time to complete this questionnaire. Please post it back to us in the enclosed pre-paid envelope.

Study Number				



# **TAGS**

## Treatment of Advanced Glaucoma Study

A multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma

Thank you for helping us with our research. We would be very grateful if you could complete this questionnaire

## **CONFIDENTIAL**

TIME AND TRAVEL QUESTIONNAIRE

This questionnaire will help us find out how much it costs **YOU** to use health services. We wish to know how much money and time were spent by you and any companion in attending health care appointments or being admitted to hospital.

Please answer all the questions about your **most recent admission to hospital** (column A) first, then about your **most recent outpatient appointment** (column B), then about your **most recent GP appointment** (column C), and then about your most recent visit to a **community optician or optometrist** (column D). These attendances could be for any reason, and do not need to be for your glaucoma. Your last visit may have been a long time ago and we understand that you may not remember the exact details. We would really appreciate your best guess.

If you have not attended the services mentioned in this questionnaire, please tick the "N/A" box and move on to the next column of questions.

Q1: Please write the date you completed this questionnaire:

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	Α	В	С	D
	Your most recent hospital inpatient admission	Your most recent outpatient consultation	Your most recent GP appointment	Your most recent visit to a community optician or optometrist
1. Not applicable (N/A)	If you have <b>not</b> been admitted as an inpatient, go directly to column B (outpatient consultation)	N/A  If you have <b>not</b> been to the hospital outpatients, go directly to column C (GP appointment)	If you have <b>not</b> been to the GP, go directly to column D (community optician or optometrist appointment)	If you have <b>not</b> been to the community optician or optometrist, you have now completed the questionnaire. Please return to the address on the final page.
2. How did you travel? If you used more than one form of transport, please indicate the way you travelled for the main (in terms of distance) part of your journey. (Please tick the appropriate box)	Train  Bus/Tram  Private Car  Taxi  Hospital Car  Ambulance  Walk  Cycle  Other (please specify)	Train  Bus/Tram  Private Car  Taxi  Hospital Car  Ambulance  Walk  Cycle  Other (please specify)	Train  Bus/Tram  Private Car  Taxi  Hospital Car  Ambulance  Walk  Cycle  Other (please specify)	Train Bus/tram Private car Ambulance Walk Cycle Other (please specify)
3. How many miles did you travel one-way? (Please give your best guess about the distance travelled to the place of your appointment)	Miles	Miles	Miles	Miles

	Your most recent hospital inpatient admission	Your most recent outpatient consultation	Your most recent  GP appointment	Your most recent visit to a community optician or optometrist
4. If you travelled by taxi or public transport, what was the total cost of the return fare(s)?  (Please state '£0' if no fares were incurred)	£	£	£	£
5. If you travelled by car (or similar), how much did you or your companion have to pay in parking fees? (Please state '£0' if no fares were incurred)	£	£	£	£
6. How long did you spend away from doing other things to attend your appointment? (Please include time travelling and time at the appointment or admission itself)	Days Hours	Hours Minutes	Hours Minutes	Hours Minutes
7. If you were not attending your appointment, what would you have otherwise been doing as your main activity? (Please tick the box that best applies)	Paid Work  Homemaker  Childcare  Caring for a friend/relative  Retired  Full-time education  Unemployed  Voluntary work  Leisure Activities  Other (please specify)	Paid Work  Homemaker  Childcare  Caring for a friend/relative  Retired  Full-time education  Unemployed  Voluntary work  Leisure Activities  Other (please specify)	Paid Work  Homemaker  Childcare  Caring for a friend/relative  Retired  Full-time education  Unemployed  Voluntary work  Leisure Activities  Other (please specify)	Paid Work  Homemaker  Childcare  Caring for a friend/relative  Retired  Full-time education  Unemployed  Voluntary work  Leisure activities  Other (please specify)

	Your most recent hospital inpatient admission	Your most recent outpatient consultation	Your most recent  GP appointment	Your most recent visit to a community optician or optometrist
8. Did someone accompany you to your appointment? (Please tick either "no" or "yes")	Please continue to column B – outpatient consultation Yes  Please continue below	Please continue to column C  – GP appointment  Yes  Please continue below	Please continue to column D – Optician appointment Yes Please continue below	No Please return completed questionnaire Yes Please continue below
9. If someone accompanied you to your appointment, what would this person otherwise have been doing, had they not gone with you? (Please tick the box that best applies)	Paid work  Homemaker  Childcare  Caring for a friend/relative  Retired  Full-time education  Unemployed  Voluntary work  Leisure Activities  Other (please specify)	Paid work  Homemaker  Childcare  Caring for a friend/relative  Retired  Full-time education  Unemployed  Voluntary work  Leisure Activities  Other (please specify)	Paid work  Homemaker  Childcare  Caring for a friend/relative  Retired  Full-time education  Unemployed  Voluntary work  Leisure Activities  Other (please specify)	Paid work  Homemaker  Childcare  Caring for a friend/relative  Retired  Full-time education  Unemployed  Voluntary work  Leisure activities  Other (please specify)
10. How long did your companion spend away from doing other things to accompany you? (Please include time travelling and time at the appointment or admission with you)	Days Hours	Hours Minutes	Hours Minutes	Hours Minutes
	Please go to column B (page 3)	Please go to column C (page 3)	Please go to column D (page 3)	

## **THANK YOU**

Once you have completed the form, please return it in the pre-paid envelope provided or to the address below:

Thank you very much for your time and patience in filling in this questionnaire.

The information you have given us will be extremely useful in helping us carry out our research into treatments for glaucoma.

It will be treated with the strictest confidence and kept securely.

If you would like any further information or have any queries about the study, please contact:

TAGS Study Office
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen
AB25 2ZD
UK

Telephone: 01224 438196 Email: tags@abdn.ac.uk Website: www.tagsstudy.co.uk

The questionnaires are processed in Aberdeen at the Centre for Health Care Randomised Trials (CHaRT), Health Services Research Unit, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD, UK.