1 **Seeking a practical definition of stable glaucoma: A Delphi consensus survey of UK glaucoma**

2 **consultants.**

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29 **Abstract**

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31 Background: To generate a practical and clinically useful consensus definition of 'stable glaucoma' to aid

32 provision of glaucoma services in the UK and to provide guidance for the criteria that should be used for

33 monitoring of glaucoma patients in primary care services.

34

35 Methods: A Delphi exercise was undertaken to derive consensus through an online questionnaire.

36 Participants were asked to score their strength of agreement for a series of clinical parameters. Results

37 and comments from each round were used to inform subsequent rounds. A total of 3 rounds were

38 undertaken.

39

40 Results: 32 glaucoma experts participated in the study with over 90% completion rate achieved over

41 three rounds. Consensus was reached for the following parameters: IOP levels to be used for defining

42 stability, visual field-testing techniques to define stability, the number of medication changes acceptable

43 to define stability and the number of treatment medications allowed to define stability. No consensus

44 was reached on the period of time over which stability was defined, however there was considerable

45 agreement that longer durations of follow up (36-48 months) were required. A combination of optic disc

46 photos and Ocular Coherence Topography (OCT) Retinal Nerve Fibre Layer (RNFL) assessment/ OCT disc

47 structural evaluation are the preferred imaging methods for the assessment of structural stability.

48 Oversight by a glaucoma consultant was considered important for glaucoma monitoring schemes.

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50 Conclusion: The consensus definition of glaucoma stability generated through this Delphi exercise

51 provides guidance for allocation of patients suitable for monitoring in primary care glaucoma monitoring

52 schemes.

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INTRODUCTION

Over 172,000 referrals for patients with 'suspect' glaucoma are made to specialist Ophthalmology services in England annually, of which an estimated one third require long term follow up. (1) The referrals for suspect glaucoma in combination with Ocular Hypertension (OHT) account for over 30% of current ophthalmology outpatient activity. (2) The Royal College of Ophthalmologists (RCOphth) reports that over the next 20 years glaucoma cases are set to rise by 44%. (3)

The increasing demand on hospital services has led to the development of alternative community-based services often run by optometrists for monitoring 'stable' and low risk glaucoma patients. (1) (3)NICE estimates that approximately 56,320 patients out of the 169,500 currently being managed in secondary care with chronic open angle glaucoma (COAG), suspect COAG and OHT could be managed in the community. (4) The NICE guidelines for managing glaucoma outline the general principles of monitoring patients who have, or are suspected of having, COAG or OHT. (4) Intraocular pressure readings with Goldmann applanation tonometry, assessment of anterior chamber depth, assessment of the optic nerve head (including imaging) and visual field assessment should all be undertaken.

Despite the move to commission a greater number of community services for the monitoring of OHT and suspect glaucoma, (1) there is no established consensus on the clinical definition of 'Stable Glaucoma' currently available in the literature. This definition is left to the discretion of local service providers and so it is likely that there is inconsistency in how patients are monitored in these community-based clinics. A definition of 'stable glaucoma' would not only inform the effective design and commissioning of glaucoma services in the NHS by identifying those patients who can safely be monitored outside a secondary care environment, but also contribute to developing standards for these patients to be managed safely within the community and aid in accurately identifying those who need to be re-referred back to secondary care allowing consistent delivery of glaucoma services.

The aim of this study is:

85   1. To establish a consensus on the definition of "stable" glaucoma amongst consultant
86   ophthalmologists with a recognised expertise in glaucoma.
87   2. To evaluate which factors are important when discharging 'stable glaucoma' patients to
88   different oversight models of community-based care.

89

90   **METHOD**

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92   An expert panel, consisting of Ophthalmology consultants with glaucoma subspecialist interest in the UK,
93   were consulted in an adapted (3-round) Delphi exercise (5) (6) (7) to establish consensus on the definition
94   of stable glaucoma.
95   We approached 33 of the 150 glaucoma specialists registered with the RCOphth. The group was a
96   representative mix of teaching and district general hospital consultants and geographical distribution
97   within the UK. The experts were identified via their membership of the UK and Eire Glaucoma Society
98   and initially approached via an email which described the purpose of the exercise. Thirty-two responded
99   to confirm their interest in participating and this was deemed to be an appropriate number of
100   respondents to undertake a valid Delphi process. They were provided with further information about the
101   survey and were subsequently involved in the Delphi process. No incentives were offered to participants.
102   Prior research has suggested that a panel with a minimum of twelve members is required for the findings
103   of a Delphi exercise to be considered valid. (5)

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105   The University of Nottingham School of Medicine Ethics committee confirmed that this consultative
106   survey did not require ethical approval.

107

108   The survey process was managed using the online survey tool *Survey Monkey* with each questionnaire
109   designed to take around 15 minutes to complete. Participants were sent a personalised link to the
110   questionnaires and asked to indicate their strength of agreement for each of a series of parameters using
111   a 0-10 scoring scale, where 10 indicated strong agreement and 0 strong disagreement.

112

113 The clinical parameters examined in this way were:

1. Time Period: How long should a patient be monitored before being considered stable.

2. Visual Field Methods: Which Visual field (VF) assessment methods should be used to define stability.

3. Imaging Methods: Which imaging assessment methods should be used to define stability.

4. Intra-ocular pressure (IOP): What IOP level should be used to define stability?

5. Use of drops: Whether the total number of IOP lowering agents drops being used by a patient or a change in number of drops required should be used to define stability.

6. Consultant Oversight: the nature and clinical expertise of the consultants overseeing patients within community monitoring services.

124 After each round scores were synthesised and descriptive statistics for all (whole group) responses were generated for each parameter. A group median score 8-10 was considered to indicate 'strong agreement' with a parameter; a median score 0-2 strong disagreement. The use of median scores to summarise group responses in this way is common in Delphi research (7) however, median scores in isolation may disguise a broad range of scores which might be typical of panel disagreement. To counter this and to add rigour to our Delphi process, we combined a median score with an Interquartile Range (IQR) assessment (6) (7) (8) (9). An IQR score indicates the concentration of scores across the range of scoring options; an IQR of 2 indicates that 50% or more of responses are within 1 score of the median, an IQR of 8 indicates that scores are more broadly dispersed. To be confident that agreement about parameters had been reached we defined consensus as: a median score indicating strong agreement (8-10) or strong disagreement (0-2) in combination with an IQR of 2 points or less (demonstrating a concentration of scoring around the median). In all other circumstances, less strong agree/disagree (median 3-7) or dispersed scoring (IQR>2), consensus was not considered to have been reached.

138 Alongside scoring, participants were given the opportunity to offer free-text comments which might contextualize or explain their responses.

140

Those parameters where scoring demonstrated consensus amongst the expert panel were either accepted as a *characteristic of stable glaucoma*, or rejected from our process. These parameters were fixed and not scored in subsequent survey rounds.

Where consensus was not achieved, parameters were amended (in accordance with previous scoring and any relevant free-text comments) in such a way as to support the generation of consensus. For example, the duration of time for monitoring stable glaucoma was increased to support the generation of panel agreement about it. Revised parameters, along with summary scores from previous rounds and any indication of changes to the parameter, were included in the next iteration of the survey for scoring.

This process was repeated twice in this amended, 3-round Delphi exercise. In the final round, for parameters where consensus was not established, participants were asked to rank options in an attempt to find a weaker form of agreement about a parameter. Also in the final round an additional question, quantifying visual field progression in stable glaucoma, was added to further our understanding of Visual Field stability.

RESULTS

In round 1 there were 32 responses (100%), 31 in round 2 and 29 in round 3, giving a final response rate of 90.63%. (10) Out of the 21 questions in which a consensus was reached, 10 out of 21 questions reached consensus in the first round, 7 in round two and 4 in round three (Figure1). The results for each clinical parameter are presented in Table 1.

Strong agreement consensus was achieved that visual field stability should be assessed by trend analysis or by summary measures of VFI/ MD progression. Other methods of assessment or combinations of assessment methods did not reach consensus agreement.

168   The supplementary question (scored $1-4$) to quantify the amount of visual field progression (MD) that

169   can be defined as 'stable' found strong agreement on 0dB of change being stable (M4) and <4dB being

170   unstable (M1) with stability scoring decreasing with greater change in MD. (<1dB:M3, <2dB:M2).

171

172   Strong consensus agreement was reached on the following (Figure 2):

173   •   IOP level used to define stability should be based on a clinician defined target IOP tailored for

174   individual patients

175   •   Having no drop treatment change during the stability assessment period is considered stable

176   •   An increasing number of drop changes indicates instability (3 drop changes for the optimisation

177   of IOP control during the stability assessment period is not considered 'stable')

178   There was no consensus on the number of agents used for the optimisation of IOP when defining stability

179   and 'The number of agents required for the optimisation of IOP control is **not** important for defining

180   glaucoma stability' (M0, IQR0) (Figure 3)

181

182   No consensus was reached on what method or combination of imaging techniques, should be used to

183   define structural glaucoma stability. In round 3 when respondents were asked to rank combinations of

184   methods in order of preference, the combination of Optic disc (OD) photos (including stereoscopic disc

185   photos) and OCT RNFL assessment was the most preferable followed by the combination of OD photos

186   and OCT disc structural evaluation, with the combination of OCT RNFL assessment and OCT structural

187   evaluation being the least preferred.

188

189   No consensus was achieved for length of the monitoring period required to define stability for patients

190   identified with 'high' and 'low' risk glaucoma. There was a trend of increasing agreement with longer

191   time periods of 36 and 48 months. This is illustrated in Figure 4a and 4b.

192

193   For independent community glaucoma monitoring schemes run by optometrists with Higher Certificate

194   Glaucoma A or Glaucoma B or level III or IV qualifications (2) there was strong agreement consensus that

195   they should be overseen by consultants with glaucoma speciality expertise.

196

197   For all community scheme models: (1) without consultant overview, (2) overseen by general

198   ophthalmologists and (3) overseen by a consultant with glaucoma expertise – there was strong consensus

199   agreement that an assessment of glaucoma stability should be made before patients are transferred to

200   a glaucoma-monitoring scheme and that only patients with "stable" glaucoma should be transferred to

201   these schemes. Severity and type of glaucoma were regarded important factors to consider when

202   discharging patients to a community-based monitoring scheme. There was no consensus on the

203   importance of considering a patient's age unless referring patients to a service with no consultant

204   overview, when it is deemed important.

205

206   **DISCUSSION**

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208   Currently there is no definition of 'stable glaucoma' and there has been no previous attempt to generate

209   a consensus definition of 'stable glaucoma'. The Delphi method originated in the 1950s when the US Air-

210   Force commissioned the RAND project to reach a consensus amongst military experts. (11) It has since

211   become an established method of consensus development in the health field and has specifically been

212   used to establish consensus in the field of glaucoma in multiple settings from developing standards for

213   glaucoma virtual clinics (12) to developing specifications of open angle glaucoma screening interventions

214   in the United Kingdom. (13) (14) (15) (16)

215

216   The method focuses on measuring the consensus of a group of qualified participants and has

217   demonstrated decision-making advantages over other traditional methods, (17) allowing for the

218   discussion of complex problems whilst giving participants sufficient time to respond at their own

219   convenience.

220

221   It has been established that the selection of the participants is likely to have little impact on the group

222   decision as long as the selection reflects the range of experience and characteristics of the population

223   from which the participants are selected. (18) It is not possible to make any definite statement about

224   whether similar groups will produce similar/ the same results. Having less than six participants has low

225   reliability and with large groups (above twelve) the increase in reliability needs to be balances with

226   diminishing return rates. (5) Thus, reliable outcomes can be obtained with a relatively small Delphi panel

227   size with a response rate of over 70%. (10)

228

229   Taking this into account, our panel of 32 respondents and our response rate of over 90% on the definition

230   of 'stable glaucoma' carries weight for the formation of clinical guidelines. Consensus was reached on

231   the majority of key clinical parameters and where consensus was not reached there was a strong

232   consensus trend. We have used the consensus agreement obtained to generate a definition of stable

233   glaucoma as follows:

234

235   1) *IOP control should be below a target defined by the patients' clinician* – This ensures a tailored

236   approach for each patient and allows clinicians to incorporate important factors such as age,

237   presenting IOP, extent of visual field loss and known rate of visual field progression into this

238   target. (19) (20)

239   2) *Visual field loss can be monitored by Visual field testing with trend analysis of VFI/ MD*

240   *progression* – This represents a simple and practical method of assessing visual field progression

241   used in standard clinical practice. It is no surprise that 0 dB of change is considered stable as

242   essentially this indicates no change. Questioning if clinicians were comfortable with small

243   amounts of visual field loss in the context of stability we found that as larger changes in VF loss

244   are suggested - these changes are considered progressively unstable.

245   3) *No change to the medication regime indicates stability*

246   We were unable to generate a consensus on length of time required to define stability, but our data

247   suggests assessment of stability should take place over an extended period of time at least 36-48

248   months. The lack of consensus on the exact duration of follow-up required before glaucoma can be

249   defined as stable may be a reflection of nervousness amongst clinicians in considering glaucoma a

250   stable disease, as one respondent commented – "glaucoma is by definition a progressive condition and

251   may progress at any time during the patients' lifetime, even after it has been stable for many years".

252   Lack of Delphi consensus on imaging techniques may indicate that when considered on their own, no

253   single imaging technique is currently seen as sufficient or reliable for indicating stability, this may change

254   with the development of improved technologies. However, when asked to rank the available options the

255   combination of OD photos and OCT RNFL assessment/ OCT disc structural evaluation were the preferred

256   imaging methods for the assessment of structural stability. (21) Again this may indicate unease with

257   relying on a single technology at present and a move towards the use of multimodality imaging when

258   organising a monitoring service.

259

260   Based on the findings of this Delphi process, we suggest that the following could be used as a practical,

261   working definition of stable glaucoma:

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263   Glaucoma may be defined as "stable" when the IOP remains below the target IOP defined by the

264   patients' clinician, on less than three medications and requiring no medication changes over a 48-month

265   period during which no further visual field loss monitored by Visual field testing with trend analysis of

266   VFI/ has occurred.

267

268   The aim of this project was to identify a consensus agreement for defining stable glaucoma to allow

269   patient entry into 'stable glaucoma' monitoring schemes and to determine the oversight that would be

270   necessary to run different models of such schemes.

271

272   Despite current governance around community glaucoma schemes and Glaucoma certificates, the

273   consensus was that all community glaucoma monitoring schemes should be overseen by consultant

274   ophthalmologists with glaucoma speciality expertise and it is not acceptable to have no consultant

275   overview of the scheme. This may seem counter intuitive in the context of established recognised higher-

276   level qualifications for optometrists which acknowledge their expertise in the assessment and

277   management of glaucoma and the development of prescribing qualifications which allow optometrists

278   to actively treat patients – however, the consensus may simply reflect consultants erring on the side of

279   caution and it may be that with time, as these schemes become more established and integrated into

280   the continuous model of care - this attitude will change.

281

282   The decision of when to transfer patients to a community monitoring scheme varies between regions,

283   some involving clinician's acumen, others a set of criteria given by the community provider or a

284   combination of the two. The criteria for monitoring and referral back to Hospital Eye Services (HES) is a

285   generally not clear and reliant on the internal governance of community providers.

286

287   In our survey, there was consensus that an assessment of glaucoma "stability" should be made prior to

288   transferring patients to community glaucoma monitoring schemes and only patients who are considered

289   "stable" should be transferred. The use of our definition of glaucoma stability will increase consistency

290   and transparency within glaucoma service provision.

291

292   Other important factors to consider on discharge include: glaucoma diagnosis, severity and the patients'

293   age. It is interesting that regardless of the level of oversight for the community scheme, there was little

294   difference in the results for each parameter.

295   When assessing patients within the community monitoring schemes, the key is to identify patients who

296   are stable and those who do not meet the parameters of stability. Patients who are not stable need to

297   be referred back to HES for further management and intervention. Our consensus definition helps to

298   refine this process by providing some parameters of stability which are important regardless of the level

299   of oversight supporting a particular scheme model.

300

301   **Limitations**

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303 Ensuring confidentiality is an important aspect of formal consensus development. However, the Delphi

304 method can be criticised for losing the benefits of face-to-face interaction which other forms of

305 consensus development such at the nominal group technique (NGT) allow. Although the NGT may have

306 enabled a more sophisticated and nuanced consideration of stable glaucoma, it places a greater time

307 demand upon participants and rests upon all members of an expert group being able to attend an

308 extended meeting (a full day) - It is hard to imagine that we would have been able to achieve this with

309 the 32 glaucoma specialists.

310

311 The survey sample of Ophthalmology consultants was selected from registered Glaucoma Specialist

312 Consultants who are recognised as authorities in the clinical aspects of glaucoma. However, many

313 clinicians who are non– glaucoma specialists and health care professionals with glaucoma expertise are

314 involved in the delivery of Glaucoma services and further study of their understanding and consensus of

315 the parameters which are used to define stability is warranted.

316

317 It could be argued that there is a potential for bias in asking consultant ophthalmologists with glaucoma

318 speciality expertise whether their oversight is important in running stable glaucoma monitoring schemes.

319 However, for a consensus exercise it is appropriate to approach those most knowledgeable in a specific

320 field in this case glaucoma for their expert opinion. This consensus outcome can then be used to inform

321 both specialist and non-specialist of consensus driven best practise. At present, many general

322 ophthalmologists manage this patient cohort already and there are established optometry–led glaucoma

323 clinics managing stable glaucoma within the hospital setting without sub-specialist ophthalmic oversight.

324 This consensus outcome will further inform the future structure of such services.

325

326 We are unable to address this possibility directly, however there is a recognition that glaucoma

327 consultants are already overwhelmed and insufficient in numbers to provide a service sufficient to meet

328 the needs of the aging population (3) and unlikely therefore to want to continue to contribute to a service

329 that they did not believe requires their oversight. Further exploration of this would be helpful and seeking

330 opinion of non-ophthalmologists would clarify whether this opinion is shared by other health care

331 professionals providing glaucoma care.

332

333 **CONCLUSION**

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335 We believe this study has achieved a practical, multifactorial consensus definition of "stable" glaucoma

336 for evaluation of transfer of patients to primary care glaucoma monitoring schemes and a consensus that

337 all such schemes should have glaucoma consultant oversight. This will aid planning and allow consistent

338 modeling of future primary care glaucoma monitoring schemes.

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