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Specialised Independent Prescribing Optometrists Delivering a Community Shared-Care Glaucoma Service: A Pilot Study

RUNNING TITLE: Independent Prescribers run safe and effective services

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Abstract

Aim: Reporting 3 year outcomes of a community shared care scheme run by specialised independent prescribing (IP) optometrists for stable glaucoma and ocular hypertension (OHT) patients in West Kent, England.

Purpose: Shared Care Schemes for glaucoma exist to alleviate the burden on Hospital Eye Services (HES) glaucoma clinics. We studied the effectiveness of community care by highly trained and qualified IP optometrists in terms of disease stability and referral rate into HES.

Methods: Retrospective longitudinal review of 200 eyes with stable early to moderate stage glaucoma and OHT followed-up in two specialist optometry practices. Outcome measures included visual field mean deviation (VFMD), intraocular pressure (IOP), changes to treatment and referral rate into HES. Inclusion criteria included all patients with OHT and glaucoma

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(open angle and primary angle closure) referred for community follow-up. Incomplete data sets were excluded.

Results: Mean age 71yrs (range 28 - 93yrs) and equal male: female ratio. n= 159 at year 3. The results for both outcomes showed no significant change from baseline at 12 or 24-month time points. However, a significant change from baseline at 36 months was observed for both outcomes: mean reduction of 0.7 mmHg in IOP, and a mean reduction of 0.3 dB in VFMD. There was a statistically significant change in the number of drops used at 36 months (p=0.001). 11 patients had a change in medication within 3 years. One patient was referred back to HES for uncontrolled IOP and consideration of trabeculectomy.

Conclusion: Community follow-up of stable cases of glaucoma and OHT by highly qualified IP optometrists was safe, with stability of disease maintained and few referrals back to HES.

Introduction

Glaucoma (POAG) is the leading cause of irreversible blindness globally, with an estimated worldwide prevalence of 76.0 million affected individuals[1]. It is the second major cause for blind registration in the UK[2]. The prevalence of open-angle glaucoma increases exponentially with age and the level of intraocular pressure[3, 4]. The European Glaucoma Society defines glaucoma as a chronic, progressive optic neuropathy[5], and the core principle of treatment is deceleration of disease progression. Once diagnosed, glaucoma requires lifelong treatment and management. The exponential rise in technologies available for diagnosis and treatment outpaces our abilities to increase clinical capacity. Glaucoma patients currently account for 20% of ophthalmology outpatient activity, with 10-year predictions in The Way Forward

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Report projecting a doubling of this figure[6]. With increasing longevity of the population, forecasted higher detection rates and the need for lifelong monitoring, there is an ever-increasing demand for glaucoma services. Increasing capacity remains fundamental to providing patients with the timely care they need.

A 'Shared Care' glaucoma service by definition involves 'the devolvement of clinical management to non-medical staff[7]'. It is a means of adding capacity to overstretched services. The West Kent Community Ophthalmology Team (COT) is a shared care scheme and was established in 2005 to help serve the regional population of ~500,000 in West Kent. It involves 16 trained community optometrists based in 12 geographically-distributed practices. It deals with a range of chronic eye conditions, mainly including glaucoma. Suitable patient are identified by Hospital Eye Services (HES) and referred to a designated local COT service for ongoing management.

Although twelve practices assess glaucoma cases, we particularly wanted to focus on the contribution of two practices led with IP optometrists with higher glaucoma qualifications (Professional Diploma - designed for optometrists working in hospital clinics, or for community practitioners offering commissioned services or running specialist clinics). "Independent Prescribing enables optometrists to clinically assess a patient, establish a diagnosis, determine the clinical management required and prescribe where necessary" (College of Optometrists). Although there are growing numbers of IP optometrists, there is little information on their contribution to eye care in that capacity.

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Compared to evaluating all the practices, this approach allowed for a more consistent analysis in terms of the abilities of practitioners involved. Furthermore, it allowed us to assess the quality of care by those optometrists who, by virtue of their qualifications and skill set, were working in a more autonomous capacity in the community. This level of independence is obviously advantageous for any shared care system, but more safety and efficacy data are required to bolster the confidence of HES clinicians and commissioners. Therefore, our analysis focused on these IP practices.

Here, we describe real-world data and patient outcomes up to and including 3 year follow-up of OHT and glaucoma cases managed by IP optometrists in the community.

Methods

Prior to shared care schemes, follow-up care for glaucoma patients in West Kent was limited to Hospital Eye Services (HES). Upon the formation of the Community Ophthalmology Team (COT) as detailed above, HES had the option to refer appropriate patients for community-based care. To identify these patients, clear criteria were outlined following individual risk stratification, and have been shown in figure 1. Patients meeting the criteria were informed and referred to their local COT practitioner for ongoing follow-up and management.

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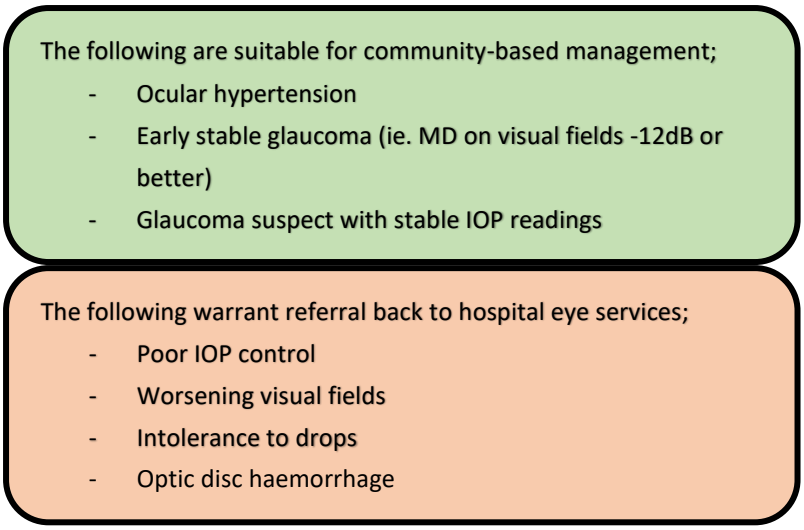

Figure 1: Referral criteria for glaucoma patients being discharged from Hospital Eye Services to Community Shared Care schemes and the re-entry criteria warranting referral back to HES.

Only patients with stable parameters were referred to COT. Stable disease was defined as three consecutive hospital visits (over a period of 18 months) with no change in therapy, treated IOP in the target range (≥ 20% reduction from baseline) and average visual field mean deviation (VFMD) <1dB decline/annum. VFMD had to be at an early to moderate stage up to -12dB with good reliability. Reliability criteria for visual fields were established as <20% fixation losses, <33% false-negative error, and <33% false-positive error, as recommended by Humphrey Instruments, Inc. (San Leandro, California). VF with scotomata encroaching on 10 degrees of fixation were not referred to the community. Corrected acuity (CA) of at least 6/24 with clarity of ocular media was required to allow optic disc imaging. Referral letters clearly communicated the condition, treatment, and when to refer back to HES, for which a fast-track system was established.

Patients were referred back to HES if IOP increased beyond the target value (<20% reduction from baseline) or if there were 2 consecutive changes to topical treatment, worsening of visual fields defined by Glaucoma Progression Analysis (GPA) software (Carl Zeiss Meditec,

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Inc., Dublin CA), i.e. same three points deteriorating in at least 3 consecutive tests, intolerance to drops, optic disc haemorrhage.

After each follow-up in the community, optometrists sent a full report to the glaucoma consultant by hard copy or NHS e-mail. Depending on the results, the glaucoma consultant would decide whether to review back in HES or to continue community follow-up.

Two community-based optometrists participated in anonymised data collection, covering a good geographical spread of the region. After eliminating incomplete datasets, a total of 160 eyes were included in the 3 year analysis. An additional 40 patients had complete 2 year data, totalling 200 eyes

We conducted a retrospective review of this observational data over three years, measuring intraocular pressures (IOP) by Goldmann applanation tonometry, visual field mean deviation (VFMD) on Humphrey visual field analyzer and the number of pressure-lowering drops used. The raw data was collected anonymously and provided by the participating optometrists. This study was compliant with Declaration of Helsinki principles. Ethics board review was not deemed necessary.

Statistical Methods

Statistical analysis was performed using Stata (version 15.1). In the tests described, $p<0.05$ was considered statistically significant. There were two main study outcomes, IOP and VF mean deviation (VFMD), both of which were measured on continuous scales.

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A feature of the data is the majority of the patients in the study had information from both eyes. It is likely that outcomes from two eyes from the same patient are more similar than from two eyes from different patients. To allow for the lack of independence in the data, the analysis was performed using multilevel linear regression models. Two-level models were used, with information from individual eyes nested within patients. The outcome was the change from baseline to a subsequent time point, with just an intercept term included in the model.

Results

The study consisted of data obtained from 157 eyes. These were collected from 80 different patient.

The first set of analyses summarised the characteristics of the 80 patients in the study, with the information shown in Table 1. Continuous variables are summarised by the mean, standard deviation and data range, whilst categorical variables are summarised by the number and percentage in each category.

The results suggested a mean age of 71 years, with a roughly equal number of males and females.

Table 1: Patient level demographics

Variable	*Category*	*Summary*
Number of eyes	*1 eye* *2 eyes*	*3 (4%)* *77 (96%)*
Age	*-*	*71.6 ± 12.2 {28, 93}*
Gender	*Female* *Male*	*41 (51%)* *39 (49%)*

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Figures are: number (percentage), or mean ± standard deviation {range}

Changes in outcome from baseline to each subsequent time point were evaluated, with the results summarised in Table 2. The first figures shown are the number of eyes at each time point, along with the mean and standard deviation outcome values at each point. Mean changes from baseline are also presented, along with corresponding confidence intervals. The final column shows the significance of the changes from baseline. The results for both outcomes showed no significant change from baseline to either the 12 or 24-month time points. However, a significant change from baseline to 36 months was observed for both outcomes. Both outcomes showed a reduction in values between these two time points. There was a mean reduction of 0.7 mmHg in IOP, and a mean reduction of 0.3 dB in VFMD. The residual values from the analyses were checked to ensure that the assumptions of the models were met. These were met in all instances.

Table 2: Changes in outcome from baseline (standard deviation (SD); intraocular pressure (IOP); visual field mean deviation (VFMD)

Outcome	*Time point*	*n*	*Mean ± SD*	*Change from baseline Mean (95% CI)*	*P-value*
IOP	*Baseline*	*157*	*17.6 ± 3.5*	*-*	
	12 months	*157*	*17.2 ± 3.1*	*-0.4 (-0.8, 0.1)*	*0.15*
	24 moths	*157*	*16.8 ± 3.0*	*-0.4 (-0.9, 0.2)*	*0.18*
	36 months	*157*	*17.2 ± 3.1*	*-0.7 (-1.2, -0.2)*	***0.007****
VFMD	*Baseline*	*156*	*-3.03 ± 4.30*	*-*	
	12 months	*156*	*-3.19 ± 4.14*	*-0.16 (-0.45, 0.12)*	*0.26*
	24 moths	*156*	*-3.29 ± 4.13*	*-0.25 (-0.55, 0.05)*	*0.10*
	36 months	*154*	*-3.37 ± 4.25*	*-0.30 (-0.59, -0.01)*	***0.04****
Number of drops	*Baseline*	*157*	*1.24 ± 0.93*	*-*	
	12 months	*157*	*1.34 ± 0.96*	*0.10 (0.02, 0.18)*	***0.02***
	24 moths	*157*	*1.39 ± 0.96*	*0.16 (0.07, 0.24)*	***<0.001****
	36 months	*157*	*1.45 ± 1.00*	*0.21 (0.09, 0.34)*	***0.001****

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Although the changes in VFMD are calculated to be statistically significant for year 3, the mean reduction of 0.3dB reassure this to be an acceptable rate of change in MD for early to moderate glaucoma[6]. A graphical illustration of the outcomes at the different time points are shown in Figures 2A and 2B.

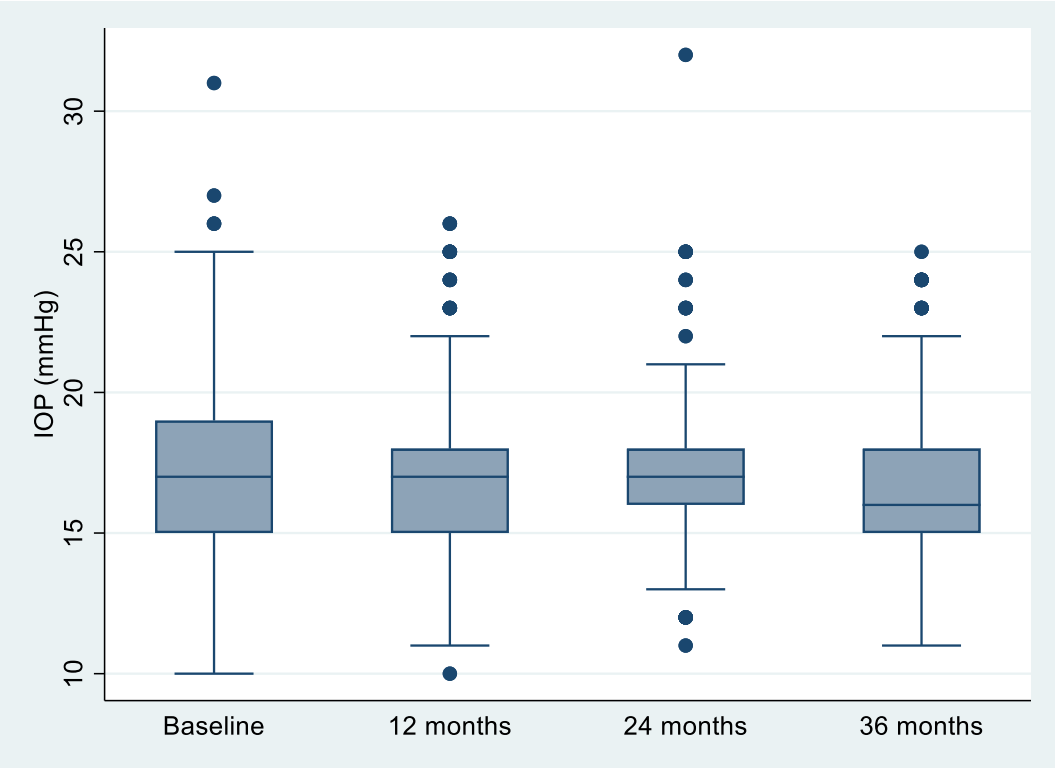

Figure 2A: Boxplot of IOP over time

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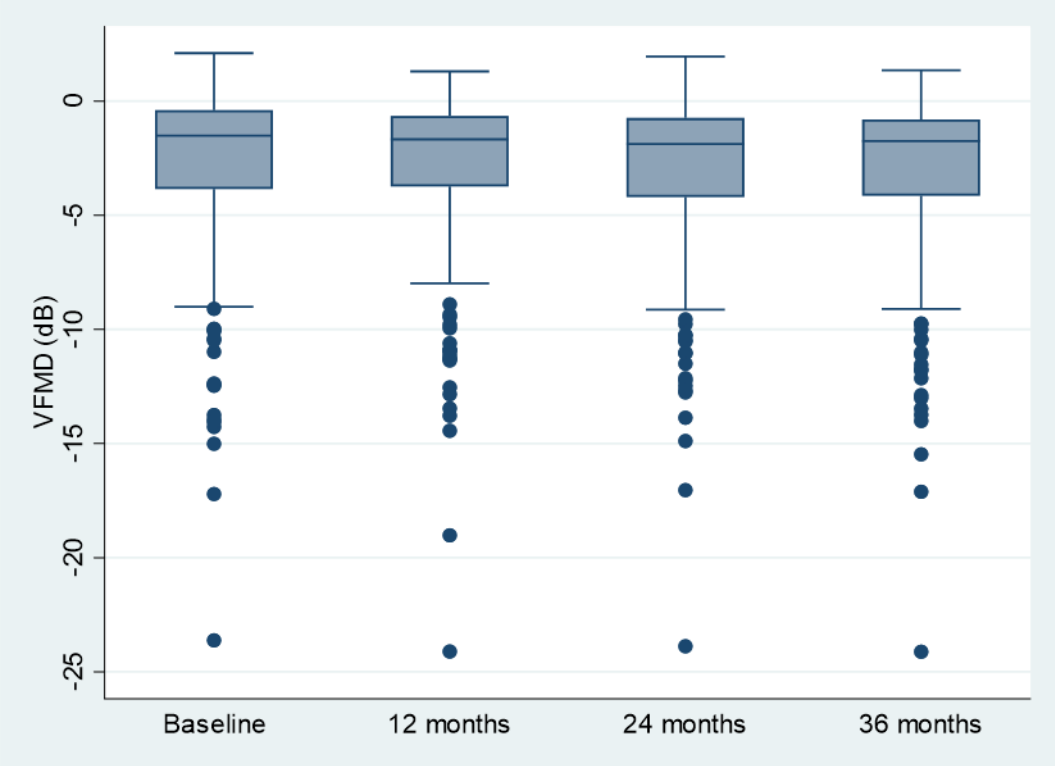

Figure 2B: Boxplot of VFMD over time

There was a statistically significant increase from baseline to each of the subsequent time points for the number of drops used. The number gradually increased throughout the study. Although statistically significant, the sizes of changes were relatively small Table 2 and figure 3).

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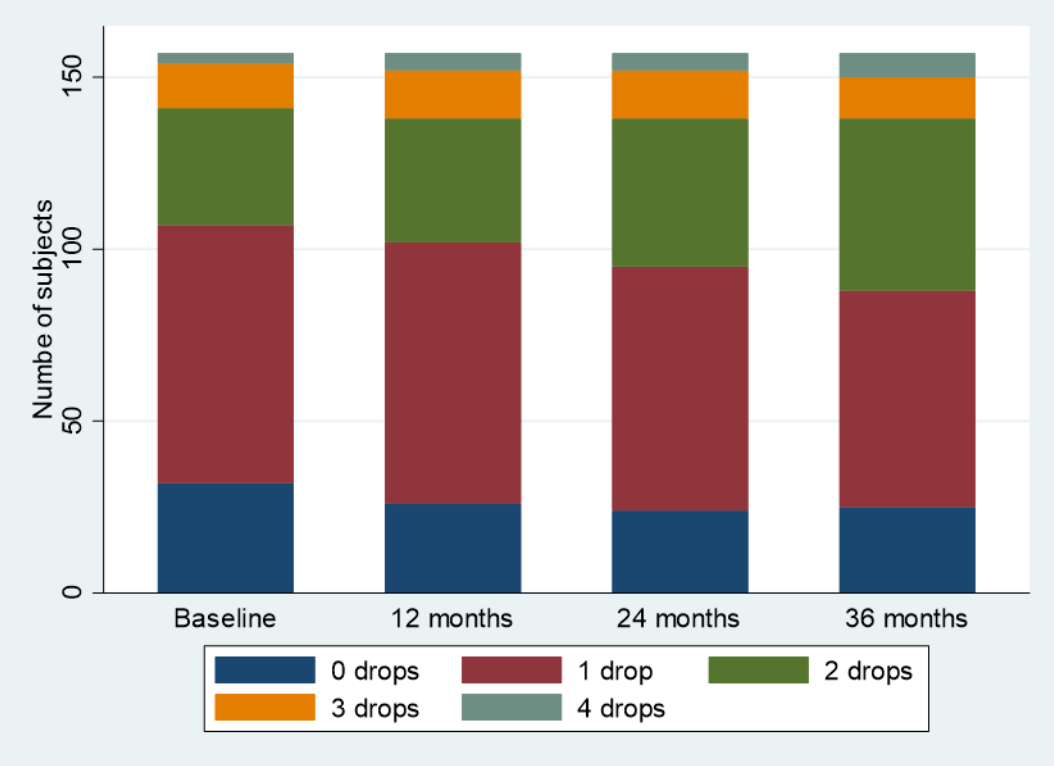

Figure 3: Bar chart of Number of Drops over time

Eleven patients (11%) had a change in treatment initiated by the IP according to EGS guidelines. Three had treatment escalation at 12 months, six at 24 months and two at 36 months. One case (1%), OHT, was discharged to referring optometrist at 36 months.

Only one patient satisfied criteria for referral back to HES during the period of monitoring. This patient was a 71 year old female with a diagnosis of primary open angle glaucoma. She trialled two combination regimes with COT (Travaprost-Timolol/Brinzolamide and Travaprost-Timolol/Brinzolamide-Brimonidine for 12 and 6 months respectively), however at 18-month follow-up IOP recorded 26mmHg in both eyes with progression of MD from -3.78 to -4.91 in the worse affected eye. This lack of disease control and trial of maximal topical treatment warranted a referral back to HES for consideration of surgery.

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Conclusion

The West Kent Shared Care Scheme for Glaucoma (WKSCG) run by IPs was an effective and efficient means of monitoring suitable cases in the community, thereby helping to relieve the burden on HES services. The system was safe, with no cases losing vision, and with only one case being referred back to HES for further management.

In its paper The Way Forward (Glaucoma Summary)[6], the RCOphth states "a strong team of competent and motivated HES optometrists can be built over time to add some capacity to complex patient clinics, and to independently manage moderate risk patients under your care. This is a long term project, bearing long term fruit". In addition it recommends considering sessions funded for optometrists/Health Care Professionals (HCPs) working in the community, which is advantageous in adding much needed capacity. It also encourages upskilling as being essential for ensuring that patients with various levels of disease complexity are cared for by appropriately qualified and experienced HCPs. This also aids career development, staff retention and morale. However, it acknowledges that "training and progression through the various higher (optometric) qualifications takes time and effort on the part of the shared care staff as well as the consultant and other medical staff". As a department, we have found this approach to be very beneficial and the time and effort taken to upskill was well worth it since the specialised IPs could see a broader range of cases independently and safely.

Close collaboration between the specialised optometrists and glaucoma consultant, together with strict criteria for repatriation of suitable cases and a clear pathway back to HES, helped

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to enhance the safety of this system. Since only stable early to moderate cases of glaucoma were referred out, there was reduced risk of significant clinical deterioration within the community.

There are different definitions of 'stable' disease[8], but our criteria were three consecutive appointments with good tolerability of medication, reduction of IOP ≥ 20% from baseline and stability of visual fields (mean VFMD <1dB decline/annum).

The optometrists involved in this evaluation not only had IP qualifications, but also held the Diploma in Glaucoma. This enables optometrists to provide the following services:

- Diagnose and manage OHT/suspect glaucoma
- Referral refinement and enhanced case finding
- Manage low and medium risk glaucoma patients
- Diagnosis and management of high risk patients only under the supervision of a consultant ophthalmologist

Optometrists with specific training reach high degrees of agreement with ophthalmologists in clinical decision making[9-11]. Suitably trained optometrists have also shown good adherence to guidelines regarding initial treatment decisions and the timing of regular monitoring[12]. Previous studies have included shared care assessments of new and follow up cases of glaucoma by optometrists with a range of experience and qualifications[13, 14]. This study concentrated only on follow-up cases seen in the community by the most highly qualified optometrists with Independent Prescriber (IP) rights. Therefore, our study included fewer cases but was still useful in assessing the management of such cases by community

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professionals working in semi-autonomous roles. Therefore, this study cannot be compared directly to previous studies.

There are few studies assessing the performance of IP optometrists. One study demonstrated good agreement between IP optometrists and hospital clinicians [15]. Despite increasing numbers of IP optometrists, their roles in the wider healthcare setting have yet to be defined and incorporated. In August 2018 there were 695 IP optometrists registered with the General Optometric Council (GOC) and the numbers are rising (personal communication, GOC). There is very little literature on how the skills of IP optometrists are being utilised. Extended pathways and optometrist involvement in community services has been reviewed[16] but this was not specifically in relation to IPs. The work of an IP optometrist needs to be demarcated by the scope of the Clinical Management Guidelines, College of Optometrists, but to assist this process more published research into this area of practice is required.

This study was retrospective in nature with inherent limitations. For example it did not address patient satisfaction, patient or carer experiences and medication adherence. A cost-effectiveness analysis would be important for any future evaluation of this shared care model. However, the data set was complete for the first two years, accurate and regularly updated. There was no drop-out for the initial two years, with 21% of records having incomplete data in year three. The follow-up period was relatively short but allowed a useful insight into the initial effectiveness of this service, which augurs well for longer-term follow up of these and additional cases. This model of practice is quite limited at the moment nationally and in other parts of the world, but this pilot study provides encouraging data that supports shared care

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by IP optometrists, which is safe, which helps to reduce the burden on hospital eye clinics and which could be implemented more widely in the future.

Specialised IP optometrists are an important and growing resource, delivering much needed input in an environment of ever-increasing demands being placed on the wider ophthalmic healthcare system. More research is required to help inform HES, College of Optometrists, RCOphth and commissioners on how best to fully utilise the skills of IP optometrists to address increasing demands for the future[17]. This study adds important evidence for future healthcare models incorporating the work of specialised IP optometrists.

What was known before:

1. IP optometrists are increasing in number in the UK.
2. There is very little data on IP optometrists' roles in shared care initiatives.

What this study adds:

1. This study adds valuable data on IP optometrists' performance in community based shared care settings.
2. This study provides evidence for a safe and effective system for community based shared care of glaucoma cases involving IP optometrists.
3. This study offers a model of care involving IP optometrists that could be replicated in different regions throughout the country.
4.

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