Asian J Ophthalmol. 2018;16:193-210

Feasibility, safety and clinical efficiency of optometric service pathways at primary and tertiary care level in Ampang, Malaysia: a pilot study

Duratul Ain Hussin[1,6], Peter Hendicott[1], Andrew Carkeet[1], Philip Baker[2], Ai-Hong Chen[3], Zalifa Zakiah Asnir[4], Zairah Zainal Abidin[4], Rusnah Hussain[4], Azlina Mokhtar[5]

[1]Queensland University of Technology (QUT), School of Optometry and Vision Science, Kelvin Grove, Australia; [2]Queensland University of Technology (QUT), School of Public Health and Social Work, Kelvin Grove, Australia; [3]Universiti Teknologi MARA, Department of Optometry, Puncak Alam, Malaysia; [4]Hospital Ampang, Department of Ophthalmology, Ampang, Malaysia, [5]Universiti Sains Islam Malaysia, Ophthalmology Unit, Nilai, Malaysia; [6]Hospital Kuala Lumpur, Department of Ophthalmology, Kuala Lumpur, Malaysia

Abstract

Aim: *To evaluate feasibility, safety, and clinical efficiency of optometrists in conducting diabetic retinopathy screening and ocular health screening.*

Methods: *This was a prospective observational trial study of newly developed optometric service pathways established at a community health clinic for diabetic retinopathy screening and a hospital ophthalmology clinic for ocular health screening. The study was carried out to assess the feasibility and safety of eye examinations conducted by optometrists. Patients were examined by optometrists using a standard eye examination at both clinics and re-examined by ophthalmologists as the reference standard. Optometrists recorded diagnoses of ocular conditions and classified referral urgency for each patient and these were compared with the diagnoses made by ophthalmologists, who were masked to the optometrists' findings.*

Results: *There was a high concordance of 87.0% (95% CI 80.4%-93.6%) for the diagnoses between the optometrists and ophthalmologists. Of 26 patients considered by the optometrists to need ophthalmology referral, 23 were agreed as such by the ophthalmologists, giving good agreement, $\kappa = 0.76$ (95% CI 0.53 -0.94) between the optometrists and ophthalmologists on referral classification. Agreement by the ophthalmologists for referral urgency classifications (very urgent/urgent or non-urgent) was very good ($\kappa = 0.85$, 95%CI 0.62-1.00).*

Conclusions: *Ocular health examination by optometrists using optometric-eye care pathways is feasible and safe. Optometrists showed strong agreement with*

Correspondence: Duratul Ain Hussin, Ophthalmology Department, Hospital Kuala Lumpur, 50586 Jalan Pahang, Wilayah Persekutuan Kuala Lumpur, Malaysia.
E-mail: duratulain.hussin@gmail.com

ophthalmologists when diagnosing patients who had a range of ocular conditions. Optometrists were also able to triage referrals and their urgency accurately, suggesting that they could play an extensive role as primary eye care providers, thus reducing unnecessary referrals to ophthalmology clinics.

***Keywords**: diabetic retinopathy screening, diagnosis accuracy, evaluation, ocular assessment, optometric services, primary eye care, referral, sensitivity, specificity*

Introduction

In the Malaysian public health system, primary eye care services, specifically general eye examinations and ocular health screening, are mainly undertaken by ophthalmologists in a hospital setting. As a consequence, the ophthalmology burden at public hospitals has increased considerably in recent years, with the number of outpatients visiting hospital ophthalmology clinics each year doubling from 365,685 in 2002 to 735,085 in 2010.[1] There was also a large increase of new cases from 93,797 (2002) to 153,715 (2010) within this period.[1] In addition, throughout this period, the number of diabetic retinopathy screenings conducted at hospitals also increased steadily every year: from 4323 patients to 18,545 patients.[2,3] If this situation persists, it is likely the public health system will be unable to cope with the growth in demand and this may result in a reduction of efficiency.

Unlike many developed countries,[3-5] the role of optometrists in Malaysia in providing ocular health assessment is not widely recognised. Although Malaysian optometrists are trained in ocular pathology, including full eye assessment during undergraduate training, their knowledge and skills are relatively underutilised,[7,8] with the majority of optometrists in public and private sectors undertaking clinical roles limited to refraction in practice. Whilst the provision of refractive services is valuable, optometrists' potential to be primary eye care providers who can conduct ocular health screening may also be valuable for the Malaysian eye care system.

Studies have shown that optometrists in community, hospital, and emergency eye clinics are effective in detecting ocular conditions, thus reducing unnecessary referral to ophthalmologists., In the United Kingdom for example, optometrist-led screening for diabetic retinopathy and glaucoma have reduced the number of patients presenting to a hospital eye clinic by 40% to 70%, through provision of accurate diagnosis and triaging.[8-12] A study at an emergency eye clinic also showed high agreement (89.3%) in diagnoses between optometrists and ophthalmologists.[3] In Wales at the community level, one study found that optometrists achieved high diagnosis accuracy, with only 1% of inappropriate management and no sight-threatening management errors.[5] There are, however, no published data in Malaysia regarding optometrists' ability to conduct ocular

health assessment and to initiate referral to ophthalmologists.

To address this lack of information, the "Optometric eye-care in the Primary and Tertiary Evaluation" (OPTION) study was conducted as a pilot evaluation of two optometric service pathways in diabetic retinopathy screening and ocular health screening, to give information on diagnosis accuracy, referral decision, and referral urgency.

Methods

This was a prospective non-experimental cross-sectional study carried out between March 18, 2013 and April 3, 2013 at two locations in Malaysia: the Ampang Community Health Clinic for diabetic retinopathy screening and the Ampang Hospital Ophthalmology Clinic for ocular health screening. Ethical approval was obtained from the Medical Research and Ethics Committee (MREC) Malaysia (Approval Number NMRR-12-875-11483) and the Queensland University of Technology Human Research Ethics Committee (Approval Number 1200000688). Written consent was obtained from all participants: ophthalmologists, optometrists, and patients. The first author approached patients at respective study locations to obtain informed written consent. The study adhered to the tenets of the Declaration of Helsinki.

Eight optometrists from public eye hospitals, where their current clinical role was primarily refraction, participated in the study. The optometrists were given refresher training on ocular health assessment for three days prior to the study. At both locations, optometrists and ophthalmologists performed a standardised eye examination using similar instruments. Intraocular pressure (IOP) was measured using a Goldmann tonometer AT900 (Haag-Streit, Switzerland). Fundus examination under mydriasis was carried out in nine directions of gaze using the slit-lamp biomicroscope (Haag-Streit, Switzerland) and a 90 D (Volk, USA) or 54 D (Ocular Science, USA) condensing lens. Gonioscopy was performed prior to dilating the patient's pupil using a Goldmann 3-mirror universal lens (Haag-Streit, Switzerland) when indicated. Other clinical procedures such as refraction and perimetry were conducted on the same day if required.

Examination began with habitual visual acuity (VA) testing, followed by full history-taking. Pre-screening for pupil dilation, such as pupil reflexes, Van Herick test, and IOP measurement, was conducted prior to administration of the dilating agent (tropicamide hydrochloride 1%) and was verified by the first author (at the Health Clinic) or ophthalmologists (at the Ophthalmology Clinic). This pre-screening step was to ensure that no patient underwent pupil dilatation by optometrists if this was contraindicated. If an optometrist decided to dilate in contraindicated conditions, the first author notified the optometrist not to proceed with this examination. If that occurred, the patient would be excluded

from the study and returned to the ophthalmologist to complete their examination in the usual care pathway at the clinic or hospital.

Standards were set for correspondence with ophthalmologists, and diagnostic classifications based on ICD-10 coding[13] were used. A clinical guideline for referral was also established for the study, as summarised in Table 1. At the end of each examination, both ophthalmologists and optometrists made ocular diagnoses and indicated appropriate management for the patient. In establishing the study, prior discussion with the head ophthalmologist at the Ampang Hospital Ophthalmology Clinic and the local health authority took place to consider patient safety during the study. As a result, the safe level (for the pilot study to be considered safe) of concordance in ocular diagnoses between ophthalmologists and optometrists was pre-set at a level of at least 80% agreement.

Ocular diagnosis was defined in the study as any diagnosis made about each patients' eyes following a full eye examination, including primary and secondary diagnoses. Hence, a patient may have multiple diagnoses for each eye. For diabetes mellitus patients, in addition to the ocular diagnoses, the diabetic retinopathy status for each eye was also determined by optometrists. As a result, these patients may have more diagnoses than those patients without diabetes mellitus. Diabetic retinopathy was graded according to the Malaysian CPG for diabetic retinopathy screening.[14] A definitive glaucoma diagnosis was made only if patients had their visual field tested. When visual field testing was not conducted, but other signs suggestive of glaucoma were present, the diagnosis was recorded as "glaucoma suspect". Ophthalmologists were aware that the patients were already examined by the optometrists but had no access to the findings. Ophthalmologists indicated diagnoses, masked from any information about the optometrists' diagnoses, followed by a treatment plan such as medicine prescription and surgery.

Patient management analysis evaluated whether a decision to refer to the ophthalmologist was made (*i.e.*, refer or not refer) and its referral urgency (very urgent/urgent or non-urgent). If needed, referral was made for a patient regardless of the number of diagnoses made for the patient. Referral timing was based on severity and grading of the eye conditions.

Table 1. Summarised referral guidelines (timing and urgency) for the diagnosis/eye conditions detected by optometrists

Diagnosis	Referral timing	Referral urgency
Inflammation and infection of eyelids, lacrimal gland and margins, and nasolacrimal system		

Diagnosis	Referral timing	Referral urgency
Blepharitis, meibomitis, chalazion, dry eye	4 weeks	Non-urgent
Allergic conjunctivitis, viral conjunctivitis, bacterial conjunctivitis	2-4 weeks same day if there is a punctuate epithelial defect or sterile ulcer or sub-epithelial infiltrates or pseudo membrane present	Urgent
Inflammation and infection of cornea		
CLARE	2 weeks	Non-urgent
Bacterial keratitis, filamentous fungal keratitis	same day	Very urgent
Inflammation and infection of sclera and uvea		
Scleritis, uveitis	same day	Very urgent
Cataract		
Mild cataract	6 months	Non-urgent
Moderate cataract	3 months	Non-urgent
Severe cataract	same day	Very urgent
Diabetic retinopathy		
No DR	6 months to 12 months	Non-urgent
Mild NPDR without maculopathy		
Moderate NPDR without maculopathy		
Mild/moderate NPDR with maculopathy	1 week	Urgent referral
Severe NPDR without maculopathy		
Any maculopathy		
Proliferative DR	same day	Very urgent
ADED	same day	Very urgent

Diagnosis	Referral timing	Referral urgency
No DR to mild NPDR in pregnancy	1 week	Non-urgent
Moderate/severe NPDR in pregnancy	same day	Very urgent
Glaucoma		
ACG	same day	Very urgent
POAG, NTG, OHT	1 week same day if VF affected	Urgent

CLARE: contact lens associated red eye; DR: diabetic retinopathy; NPDR: non-proliferative diabetic retinopathy; ADED: advanced diabetic eye disease; ACG: angle closure glaucoma; POAG: primary open angle glaucoma; NTG: normal tension glaucoma; OHT: ocular hypertension

Diabetic retinopathy screening

At the Ampang Health Clinic, eligibility criteria for patients to be included were having either type 1 or 2 diabetes mellitus with no history of prior diabetic retinopathy screening (unknown retinopathy status). Patients were examined on the same day as recruitment or given an appointment, according to their time availability.

Optometrists conducted diabetic retinopathy screening using a fundus biomicroscopy examination through dilated pupils, graded diabetic retinopathy for each eye, and determined if the patients required an ophthalmology referral. Other significant findings were also recorded by the optometrists. The patients were given an appointment date for ophthalmology re-examination at Ampang Hospital Ophthalmology Clinic within one week of the optometric examination. Patients were treated according to the existing ophthalmology clinic protocol when they came for the ophthalmologist's examination.

Ocular health screenings

At the Ampang Hospital Ophthalmology Clinic, all patients with referral letters were eligible to participate except those with ocular trauma, strabismus, or known ocular comorbidity. Optometrists were masked to the clinical information in the referral letter, such as provisional diagnosis.

Optometrists performed ocular health screening through dilated pupils if indicated. They concluded the examination with diagnoses for each eye including diagnosis of normal eye/no diabetic retinopathy and decided on whether referral was required. Once the optometric examination was completed, patients were then taken for an ophthalmologist's re-examination whilst the patients' pupils remained dilated.

Assessment of outcome and data analysis

Three main indices were assessed in this pilot study:

1. feasibility and safety of study protocol (patient recruitment, attrition rate, indication for pupil dilatation);
2. accuracy of diagnosis; and
3. accuracy of referral decision.

For feasibility, it was also important to determine whether the clinical protocol adopted in the study disrupted existing clinic protocols.

To analyse the optometrists' accuracy of diagnosis and referral decisions, the primary diagnoses and referral decisions data from both study locations were combined to form one data set. Patients' and optometrists' names were assigned an identifier code by the first author. All diagnoses made for each eye were analysed as an individual diagnosis. Subsequently, a meeting was conducted with the participating ophthalmologists where the first author presented each patient's diagnoses data at a time to the ophthalmologists as a group. The ophthalmologists discussed and decided as a group if they agreed or disagreed with the optometrists' diagnosis and secondary diagnoses. The percentage of agreement for diagnosis made between ophthalmologists and optometrists was determined.

During the meeting, ophthalmologists as a group also rated the patient management plan (referral decision and referral urgency) using the same categorizations as the optometrists. Accuracy of referral decision and referral urgency was measured using the Kappa (κ) statistic with quadratic weights, analysed by using the statistical program SPSS version 21 (IBM). The magnitude of agreement for kappa statistics is between 0 and 1.0 and was classified as poor (< 0.20), fair (0.21-0.40), moderate (0.41-0.60), good (0.61–0.80, and very good (0.81–0.99).[16]

Agreement decisions for diagnosis and referral were undertaken collectively and any differences among the ophthalmologists as to the rating were resolved by consensus. In these instances, clinical notes from both ophthalmologists and optometrists were referred to in order to obtain more details on assessment findings to reach this consensus decision. If there was a tie between agreement and disagreement, the decision of the most senior ophthalmologist was the final arbiter.

Results

Feasibility and safety of the study protocol

The number of patients recruited for eye examinations varied across every clinic session (range: 4 to 7 patients) at both locations, depending on how many patients agreed to take part. Patient consent was obtained on the day of recruitment for

56 patients (31 patients from Ampang Health Clinic and 25 patients from Ampang Hospital Ophthalmology Clinic). Most participants were in the age group of 50-59 years, with mean age at the Health Clinic slightly older (56.7 years, SD 8.2, range 33-73 years) than the mean age for the patients at the Hospital Ophthalmology Clinic (52.3 years, SD 18.9, range 14-78 years).

A total of 43 patients were re-examined by ophthalmologists because of patients dropping out. Of the 31 patients recruited at the Ampang Health Clinic, 13 patients (41.9%) did not present at the Ophthalmology Clinic for re-examination. Patients who did not attend were not asked about reasons for non-attendance. A review of their optometric records indicates that those patients had no diabetic retinopathy (DR) during screening. No patients recruited at the Ophthalmology Clinic dropped out and all of them were re-examined on the same day as the optometrist's examination. Patients at both locations were concerned about the potential side effects of the pupil dilatation. Therefore, some patients requested to be examined on a different day to arrange their transportation and work schedule. During the pilot study at the Ophthalmology Clinic, none of the optometrists incorrectly decided on pupil dilatation in patients where the ophthalmologist subsequently considered this contraindicated. The optometrists also decided not to dilate pupils in two patients. One patient presented with a mid-dilated pupil and the other with a corneal ulcer. This decision was in concordance with the ophthalmologist, who had assessed the patients initially and thought these two patients needed immediate referral without pupil dilatation. The remaining patients were considered by the ophthalmologists as safe for pupil dilatation. No adverse effects, such as lid swelling or red eyes occurred, in any patient participant following pupil dilation and the optometrists' examination at either study location. After dilation, most patients reported experiencing blurry vision and light sensitivity, which they had been warned about as part of the informed consent. They were provided with free sunglasses for their participation.

Accuracy of ocular diagnoses

Ocular diagnoses from 86 eyes (n = 43 patients) examined by both the optometrists and ophthalmologists were matched and tabulated for comparison. In 54% of the eyes, more than one diagnosis was made (range: 2 to 4 diagnoses), specifically those with diabetes mellitus; hence, the total ocular diagnoses gathered were greater than the number of eyes. Figure 1 shows the overview of diagnoses made by the optometrists and ophthalmologists with respect to ophthalmologists' agreement. A total of 229 ocular diagnoses were collected from both practitioners, with the number of ophthalmologists' and optometrists' diagnoses being 121 and 108 respectively. Of 108 diagnoses made by optometrists, ophthalmologists did not detect and record 8 diagnoses, which were all mild dry eyes. Ophthalmologists by consensus agreed that these 8 diagnoses be excluded

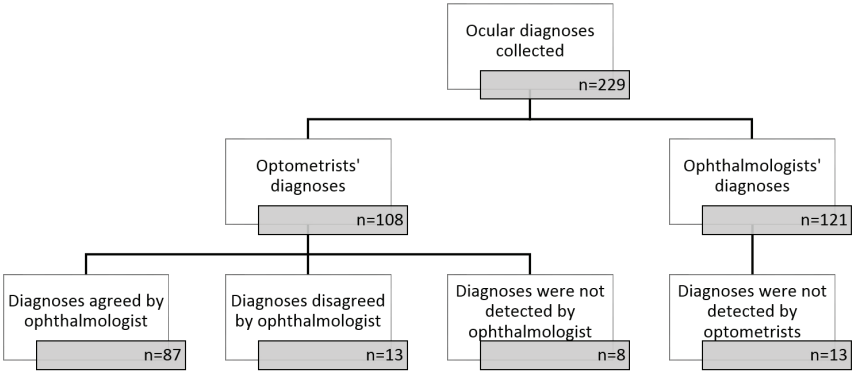

Fig. 1. Ocular diagnoses made by the optometrists, compared with the ophthalmologists' diagnosis.

from the comparison as they were very mild conditions that they may not have recorded even when present. In the remaining 100 diagnoses, concordance of 87.0% (95% CI 80.4% to 93.6%) was found between the optometrists and ophthalmologists. However, 13 (13%) of optometrists' diagnoses were found not to be in agreement with the ophthalmologists' diagnoses.

Table 2 shows the 87 diagnoses in which optometrists and ophthalmologists were in agreement, classified as sight threatening, non-sight threatening, or no abnormalities detected (NAD). The 25 (28.7%) diagnoses of sight threatening conditions included branch retinal vein occlusion (BRVO), corneal ulcer, central retinal vein occlusion (CRVO), dense cataract, and acute closure glaucoma (ACG). Glaucoma suspects, irrespective of the subtype, contributed to 16.1% (n = 14) of the diagnoses correctly identified by the optometrists, followed by dense cataract (n = 4, 4.6%), and non-proliferative diabetic retinopathy (NPDR) (n = 3, 3.4%). A total of 66.7% of diagnoses made by optometrists were non-sight-threatening conditions. No diabetic retinopathy (No DR) or normal fundus were the most frequent diagnoses (42.5%) agreed with by the ophthalmologists. Other, more frequent, non-sight threatening conditions were: moderate cataracts (n = 11, 12.6%), followed by chalazion, corneal scar, and dry eye. Four diagnoses (4.6%) were considered normal eyes by the optometrists and also by the ophthalmologists.

Of the 13 disagreements, 12 diagnoses were classified as non-sight threatening, except for old toxoplasmosis (Table 3). Disagreement was mostly due to optometrists' different diagnoses for mild retinopathy (9 eyes). In the remaining eyes, review of the patient's fundus record indicated the optometrist had actually detected pigmentary retinal abnormalities in Patient 9, but made a diagnosis of retinitis pigmentosa, where ophthalmologists regarded this as normal temporal

pigmentary spots. This was also similar to Patient 11, in whom an optometrist classified corneal abnormalities as corneal infiltrates, which an ophthalmologist classified as a corneal scar. In comparison, for another patient, an optometrist diagnosed a normal cornea as bacterial keratitis, as the optometrist noted significant corneal staining with fluorescein, which was noted as not significant by the ophthalmologist. This was later considered in the review discussion to be possibly a staining subsequent to prior applanation tonometry.

Table 2. Optometrist diagnoses which agreed with ophthalmology diagnoses, categorized by sight-threatening and non-sight threatening conditions

	Optometrist's diagnoses	N	%
Sight threatening (n = 25, 28.7%)	BRVO	1	1.1
	Corneal ulcer	1	1.1
	CRVO	1	1.1
	Dense cataract	4	4.6
	Glaucoma suspect (ACG)	1	1.1
	Glaucoma suspect (NTG)	7	8.0
	Glaucoma suspect (POAG)	6	6.8
	Maculopathy	1	1.1
	Mild NPDR with moderate maculopathy	1	1.1
	Moderate NPDR with macular Haemorrhage	1	1.1
	Moderate NPDR with maculopathy	1	1.1
Non-sight threatening (n = 58, 66.7%)	Chalazion	1	1.1
	Corneal scar secondary to old trauma	1	1.1
	Dry eye	2	2.3
	Hyperpigmented cornea	1	1.1
	Mild NPDR	1	1.1
	Moderate cataract	11	16
	No DR	37	45
	Papillary conjunctivitis	1	1.1
	PCO	1	1.1
	Refractive error	2	2.3
NAD	Normal eye	4	4.6

BRVO: branch retinal vein occlusion; CRVO: central retinal vein occlusion; POAG: primary open angle glaucoma; ACG: angle closure glaucoma; NTG: normal tension glaucoma; NPDR: non-proliferative diabetic retinopathy; DR: diabetic retinopathy; PCO: posterior capsular opacification

Table 3. Optometrists' diagnoses which were disagreed by the ophthalmologists

Patient No.	Optometrists' diagnoses	Ophthalmologists' diagnoses
9	Early retinitis pigmentosa (RE)	Pigmentary spots temporal retina (RE)
11	Traumatic corneal infiltrates (RE)	Cornea scar secondary to previous trauma (RE)
16	No DR (LE)	Mild NPDR (LE)
21	Moderate NPDR without maculopathy (RE)	Mild NPDR with mild maculopathy (RE)
25	Bacterial keratitis (LE)	Normal eye (LE)
40	No DR (LE)	Mild NPDR (LE)
43	No DR (RE)	Mild NPDR (RE)
43	No DR (LE)	Mild NPDR (LE)
44	No DR (RE)	Mild NPDR (RE)
46	Mild NPDR (RE)	No DR (RE)
48	Retinitis pigmentosa (RE)	Old toxoplasmosis (RE)
53	Mild NPDR without maculopathy (RE)	No DR (RE)
53	Mild NPDR without maculopathy (LE)	No DR (LE)

DR: diabetic retinopathy; NPDR non-proliferative diabetic retinopathy

Optometrists did not identify 13 additional diagnoses made by the ophthalmologists. The most frequently missed diagnoses were glaucoma suspicion (n = 5) and no DR (n = 3). Review of the optometrists' clinical records showed that the optometrists had actually recorded some ocular structure abnormalities, such as increased vertical cup-to-disc ratio (CDR) and blocked Meibomian glands, but did not formulate an appropriate diagnosis for these clinical signs. Table 4 shows the clinical findings recorded by the optometrists for these missed diagnoses. In Patient 14, diagnosis was unable to be made because the optometrist, correctly, did not perform dilated fundus examination due to shallow angle estimates and high intraocular pressure. Obscuration of the fundus view was also noted in one patient due to dense cataract in the eye. For two patients in whom ophthalmologists identified abnormalities in the cornea, optometrists did not find any abnormalities.

Table 4. Ophthalmologist's diagnoses which were not identified and/or diagnosed by optometrists

Patient No.	Ophthalmologist's diagnoses	Optometrist' clinical notes
1	No DR (RE)	Difficult view due to cataract (RE)
10	Glaucoma suspect (NTG) (RE)	Vertical CDR 0.4 to 0.5 (RE)
13	Hypertensive retinopathy (BE)	NAD fundus (BE)
14	Moderate cataract (RE) Glaucoma suspect (CACG) (LE) No DR (BE)	Pupil was not dilated as contra-indicated by shallow anterior angle, high IOP, poor VA 6/60 (RE), 6/48 (LE)
17	Iridocorneal endothelial syndrome (ICE) (RE)	Not recorded
23	Meibomitis (LE)	Meibomian gland blocked (LE)
38	Allergic conjunctivitis (RE)	NAD (RE), papillary conjunctivitis (LE)
41	Glaucoma suspect (NTG) (RE)	Glaucoma suspect (NTG) (LE), vertical CDR 0.3 (RE), 0.5 (LE)
52	Cornea degeneration (LE) Cornea scar (LE)	Not recorded
53	Glaucoma suspect (NTG) (BE)	Normal CDR (BE), normal IOP (BE)

NAD: nothing abnormal detected; CDR: cup-to-disc ratio; CACG: chronic angle closure glaucoma; NTG: normal tension glaucoma; IOP intraocular pressure; ARMD: age-related macular degeneration; TBUT: tear break-up time

Accuracy in patient referrals

Of the 43 patients included in the analysis of the pilot study, there were 26 patients considered by an optometrist as requiring referral to an ophthalmologist based on their diagnosis. This group consisted of 20 patients from the Ophthalmology Clinic and 6 patients from the Health Clinic. This difference in the number of patients needing referral between the clinics is statistically significant χ^2 (1, n = 26) = 7.538, p = 0.006, consistent with the fact that patients presenting at the Ampang Hospital Ophthalmology Clinic had already been referred for ophthalmological assessment, whereas patients from the Ampang Health Clinic were presenting for primary medical care for diabetes mellitus. For the remaining 17 patients considered by the optometrists as not needing referral, yearly follow-up was recommended for 12 patients and 5 patients were discharged. The follow-up examinations were for patients attending for DR screening, with one patient diagnosed as mild NPDR and the remaining 11 patients as having diabetes but no DR. For the discharged patients, one was identified as having mild dry eye

needing artificial tears and four patients were provided with a spectacle prescription for refractive error.

Table 5 shows a comparison between referral decision for the patients by optometrists and ophthalmologists. Of 26 patients who had been referred by optometrists to ophthalmology, ophthalmologists agreed with the referral decision in 23 of the cases, while they considered 3 patients as not needing referral. For the 17 patients not referred by optometrists, ophthalmologists agreed with the decision of not referring in 15 cases. Ophthalmologists considered two patients should have been referred to ophthalmology as non-urgent referrals. In these patients, the optometrist gave a 3-month follow-up to monitor dry eye and refractive error, while missing mild cataract, irido-corneal endothelial syndrome (ICE), and branch retinal vein occlusion (BRVO) diagnosed by the ophthalmologists. Twenty-three patients (92.0%, 95% CI 74.0%-99.9%) requiring ophthalmological care would have been referred (true positives), while only 2/25 (8.0%, 95% CI 10.0%-26.0%) of patients not requiring referral would have been inappropriately referred (false negatives). There was very good agreement on the referral classifications of whether to refer or not refer ($\kappa = 0.76$, 95%CI 0.53-0.94) between optometrists and ophthalmologists.

Table 5. Comparison of optometrists' and ophthalmologists' decisions for referring patients

		Ophthalmologist's classification		Total
		Refer	Not refer	
Optometrists' classification	Refer	23	3	26
	Not refer	2	15	17
Total		25	18	43

Of the 26 patients classified by optometrists as needing referral, urgency of referral was classified equally as non-urgent (n = 13, 50.0 %) and urgent/very urgent (n = 13, 50.0 %).

Table 6 shows the results of optometrists' referral urgency decision for the patients as compared with ophthalmologists. Ophthalmologists agreed with referral classification for all 13 patients classified by optometrists as non-urgent referrals, and also agreed on the urgency of referral in all 11 of 13 patients classified as "urgent/very urgent". Agreement by the ophthalmologists for these classifications was also very good ($\kappa = 0.85$, 95%CI 0.62 to 1.00).

Table 6. Comparison of optometrists' decisions for referral urgency (non-urgent and urgent/very urgent) with ophthalmologists' decisions

		Ophthalmologist's classification		Total
		Non-urgent	Urgent/Very urgent	
Optometrists' classification	Non-urgent	13	0	13
	Urgent/ Very urgent	2	11	13
Total		15	11	26

Discussion

This study provides useful information concerning the feasibility, safety, and accuracy of diagnosis and referrals of ocular health examination conducted by a group of optometrists in Malaysia. To our knowledge, this is the first study in Malaysia to compare the performance of optometrists in making diagnoses with ophthalmologists' decisions as a reference standard at an actual clinic setting.

As it was the first time such a study had been conducted in Malaysian eye care services, it was important to assess whether the studies at both clinics were feasible and safe. The pilot study adequately recruited patients who met the study eligibility criteria. This was important because when the study was planned, it was not clear that patients would be inclined to be examined by an optometrist, l*et alo*ne spend more time waiting for re-examination by an ophthalmologist. Attrition or drop-out is a major aspect of assessing feasibility in this study, which was evident at the Health Clinic. Patients might possibly have defaulted on the appointment for the ophthalmologist re-examination because this required additional travel and time for another similar test a few days later. As approximately half of the patients from the Health Clinic dropped out, this indicates that a similar trend might occur in a future study. One strategy to minimize this might be to use appointment reminders or to make arrangements for ophthalmologist re-examination at the same clinic where the screening took place.

This study also provides strong evidence of the patient safety of optometric eye care pathways. It addressed the concerns by the local health authority in regards to safety of the patients undergoing redesigned eye care pathways conducted by optometrists who had very limited experience in ocular health assessment. The study showed there were no patients who experienced adverse reactions to the pupil dilatation or as a consequence of the optometrists' examinations. To encourage participation, patients who were concerned with pupil dilatation were given an appointment for an eye examination at a later date.

The current study achieved the minimum 80% inter-practitioner agreement standard established by the health authority, with results showing very high agreement in accuracy of ocular diagnoses (87.0%). Optometrists also made very urgent diagnoses of potentially sight-threatening conditions correctly (those which required immediate ophthalmological attention), specifically a CRVO and BRVO, corneal ulcer, and ACG. This indicates that the optometrists in the study were able to ensure patient safety effectively.

Disagreement about diagnoses occurred primarily in clinical findings such as mild NPDR, corneal scar, and old toxoplasmosis, which were considered by the ophthalmologists a result of differences in grading. Such disagreements were typically for non-urgent referrals. In cases where misclassification of diagnosis occurred, this was for non-sight threatening conditions and no patients were found to have any complications from the diagnoses and management made by optometrists. Additionally, diagnoses which optometrists missed were relatively uncommon conditions. For example, optometrists missed a case of ICE syndrome,[16] often associated with secondary glaucoma.[17] This condition is relatively rare in the Western population and even more so among the Asian population.[18] In the study by Teekhasaenee and Ritch,[19] even ophthalmologists missed ICE in 68% of patients due to the complexity of its clinical variations and spectrums, emphasizing the fact that clinical experience is an important factor for diagnosing this condition accurately. For these reasons, it is expected that optometrists in the current study would have missed such a diagnosis, but it should be noted that, even without the diagnosis, the optometrist correctly referred this patient to the ophthalmologist.

Another missed diagnosis was normal tension glaucoma (NTG) which has very low prevalence (6.51%) in Malaysia,[19] so the likelihood of encountering NTG is rare, except in sleep apnea syndrome.[21] In this pilot study, the optometrist's record did not contain any notes on sleep history, such as snoring, as compared to the ophthalmologist's notes. However, record reviews showed that optometrists detected abnormal optic discs in this patient, but this was only identified as physiological disc cupping. It may be that continuing education and extensive clinical exposure will improve optometrists' history-taking and diagnostic ability in more complex glaucoma cases. Myint *et al.*[21] suggested that development of glaucoma training needs to be more practice-based, which is more effective than the didactic approach. This supports the importance of providing hands-on exposure as part of their professional development, especially for those who have potential to share glaucoma care.

Despite some diagnostic inaccuracies, the patients examined by the optometrists were referred ($\kappa = 0.76$) and triaged ($\kappa = 0.85$) correctly with agreement to those of the ophthalmologists. The ability to differentiate urgency of referral can

influence service efficacy, accessibility, waiting time, and appointment scheduling for patients.[22,23] In the current study, almost all of the patients (92.0%) requiring ophthalmological care would have been referred correctly by the optometrists (true positives), and only 8.0% of patients were inappropriately classified as not requiring referral (false negatives). The concordance of referral outcomes in the current study (92%) is higher than that reported in a community setting at 75%[6] and at an emergency setting at 90.7%[4] in the United Kingdom. These findings constitute evidence that current participating optometrists can effectively triage the urgency of referrals despite having limited experience.

The majority of the patients (81.1%) screened for diabetic retinopathy had normal fundi (no DR) in this pilot study, with only 18.9% having any form of retinopathy. The figure is consistent with previous studies in Malaysia, in which most patients referred for screening were normal.[24,25] In these two studies, any form of retinopathy was only diagnosed in 36.8% to 28.9% of referred patients. These studies indicate that a number of diabetic patients were referred unnecessarily to a hospital for eye examination and diagnosis of normal eye and non-urgent conditions. This pilot study provided support for the development of DR screening at a primary care level and shows that it could be safely conducted independently by optometrists without many patients even needing to attend an ophthalmology clinic until proliferative retinopathy was found.

Most eye conditions (66.7%) found in this pilot study at the Ophthalmology Clinic were non-sight threatening, such as conjunctivitis, chalazion, and dry eye. This suggests that if misdiagnosis from the optometric eye care pathways occurred, the complications may not be serious. However, under the existing referral and clinical care pathways at the hospital, all these patients would have seen an ophthalmologist for examination. Our study was comparable to that of Hau *et al.*[3] who also found that almost 50% of the diagnoses in patients presenting in an ophthalmic emergency setting were actually of non-sight threatening ocular conditions. As most patients who were referred to the hospital have ocular conditions that present a risk to vision or ocular health, the outcome of our pilot study and the findings of Hau *et al.*[3] would indicate that many patients could be appropriately examined and managed by optometrists as opposed to ophthalmologists.

Conclusion

The information reported from this pilot study will be useful for the design of future optometric eye care pathways studies in Malaysia. Ocular health examination by optometrists appears to be feasible and safe for patients, with high accuracy of diagnosis and referral decisions. Such optometrist-led screening at both eye care levels may reduce unnecessary referrals to ophthalmology clinics, particularly for

screenings. More training and clinical exposure can improve optometrists' skills in ocular health examination which would further increase diagnostic accuracy. Although exploratory in design, the outcomes of this study provide important evidence to policy makers in the planning and development of eye care delivery in Malaysia.

Acknowledgements

The study was sponsored by a Ministry of Health Malaysia Research Grant (NMRR-12-875-11483). The authors are grateful to all the participating ophthalmologists and optometrists for their time and commitment in the study. We also thank the General Director of Health, Ministry of Health Malaysia for permission to publish this article.

References

1. Salowi, MA, Goh PP (Eds). Fourth Report of the National Eye Database 2010. 2012; Kuala Lumpur:118.
2. Goh PP, Omar MA, Yusoff AF. Diabetic eye screening in Malaysia: findings from the National Health and Morbidity Survey 2006. Singapore Med J. 2010;51(8):631-634.
3. Hau S, Ehrlich D, Binstead K, Verma S. An evaluation of optometrists' ability to correctly identify and manage patients with ocular disease in the accident and emergency department of an eye hospital. Br J Ophthalmol. 2007;91(4):437-440.
4. Harper R, Creer R, Jackson J, et al. Scope of practice of optometrists working in the UK Hospital Eye Service: a national survey. Ophthalmic Physiol Opt.2016;36(2):197-206.
5. Sheen NJ, Fone D, Phillips CJ, Sparrow JM, Pointer JS, Wild JM. Novel optometrist-led all Wales primary eye-care services: evaluation of a prospective case series. Br J Ophthalmol. 2009;93:435-438.
6. Mohidin N, Hashim A. Amalan optometris di praktis swasta sekitar Kuala Lumpur dan Lembah Klang: Satu kajian awal (Optometric practice in private sector around Kuala Lumpur and Klang Valley: a preliminary study). Jurnal Sains Kesihatan Malaysia 2011; 9:29-34.
7. Tan KO, C Lam. Optometry graduates: are they practicing what they have learnt? In: World Conference on Optometry Education. 2010. Durban, South Africa.
8. Bourne RR, French KA, Chang L, Borman AD, Hingorani M, Newsom WD. Can a community optometrist-based referral refinement scheme reduce false-positive glaucoma hospital referrals without compromising quality of care? The community and hospital allied network glaucoma evaluation scheme (CHANGES). Eye 2010; 24(5):881-887.
9. Lockwood AJ, Kirwan JF, Ashleigh Z. Optometrists referrals for glaucoma assessment: a prospective survey of clinical data and outcomes. Eye. 2010;24(9):1515-1519.
10. De Souza N, Cui Y, Looi S, et al. The role of optometrists in India: An integral part of an eye health team. Indian J. Ophthalmol. 2012;60(5):401-405.
11. Sundling V, Gulbrandsen P, Straand J. Sensitivity and specificity of Norwegian optometrists' evaluation of diabetic retinopathy in single-field retinal images - a cross-sectional experimental study. BMC Health Serv Res. 2013;13(1):13-17.
12. Syam P, Rughani K, Vardy SJ, et al., The Peterborough scheme for community specialist optometrists in glaucoma: a feasibility study. Eye. 2010;24(7):1156-1164.
13. World Health Organization. Diseases of the eye and adnexa, international statistical classification of diseases and related health problems. 10th revision (ICD-10). 2007: Geneva.

14. Ministry of Health Malaysia, Clinical practice guidelines for screening of diabetic retinopathy. 2011; Percetakan Nasional Berhad: Putrajaya.
15. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics. 1977;33(1): 159-174.
16. Morris RW, Dunbar MT. Atypical presentation and review of the ICE syndrome. Optometry. 2004;75(1):13-25.
17. Laganowski HC, Kerr Muir MG, Hitchings RA. Glaucoma and the iridocorneal endothelial syndrome. Arch Ophthalmol. 1992;110(3):346-350.
18. Teekhasaenee C, Ritch R. Iridocorneal endothelial syndrome in Thai patients: clinical variations. Arch Ophthalmol. 2000;118(2):187-192.
19. Selvarajah S. An analysis of glaucoma patients seen at the General Hospital Kuala Lumpur over a five year period: 1986 to 1990. Med J Malaysia. 1998;53(1): 42-45.
20. Sergi M, Salerno DE, Rizzi M, et al., Prevalence of normal tension glaucoma in obstructive sleep apnea syndrome patients. J Glaucoma. 2007;16(1):42-46.
21. Myint J, Edgar DF, Murdoch IE, Lawrenson JG. The impact of postgraduate training on UK optometrists' clinical decision-making in glaucoma. Ophthalmic Physiol Opt.2014;34(3): 376-384.
22. Azuara-Blanco A, Burr J, Thomas R, Maclennan G, McPherson S. The accuracy of accredited glaucoma optometrists in the diagnosis and treatment recommendation for glaucoma. Br J Ophthalmol. 2007;91(12):1639-1643.
23. Parkins DJ, Edgar DF. Comparison of the effectiveness of two enhanced glaucoma referral schemes. Ophthalmic Physiol Opt. 2011;31(4):343-352.
24. Goh PP. Status of diabetic retinopathy among diabetics registered to the Diabetic Eye Registry, National Eye Database, 2007. Med J Malaysia. 2008; 63(Supplement C): 24-28.
25. Keat EL, Keat WK. Audit of diabetic retinopathy referrals to Penang Hospital, a tertiary Ophthalmology centre in Malaysia. Asian Journal of Ophthalmology 2009;11:17-19.