

# Referral in a routine Italian optometric examination: towards an evidence-based model.

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## Abstract

Whilst Italian optometrists refract patients and prescribe optical appliances, it is ophthalmologists who are responsible for the detection, diagnosis, and treatment of ocular pathology. In settings with similar scope of practice, close collaboration between optometrists and ophthalmologists is required to minimise avoidable visual impairment. Referral to ophthalmology represents the basis of this synergy, yet no formal guidance is available to Italian optometrists indicating when referrals are warranted. This study aimed to identify circumstances deserving a referral in a routine Italian optometric examination in adults, constituting preliminary evidence-based indications of a referral model.

A literature review was conducted using Pubmed and the Cochrane Library. To derive clinical guidance, the main focus was high quality secondary literature such as systematic reviews and clinical guidelines.

Several signs and symptoms detected during a routine Italian optometric exam might constitute reasons for referral. Further, while a wide range of anomalies of the visual system are likely to be detected by the exam, up to 19% of patients could suffer an asymptomatic condition potentially undetected by the current assessment. This results in the need to refer seemingly healthy patients if they have not attended routine ophthalmological examinations within optimal time frames.

The current training and scope of practice of Italian optometrists requires close collaboration with ophthalmologists to safeguard the ocular health of patients. Referral is a fundamental instrument that in Italy, and countries with similar settings, optometrists must use to enable early diagnosis and treatment of ocular conditions by ophthalmologists. We have presented a preliminary evidence-based framework for optometric referral which identifies categories constituting reasons for referral. This has the potential of standardising optometric practice, enhancing optometry-ophthalmology synergism and, more importantly, improving ocular and general wellbeing of patients.

*Keywords:* Referral, routine eye examination, avoidable vision loss, refraction, asymptomatic patients, public health

## Introduction

Optometrists across the world have varied roles depending on their country of practice (ECO European Council of Optometry and Optics, 2020). Specifically, in Italy, optometrists refract patients and prescribe optical appliances such as spectacles, and fit contact lenses (Naroo & Grit, 2009). Routine eye examinations conducted in this context presently lack a comprehensive ocular health assessment and, according to current legislation,

Italian optometrists have no legal responsibility to detect ocular pathology. In Italy, access to the optometric profession is granted either by a 3-year university-based BSc degree or by professional diplomas implemented by private institutions. Although the duration of diploma courses varies across different institutions, these are usually 1 year long and accessible only by individuals already qualified as opticians (i.e. level 2 from the WCO competences model (Kiely & Chappell, 2015)). Overall, educational programmes mirror the scope of practice, with reduced focus on competencies required for the diagnosis and practical management of eye disease, in favour of skills relevant to optical technology and investigation, and correction of visual function. This is in contrast to other parts of Europe, such as the United Kingdom, where optometrists are also trained in the detection and management of eye disease, both roles that pertain solely to ophthalmologists in Italy. Nevertheless, the relationship between the Italian optometrist and patient is one of assistance and care. Accordingly, the care an optometrist provides must be given in the best interest of the patient (Schwartz, 2002). This translates to an aim of promoting general and ocular health in order to reduce visual loss to individuals seen in practice.

Vision impairment is one of the main causes of disability (Kassebaum et al., 2016), and is consistently reported to affect quality of life and psychological wellbeing (Kempen & Zijlstra, 2014; Lamoureux et al., 2009; Patino et al., 2010; Senra et al., 2015). Because of the associated sequelae, vision loss is a well-defined public health issue linked to remarkable burden. Approximately 0.5% and 4.5% of adults living in central Europe are estimated to be blind and suffer moderate-severe visual impairment (MSVI), respectively. Age-related macular degeneration (AMD), glaucoma and diabetic retinopathy are among the main causes of irreversible vision loss in the Western world (Bourne et al., 2018; Bourne et al., 2014; Flaxman et al., 2017), and recent European population-based studies show their prevalence to range between 2 and 4%, increasing significantly with age (Colijn et al., 2017; Kapetanakis et al., 2016; Li et al., 2020; Yau et al., 2012). Notably, almost half of MSVI in Europe results from uncorrected refractive error (Bourne et al., 2018). Beside the effects on visual function, uncorrected refractive error can also affect independence and quality of life (Wolffsohn et al., 2011). As such, minimising barriers to visual correction (e.g. a low clinician to population ratio and long waiting times for eye examinations) is a priority of many countries, in which optometry can play a pivotal role (R. S. Baker et al., 2005; Durr et al., 2014).

For many eye diseases early diagnosis and timely treatment would prevent visual damage, making the majority of global blindness avoidable (Flaxman et al., 2017; Robinson et al., 2012). Yet, applying the idea of safeguarding the visual integrity of patients to the Italian setting requires some consideration of the education system and professional regulation. Indeed, the lack of a thorough assessment of ocular health within the optometric eye examination hampers the ability to identify people at risk of visual impairment. Therefore, in Italy and other countries with similar frameworks, a strong collaboration between optometrists and ophthalmologists is essential for early detection of eye disease and, ultimately, prevention of vision loss.

Optometric referral of patients with suspected ocular pathology to ophthalmologists represents the basis of optometrist-ophthalmologist collaboration and is a crucial step for safeguarding ocular health. In different contexts, where assessment of ocular health is a central component of optometric practice, accurate referrals have been shown to enhance the overall man-

agement of patients, leading to better visual outcomes (Davey et al., 2011; Scully et al., 2009). However, formal guidance on the content of optometric examination and which findings should result in a referral to ophthalmology is currently lacking in Italy and other countries with similar eye-care sectors. As such, in this review we aimed to identify circumstances requiring a referral within a routine eye test in adults and develop an evidence-based framework for referring in the Italian optometric scenario. Although there is no legal limitation regarding the lower age-limit of patients seen in Italian optometric practices (ECOO European Council of Optometry and Optics, 2020), our analysis focused on adults (older than 16 years), intended as patients beyond the plastic period. The resulting recommendations represent an aid to enhance ocular and general health of patients seen in practice.

## Methods

In view of the broad research question, the first focus of the review was on the content of a routine optometric examination and what anomalous findings could be detected through the typically performed clinical procedures. A literature search was carried out in Pubmed and the Cochrane Library databases (last updated, June 2020) using a combination of free text, synonyms and subject headings regarding the keywords 'routine eye examination', 'optometric referral', 'eye signs', 'eye symptoms' and 'refractive modifications'. Additional relevant publications were retrieved from bibliographies of identified papers and reference checking. Attention was mainly directed towards secondary literature such as systematic reviews, meta-analysis and clinical guidelines. While considering ideal clinical practice patterns, we focused on recommendations provided in published optometric and ophthalmological guidelines.

Because of limitations influencing Italian optometric clinical examination, patients with unremarkable findings might still be at risk of developing vision loss. Hence, the review secondarily focused on the epidemiology of eye disease in asymptomatic populations and the ideal frequency of ophthalmological eye examinations in healthy individuals. Another literature search was conducted with similar methods as before using the same databases (last updated, June 2020) relating to the keywords 'asymptomatic eye disease', 'vision loss risk', 'eye exam frequency', and 'routine ophthalmological examination'.

## Results

### *Optometric findings requiring a referral*

A comprehensive optometric eye examination comprises several sections (American Optometric Association, 2015; The College of Optometrists, 2020). Although there is no guidance on the exact content of the examination within the Italian optometric eye care system, clinical procedures expected to constitute a routine exam will be reported in the sections below. Accordingly, the lack of a thorough eye health assessment within the Italian optometric setting (e.g. no, or limited, ophthalmoscopy) demands some adaptations to international guidelines. As such our analysis will consider the following sections: i) patient history and symptoms, ii) preliminary examination, iii) refraction, iv) visual acuity, v) binocular vision, and vi) ocular surface and anterior segment. Each of these stages may reveal signs, symptoms or risk factors that could indicate an abnormality of the visual system, hence demanding a referral. These will be discussed in detail below and summarised in Table 2.

### *Patient history and symptoms*

This stage allows clinicians to collect information on how patients perceive their own vision as well as relevant clues about ocular and general health (American Optometric Association,

2015; Elliott, 2013). Patients might present with symptoms potentially due to pathology (e.g. sudden onset flashes/floaters) rather than due to conditions that can be managed within the scope of practice of Italian optometry (e.g. refractive errors). In this case, referral to ophthalmology would be required for diagnosis and subsequent treatment. Further, the recent and sudden onset of seemingly minor symptoms such as blurred vision, asthenopia and headache might demand a referral too. Indeed, although these complaints can be frequently induced by a de-compensated phoria or uncorrected refractive error, the acute onset is atypical and might be suggestive of pathology (Elliott, 2013).

Findings from the ocular, general, and family history might include potential risk factors for the development of vision loss. Moreover, a diagnosis of any ocular condition as well as previous surgical procedures or ocular trauma require particular consideration (Feder et al., 2016). Patients with general health conditions (e.g. diabetes, hypertension and dyslipidaemia) might require a more frequent and detailed ocular health examination (American Optometric Association, 2015; Elam & Lee, 2013; Elliott, 2013). For example, duration of diabetes is reported as the main risk factor for the development and progression of diabetic retinopathy, with a significant reduction of the risk in the case of adequate glycaemic control (Ting et al., 2016). Patients with a diagnosis of diabetes who do not adhere to recommended frequency of eye exam (see Table 2) should be counselled and referred accordingly. Additionally, the use of drugs with associated ocular side-effects must also be investigated. For instance, corticosteroid treatment exposes patients to side effects such as cortical cataract and the increase of intraocular pressure (Elliott, 2013). A comprehensive list of general health conditions and drugs potentially associated with ocular side-effects can be found elsewhere (American Optometric Association, 2015).

Lastly, a positive family history is known to be a risk for several diseases affecting the visual system (American Optometric Association, 2015; Elam & Lee, 2013; Elliott, 2013). For example, a patient with a first-degree relative with open angle glaucoma is at significantly greater risk of developing glaucoma, compared to a patient without this family history (Weinreb et al., 2016).

### *Preliminary examination*

Clinical procedures performed here vary significantly according to clinical characteristics and symptoms reported by the patients. Anomalous findings could arise after the external gross evaluation of the adnexa (e.g. anomalous position and/or motility of the lids) and orbital structure (e.g., proptosis and exophthalmos). These signs could develop as a consequence of neurogenic, myogenic, inflammatory, or expansive disorders, and referral is required regardless of the specific aetiology (Gerstenblith & Rabinowitz, 2012). Also, the assessment of colour vision may show acquired colour vision defects, which are frequently asymmetrical and associated with visual reduction (Elliott, 2013). Several diseases could result in abnormal colour vision, including ocular media opacity, as well as retinal and visual pathway disorders (Simunovic, 2016). Clinical examination of pupillary function requires attention to a number of details such as diameters, symmetry, shape, and light and near reflexes (Elliott, 2013). Afferent and/or efferent pupillary anomalies are often linked to neurological disorders and require immediate medical evaluation (Evans, 2007; Kosmorsky & Diskin, 1991).

### *Refraction*

Spherical refractive error undergoes consistent changes with age (Guzowski et al., 2003; Hyman, 2007; Laughton et al., 2018; Williams et al., 2015), with a hyperopic shift between 35 and 65 years of age, followed by an increase of myopia over the age of

65 (see Figure 1). Whilst this myopic shift is unanimously explained by the nuclear sclerosis of the lens (Diez Ajenjo et al., 2015; Pesudovs & Elliott, 2003), hyperopic changes might arise from a combination of reduction of lens refractive index and latent components of hyperopia becoming manifest (Mutti & Zadnik, 2000). Lifelong alterations of astigmatism are also reported (Leung et al., 2012; Sanfilippo et al., 2015; Schuster et al., 2018). Indeed, there exists a tendency of astigmatism to change from 'with the rule' to 'against the rule', and an overall increase of the prevalence of astigmatism (Laughton et al., 2018; Leung et al., 2012; Sanfilippo et al., 2015; Schuster et al., 2018; Williams et al., 2015).

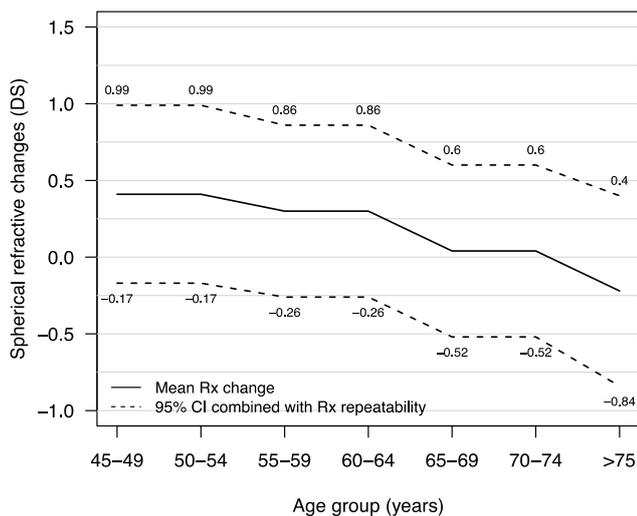


Figure 1: Refractive shift with ageing. Age-related refractive modifications reported in spherical dioptres (DS, on the y axis). Solid line shows the mean refractive change, dashed lines represent the upper and lower 95% confidence interval (CI) limits combined with subjective refractive repeatability of  $\pm 0.50$  DS (Goss & Grosvenor, 1996; McKendrick & Brennan, 1995; Raasch et al., 2001; Zadnik et al., 1992). Refractive data from Guzowski et al. (2003).

While monitoring the development of spherical refractive errors in adults, therefore, there will be some expected changes. Yet, when changes significantly differ from expected values (see Figure 1), optometrists should be aware of potential pathological implications and consider further investigation by ophthalmologist. Likewise, changes of astigmatism should be unremarkable between two consecutive optometric examinations (i.e. 1 to 3 years), and anomalous progression or onset may require a referral. Several disorders might be responsible for unexpected refractive error changes (see Table 1) and must be considered.

One additional reason for a referral might be the need for cycloplegic refraction, which, unlike in other countries (e.g. United Kingdom (Doyle et al., 2019)), cannot be independently performed by Italian optometrists. Although cycloplegia represents the standard procedure for the determination of refractive error in paediatric practice (American Optometric Association, 2017), clinicians can typically measure refraction reliably without cycloplegia from adolescence onward. Indeed, after the age of 15 differences between cycloplegic and non-cycloplegic refraction become smaller than refraction test-retest variability (Goss & Grosvenor, 1996; McKendrick & Brennan, 1995; Raasch et al., 2001; Zadnik et al., 1992), and therefore not clinically relevant (Fotouhi et al., 2012; Sanfilippo et al., 2014)). Nonetheless, cycloplegia might still be required to achieve a reliable measurement of refraction in young adults with excessive accommodative fluctuation, pseudomyopia, or suspected latent hyperopia, hence requiring a referral (Elliott, 2013).

Table 1: Main causes of unexpected refractive changes demanding a referral in Italian optometric practice.

Condition	Type of refractive change	Procedure that would alert the practitioner
Cataract (Diez Ajenjo et al., 2015; Pesudovs & Elliott, 2003)	Myopic or hyperopic (can be greater than 1.50 DS), astigmatic	Retinoscopy, anterior eye examination
Poorly controlled diabetes mellitus (Huntjens et al., 2012; Klein et al., 2011)	Myopic (hyperglycaemia) and hyperopic (hypoglycaemia), changes greater than 0.75 DS	Case history and prior records
Medications (American Optometric Association, 2015).	Varies depending on the drug	Case history
Corneal and/or adnexa changes (Goebels et al., 2015; Weiss et al., 2015)	Typically, astigmatic (asymmetric)	Retinoscopy (e.g., keratoconus), anterior eye examination (e.g. chalazion/ptosis, corneal dystrophies), case history (e.g. refractive surgery)
Subluxated lens (Nelson & Maumenee, 1982)	Astigmatic	Anterior eye examination

### Visual acuity

Visual performance is known to decline with age in response to physiological optical and neural deterioration (Martinez-Roda et al., 2016). For instance, visual acuity and contrast sensitivity steadily decrease from their peaks after the age of 20 and 30, respectively (Andersen, 2012; Martinez-Roda et al., 2016; Owsley, 2016). Though best corrected visual acuity (BCVA) only gives a basic indication of central visual function, it represents a widely used test in practice and anomalous values of BCVA require further evaluation by ophthalmologists. These might include: i) BCVA values below age-matched reference intervals (see Table 2); ii) BCVA values significantly below previous examination ( $> 0.1$  LogMAR in visually normal patients); and iii) significant difference between the two eyes ( $> 0.1$  LogMAR in visually normal patients), in absence of known and stable ocular conditions (McGraw et al., 2000).

Importantly, several disorders affecting central vision could coexist with normal, or close to normal levels of VA, at least at their earlier stages (Cocce et al., 2018; Scanlon et al., 2008; Scilley et al., 2002). Accordingly, for at-risk patients, e.g. those at risk of AMD (Chakravarthy et al., 2010), a more detailed examination of central vision is required. Several clinical procedures could be used, amongst which the Amsler grid represents an effective screening test for macular disorders such as AMD (Faes et al., 2014). In cases of Amsler grid distortions, metamorphopsia or central scotoma, further medical examination and therefore a referral is required.

### Binocular vision and ocular motility

Binocular vision assessment provides essential information for an effective prescription (American Optometric Association, 2015; The College of Optometrists, 2020), and allows for the screening of ocular and systemic diseases (Martinez-Thompson et al., 2014; Patel et al., 2005). A new strabismus or the change of an existing one might signify underlying pathology (American Optometric Association, 2015), hence requiring a medical examination and a secure ophthalmological diagnosis. Depending on the time of onset of strabismus, the management and the need for referral will differ significantly. Adults with long-standing strabismus often present with a totally asymptomatic deviation, evidenced by a concomitant strabismus and a binocular sensory adaptation responsible for the lack of diplopia (Bagolini, 1974). In this case, integrating the history to collect relevant in-

formation supporting the early onset of the binocular anomaly is recommended. A diagnosis of 'lazy eye' in a previous ophthalmological exam, a positive history of patching or strabismus surgery, and the absence of any symptoms of double vision could allow the optometrist to consider the condition stable, and not associated with active pathology. After initial diagnosis, these cases are usually stable and do not require referral. Alternatively, adults might present with recently acquired strabismus, which, as a result of their causative nature are often incomitant. Indeed, several ocular and systemic disorders might result in strabismus (Martinez-Thompson et al., 2014; Patel et al., 2005), requiring immediate neuro-ophthalmological examination. Although these patients might seek medical assistance first, acquired deviations could be encountered at their earliest stages such as an incomitant heterophoria, i.e. compensated phoria in primary position of gaze with diplopia in the peripheral gazes (Evans, 2007). The sudden onset of diplopia coupled with the incomitant nature of the deviation are strong indicators of recent onset strabismus, and prompt referral for an early diagnosis is essential.

Table 2: Summary of findings in an Italian routine optometric examination that would require to refer the patient for ophthalmological examination.

Category	Details
Non optometric symptoms	These include: transient visual loss (sustained visual loss [lasting > 24 hours] either sudden and painless or painful and posttraumatic); binocular diplopia (recent onset with no history of decompensated heterophoria); loss of eyelashes; oscillopsia (vertigo and dizziness); flashes of light; floaters (new, recent onset or progression of existent ones); halos around lights (in non-contact lens wearers, with unknown corneal disorder and/or refractive error); headache (not related to vision tasks); photophobia; ocular, periorbital and orbital pain (if mild to moderate, this could be caused by eye strain from uncorrected refractive error or dry eye); red eye (dry eye and corneal involvement must be ruled out; for contact lens wearers decisions will be taken following the after-care); positive or negative scotoma; excessive tearing, discharge, itchy eyes.
Positive family history	For ocular diseases and/or systemic disorders with ocular involvement, leading to an increased risk of developing ocular disorders. Positive family history of glaucoma requires eye examination every 1–2 years (Feder et al., 2016).
Anomalous previous ocular history	Patients presenting with previous ocular: i) trauma, ii) surgery, iii) disease, iv) high or progressive ametropia, v) functional vision in only one eye, who are not receiving adequate medical attention/follow-up.
General health disorder	Patients presenting with factors related to general conditions, lifestyle, medications (e.g. steroids) associated with potential ocular damages. E.g: Type 1 DM patients require a comprehensive medical eye examination 5 years after diagnosis, then annually; Type 2 DM patients require a comprehensive medical eye exam at diagnosis, then annually (Feder et al., 2016).
Acquired colour vision defect	Newly onset (or long standing but not diagnosed) colour vision disorder in the absence of medical examination.
Pupillary defect	Newly onset (or long standing but undiagnosed) pupillary anomalies in the absence of medical examination.
Orbital and Lids disorder	Orbital and eyelid disorders (proptosis, ptosis, eyelid swelling, lagophthalmos, excluded: physiologic age-related modifications).
Abnormal spherical changes	Physiological refractive changes are a slight hyperopic shift between 30–35 and 65–70 years of age followed by a myopic shift beyond the age of 70–75 years (see refraction section). In case of anomalous shift, pathological causes might be linked to cataract, progressive myopia, drugs or medications use, previous refractive surgery, corneal ectasia, undiagnosed (or uncontrolled) diabetes, other.
Abnormal astigmatic changes	Expected modification is a slight progressive increase of against the rule component – unremarkable between consecutive routine exams (2–3 years). After excluding previous under-correction, pathological causes to be considered are corneal ectasia, cyst, cortical cataract, previous refractive surgery, other.

Table 2: Continued...

Category	Details
Cycloplegic refraction	Clinical examination reveals conditions (e.g., accommodative spasm) requiring cycloplegic refraction.
Reduced vision	Anomalous BCVA: i) lower than age-matched expected values (Elliott et al., 1995): < -0.02 LogMAR (20–49), < 0.00 LogMAR (50–59), < 0.04 LogMAR (60–69), < 0.08 LogMAR (70+); ii) significantly lower than previous examination (> 0.1 LogMAR); iii) Significant difference between the two eyes (> 0.1 LogMAR).
Positive Amsler test	Amsler test showing anomalous findings (e.g. scotoma, metamorphopsia, etc).
Binocular vision disorder	Recent onset of any strabismus, modification of the motor component of existing strabismus, and previously undiagnosed strabismus require medical assessment. Further, any new onset of diplopia (in at least one position of gaze) requires referral.
Vergence or accommodative disorder	Non strabismic binocular vision anomalies and/or accommodative disorders with suspicious pathological aetiology: Acute onset of symptoms, symptoms not related to visual tasks, incomitant deviation, co-existence of neurologic symptoms (e.g. vertigo, dizziness).
Anterior segment disorder	Evolving disorders and/or disorders not previously diagnosed by ophthalmologist involving anterior chamber, irido-corneal angle, cornea, conjunctiva, adnexa, lids, iris, lens.
Lacrimal disorder	Excessive tearing (epiphora) or dry eye disorders.
Glaucoma risk	Patients exposed to an increased risk of developing glaucoma: affected first grade relative, shallow anterior chamber (Van Herick < grade 2), myopia > 6.00DS, pigment dispersion or pseudo-exfoliation syndrome, thin cornea (< 510µm), on treatment with steroids.
Abnormal IOP	IOP > 21 mmHg; increased IOP according to previous examination (> 4 mmHg); significant IOP differences between two eyes (> 4 mmHg); IOP < 7 mmHg.

A considerable proportion of the population may present with a non-strabismic binocular vision anomaly or an accommodative dysfunction (Cacho-Martinez et al., 2014; Cacho-Martínez et al., 2010). Although these disorders have been reported to be typically functional in nature (i.e., not caused by active pathology), several of their signs and symptoms could also be observed in case of disease (Cacho-Martinez et al., 2015; Garcia-Munoz et al., 2014). A pathological cause should be especially suspected in cases of sudden and acute onset of symptoms unrelated to visual task, presence of an incomitant element, and the association of neurologic signs (e.g. vertigo, dizziness, headache, etc.). In such cases, patients should be referred to exclude any potential underlying pathology, and management undertaken only afterwards.

### Ocular surface and anterior segment evaluation

Routine optometric examinations in different countries often include a thorough ocular health assessment targeting the whole eye (American Optometric Association, 2015; Robinson et al., 2012; The College of Optometrists, 2020). As reported earlier, a comprehensive exam of ocular health is not performed by Italian optometrists. Hence, this section only focuses on the exam of the anterior segment, which we speculate is the focus of this part of the exam given that Italian optometrists are not extensively trained in ophthalmoscopy.

Slit lamp examination allows for the evaluation of different structures of the anterior segment and ocular adnexa. At this stage, all conditions identified as evolving and that have not received ophthalmological diagnosis must be considered as abnormal and require a referral. It is beyond the scope of this article to detail all possible conditions, yet, a knowledge of the anatomy of all the structures, as well as their physiological age-related variations is required for every practitioner (Elliott, 2013). Examination of the tear film and ocular surface is routinely performed for contact lens wearers, yet still required

on every patient. This is particularly necessary if history reveals dry eye symptoms or predisposing risk factors. Notably, some cases of aqueous deficiency dry eye could result from auto-inflammatory disorders that require medical investigation (Craig et al., 2017; Vitali et al., 1994).

Anterior chamber depth estimation using the van Herick technique (Van Herick et al., 1969) can be performed on all patients, being a crucial marker in those at risk of glaucoma. The technique can help to identify individuals with an increased risk of angle closure, i.e. < Grade 2 on a 0–4 graded scale (Campbell et al., 2015), and individuals with a narrow angle require to be referred for further investigation. Similarly, signs of pigment dispersion or pseudo-exfoliation require ophthalmological examination, since these conditions are associated with an increased risk of developing open angle glaucoma (McMonnies, 2017).

Italian optometrists do not have permission to use diagnostic drugs or invasive clinical procedures, hence Goldmann Applanation Tonometry (GAT) cannot be performed. Non-invasive methods to assess intraocular pressure (IOP) are, however, available, and non-contact tonometry is a reliable method of measuring IOP, with 2/3 of the measurements within 2 mmHg of the reference GAT's IOP (Cook et al., 2012). However, clinical guidelines indicate that every patient with glaucoma or at risk of developing it requires IOP measurement by GAT (National Institute for Health and Clinical Excellence (NICE), 2017). Further, relying solely on IOP measurement is a poor screening test for glaucoma, with 40% of patients with the condition presenting with IOP lower than 21 mmHg (Shah & Wormald, 2011). Accordingly, although raised IOP is the main risk factor for developing glaucoma and often requires a more frequent follow-up and/or treatment (Prum et al., 2016), the use of non-contact tonometry in isolation has little value in the detection of glaucoma. It is essential for clinicians performing non-contact tonometry to be aware that 'normal' IOP values do not rule out glaucoma, and a comprehensive medical eye examination including visual field testing and optic disc assessment is essential for diagnosis (National Institute for Health and Clinical Excellence (NICE), 2017). As such, in Italy patients at risk of glaucoma need to undergo comprehensive medical eye examinations by ophthalmologists. For those practitioners performing non-contact tonometry, the technique could be performed on every patient seen in practice, referring those with: i) risk factors for glaucoma and ocular hypertension, such as: affected first grade relative, shallow anterior chamber [van Herick below Grade 2], myopia > 6.00 DS, pigment dispersion or pseudo-exfoliation syndrome, thin cornea (< 510  $\mu\text{m}$  (Prum et al., 2016)), ongoing treatment with steroids (The College of Optometrists, 2020); ii) IOP > 21 mmHg; iii) increased IOP compared to previous examination (> 4 mmHg); iv) significant IOP differences between two eyes (> 4 mmHg); v) IOP < 7 mmHg (Elliott, 2013).

In summary, Table 2 details reasons why patients attending an optometric examination would require referral.

### Referral need for patients with normal optometric findings

Asymptomatic patients might still suffer an ocular condition not identified by the Italian optometric assessment or be at increased risk of developing an eye disease. Several studies indicate that between 14% and 26% of patients might present asymptomatic eye pathologies (Irving et al., 2016; Michaud & Forcier, 2014; Robinson, 2003; Wang et al., 1994). Findings from a Canadian study provide disease-specific prevalence data in a cohort of patients without visual symptoms undergoing a comprehensive ocular examination, including dilated fundus examination (Michaud & Forcier, 2014). Accordingly, 220 patients (26.1%) were diagnosed with at least one ocular condition (see Table 3), most frequently affecting the retina.

Table 3: Ocular conditions as detected during routine eye examinations on asymptomatic patients at a university eye clinic in Canada.

Likely detected ocular condition	Prevalence (%)
Blepharitis; dry eye syndrome	2.9
Pathology related to contact lenses	1.2
Cataracts; intra-ocular lens opacities	0.9
Anterior segment dystrophy, degenerations; conjunctivitis	0.8
Binocular vision problems impacting work/school	0.6
Overall	6.4
Likely undetected ocular condition	Prevalence (%)
Retinal hole; lattice degeneration; peripheral retinal abnormalities	7.7
Glaucoma; ocular hypertension; angle closure glaucoma suspect (narrow angles)	4.9
Suspicious lesion in the fundus (naevus, etc.)	2.7
Macular degeneration or other maculopathy	1.9
Suspicious lesion of adnexa or lids	1.1
Hypertensive and diabetic retinopathy	0.9
Optic neuropathy (non-related to glaucoma)	0.5
Overall	19.7

Note: Conditions are grouped according to the likelihood of being detected during an Italian optometric examination. Data reproduced with permission from Michaud and Forcier (2014). Prevalence in % of patient visits.

There are no reports on the epidemiology of asymptomatic eye disease in Italian optometric practice. Although international findings might not be generalisable to the Italian setting, by applying the characteristics of the Italian eye test to published prevalence data (Michaud & Forcier, 2014), it is possible to estimate the rate of disease which might remain undetected. As detailed in Table 3, the Italian routine eye test could have failed to detect pathology in up to 19.7% of asymptomatic patients in the Canadian cohort. Notably, some of the conditions that are likely to remain unnoticed by Italian optometrists are also the ones most likely to result in sight loss (e.g. diabetic retinopathy, optic neuropathies and glaucoma).

The risk of developing a new asymptomatic eye disease has been shown to increase with age and the interval between consecutive exams (Irving et al., 2016). Indeed, age is an unmodifiable risk factor for most ocular diseases, whereas larger time intervals between eye exams would provide more time for pathological processes to develop. Several factors might affect the uptake of eye examinations, including exam cost, provided recommendations, and recalls from practices (Alexander et al., 2008; Irving et al., 2016). Additional factors demanding consideration are the patient's risk perception and their understanding of outcome determination (Elam & Lee, 2013; Irving et al., 2016; Livi et al., 2017). The former refers to the individual's awareness of being at risk of developing visual impairment, whereas 'outcome determination' describes the comprehension by patients of the negative consequences of not having their eyes checked routinely. Both these factors can affect the uptake of optometric examinations – even in Italian settings (Livi et al., 2017) – and can be directly influenced by optometrists through their communication with patients. A positive impact on risk perception and outcome determination could be achieved, either by giving patient recommendations or spreading awareness about the need for ocular health exams by ophthalmologists. In contrast, the misconception that unremarkable findings from a routine Italian optometric examination mean good ocular health might negatively affect the frequency of ophthalmological eye exams.

These findings applied to the Italian context emphasise the need for systematic ocular health assessment by ophthalmolo-

gists. Undergoing such examinations enables the opportunistic identification of early signs of eye disease, preventing vision loss and improving ocular and general health of patients (Elam & Lee, 2013; Picone et al., 2004). Although the ideal frequency of routine eye tests is patient-specific, it is generally suggested that patients more likely to develop vision loss should be examined more often (American Optometric Association, 2015; Elam & Lee, 2013; Feder et al., 2016). For instance, diabetic patients require more frequent ocular assessment (see Table 2) as pathological changes might develop more frequently and at a faster rate (Sabanayagam et al., 2019). Patients with healthy eyes and no specific risk-factors for eye disease can be considered at 'low risk' of developing visual impairment. Yet, as recommended in ophthalmological guidelines, they still require periodical assessments of ocular health, which becomes more frequent with age: every 5–10 years (under 40), every 2–4 years (40–54), every 1–3 years (55–64), and every 1–2 years in 65 or older (Feder et al., 2016).

The time relationship between the last medical eye exam and the current ophthalmological recommendations on the frequency of ocular health assessments allows a gross estimate of ocular safety to be made – later referred to as the Ocular Safety Index (OSI). The OSI represents the need to have an ophthalmological assessment. For example, a patient with a normal optometric examination who had received an ophthalmological examination within the recommended interval (see above) would have a positive OSI. On the other hand, a patient with unremarkable optometric examination who hadn't had an ophthalmological examination recently (i.e. within recommended interval) would have a negative OSI, hence requiring counselling and appropriate referral. Accordingly, the OSI is independent of the patient receiving an optometric examination.

## Discussion

Preventing visual impairment and the consequent disability is a well-defined public health interest to be pursued unanimously by eye-care practitioners (Frick & Foster, 2003). In this regard, early diagnosis and prompt commencement of treatment are essential. In Italy, as in many other countries, ophthalmologists are uniquely responsible for the detection, diagnosis, and treatment of ocular pathology. Because of the limited scope of practice of Italian optometrists, the referral to ophthalmologists is a fundamental instrument that must be used to promote timely detection of ocular disease and therefore prevention of avoidable vision loss.

At present, there are no formal guidelines available to Italian optometrists indicating actions to be taken according to the findings of an eye examination. Addressing this gap, this review explored the circumstances requiring a referral within the Italian optometric eye-care system. Every stage of the optometric exam could potentially lead to the detection of signs and symptoms demanding a referral of a patient to an ophthalmologist (see Table 2). In these patients, some of the clinical procedures performed may indicate abnormalities which demand further medical investigation for the diagnosis and potential treatment of ocular conditions. While considering the content of the examination currently performed within Italian optometry, referral to ophthalmology might also be needed after an uneventful optometric exam. Indeed, a considerable proportion of patients seen in practice (up to 19%) might develop eye disease asymptotically and with signs remained undetected during the exam. Accordingly, apparently low risk patients could still present an eye disease and still require an ophthalmological examination. In cases where the ideal frequency of medical eye exams is unmet (negative OSI), referral is, therefore, warranted.

Considering adults presenting for an optometric examination

in Italy, four clinical case scenarios might be delineated according to the need for an ophthalmological assessment (see Figure 2). Categories identified in Figure 2 define a potential framework for referral in Italian optometric practice. This framework has the potential to constitute an initial evidence base for driving a more defined referral pathway, and its adoption should result in an improved optometrist-ophthalmologist synergy. This should also result in more timely detection of ocular disorders, ultimately leading to enhanced quality of care delivered by optometrists and better visual outcomes for patients (Peters et al., 2014; Taylor et al., 2004).

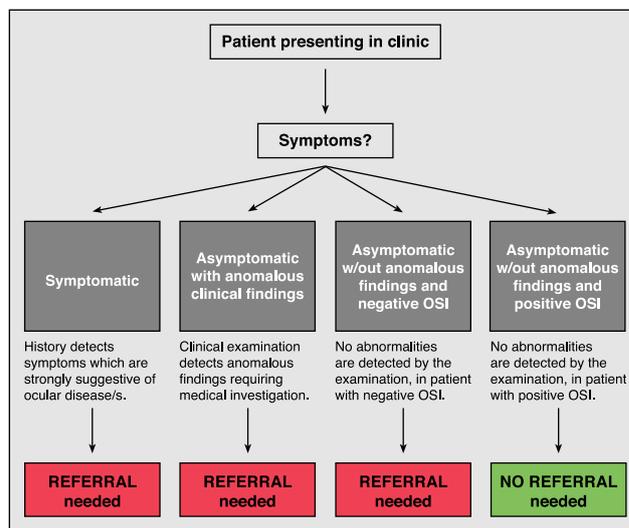


Figure 2: Need for referral of patients presenting for optometric examination. The flowchart indicates those patients who need to be referred following a routine Italian optometric examination in adults (> 16 years old). The OSI refers to the Ocular Safety Index. OSI will be either negative, when patient is not attending the optimal frequency of eye health exams, or positive, when the follow-up is successfully respected.

It must be stressed that weaknesses of Italian optometric examinations demand a conservative referral approach when aiming to avoid visual impairment. Indeed, it could be said that the proposed framework is likely to result in a large number of healthy patients being sent for ophthalmological exams, commonly defined as 'false positives' (Bowling et al., 2005). Also, it is important to consider whether ophthalmological capacity is capable of meeting the demands of an increasingly ageing population (United Nations, 2017). This, coupled with the already overwhelmed ophthalmological sector of the National Health Service (Consorzio per la Ricerca Economica Applicata in Sanità, 2017), makes the referral of a large number of potentially healthy people detrimental. Once referred, false positive patients might seek assistance through the National Health Service, unnecessarily increasing waiting times, which is in itself can result in avoidable deterioration of patients' eye health (Foot & MacEwen, 2017). Alternatively, these patients could receive private ophthalmological exams, resulting in considerable costs especially with the increase in suggested frequency of ocular health assessment with increasing age. A health care system based on ability to pay, however, is likely to disproportionately affect those from lower socio-economic backgrounds.

The lack of a comprehensive ocular examination by the Italian optometrist means that reduction of 'false positives' is not achievable without increasing the risk of patients with potential pathology being classified as healthy. Elsewhere, in countries such as the United Kingdom, where optometrists are trained in techniques such as (in)direct ophthalmoscopy and GAT, solutions that have been adopted to enhance accuracy of refer-

rals include referral refinement schemes (Henson et al., 2003). These include intermediate centres between the referring practitioner and ophthalmologists, in which specifically trained optometrists reassess the actual need for a referral by repeating essential clinical tests and/or performing additional procedures. Implementations of refinement schemes have widely demonstrated improvements to the quality of referral, reducing the number of false positives and therefore unnecessary demands on already overstretched ophthalmological sectors (H. Baker et al., 2016; Barrett et al., 2018; Ratnarajan et al., 2013). Patients referred because of a 'negative OSI' would seem particularly suitable for utilising similar schemes, perhaps run in close collaboration between ophthalmology and optometry, upon further and specialised training. This might offer additional pathways for timely and affordable ocular health checks, without creating additional demand on the national health system or individual patients' finances. Along with solutions to enhance referral accuracy, an alternative to be mentioned is the modification of training received by optometrists in Italy and an extension of the scope of practice. Such changes could be targeted to enhance the overall ability of optometrists in case detection, with considerable contribution to the reduction of unnecessary referrals of healthy people. More collaborative eye-care models are increasingly proposed worldwide to alleviate the workload on ophthalmologists, due to increased demand not adequately matched by a similarly growing capacity (Barrett et al., 2018; George et al., 2019; Mets et al., 2012). Nonetheless, both mentioned approaches would require formal assessment of their feasibility as well as of the associated cost-effectiveness.

### Limitations

It is important to state that this study has limitations. This was not a systematic review, therefore, potentially relevant literature may have been missed. However, the combination of a literature-search on two databases with the reference checking of included publications is likely to have minimised not-retrieved publications. A further shortcoming of using a non-systematic approach is the lack of a standardised and repeatable critical appraisal of included studies. Yet, the recommendations presented are largely derived from optometric and ophthalmological guidelines, which rely on systematic search and appraisal of the literature. It is also worth noting that the review aimed to address the broad question of when Italian optometrists need to refer their patients, and there are significant deficiencies in the available evidence. Indeed, there is a i) lack of peer-reviewed publications directly relating to the Italian setting; and ii) the majority of available studies have an observational design. Hence, considerable interpretation was required to translate the retrieved evidence in potential clinical guidance. Overall, considering the underlying settings, a systematic review might not have been ideal to answer the broad query, and it has been suggested that narrative approaches may also be appropriate (Greenhalgh et al., 2018).

The shortage of data describing patients' demographics and current practice pattern of optometry in Italy is a major limitation and detailed information urges for better organisation of assistance for this sector. Primary research conducted in Italy is also essential to further understand whether findings generated elsewhere are generalisable to Italian settings. In fact, the bulk of research within the optometric area is conducted in high-income countries with an eye-care sector notably different from Italian one (e.g. US, UK, Canada, Australia), where primary eye-care is led by optometrists. This is likely to result in differences of the characteristics of patients seen in practice compared to Italy. Generalisability is a key concept when appraising literature, defining whether findings from a given piece of evidence can be transferred to the population of interest (Fer-

guson, 2004; Kukull & Ganguli, 2012). On one hand it depends on the study design and its internal validity, yet to define generalisability a thorough understanding of the target population is essential. Lack of knowledge of the demographics and clinical characteristics of patients seen in Italian optometric practice currently prevents the establishment of generalisability from other settings.

Further limitations include the absence of a more inclusive study design to define recommendations. Work from a more heterogeneous group, comprising of ophthalmologists, public health consultants and patients, would be desirable to achieve consensus and refine the proposed scheme. It must also be considered that, although the categories presented in Table 2 are directly applicable in practice, they lack the ideal amount of detail and could be caused by a variety of ocular disorders, whose aetiology cannot always be ascertained. Overall, this is likely to impede the accurate definition of urgency of the referral, which is an essential component of the referral letter and a determinant of its accuracy (Davey et al., 2016).

Lastly, it must be remarked that the present lack of regulation that Italian optometrists face might limit wide adoption and uniformity of the proposed guidelines. It seems clear that the profession would dramatically benefit from an official and clear arrangement of optometry in the public health scenario by national authorities.

### Conclusion

Irrespective of the practising country, the best interests of patients must be central in guiding optometric clinical practice. According to the current scope of practice and training, optometrists in Italy must operate in close collaboration with ophthalmologists to safeguard ocular health of patients. Hence, referral is a crucial management strategy that must be largely adopted. A variety of signs and symptoms determine the need for a referral. However, as many as one in five patients may suffer underlying conditions remaining undetected by the current Italian optometric examination. In order to allow for early diagnosis and treatment of ocular conditions by ophthalmologists, referral is a fundamental instrument that Italian optometrists must use to play their part in the reduction of preventable visual impairment. We have presented here a preliminary evidence-based framework for referral in optometric clinical practice. Although considerable refinement is still required, this instrument identifies categories constituting reasons for referral. This has the potential to aid in standardising optometric practice, enhancing optometry-ophthalmology synergism and, more importantly, improving patients' visual and general outcome.

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## Videre henvisning i rutinemessig italiensk optometrisk praksis: mot en kunnskapsbasert modell

### Sammendrag

Mens optometrister i Italia refraksjonerer pasienter og foreskriver optiske hjelpemidler, er det oftalmologer som er ansvarlige for å avdekke, diagnostisere, og behandle øyesykdommer. I settinger med denne type praksis er nært samarbeid mellom optometrister og oftalmologer nødvendig for å begrense unngåelig tap av syn. Henvisning til oftalmolog danner grunnlaget for dette samarbeidet, men foreløpig finnes det ikke tilgjengelig noen veiledning for italienske optometrister som indikerer når henvisning er anbefalt. Målet med dette studiet var å indentifisere omstendigheter der henvisning er anbefalt i italiensk rutinemessig optometrisk undersøkelse av voksne, som kan utgjøre et innledende rammeverk for en kunnskapsbasert henvisningsmodell.

Et litteratursøk ble foretatt ved hjelp av Pubmed og The Cochrane Library. For å utlede kliniske rutiner var hovedfokuset på sekundær litteratur av høy kvalitet, som systematiske oversikter og kliniske retningslinjer.

Flere tegn og symptomer som avdekkes under en rutinemessig italiensk optometrisk undersøkelse vil kunne være årsak til henvisning. I tillegg til at mange anomalier av syn og øyne sannsynligvis vil oppdages i løpet av undersøkelsen, er det mulig at opptil 19% av alle pasienter har tilstander uten symptomer som muligens ikke vil avdekkes av dagens rutineundersøkelse. Dette betyr at det er behov for å henvise symptomfrie pasienter dersom de ikke har hatt rutineundersøkelse hos oftalmolog i løpet av anbefalte tidsrammer.

Dagens utdanning innen optometri i Italia og omfanget av italiensk optometrisk praksis er avhengig av et nært samarbeid med oftalmologer for å sikre pasientens øyehelse. Henvisning er et fundamentalt verktøy som optometrister i Italia og andre land med liknende praksis må bruke for å oppnå tidlig oftalmologisk diagnose og behandling av øyetilstander. Vi har presentert et foreløpig kunnskapsbasert rammeverk for optometrisk henvisning som identifiserer kategorier av årsaker for henvisning. Dette har potensiale til å standardisere optometrisk praksis, styrke samarbeidet mellom optometri og oftalmologi, og ikke minst bedre pasientenes okulære og generelle helse.

*Nøkkelord: Henvisning, rutinemessig synsundersøkelse, unngåelig synstap, refraksjon, symptomfrie pasienter, folkehelse*

## Invio al medico a seguito dell'esame optometrico: verso un modello italiano basato sulle evidenze scientifiche

### Riassunto

In Italia, l'optometrista si occupa di refrazione e prescrizione di dispositivi ottici, mentre è il medico oculista la figura responsabile della diagnosi ed il trattamento delle patologie oculari. In un contesto simile, una stretta collaborazione tra optometrista e medico oculista è essenziale per ridurre il rischio di danno visivo evitabile. L'invio al medico rappresenta la base di tale sinergia, ma non sono ancora disponibili linee guida optometriche che delineino quando tale gestione sia necessaria. Lo scopo di questo studio è identificare le indicazioni circostanze di invio al medico a seguito dell'esame optometrico in soggetti adulti, all'interno del calendario delle visite oculistiche consigliate per la prevenzione delle malattie oculari. Le indicazioni ottenute possono rappresentare un modello preliminare di invio al medico, basato sulle evidenze scientifiche.

È stata condotta una revisione della letteratura tramite i database PubMed e Cochrane Library. Sono state particolarmente utilizzate le fonti di ricerca secondaria di elevata qualità come revisioni sistematiche e linee guida, al fine di stabilire indicazioni per la pratica clinica.

L'indagine optometrica condotta nel contesto italiano può rilevare numerosi segni e sintomi che richiedono l'invio al medico. In ogni modo, sebbene l'esame optometrico sia capace di riscontrare un'ampia gamma di anomalie visive, fino ad un 19% dei pazienti osservati potrebbe presentare un disordine asintomatico potenzialmente non rilevato dalla valutazione. Per questo motivo, anche quei pazienti con esame optometrico apparentemente nella norma potrebbero richiedere un invio al medico, qualora l'ultimo esame oftalmologico non sia stato eseguito all'interno del calendario delle visite oculistiche consigliate.

Il ruolo che l'optometrista ricopre attualmente in Italia, e la formazione ricevuta, richiedono una stretta collaborazione con il medico oculista, al fine di salvaguardare la salute oculare dei pazienti. L'invio al medico rappresenta uno strumento fondamentale che gli optometristi in Italia, ed in paesi con sistema assistenziale simile, devono utilizzare per favorire la diagnosi precoce ed il trattamento di patologie oculari da parte del medico oculista. In questo studio è stato presentato un modello preliminare basato sulle evidenze scientifiche, che identifica una serie di categorie di anomalie che richiedono l'invio al medico. Questo modello ha la potenzialità di contribuire alla standardizzazione della pratica optometrica in Italia, potenziare la sinergia optometrista-oculista e, primariamente, migliorare la salute oculare e generale dei pazienti assistiti.

*Parole chiave: invio al medico, esame optometrico, danno visivo evitabile, refrazione, pazienti asintomatici, salute pubblica*