Universidade do Minho
Escola de Ciências

Vera Lúcia Alves Carneiro

Advocacy for Promotion and Integration of Refractive Error Services into National Health Services

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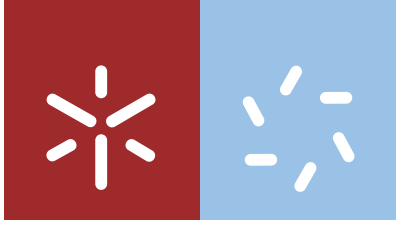

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Advocacy for Promotion and Integration of Refractive Error Services into National Health Services

PhD Thesis
Doctoral Program in Optometry and Vision Sciences

Work developed under the supervision of:
Professor Doutor José Manuel González-Méijome

December 2021

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STATEMENT OF INTEGRITY

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Abstract

Title: Advocacy for Promotion and Integration of Refractive Error Services into National Health Services

Refractive error is a public health concern and even with relatively simple and cost-effective interventions it remains the leading cause of vision impairment worldwide. Addressing the ongoing met and unmet needs of refractive error has become a matter of interest and to generate evidence is crucial to identify current needs and future trends. Data on the prevalence, trends, and progression of refractive error in Portugal are scarce and heterogeneous but are essential to inform decision-makers in the process of planning eye care services. This study aimed to determine the prevalence and distribution of refractive error among the Portuguese population, to place it in a public health perspective and to propose a strategy to address it within the NHS. A first approach systematically reviewed and meta-analysed epidemiological data of refractive error prevalence. A second approach estimated the prevalence and distribution of refractive error based on a clinical sample of consecutive patients from optometric practices distributed by the country. And lastly, a third approach estimated the distribution of refractive error based on ophthalmic lens manufacturer big data. This three-studies approach allows a more realistic estimate. Finally, an integration proposal to address refractive error within the NHS was developed. The main conclusions were that refractive error prevalence in Portugal is between 20 to 45% (95% CI). This value shows that at least 2 to 4 million Portuguese have a refractive error and that places the refractive error as one of the conditions with more burden on the health system and population. Myopia is the most prevalent refractive error (41.3%) and the most prevalent among younger populations, representing a considerable burden for group ages between the 6 and 29 years old (69.3%). A trend of increasing prevalence of myopia and high myopia was observed from 40.89% in 2010 to 50.66% in 2020. This shift towards the increase of myopia prevalence has important implications for public health and services planning, not only to manage the refractive error itself, but also, future expected myopia-related complications. Alternative sources of epidemiological data were identified. An action plan demonstrate that is possible and effective to integrate refractive services into the already existing infrastructures of primary care, and with already trained workforce.

Key Words: Epidemiology, Prevalence, Public Health, Refractive Error, Vision Impairment.

Resumo

Título: Advocacia para a Promoção e Integração de Serviços Refrativos nos Serviços Nacionais de Saúde

O erro refrativo é considerado um problema de saúde pública e, mesmo com intervenções simples e ótima relação custo-benefício, mantém-se como a principal causa global de deficiência visual. Abordar as necessidades contínuas, atendidas e não atendidas, dos portadores de erro refrativo tornou-se uma questão de interesse e gerar evidência é crucial para identificar as necessidades atuais e tendências futuras. Os dados sobre prevalência, tendências e progressão de erro refrativo em Portugal são escassos e heterogéneos, mas são essenciais para informar os decisores no processo de planeamento dos serviços de saúde. O presente estudo teve como objetivo determinar a prevalência e distribuição do erro refrativo na população portuguesa, enquadrá-lo numa perspetiva de saúde pública e propor uma estratégia para o abordar ao nível do SNS. Numa primeira abordagem foi efetuada uma revisão sistemática e meta-análise de dados epidemiológicos de prevalência de erro refrativo. Uma segunda abordagem estimou a prevalência e distribuição do erro refrativo com base numa amostra clínica de pacientes consecutivos de consultórios optométricos distribuídos pelo país. E, por último, uma terceira abordagem estimou a distribuição do erro refrativo com base em *big data* de distribuidores de lentes oftálmicas. Esta abordagem de três estudos permite uma estimativa mais realista. As principais conclusões expõem uma prevalência de erro refrativo em Portugal entre 20 e 45% (IC 95%), isto é, pelo menos 2 a 4 milhões de portugueses possuem um erro refrativo, o que coloca o erro refrativo como uma das condições que maior peso sobre o sistema de saúde e a população. A miopia é o erro refrativo mais prevalente na generalidade (41.3%) e o mais prevalente entre a população mais jovem, representando 69.4% para a faixa etária entre 6 e 29 anos. Uma tendência de aumento da prevalência de miopia e alta miopia foi observada de 40.89% em 2010 para 50.66% em 2020. Esta mudança epidemiológica de aumento da prevalência da miopia tem implicações importantes para a saúde pública e no planeamento de serviços, não apenas para abordar a condição em si, mas também as complicações patológicas futuras associadas à miopia. Foram identificadas fontes alternativas de dados epidemiológicos. Por fim, foi desenvolvida uma proposta de integração de serviços refrativos no SNS português que demonstra ser possível e eficaz a integração nas infraestruturas de cuidados primários já existentes e com a força de trabalho disponível no país.

Palavras-Chave: Deficiência Visual, Epidemiologia, Erros Refrativos, Prevalência, Saúde Pública.

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Glossary of Terms and Abbreviations

ACeS	Health Centres Groups (*Agrupamento de Centros de Saúde* in Portuguese)
BCVA	Best-corrected Visual Acuity
IPEC	Integrated People-centred Eye Care
LE	Left Eye
NHS	National Health Service (*Serviço Nacional de Saúde* – SNS in Portuguese)
PVA	Presenting Visual Acuity
PECI	Package of Eye Care Interventions
PNSV	Portuguese National Programme for Eye Health (*Programa Nacional para a Saúde da Visão* in Portuguese)
RE	Right Eye
SE	Spherical Equivalent
URAP	Shared Assistance Resources Units (*Unidades de Recursos Assistenciais Partilhados* in Portuguese)
URE	Uncorrected Refractive Error
VA	Visual Acuity
VI	Vision Impairment
WHO	World Health Organization

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List of Publications

Papers

Not included but related to this Thesis

GBD 2019 Blindness and Vision Impairment Collaborators on behalf of the Vision Loss Expert Group of the Global Burden of Disease Study. **Causes of blindness and vision impairment in 2020 and trends over 30 years, and prevalence of avoidable blindness in relation to VISION 2020: The Right to Sight: an analysis for the Global Burden of Disease Study**. *The Lancet Global Health*, 2020; Volume 9, Issue 2, e144 - e160

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Oral Presentations

Carneiro VLA. **Prevalence of the Refractive Error in Portugal**, APLO World Optometry Day Event, March 2021.

Award

International Agency for the Prevention of Blindness (IAPB) **Eye Health Hero 2020** in the Change-Maker category.

"The world is full of frameworks, roadmaps and action plans that sit on shelves collecting dust, and never make a difference to people. I urge you, starting now, to translate your good intentions into concrete actions that transform the health of your people."

- Dr. Tedros Adhanom Ghebreyesus, WHO Director-General, 2017

Chapter 1. Introduction

1.1. Vision Impairment Due to Uncorrected Refractive Error

The increase in the average age of the population, leads, inevitably, to a shift in the burden of non-communicable diseases and disabilities that contribute to a decline in quality of life. This epidemiological transition takes on greater importance for the main causes of vision impairment (VI) and blindness, [1] representing health, autonomy, social and productivity losses that affect both the individual and the society. [2–4] Every individual, at any point in their life, will experience at least one eye condition. [5] Refractive error and uncorrected refractive error (URE) (myopia, hyperopia, astigmatism and presbyopia), are the main cause of VI worldwide. [5–7]

It is estimated that, globally, at least 2.2 billion people have a VI or blindness and at least 1 billion of those have a VI that could have been prevented or has yet to be addressed. [5] These numbers place VI as one of the most common public health conditions and demonstrate the need to be addressed in a public health strategy. [1,8,9]

According to the International Classification of Diseases 11th Edition (ICD 11), VI results when an eye condition affects the visual system and one or more of its functions. [10] VI is typically measured and categorized according to visual acuity (VA), however, clinically, other visual functions as the contrast sensitivity or visual field, are often assessed. [11,12] In this work, justified by its purpose and because it is the most common and accepted definition, only the measurement and categorization based on VA will be addressed. The definition of VI based on VA by the World Health Organization (WHO) is a "presenting" visual acuity (PVA) of less than 6/12 in the better eye. The most common way to define VI is based on VA, categorized as mild, moderate, or severe distance VI or blindness, and near VI (table 1). Blindness is further subcategorized into three distinct levels of severity. [5]

Category	VA in the better eye		Intervals*
	Worse than:	Equal to or better than:	
Mild VI	6/12	6/18	6/18 ≤ VA < 6/12
Moderate VI	6/18	6/60	6/60 ≤ VA < 6/18
Severe VI	6/60	3/60	3/60 ≤ VA < 6/60
Blindness	3/60	-	VA < 3/60
Near VI	N6 or m0.8 at 40 cm	-	

Table 1: Classification of severity of VI based on VA in the better eye (World Report on Vision 2019, WHO). *Modified by the author

On 2010, WHO replaced the previous terminology "best-corrected" visual acuity (BCVA) by PVA, that is the VA presented by the individual on the examination with the currently available refractive correction, to assess the extent of VI that could be improved with appropriate corrective refraction and in that way consider the large proportion of people with VI due to URE, which were being disregarded when considered the BCVA. [12]

Despite those efforts on the terminology replacement, it is important to notice that given the ongoing need for eye care for individuals with refractive error, and the need to plan and monitor those eye care services, the PVA does not give information on individuals whose VI is compensated with refractive devices. [5] This allows to realize that the global estimates of individuals with VI are in fact underestimated.

To assess the total number of VI cases, even when correctable by refractive devices, is extremely important to identify and respond to the present and future needs, to design and implement effective services and to provide evidence-based care. For this reason, when collecting and reporting data on VI, VA should be measured without the refractive correction. [5]

VI is associated with important limitations in everyday functioning. Visually impaired individuals, that are unable to get vision care or medical devices, experience limitations and restrictions when interacting with their own environment. The experienced VI disability can be described by the International Classification of Functioning, Disability and Health (ICF), a global framework for classifying problems in functioning and the influence of contextual factors, in a health, individual and social, perspective. [13]

The consequences of VI affect the individual across the entire life-course, from young children development to the learning processes in school-age or from the adult productivity to the elderly autonomy. Also, VI has an important impact on the society and the families by posing a significant financial burden on the individual care, caretaking requirements and productivity losses. [5]

A comprehensive assessment of incidence, prevalence, and years lived with disability, placed VI (including blindness) as the third cause among all impairments for years lived with disability worldwide. [14] In Portugal, data from the 2001 Portuguese censuses, reveals 163 569 disable individuals from VI (including blindness), representing 1.58% of the total country population and placing VI as the biggest contributor to the total burden of disability in Portugal [15]. More recent data, from the 2011 Health and Disability Report in Portugal from the National Statistics Institute, shows that for Portuguese people with at least one disability, which represents 17.4% of people between 15 and 64 years old, visual

impairment, even with optical correction, represents 17,2%, most affecting women; and for people aged 65 years old or more with at least one disability, 50% had visual impairment, even with optical correction [16].

Data from a 2004 estimate 153.198 million (range of uncertainty: 123 – 184 million) case of VI or blindness from URE worldwide, representing a prevalence of 2,65% of the global population in that year, with the usual variations across regions/countries (figure 1). It is important to notice that these are numbers prior to the criteria change, since the cut-off of VA used on the definition of VI was less than 6/18 and not the currently adopted less than 6/12. Additionally, when combining the number of cases of VI and blindness from URE with all the other causes (314.319 million cases of VI and blindness worldwide), it is observed that URE are the cause of almost half of the VI and blindness causes worldwide. [17]

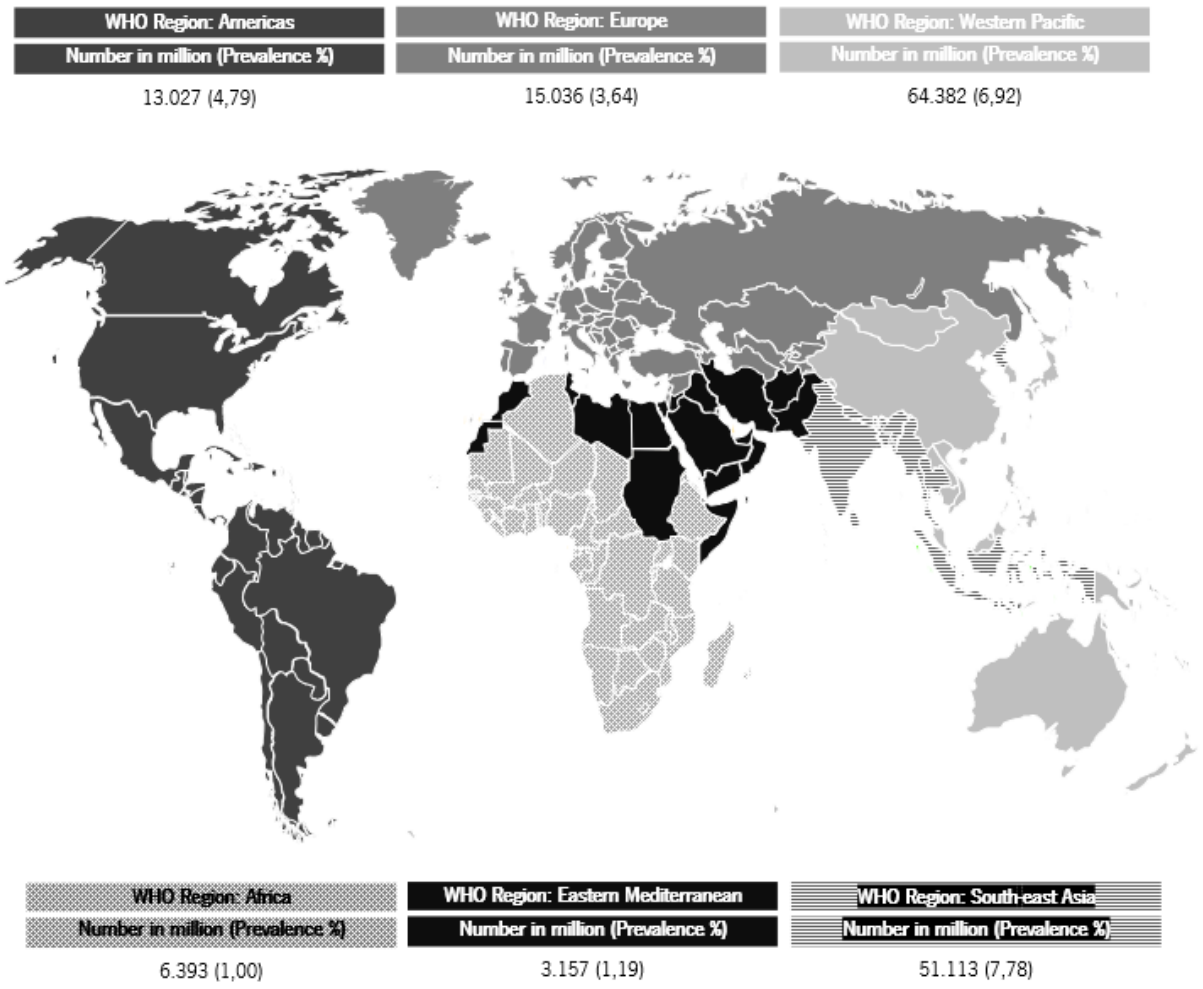

Figure 1: Total number of people, age 5 to >50 years, with VI from URE and the prevalence within the population by WHO Region in 2004. Elaborated based on the data from Resnikoff *et al.*, 2008. [17]

More recent data shows that, when analysing the contribution of individual causes to global visual impairment in 2020, URE were the third leading global cause of blindness, with 2.3 million cases ([95% UI 1.8–2.8]), and the leading cause of moderate and severe VI with 86.1 million cases worldwide ([95% UI 74.2–101.0]), in those aged 50 years and older. Globally, 75% of the cases of moderate and severe VI are related to cataract and URE, representing the URE 42% of the cases.[1]

Despite all efforts in the last decades in addressing URE, this condition remains the leading cause of VI and the third leading cause of blindness worldwide.

Considering this data on the burden of VI and blindness to the total burden of disability, and on the burden of refractive error to the total burden of blindness and VI worldwide, [5–7] the importance of addressing refractive error care, its prevention, promotion and treatment, from a public health perspective at national and global levels should be a priority for eye care programmes and strategies.

1.2. The World Report on Vision Recommendations on Refractive Error Interventions

The epidemiological transition related to the increase in the average age of the population and consequent rise of life expectancy, combined with the current lifestyle, will contribute to an increase in the incidence and prevalence of refractive error, creating a dramatic global demand for eye care services. [1,18] Furthermore, it is important to keep in mind that eye care, for both healthy and non-healthy individuals, require an ongoing need for access to services, that poses additional challenges to the health system.

To meet those challenges and strength the health system, the WHO 2019 World Report on Vision proposes five recommendations and concerted actions, approaching eye care integrated into the national health systems and delivering promotive, preventive, treatment, and rehabilitation interventions, distributed by the different levels of care and throughout the life course. These five recommendations require specific actions that are, or can be, applied to refractive services.

The first recommendation is to make eye care an integral part of the universal health coverage, ensuring accessibility, affordability, and equity in the provision of eye care services. The actions recommended that are applied to refractive error services rely on the ongoing need for access to services or devices and on the financial risk protection on acceding these ongoing and priority eye care interventions. Additionally, the collection of information, both on met and unmet needs, and the

development of monitor and evaluation frameworks with the ability to make national and international comparisons with the definition of desired outcomes on quality and effective coverage, is extremely relevant due to the adoption of the global eye care targets for 2030 by the Member States in the 74th World Health Assembly (2021), which include a 40% increase in effective refractive error coverage (eREC). [5,19] Another important action recommended was the development of a package of eye care interventions, that includes interventions on refractive error, focusing on the populations needs and included into the budgeting of universal health coverage. [20]

The second recommendation is the implementation of integrated people-centred eye care (IPEC) into the health systems and the national health strategic plans to ensure access to the most priority interventions. The challenges posed by the fragmentation of services and the projected dramatic demand for eye care services requires services capable to respond, react and adapt on a regular basis to meet population needs. It is essential the integration and coordination of eye care services, refractive services included, within other national health programmes, ensuring a provision of eye care in the same dimension and in line with the provision of another health care intervention, addressing the health promotion, prevention, treatment, and rehabilitation across the different levels of care. For refractive error services, it is important to notice the need to strength the access to these interventions at primary health care level, improving quality and increasing coverage – effective coverage – ensuring a workforce planning as integral part of the national health workforce planning. [5,19,20]

As third recommendation, the World Report on Vision refers the promotion of high-quality research with the collaboration of researchers, ministries, and other public health decision-makers, implementing health systems research for eye care that support and sustain the IPEC implementation.

The fourth recommendation approaches the process of monitoring and evaluating the trends and progress towards the implementation of IPEC and its impact. Once more the national ability to collect a representative volume of data on eye care epidemiology, services access, quality or coverage take on an important role and should be strengthened on a periodic basis. [5] Research on refractive error trends and needs, as well as refractive services access, quality and coverage are integrant part of third and fourth recommendations.

The fifth and last recommendation is for raising awareness, engaging and empowering people and communities about eye care needs, especially the most underserved populations. [5] This recommendation should be applied to the refractive services on the creation of national health campaigns that raise awareness to the importance of eye examinations, especially for pre-school and

school children, availability of effective interventions, the ongoing need for updates and the use of optical devices.

1.3. Planning and Implementing Health Services

Public health research in the field of eye care, although necessary, it's still very scarce, even in countries with mature research and health systems. Nevertheless, research in public health is a very established field and can easily be applied to the eye care. Planning and implementing health services involves a number of processes that can be summarize and schematized as six principal steps: situation analysis, setting priorities and targets, formulating interventions, determining resource allocation, preparing an action plan and develop an ongoing process of monitoring and evaluation (figure 2). [21]

Figure 2: The Planning Cycle (adapted from World Health Organization Regional Office for Africa - District Health Management Team Training Modules - Planning and Implementation of District Health Services, 2004) 21

The situation analysis has the objective to assess the multiple perspectives of the current status of a certain care service or provision to stablish the needs and to define the priorities. On this first step, governmental policies and plans are analysed and its performance is reviewed. Current resources allocations, availability of services, infrastructures and workforce are identified and changes over time

are screened to understand its impact on population needs and health delivery. Past and current constraints and specific national regulations are also assessed. The situation analysis allows to identify the problem to address. The primary problems are health conditions, normally based on epidemiological data and burden of the health condition within the population. The secondary problems to address, contributory problems to the primary one, are related to inefficient or inadequate allocation of resources, healthcare delivery or management skills. [21,22]

The health problem identified must be analysed and ranked against defined criteria:

- Magnitude of the health condition: the burden of the condition within the population must be described, as well as the sub-groups of population more affected, by sex, age groups, among others.
- Severity of the health condition: the impact of the condition on mortality, morbidity, well-being, or functioning must be explained.
- Feasibility of interventions for that health condition: evidence-based and cost-effectiveness of the interventions to address the health condition must be described.
- Political expediency to the health condition: awareness and acknowledge by the decision-makers of the need to address the health condition.

The analysis of the problem, primary and secondary, must allow to define priorities and objectives, that is, an intended result of the process within given inputs and processes. The objectives to be defined should be specific, measurable (quantitatively or qualitatively), attainable, realistic and time bound. After defining the objectives, targets should be determined. [23]

An exhaustive analysis of the gaps identified in the situation analysis is essential to develop appropriate interventions to address population needs and achieve the objectives and targets defined. The next step is the formulation of interventions. The formulation of interventions intends to investigate and decide between the different alternative approaches, measures, or assessments to address the identified problem and priority health needs. Additionally, interventions should be in line with geographical political, climatic, and sociocultural conditions. If necessary to bypass and address constraints, job responsibilities and tasks should be modified and shift to obtain additional resources. The interventions formulated, and all the activities related to these interventions, should be translated into operational activities and the resources to its concretization mapped. To support the interventions, the resources required by each activity should be listed, defined, and quantified. Human resources, financial

resources, infrastructures, materials and technology, information systems, time, among others, are some of the resources that should be determined to allocate. [21]

The compilation and collation of the information related to the definition of the problem, objectives, target and interventions, resources as well as inputs, possible risks, monitoring and evaluation frameworks and time frame, result in the action plan. The action plan guides activities, and the necessary resources, for achieving the desired outcomes and impact. The main reasons to create an action plan are to achieve the defined priorities without deviating from the optimal path, to avoid fragmentation of the health sector, to focus the policy dialogue on defined health priorities, to guide operational planning, and monitoring and evaluation of the process. [24] The implementation of the plan is the most important step of the process and the one with more impact in its success. When implementing the action plan three aspects must be considered:

- Effectiveness of the interventions and activities (refers to the achievement of the desired outputs of each activity).
- Efficiency of the interventions and activities (related to the use of resources and achieved outputs by resources inputted).
- Timeliness of the interventions and activities (ensure timely completion of interventions and activities). [21]

The implementation of the action plan will require monitoring and evaluation to ensure to track the progress towards or achievement of the priorities, objectives, and targets. The process of monitoring, normally based on indicators and data, should be systematic and continuous over time, analysing the progress of the implementation of the intervention and activities. Monitoring should occur at the level of inputs (workforce, infrastructures), processes (activities), outputs (service delivery, quality), outcome (coverage) and impact. The evaluation process, that occurs after and based on the monitoring, assesses the achievement of objectives and targets. After a monitoring and evaluation assessment, a review process should take place to consider overall progresses, identify gaps, problems, and solutions and to take corrective actions. Monitoring and evaluation frameworks should be countries surveillance mechanisms and assess health inequities. [25]

1.4. Hypothesis and Aims of the Thesis

This work intends to epidemiologically address refractive error, the main cause of VI in the world and the biggest contributor to the total burden of disability, demonstrating that its prevalence among the Portuguese population requires reformulations in the provision of services that address this eye condition.

It is intended, from the estimation of the prevalence of this condition among the Portuguese population, to define a public health strategy, accessible and affordable to all Portuguese, in a timely and equitable manner, properly integrated into the NHS, which addresses this condition in a temporal continuum, responding to the inherent ongoing needs of the population.

This work assumes greater importance at a time when a global target for effective refractive error coverage (eREC) was endorsed by WHO Member States, Portugal included, at the 74th World Health Assembly in May 2021. This target is an indicator to monitor and track progress, not only about the coverage, but also about the quality of refractive services. [19]

1.4.1 Hypothesis

The hypothesis of this work is that the prevalence of refractive error in Portugal presents values similar to those in Europe and rest of the world, and that the burden of this condition requires a public health strategy and an IPEC approach.

Another hypothesis is that data collected from different sources from electronic optometric records to optical devices industry might be low cost and valuable information to perform indirect cross-sectional estimates of refractive error prevalence and follow changes over time.

1.4.2. Aims

I. To determine the prevalence of refractive error among the Portuguese population using data from different sources.

II. To compare the prevalence of refractive error among the Portuguese population with the prevalence in Europe and worldwide.

III. To place the prevalence of refractive error in a public health perspective.

IV. To propose a strategy and delivery platform to address refractive error within the Portuguese NHS.

Chapter 2. Macro-scenario Analysis: Refractive Error Prevalence in the World and Evidence-based Interventions

2.1. Refractive Error Prevalence in the World

Refractive error, when uncorrected, is the third leading global cause of blindness, with 2.3 million cases ([95% UI 1.8–2.8]), and the leading cause of moderate and severe VI with 86.1 million cases worldwide ([95% UI 74.2–101.0]), in those aged 50 years and older. Globally, URE represent 42% of the cases of VI and blindness.[1] Despite the importance of this data, the number of cases of people with mild VI, or that have a refractive error with no VI associated, are disregarded, and their impact on the health system and the society is not considered for health planning.

The distribution of the prevalence of refractive error varies significantly between the different regions or countries, and despite for most of the countries the preferred data source is population-based surveys, many, as Portugal, do not collect national data and work on a data extrapolation basis.

A metanalysis from 2018 showed the estimated pool prevalence of refractive error in children and adults by each one of the WHO regions (figure 3). The global estimated pool prevalence for children was 11,7% (95% CI: 10,5-13,0) for myopia, 4,6% (95% CI: 3,9-5,2) for hyperopia, and 14,9% (95% CI: 12,7-17,1) for astigmatism. For adults, the global estimated pool prevalence was 26,5 (95% CI: 23,4-29,6) for myopia, 30,9% (95% CI: 26,2-35,6) for hyperopia, and 40,4% (95% CI: 34,3-46,6) for astigmatism. The definition of myopia used in this study was a spherical equivalent ≤ -0,50 diopters in children and < -0,50 diopters in adults. For hyperopia, the definition was a spherical equivalent ≥ 2 diopters in children and > 0,50 diopters in adults. The definition of astigmatism was a cylinder power > 0,50 diopters. [26]

Additionally, estimates from 2000 to 2050 show that myopia and high myopia will significantly increase in prevalence globally, posing important challenges for health systems planning. It is predicted that by 2050, 49,8% of the world population [95% CI: 43,4%-55,7%]) will have myopia and 9,8% (95% CI: 5,7%-19,4%) will have high myopia. [27]

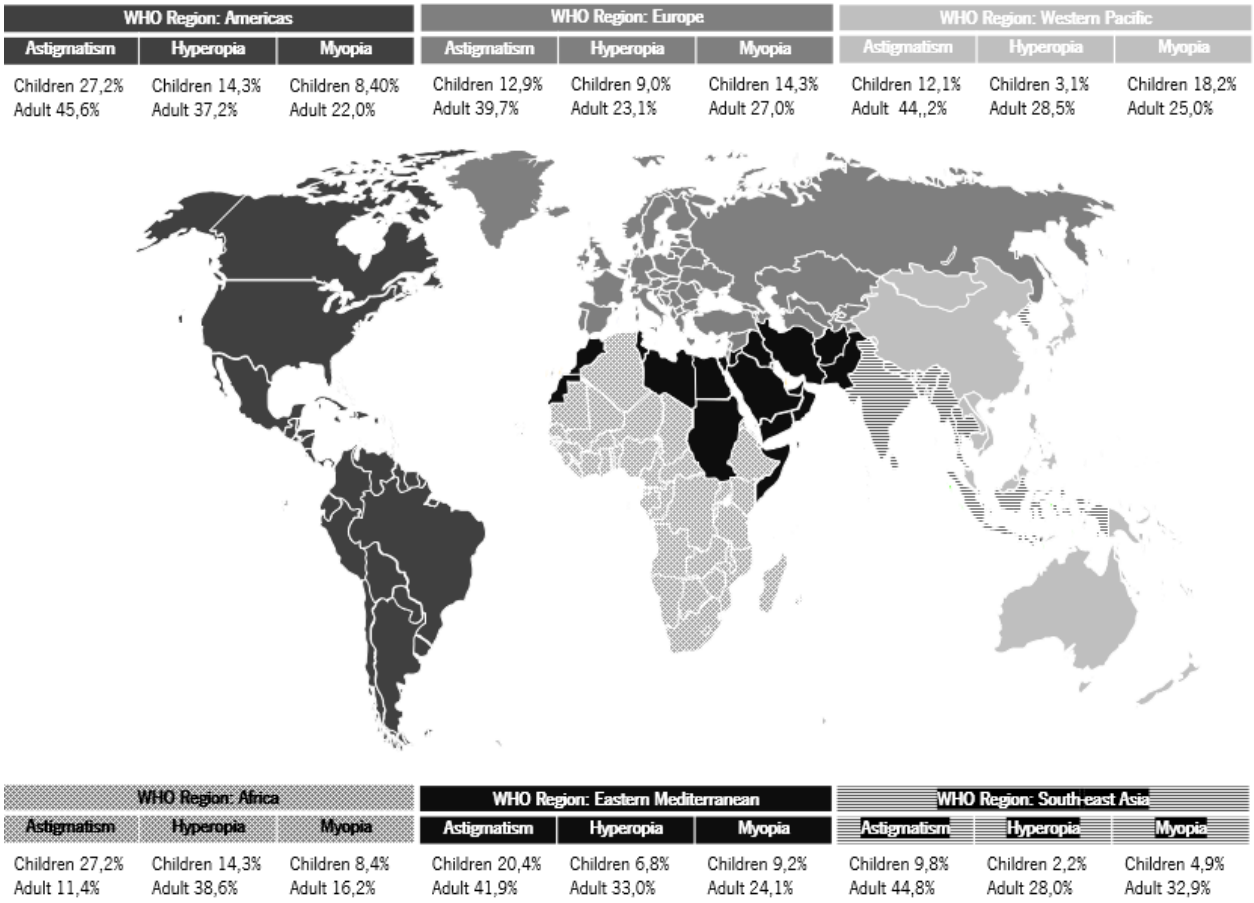

Figure 3: Estimated pool prevalence of refractive error (myopia, hyperopia, and astigmatism) in children and adult by WHO regions. Elaborated based on the data from Hashemi *et al.*, 2018. [26]

2.2. Evidence-based Refractive Error Interventions – Promotion, Prevention and Treatment

Recently, WHO has integrated a package for eye care interventions (PECI) in the universal health coverage Compendium, a database of health services and intersectoral interventions designed to assist countries in making progress towards universal health coverage. [28] The main objective of this PECI is to support the countries in the processes of prioritizing, planning, budgeting, and integrating eye care into their national health systems. One of the eye conditions selected to be included in the PECI, based on epidemiological data on the causes of VI and blindness, prevalence estimates of eye conditions and health facility data, was the Refractive Error. [20] Despite the fact that refractive error interventions are among the most cost-effective and feasible health interventions to implement in country's national health systems [5,29], in most of the countries important barriers and inequities in the access to eye care are still observed. Additionally, people who have received refractive services and an optical device

prescription need to have access to an affordable optical device dispensing service. To address inequities and improve access it is therefore important to provide comprehensive services – both refractive and optical devices dispensing services– within and as responsibility of the NHS, where they will be most accessible to the community. [30] Although the PECI considers the priority and cost-effective interventions on refractive error, in this work all the evidence-based interventions will be mentioned, divided into three different approaches: Promotion, Prevention and Treatment.

2.2.1. Promotion and Education Interventions for Refractive Error

Myopia Prevention and Control

Presbyopia, hypermetropia or astigmatism cannot be prevented, on the other hand, myopia can be prevented and is progression can be reduced through timely and appropriate management . [5] Counselling and educating about myopia prevention and control is a recommended intervention for children, parents, or other caregivers, as well as teachers and other educators. Early onset myopia is associated with higher progression rates, risk of high myopia and potential ocular complications. [31,32] Early and later childhood are the recommended age groups for myopia control procedures. [33]

To inform about evidence-based approaches to myopia management, such as the use of low concentrations of atropine drops, orthokeratology, and specific contact lenses, [34–37] and specially designed spectacle lenses as well as about the risk factors and predictors [38,39] is essential for myopia prevention, early diagnosis and management of its progression.

2.2.2. Prevention and Screening Interventions for Refractive Error

Vision Screening in Pre-school and School Ages

Eye conditions can be present even in the absence of signs, symptoms, or heredity. [40] Undiagnosed and uncorrected refractive error as well as other visual conditions that limits vision in children, can compromise cognitive and social development and motor skills, coordination, or balanced learning and psychosocial growth. [5] The permanent vision loss represents lifelong complications. Vision screening of pre-school children for the detection of reduced VA, amblyopia, and other eye conditions, with timely referral, when necessary, allows early diagnosis and treatment. Vision screening for the school-age children, with timely referral, when necessary, intends to eliminate or reduce the impact of vision loss on children development and academic performance. [33]

Despite the absence of evidence, on sensitivity and specificity, for identifying the targeted conditions of this subgroup of population, the children, [41] vision screening, in the ages 3-5 years old, has moderate benefit when compared with no assessment at all. [42] It should be noted, however, that despite the importance of vision screening, the false sense of security that school-based screenings could give to parents, educators, and the society, the false negative results, could prevent and limit the access to comprehensive eye examinations and treatment services. [33] Despite the importance of screenings in the identification of children at risk for vision problems, a comprehensive eye examination is essential for diagnosis and treatment. [43]

Vision Screening in Adults and Older Adults

One of the recommendations of the Integrated care for older people (ICOPE): Guidelines on community-level interventions to manage declines in intrinsic capacity is that older people should receive routine and periodic screening for visual impairment in the primary care setting, and timely referral and provision of a comprehensive eye examination. [44]

VI is most prevalent among older people than younger people, with the associated burden on both individual and society, limiting daily life autonomy, impacting morbidity, contributing to social isolation, and exposing individuals to poverty risk. [5]

Vision screening for adults and older people can contribute to the detection of cataract, the main cause of blindness in those aged 50 years and older in 2020, and to a timely referral for the provision of surgery that can immediately restore the vision loss. [1] People with diabetes should also have a periodic screening for diabetic retinopathy and referred to a medical examination when necessary. Additionally, a screening for detection of URE, presbyopia included, and the referral to refractive services with the provision of optical correction allows to immediately restore vision loss and improve autonomy. [44]

Screening as a stand-alone intervention has very limited supportive evidence, however, it's a first assessment of the individual needs and occurring with a functional referral system that allows the timely provision of diagnostic and treatment services, can allow early intervention, and prevent VI.

2.2.3. Diagnostic and Treatment Interventions for Refractive Error

Comprehensive Refraction Examination

The delivery of comprehensive refractive error services requires trained professionals, with the knowledge and the competences to refract, provide counselling about refractive error as part of a

general eye examination, and detect or screen for other eye conditions referring for other services. Refractive error services should be an integrant part of broader eye care services, duly linked by a functional referral system. Additionally, equipment and instruments for VA testing, refraction, among others, and affordable optical devices dispensing is essential to address refractive error. [30]

The management of refractive error can be divided into two approaches: non-surgical approach, by the prescription of optical devices, such as ophthalmic or contact lenses, or by treatments such as orthokeratology; and by surgical approaches, such as the refractive surgery. [45] Ophthalmic lenses are the safest, simplest, and cost-effective optical device to correct a refractive error and are currently the most common intervention used worldwide. Both ophthalmic and contact lenses are considered by WHO as functioning interventions, as they do not cure refractive error by treating its causes but compensate the VA reduction. [5]

Vision needs and symptoms will define the refractive compensation/correction of each individual, small and asymptomatic changes in the refractive status are generally not recommended. Distance refractive error are non-surgical managed with single vision (spheric or toric) ophthalmic and contact lenses, or orthokeratology. The surgical approach can include laser surgery, intracorneal lens implants, or intraocular lens implantation. Presbyopia, in specific, can be non-surgical managed with near, bifocal, trifocal, or progressive ophthalmic lenses or bifocal or multifocal contact lenses. The surgical approach to presbyopia, also includes laser surgery, intracorneal lens implants, or intraocular lens implantation. [45]

Although a simple intervention, as a prescription of ophthalmic lenses will manage refractive error, there still exists a high prevalence of URE worldwide, that is explained by the inaccessibility of refraction services, usually offered only at secondary and tertiary care in national health systems, and unaffordability of optical devices. It is therefore fundamental to provide comprehensive and integrated people-centred refractive care, as part of universal health coverage. [30]

Chapter 3. Micro-scenario Analysis: Refractive Error Prevalence in Portugal: A Three Studies Approach

3.1. Rationale for a Three Studies Approach of Refractive Error Prevalence in Portugal

This chapter work aims to estimate the prevalence of refractive error among the Portuguese population. Data on the prevalence, trends, and progression of refractive error in Portugal are scarce and heterogeneous, and in this way, the contribution of this condition to the total national burden of VI or blindness is unknown. To address this gap on the literature assumes bigger importance on a public health perspective. Data on the cause-specific prevalence of VI and blindness is essential to inform decision-makers, society, or researchers, in the process of planning eye care services, optimally allocate resources and make cost-effective interventions available.

A first approach aimed to systematically review and meta-analyse epidemiological data of refractive error prevalence in Portugal, using existing published evidence. However, different definitions, measurement techniques or sampled populations, from the previous studies conducted, revealed considerable heterogeneity, significant random effects, and important limitations in data comparison.

To solve this specific problem and to attempt to give strength to the result of the prevalence of refractive error in Portugal, two additional different studies approaches have been designed.

A cross sectional retrospective review of case records was the second study approach designed. Case records from optometric practices distributed across the country and dated July 2021 were reviewed to determine the pattern of distribution and the prevalence of refractive error among all the users of the optometric practices.

A third study approach relied on big data from a leading ophthalmic lens manufacturer, that, in the absence of population-based surveys, represent a potential source of refractive error epidemiological data, providing a fast and cost-effective substitute measure of refractive error distribution.

Analysing and comparing the results of the prevalence of refractive error in Portugal from the three studies approaches, homogenous or heterogeneous, allows to have a more realistic estimate of the prevalence and to withdraw more strong conclusions.

3.2. Study I. Refractive Error Prevalence in Portugal: A Systematic Review and Metanalysis

3.2.1 Introduction

A substantial increase in the number of cases of VI and blindness is anticipated due to the shift in the disease burden towards non-communicable diseases and disabilities, as is the case with refractive error, resulting from demographic and evolutionary changes in the population. [1] Data on the prevalence and progression of refractive error in Portugal are scarce and heterogeneous, and in this way, the contribution of this condition to the total national burden of VI or blindness is unknown.

Retrospective Analysis of the Portuguese National Program for Eye Health (PNSV) 2012-2016 and extension to 2020

The PNSV 2012-2016 - revision and extension to 2020 [46] had the following targets: to reduce the proportion of undiagnosed eye health problems in children, young people and adult population; to reduce the predictable incidence and prevalence of blindness and VI associated with pathologies that can be treated appropriately; and to reduce the proportion of eye care problems that cause loss of functionality and independence in people aged ≥ 55 years. To achieve these targets, two intervention strategies were defined: screening and early diagnosis. According to the established by the WHO Universal Eye Health - Global Action Plan 2014-2019 [47], the PNSV 2012-2016 - revision and extension to 2020 intervention strategies implementation should have been replicated and adapted regionally, considering the local specificities and existing resources in order to improve universal access to eye care.

The strategies definition, made in a vast way, without specific actions and interventions duly substantiated, without evidence-based or a cost-benefit analysis for each intervention, without a definition of a temporal goal and disregarding integrated-people centred care, [48] allows to retrospectively analyse that it did not met the established targets.

Data from 2017, on the coverage and response times of eye care services by the Health System Central Administration (ACSS, IP), shows that the targets are far from being achieved, with 181 824 form the 313 941 eye care patients request not being attended and 111 831 being attended out of the 150 days defined as maximum response time that must be ensured (average waiting time of 171 days, with a maximum of 603 and minimum of 38 days). Also, there was an evident deterioration in the

median wating time for ophthalmological surgery, having increased to 2,6 in 2019, with 57 170 individuals waiting for surgery. [49,50]

Access to optical devices correction is also compromised since for the access to reimbursement it is necessary to have a prescription issued by the National Health Service (NHS) with the access barriers and extensive waiting lists, making universal eye care coverage unfeasible and not allowing the achievement of the PNSV defined targets. [49]

This information allows us to conclude that the PNSV 2012-2016 - revision and extension to 2020 implementation does not have contribute to an increase in universal eye care coverage, nor to the reduction of the leading causes of avoidable VI. On the contrary, a significant deterioration in the care provided is observed, with longer waiting times and difficulties in access to care and optical devices correction.

The planning and definition of an intervention strategy must pass through a correct epidemiological diagnosis of the conditions to be intervened and direct the provision of care to the population's needs, safeguarding the predictable demographic developments. [51]

URE as Leading Cause of Vision Impairment in Portugal

Refractive error are one of the leading causes of vision impairment worldwide, [5] despite that, data on the refractive error prevalence and progression in Portugal are scarce and heterogeneous, and in this way eye care services planning have failed consecutively over the years to address this problem. [49,52,53]

Still far from achieving the feasible global target for effective coverage of refractive error, [48] the number of refractive error cases seems to be increasing, representing significant economic implications, not only immediate but in terms of potential lost productivity, in both low and high-income countries. [4,5,54,55] The scenario in Portugal, despite the lack of data, is estimated to follow the same worldwide trend, which makes refractive error a priority issue in current eye care and public health research.

Despite the limitations in the comparison of refractive error prevalence between different studies, because of different definitions, measurement techniques or sampled populations, this chapter aimed to systematically review and meta-analyse epidemiological data of refractive error prevalence in Portugal, using existing published evidence.

3.2.2. Methods

Literature Search Strategy and Sources of Epidemiological Data

A systematic search and literature review was conducted according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) procedures.

Multiple national and international electronic scientific databases, such as MEDLINE/PubMed, Web of Science, Scopus, Google Scholar, official organizations databases and academic repositorium's were systematically searched to retrieve all potentially relevant publications of epidemiological studies about prevalence and incidence of refractive error in Portugal. A comprehensive search strategy, tried to be free from error, was conducted combining terms related to epidemiology (prevalence, incidence, epidemiology, frequency), terms related to the outcome of interest (refractive error, myopia, hyperopia, astigmatism) and affiliation (Portugal) combined by Boolean operators (OR, AND) or not. No time interval for the studies conduction has been defined.

For every publication or paper found, the reference list was reviewed searching for additional studies or data in an attempt to retrieve all the relevant information.

Inclusion and Exclusion Criteria and Data Extraction

Publications were selected based on the following inclusion criteria: exploring the prevalence, incidence, or other epidemiological data of the different refractive error (myopia, hyperopia, and astigmatism); assured peer review in poster, academic thesis/dissertation, and scientific publication formats; from all the geographical regions of Portugal and in Portuguese or English language. Exclusion criteria were the same data used in separated studies.

Each paper was reviewed, and information/data was extracted based on the following characteristics: author's name, title, study year, publication format (poster, academic thesis or dissertation or scientific publication), study type, sample size, population age range, sex ratio, refractive error assessment method, refractive error definition, refractive error prevalence and, if applicable myopia, hyperopia, and astigmatism prevalence.

Statistical Analysis

A meta-analysis was conducted using the Comprehensive Meta-Analysis Software (CMA). The outcome measure was the prevalence of refractive error among the Portuguese population, including myopia, hyperopia, and astigmatism, having as moderator variable the mean age. The events and sample size

were entered as raw data and the effect size parameters (event rate, logit event rate, standard error) were computed by CMA.

3.2.3. Results

A total of 11 studies were found and 2 were excluded because they were different representations of a same study already use, a poster and a thesis already included as a scientific publication (figure 4). Data from the remaining 9 studies were pooled for the meta-analysis.

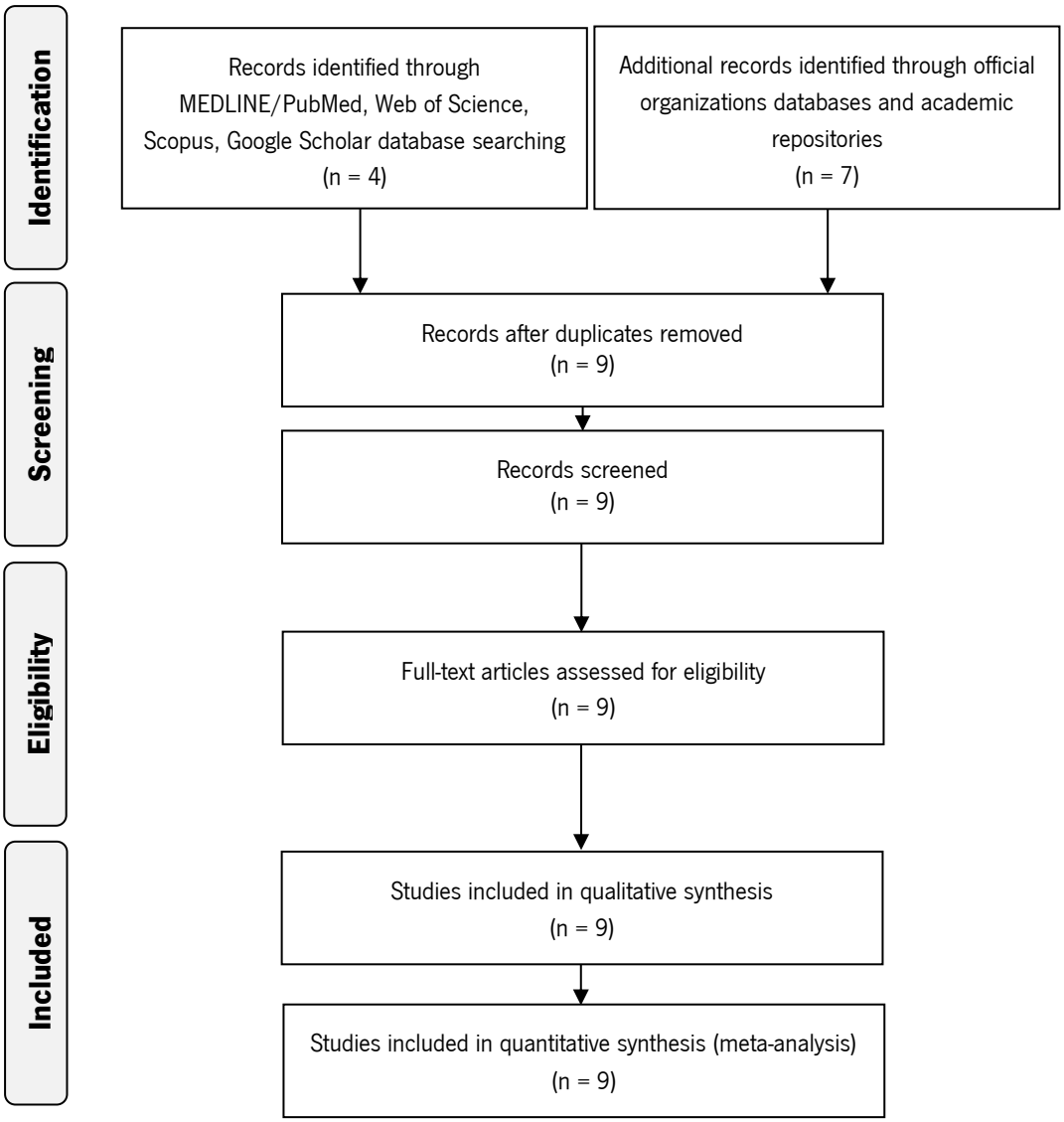

Figure 4: Flow chart of the process of study selection - adapted from Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. [56]

The characterization of the 9 studies included in the qualitative and quantitative synthesis are summarized in table 2. The studies years range from the 1999 to 2017. The immediate qualitative analysis shows a high heterogeneity between the studies regarding sample sizes and age range.

Author	Year	Study Type	Age Range (Mean ± SD)	Sex Ratio	Sample Size (N)	Refractive Error Events (n)	Refractive Error Prevalence
Queirós, António [57]	1999 - 2004	Retrospective	40.08 ± 18.75	F 2351 (54,8%); M 1937 (45,2%)	4288	2359	54,9%
Jorge, Jorge [58]	2002 - 2005	3-year longitudinal study	20.6 ± 2.3	F 54 (71,2%); M 34 (28,8%)	118	79	66,9%
Lança, Carla [59]	2012	Cross-sectional study	7.69 ± 1.19	F 362(53,9%); M 310 (46,1%)	672	202	30,1%
Carvalho, Ana Sofia [60]	2012	Populational survey	-	F 430 (66%) M 224 (34%)	654	265	40,5%
Barros, Daniela [61]	2013	Populational survey	-	F 429 (65,8%) M 223 (34,2%)	652	241	37,0%
González-Méijome, JM [62]	2013 - 2015	Longitudinal Pilot Study	9±2	F 52 (48%) M 56 (52%)	108	41	38,0%
Queirós, António et al [63]	2017	Populational	14.84 ± 4.72	F 401 (57,4%) M 298 (42,6%)	699	309	44,2%
Jorge, Jorge [64]	2017	School-based Cross-sectional Study	9.8 ± 2.9	F 733 (52,0%) M 676 (48,0%)	1409	162	11,5%
Carneiro, Inês [65]	2016	Cross-sectional study	2.2	F 635 (45,5%); M 760 (54,5%)	1395	55	3,9%

Table 2: Studies reporting on the prevalence of refractive error in the Portuguese population.

Data was entered in the CMA software as sample and number of events (myopia) and the Event Rate, Lower and Upper limits, Z-Value, p-Value were calculated as shown in table 3 for each study included in the meta-analysis. The outcomes of the meta-analysis are presented in table 4 including the statistics for the fixed and random models.

Author	Age Entered	Sample Size (N)	Refractive Error Events (n)	Event Rate	Lower Limit	Upper Limit	Z-value	p-value
Queirós, António [57]	40.08	4288	2359	0.549	0.535	0.564	6.464	<0.001
Jorge, Jorge [58]	20.6	118	79	0.669	0.580	0.748	3.607	<0.001
Lança, Carla [59]	7.69	672	202	0.301	0.267	0.336	-10.037	<0.001
Carvalho, Ana Sofia [60]	-	654	265	0.405	0.368	0.443	-4.819	<0.001
Barros, Daniela [61]	-	652	241	0.370	0.333	0.407	-6.579	<0.001
González-Méijome, JM [62]	9	108	41	0.380	0.293	0.474	-2.477	0.013
Queirós, António et al [63]	14.84	699	309	0.442	0.406	0.479	-3.057	0.002
Jorge, Jorge [64]	9.8	1409	162	0.115	0.099	0.133	-24.438	<0.001
Carneiro, Inês [65]	Mean 2.2	1395	55	0.039	0.030	0.051	-23.209	<0.001

Table 3: Data entered in the CMA software (Age, Sample and Events) and computed by the software (Event Rate, Lower and Upper limits, Z-Value, p-Value) in the shadowed cells.

The fixed and random model estimates point to an effect size in the range closer to 40% prevalence of refractive error in the Portuguese population. While the random effects model points to an estimated effect size of 31.9% within a confidence interval of 19.8% to 47%, the fixed effects model narrows down the estimate to 43% within a confidence interval of 41.9 to 44.1%. Despite the statistics of heterogeneity recommend when using a random-effects models for subsequent analysis, in the table 4 below, the results of both models are presented to ensure that all statistics produced are displayed. Subsequent graphical presentation, including forest plot in figure 5 will only represent the random-effects model. [66]

	Effect Size and 95% confidence interval			Dispersion Test (null hypothesis)		Heterogeneity		Variance Between Studies			
Model	Point Estimate	Lower Limit	Upper Limit	Z-value	p-value	Q-value (p-value)	I-squared (I^2)	Tau^2	Standard Error	Variance	Tau
Fixed	0.430	0.419	0.441	-12.416	p<0.001	1219.244	99.344	0.942	0.665	0.442	0.970
Random	0.319	0.198	0.470	-2.330	p=0.020						

Table 4: Meta-analysis results for fixed and random model estimates of effect size and 95% confident interval, Z-value.

On the test for heterogeneity, Q-value was statistically significant demonstrating that there was significant heterogeneity among studies (p<0.001). Along with the value of I-squared parameter, we can conclude that the heterogeneity was very high. Considering the I-square heterogeneity parameter of 99.344 we can conclude that over 99% of the variance between studies can be attributed to real differences in the effect size and less than 1% of the variance can be expected from random error. According to recommendations from Higgins et al, [67] considering the high value of the I-squared parameter, a random effects model needs to be applied and this is graphically shown in figure 5 below.

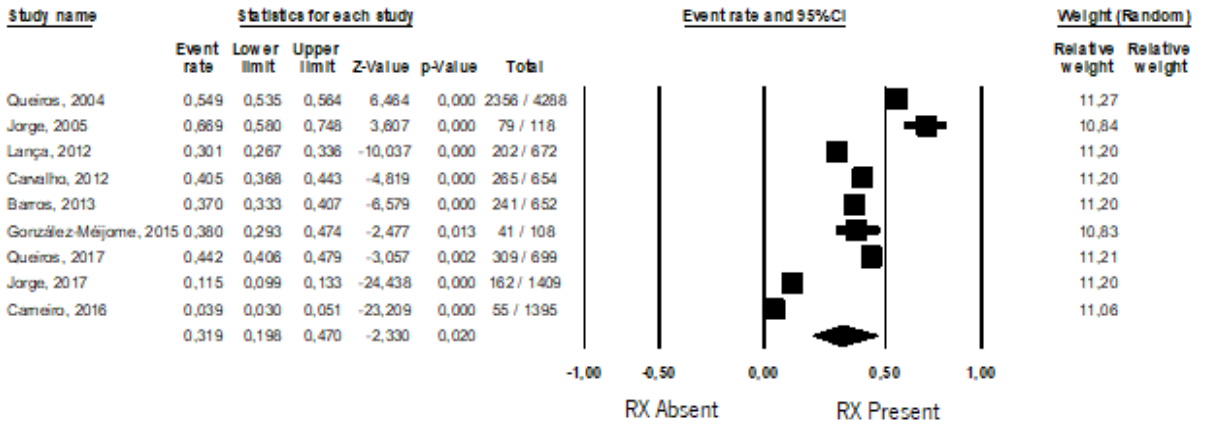

Figure 5: Forest plot for the random effects model including the effect size (middle point of each study) and within-study variance (horizontal amplitude) for each study and mean effect size (bottom diamond).

Forest plots displayed in figure 5 show graphically the results previously presented in tables. It is apparent from both plots the high between-studies variance (variable effect sizes from 0 to over 0.5).

The variance between studies was also high as shown in table 4 by the Tau-squared parameter being high (Tau^2=0.942). Some studies show a low within-study variance (narrow intervals) while others show a larger variance (larger intervals). As previously observed in the tables, the average effect size confidence interval was larger for the random effects than the fixed effects model.

3.2.4. Discussion

The meta-analysed prevalence of refractive error in Portugal of 31.9% (95% CI: 20.0-45.0%) can be considered as a conservative approach to the real burden of this condition within the Portuguese population. This value indicates that at least 2 to 4 million Portuguese individuals suffer from a refractive error. Previous national reports estimates that about 20% of children and 50% of the adult population have significant refractive error. [46]

Comparing with a more comprehensive analysis where Portugal is included, an European one, a study from an eye care epidemiological consortium estimates that over a half of European adults are affected by a refractive error.[6]

There is no exact data on VI prevalence in Portugal, however, studies have extrapolated or inferred this numbers using data from countries in the same global burden of disease region (Western Europe). According to Bourne *el al*, 2014, the estimate for Portugal shows that, for the population with 50 years old or more, there are 263 748 Portuguese individuals (6.2%) with moderate or severe visual impairment and about 42 540 (1.0%) with blindness. The uncertainty interval, however, indicates that these estimates are a very gross picture for Portugal and further prevalence studies are necessary [68]. Data from the 2001 Portuguese censuses, with the limitations inherent to this data collection source, reveals 163 569 disable individuals from visual impairment. Visual impairment thus represents the biggest contributor to the total burden of disability in Portugal, with the same proportion between men and women [15]. More recent data, from the 2011 Health and Disability Report in Portugal from the National Statistics Institute, shows that for Portuguese people with at least one disability, which represents 17,4% of people between 15 and 64 years old, visual impairment, even with optical correction, represents 17,2%, most affecting women; and for people aged 65 years old or more with at least one disability, 50% had visual impairment, even with optical correction [16].

Knowing that numerous studies, at regional or global level, conclude that refractive error are a leading cause of vision impairment contributing for approximately 40% of the cases, [5,12,69–71] and considering the

estimate values of VI prevalence mentioned for Portugal, we can consider that a refractive error prevalence of 31.9% (95% CI: 20.0-45.0%) is an estimated value very close to the real or even lower than the real verified for the Portuguese population.

Putting this prevalence of refractive error in Portugal, of 31.9%, in a public health perspective, and comparing them from a purely statistical point of view, it is observed that it assumes a value much higher than the values of the main non-communicable or chronic diseases/conditions reported in 2019, namely that of the prevalence of arterial hypertension of 26.4%, prevalence of obesity of 17.0%, prevalence of depressive disorders of 12.1% and prevalence of diabetes of 9.9%. And, just like the previous, refractive error should be addressed in a public health context.

3.2.5. Conclusion

The high heterogeneity between studies, the wide estimate for refractive error prevalence (95% CI: 20 to 45%) and the random effects involved lead to that the main conclusion to be drawn from this study being the demonstration of the need for more studies (population base surveys) and more consistent sources to obtain narrower estimates on the prevalence and incidence of refractive error in Portugal.

However, and even assuming a conservative posture, a prevalence between 20.0 – 45.0% translates into at least 2 to 4 million Portuguese individuals suffering from a refractive error and places the refractive error as one of the conditions with more burden on the health system and the national population, demonstrating the need to be addressed in a public health context.

The results of this study sustain the need to create refractive services, to adopt the IPEC strategy to address this condition, contributing to the reduction/elimination of avoidable VI due to refractive error that contribute to greater exposure to morbidities, higher mortality rates, lower quality of life and greater risk of exposure to poverty.

3.3. Study II. Refractive Error Prevalence in Portugal based on Optometric Records

3.3.1. Introduction

Although substantial variations in the estimates can compromise their interpretability and utility, clinical records and health care databases are important sources of information for estimating prevalence and incidence of eye care conditions and enable extensive study of its characteristics. [72,73] Considering the burden and clinical and economic impact of URE, clinical-based research methods are often used, along with the non-clinical, to generate evidence and estimates on the prevalence and distribution of refractive error.

Previous studies estimating the prevalence of refractive error by analysing the clinical records were conducted in different conditions. A similar design study was already performed in Portugal and referred in this work for the meta-analysis conducted. Queirós *et al.*, 2009, [57] analysed the clinical records of 4288 patients examined in five ophthalmologic and four optometric clinics in the north territory of Portugal. Gomez-Salazar et al. [74] analysed records of 676 856 patients examined in optometry clinics in 14 states of Mexico. Malu and Ojabo, 2014, [75] analysed records of 601 examined in a private hospital in Nigeria.

The similar findings of these three studies [57,74,75] were that myopia was the most prevalent refractive error in school-aged children and hyperopia the most prevalent refractive error in adults with more than 40 years old. However, the collection of the data from different type of settings/sector, from different professionals, and/or with restricted geographical coverage are limitations o be addressed.

To estimate the prevalence of refractive error within a country, a geographical coverage must be ensured, safeguarding that the methods of examination and the competency of the professionals performing it are consistent and comparable.

Considering this, the aim of this study was to estimate the prevalence and patterns of distribution of refractive error in Portugal based on a clinical sample of consecutive patients examined in a chain of optometric practices distributed by the entire country territory.

3.3.2. Methods

Study Design and Data Collection

A cross sectional retrospective study was designed to review optometric records from 20 consecutive examinations in 17 optometric practices, from a chain, located in 10 of the 20 districts of Portugal (1 Aveiro, 2 Braga, 4 Lisbon, 1 Setúbal, 4 Porto, 1 Viseu, 1 Faro, 1 Coimbra, 1 Funchal and 1 Leiria) in July 2021. The optometric practices were distributed by districts from the north to the south of mainland Portugal and on the island of Madeira. All patients signed an informed consent allowing the provision of their data, anonymized, and the study complied with ethical standards in accordance with the Declaration of Helsinki. Data were entered into a template Excel sheet previously prepared. The required data for all the cases was patient demographic information (sex, age, reason for the examination and result of the examination), patient refractive information (monocular and binocular distance PVA, refraction - sphere, cylinder, axis, and addition, if prescribed - and monocular and binocular distance BCVA) and practice information (number of the optometric practice and district). PVA is the measure of unaided vision, or, if spectacles or contact lenses are worn to the assessment, VA is measured with the person wearing them. BCVA is assessed either with the best refraction or by pinhole. The study author was not involved in the data collection, had no contact with the patients in the clinical setting or with those responsible for the data collection. The various professionals responsible for the data collection were licensed optometrists with similar backgrounds, who follow the same examination and conduct routine imposed by the chain of optometric practices. For patients who consulted more than once during the period in question, only data from one of the visits were collected, ensuring that no patient data were duplicated and avoiding recall bias.

Data Analysis

All data and information entered into the template were reviewed. Statistical analysis was conducted using the Statistical Package for Social Sciences (SPSS) version 28 (SPSS for Windows Inc., Chicago, IL, USA).

A sample characterization was made using descriptive statistics and presented as mean, standard deviation and frequencies. The variable age was grouped into 4 intervals with approximately 25% of individuals per group: 6 to 29, 30 to 44, 45 to 59 and 60 to 8 years old.

T-test and was used to analyse the differences between the means of two groups and an Analysis of Variance was used to analyse the differences between the means of more than two groups. The test Pearson Chi-Squared was used to analyse the frequency and percentage differences in refractive error according to sex and age groups, and the Bonferroni test was used to assess differences between the age groups. A *p* value of ≤ 0.05 was considered statistically significant. Estimates of prevalence were presented through percentages and corresponding 95% confidence intervals.

No significant difference for both the refractive (1.586, $p = 0.114$) and visual acuity (PVA -0347, $p = 0.729$ and BCVA -0.080, $p = 0.936$) outcomes between right eye (RE) and left eye (LE) were found ($p = 0.114$), so only the RE is presented for analysis.

Outcome Variables Criteria

The outcome variables were the refractive error parameters, namely, the spherical equivalent. Data on presbyopia were not analysed.

The quantitative definitions from the International Myopia Institute have been adopted, myopia was defined as spherical equivalent refractive error ≤ -0.50 Diopters when ocular accommodation is relaxed and high myopia as spherical equivalent refractive error ≤ -6.00 Diopters when ocular accommodation is relaxed. [76] Emmetropia was defined for those with a spherical equivalent of less than 0.50 Diopters in absolute value, regardless of whether the blur is myopic or hyperopic, and hyperopia when the spherical equivalent is ≥ +0.50 Diopters.[77]

3.3.3. Results

Sample Characterization

348 optometric records were obtained, 14 had been eliminated due to duplication or incorrect entry, resulting in a total of 334 optometric records. Subjects had a mean age of 44.2 ± 19.2 years (range 6-81) and 58.4% were female. 163 of the subjects (49.0%) had more than 45 years old. Age groups were defined according two criteria, the first was to have a balanced number of individuals in each group but also according to key-ages for refractive error, namely a group up to 29 years old when is estimated a stabilization of myopia; [78,79] a group beginning in the age 45, estimated age at onset of presbyopia; [80] and another group beginning at 60 years old, age of onset the risks associated with myopia. [81]

Sex distribution across age groups is presented in figure 6. 25% of the subjects were from Porto area; 24% from Lisbon; 11% from Braga, 6% from Setúbal, Viseu, Aveiro, Faro and Leiria and 5% from Madeira and Coimbra.

As the reason for the examination, 55% already used and intended to update the refractive device 27% had a routine examination, 7% had the first eye care assessment and 11% search eye care for other reasons.

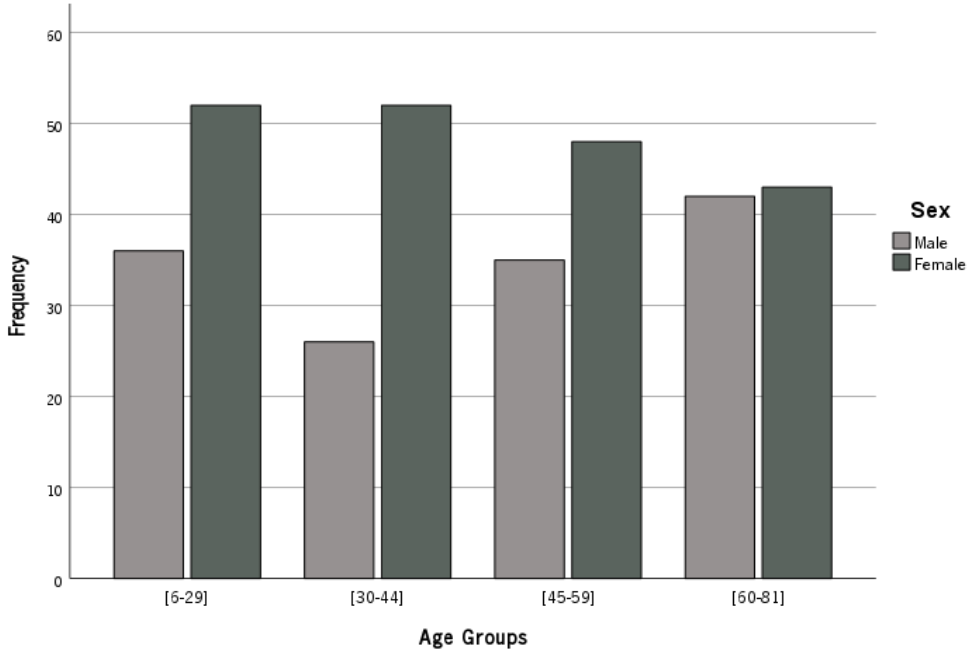

Figure 6: Sex distribution across the age groups.

78% of the examinations resulted in a prescription of a refractive error device, 11% doesn't required any action, 3% were referred for other health professionals without any prescription or action and 8% have had other results.

Visual Acuity Analysis

The mean PVA for the right eye was 0.83 ± 0.23, varying from a minimum of 0 and a maximum of 1.2, and the mean BCVA for the same eye was 0.95 ± 0.15, varying between the same values (table 5). The skewness for both VA measures was negative, -1.57 for PVA and -4.00 for BCVA.

	PVA RE	*BCVA RE*
Mean	0.83	0.95
Standard Deviation	0.23	0.15
Median	0.90	1.00
Kurtosis	2.05	19.11
Skewness	-1.57	-4.00
Minimum	0.00	0.00
Maximum	1.20	1,20

Table 5: Descriptive analysis of the PVA and the BCVA from the right eye (RE). Each visual acuity was measured for distance vision.

Statistically significant differences were found between the mean distribution of the PVA and BCVA across the age groups (12.38; $p < 0.001$ and 5.73; $p < 0.001$ respectively). For the PVA statistically significant differences were found between group [60 – 81] and the groups [6 – 29] and [30 – 44], with $p = 0.004$ in both cases. BCVA showed statistically significant differences between the group [60 – 81] and the groups [6 – 29], [30 – 44] and [45 – 59], with $p < 0.001$ in all the cases (table 6).

		N	*PVA RE (Mean ± SD)*	*BCVA RE (Mean ± SD)*
	All	334	0.83 ± 0.23	0.95 ± 0.15
Age Group	[6 – 29]	88	0.86 ± 0.23	0.98 ± 0.12
	[30 – 44]	78	0.86 ± 0.22	0.97 ± 0.08
	[45 – 59]	83	0.85 ± 0.28	0.98 ± 0.09
	[60 – 81]	85	0.74 ± 0.26	0.87 ± 0.22
	ANOVA Test		12.38; $p < 0.001$[a]	5.73; $p < 0.001$[a]

Table 6: Distribution of the PVA and the BCVA from the right eye (RE) by age groups: means and standard deviation; [a] statistically significant.

Refractive Error Descriptive Analysis and Distribution

The distribution of the refractive error within the sample, as spherical equivalent, assumes a normal distribution, centred near emmetropia but shifted to myopia side (figure 7).

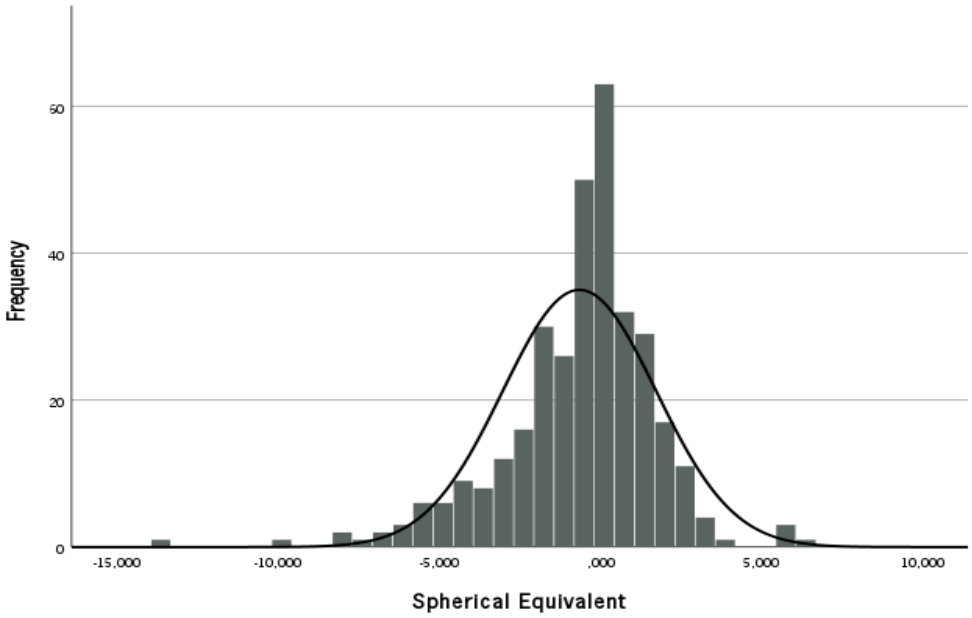

Figure 7: Distribution of the refractive error (spherical equivalent for the right eye) within the sample.

The mean spherical equivalent of the sample was myopic, -0.65 ± 2.38 Diopters, varying from a minimum of -13.63 to a maximum of 6.25 Diopters. The median value was emmetropic, -0.25. The distribution assumed a kurtosis of 3.63 Diopters and a skewness of -1.04 Diopters.

According to the sex, the mean spherical equivalent was myopic for both sex, -0.76 ± 2.29 Diopters for female and -0.49 ± 2.49 Diopters for male, with no significant difference between them (1.022; p = 0.307). The distribution of the spherical equivalent mean across the different age groups, linearly varies from a myopic -1.62 ± 1.74 Diopters in the age group of [6 – 29]; -1.58 ± 2.80 Diopters in the [30 – 44]; -0.09 ± 2.40 Diopters in [45 – 59] to a hyperopic 0.67 ± 1.61 in the age group of [60 – 81].

Statistically significant differences were found between the mean distribution of the spherical equivalent across the age groups (22.88; $p < 0.001$). Statistically significant differences of spherical equivalent mean were found between group [6 – 29] and groups [45 – 59] and [60 – 81] and between group [30 – 44] and groups [45 – 59] and [60 – 81], with $p < 0.001$ in all the cases (table 7).

		N	*SE (Mean ± SD)*	*95% CI*
	All	334	-0.65 ± 2.37	-
Sex	Male	139	-0.49 ± 2.49	[-0.91; -0.73]
	Female	195	-0.76 ± 2.29	[-1.08; -0.44]
	t Test		1.022; $p = 0.307$	
Age Group	[6 – 29]	88	-1.62 ± 1.74	[-1.99; -1.25]
	[30 – 44]	78	-1.58 ± 2.80	[-2.21; -0.95]
	[45 – 59]	83	-0.09 ± 2.40	[-0.62; -0.43]
	[60 – 81]	85	0.67 ± 1.61	[0.32; 1.02]
	ANOVA Test		22.88; $p < 0.001$[a]	

Table 7: Distribution of the spherical equivalent by sex and age groups: means, standard deviation (SD) and 95% Confidence Interval (CI)[a] statistically significant.

Refractive error was categorized according to the previous mentioned definitions. The mean of high myopia was -8.13 ± 2.37 Diopters. It is important to refer that for the age group from 60 to 81 years old, no case of high myopia was detected. For myopia, the mean was -2.21 ± 1.45 Diopters, with -2.40 ± 1.51 for females and -1.89 ± 1.29 for males but without significant differences between sex or age groups. In the case of emmetropia the mean detected was -0.05 ± 0.21 with mean values increasing linearly across the group ages from -0.13 ± 0.21 in the age group from 6 to 29 to 0.03 ± 0.21 in the group of 60 to 81 years old. Hyperopia had a mean of 1.69 ± 1.18. No statistically significant differences were found between the mean of each refractive error category and age or sex (table 8).

		N	*High Myopia (Mean ± SD)*	*Myopia (Mean ± SD)*	*Emmetropia (Mean ± SD)*	*Hyperopia (Mean ± SD)*
	All	334	-8.13 ± 2.37	-2.21 ± 1.45	-0.05 ± 0.21	1.69 ± 1.18
Sex	Male	139	-7.95 ± 2.88	-1.89 ± 1.29	-0.04 ± 0.21	1.75 ± 1.37
	Female	195	-8.50 ± 1.23	-2.40 ± 1.51	-0.06 ± 0.22	1.65 ± 1.02
	t Test		0.316; $p = 0.761$	2.018; $p = 0.046$	0.406; $p = 0.686$	0.392; $p = 0.696$
Age Groups	[6 – 29]	88	-7.25 ± 1.24	-2.16 ± 1.25	-0.13 ± 0.21	1.25 ± 0.48
	[30 – 44]	78	-9.41 ± 3.13	-2.30 ± 1.65	-0.09 ± 0.18	2.51 ± 1.76
	[45 – 59]	83	-7.00 ± 1.07	-2.27 ± 1.62	-0.02 ± 0.23	1.64 ± 1.46
	[60 – 81]	85	-	-2.07 ± 1.50	0.03 ± 0.21	1.66 ± 0.85
	ANOVA		1.075; $p = 0.399$	0.127; $p = 0.944$	2.576; $p = 0.590$	1.420; $p = 0.242$

Table 8: Distribution of the categories of refractive error by sex and age groups: means and standard deviation (SD).

High myopia had a prevalence of 2.7% in the sample, was more prevalent in males (4.3%) than females (1.5%), and the age group from 30 to 44 was the most affected (5.1%), with no correlation between high myopia and age or sex detected (table 9).

Myopia was the more prevalent refractive error in the sample with 41.3%. 69.3% of the individuals form the age group 6 to 29 years old and 56.4% of those in the age group from 30 to 44 had myopia, and myopia was more prevalent in females (45.1%) than males (36.0%). The prevalence of myopia decreased significantly with increasing age to 15.3% in the age group of 60 to 81 years old (figure 8 and table 9). No correlation between myopia and age or sex was detected.

Emmetropia prevalence was very similar between age groups and between males and females (figure 8 and table 9).

Hyperopia had a prevalence in the sample of 29.7% and was slightly more prevalent in males (30.9%) than females (28.2%), with no statistically significant differences. The prevalence of hyperopia increases substantially with the age of the sample, varying from 5.7% in the age group from 6 to 29 years old to 58.8% in the age group from 60 to 81 years old (figure 8 and table 9). No correlation between hyperopia and age or sex was detected.

		N	*High Myopia (n; %)*	*Myopia (n; %)*	*Emmetropia (n; %)*	*Hyperopia (n; %)*
	All	334	9; (2.7%)	138; (41.3%)	89; (26.7%)	98; (29.3%)
Sex	Male	139	6; (4.3%)	50; (36.0%)	40; (28.8%)	43; (30.9%)
	Female	195	3; (1.5%)	88; (45.1%)	49; (25.1%)	55; (28.2%)
	t Test		0.316; p =0.761	2.018; p =0.046	0.406; p =0.686	0.392; p =0.696
	Chi-Squared		6.770; p =0.455	28.575; p = 0.770	1.421; p =0.965	20.909; p =0.698
Age Groups	[6 – 29]	88	2; (2.3%)	61; (69.3%)	20; (22.7%)	5; (5.7%)
	[30 – 44]	78	4; (5.1%)	44; (56.4%)	23; (29.5%)	7; (9.0%)
	[45 – 59]	83	3; (3.6%)	20; (24.1%)	24; (28.9%)	36; (43.4%)
	[60 – 81]	85	0; (0.0%)	13; (15.3%)	22; (25.9%)	50; (58.8%)
	ANOVA		1.075; p =0.399	0.127; p =0.944	2.576; p =0.590	1.420; p =0.242
	Chi-Squared		14.25; p =0.431	88.73; p =0.873	19.27; p =0.376	82.26; p =0.265

Table 9: Frequency and percentage of refractive error, categorized according to definitions of high myopia, myopia, emmetropia and hyperopia, by sex and age groups and respective correlations.

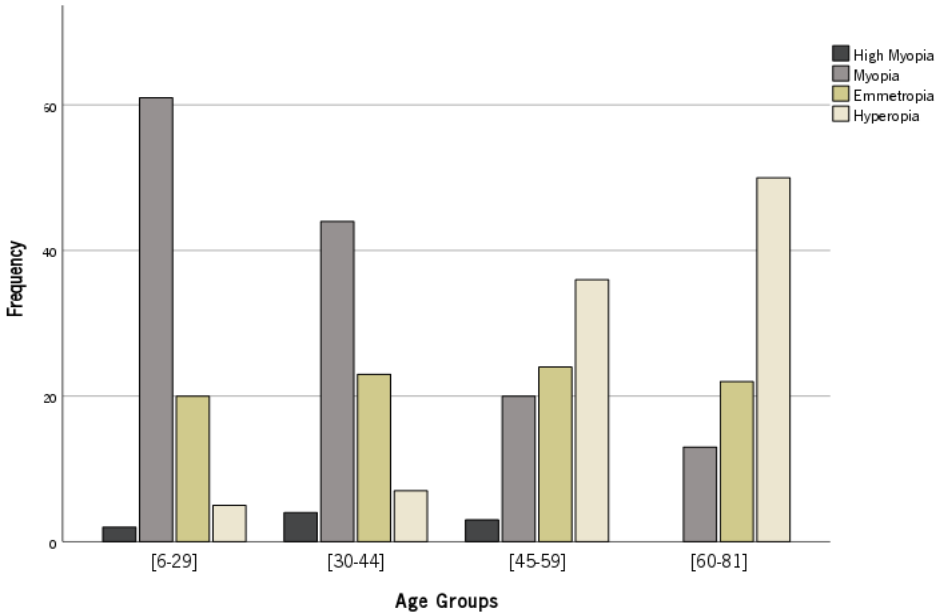

Figure 8: Distribution of the refractive error (SE RE) across the different age groups.

3.3.4. Discussion

This study aimed to estimate the prevalence and patterns of distribution of refractive error in Portugal based on a clinical sample of consecutive patients examined in a chain of optometric practices distributed by the entire country territory. Although it provides useful findings, this study design, as well as the non-probability sampling approach, limits extrapolation of those findings

The mean refractive error of the sample was myopic, -0.65 ± 2.38 Diopters and the skewness of the distribution shows an asymmetry towards the myopic side. No statistically significant differences were found between males or females. According to age, a populational shift towards the myopization of the population is observed, with the younger age group from 6 to 29 years old presenting a mean refractive error of -1.62 ± 1.74, that gets less myopic for the age group from 30 to 44 years old (-1.58 ± 2.80 Diopters), to an emmetropic mean for the age group from 45 to 50 years old (-0.09 ± 2.40 Diopters) and finally a hyperopic mean in the age group from de 60 to the 81 years old (0.67 ± 1.61), in agreement with several studies. [27,57,82,83] Statistically significant differences were found between the overall spherical equivalent mean and certain age groups, namely between the 6 to 29 years old group and the groups from 45 to 59 and 60 to 81 years old and between group the 30 to 44 group and the groups from 45 to 59 and 60 to 81 years old. The results of this study relates to the evidence that suggest that the onset of myopia in early ages, continues throughout life, stablishing or evolving , in a small

percentage, to high myopia [35] and that younger generations tend to present a higher prevalence of myopia. [27]

This hyperopia to myopia shift according to the ageing process (older people more hyperope than younger), has been linked to physiological eye changes with age. [84] However, and assuming that no hyperope at a certain age will become myope, a populational analysis and not a case-based one can better inform about trends and predictive evaluations. The hyperopia to myopia shift shows a demographic shift, were the younger generation is becoming more myope, and myopia increases, and the hyperopia is decreasing by the natural life-end of the more older population, that is known to be more hyperopic. [1,27,85]

Prevalence of high myopia within the sample was of 2.7%, and 4.3% of the male individuals in the sample had this refractive error, assuming that the evidence shows that myopia is more prevalent in males, is expected that is the sex group that more frequently develop high myopia. [27,81,86]

Myopia was the most prevalent refractive error in the sample, with 43.1% of the cases, in line with the epidemiological data and trends verified around the world. [6,26,27,79] 69.3% of the cases in the age group from the 6 to the 29 years old; 56.5% of the cases in the age group of 30 to 44; 24.1% of the cases in the group from 44 to 59 and lastly, 15.3% of the cases of the age group from the 60 to the 81 years old were myopes. Showing the same trend in the increase of myopia for the younger generations related in the literature. [6,27,82]

The prevalence of hyperopia in the sample was 29.3%, showing the inverse trend of myopia, with a decrease of prevalence for the younger generations. [6,26] Hyperopia represented 5.7% of the cases in the age group from the 6 to the 29 years old; 9.0% of the cases in the age group of 30 to 44; 43.4% of the cases in the group from 44 to 59 and 58.8% of the cases of the age group from the 60 to the 81 years old.

Comparing the values of prevalence found in this study with findings from the same country, we observe a higher value of myopia prevalence in this study, 43.1%, than by Queirós *et al.*, 2009, 29.8%, and a very similar value of hyperopia prevalence with 29.3% in this work compared to 25.2% founded by Queirós *et al.*, 2009. Also, it is important to note that temporal differences of this studies (2009 to 2021) can contribute to higher prevalence of myopia and a shift of the distribution of refractive error to have more myopic younger generations. [27,57]

Making a comparative analysis of the findings of this study, specifically the prevalence of myopia (high myopia included) and hyperopia according to age groups, with the values founded by Williams *et al.*, 2015, in an epidemiological study to estimate the prevalence of refractive error in adults across Europe [6] (figure 9), similarities in the trends are realized. The temporal distance between the studies (2015 to 2021) is also an effect to consider, assuming that an increase in the prevalence of myopia for younger generations is expected over the years. [27]

For the group age of 6 to 29 years old, the prevalence of hyperopia assumes the same value in both studies, 6%, and the prevalence of myopia is 72% in this work and 48% for Williams *et al.*, 2015. From the 30 to 44 years old both the hyperopia and myopia prevalence are very similar, 9% in this work and 6% in Williams *et al.*, 2015, for hyperopia and 40% in this work and 41% in Williams *et al.*, 2015, for myopia. A prevalence of 33% of myopia and 20% of hyperopia was found for the age group of 45 to 59 years old by Williams *et al.*, 2015, very similar to the 28% of myopia but not to the 43% of hyperopia found in this work, that can be justified by the differences in the mean age and sample (n) within the age group. And lastly, for the group age of 60 to 81 years old, the prevalence of hyperopia is 59% in this work and 49% for Williams *et al.*, 2015 and the prevalence of myopia is 15% in this work and 17% for Williams *et al.*, 2015.

Despite the differences in the study design, methodology and samples, values of refractive error prevalence according to age groups were very similar.

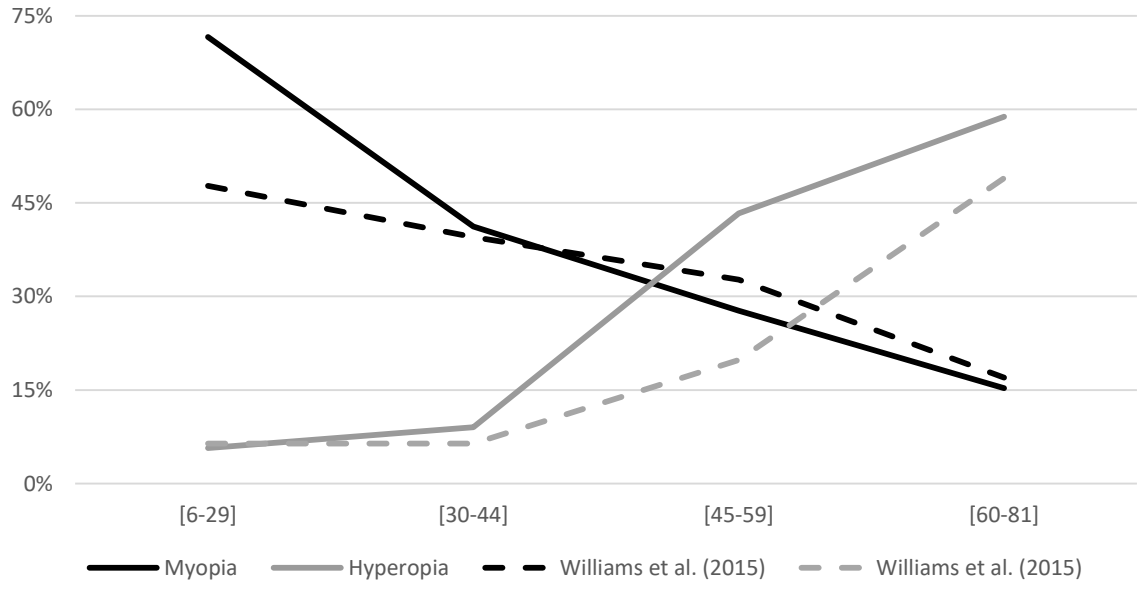

Figure 9: Comparison between the values of prevalence found in this study with Williams et. al (2015) for myopia and hyperopia according to the age groups. * [6,29] range in Williams study is restricted to [25-29].

3.3.5. Conclusion

In conclusion, this study showed that myopia represents the most prevalent refractive error within the sample of optometric practices analysed. More important, myopia is more prevalent in the younger age groups than the older ones, demonstrating a shift towards an increase of myopia in the next years. That trend has important implications for public health, in the planning of services, not only to manage the increase in the prevalence of myopia, but also, future expected myopia-related complications likely to cause visual impairment.

Findings from this study shows what to expect at service level and allows decision-makers to plan at service delivery level, informing on the distribution of refractive error, frequency and ranges to expect for different age groups. Additionally, this study allows to identify alternative sources of epidemiological data, demonstrating to be a low-cost design when compared to population-based surveys, and an important instrument for public health purposes.

3.4. Study III. Refractive Error Prevalence in Portugal based on Data from Ophthalmic Lens Manufacturers

3.4.1. Introduction

Refractive error are considered a public health challenge affecting all age groups and with important implications on the individual development and quality of life and on society economics and productivity[3,18,87,88]. Due to the importance of epidemiological data on refractive error, this is a research area of continuing interest.

To investigate the prevalence of refractive error, their trend and progression, and to adopt a strategy for prevention and treatment of these conditions, should be a public health priority, in particular if noted that future generations may become even more myopic.[1]

To do so, updated, valid and accessible refractive error epidemiological data must be available and are essential for planning more effective eye care services, to offer evidence-based interventions, and to allocate resources effectively. Ophthalmic lens manufacturer big data can, in the absence of population-based surveys, represent a potential source of refractive error epidemiological data, providing a fast and cost-effective substitute measure of refractive error distribution.[89]

3.4.2. Methods

Totally anonymized data from ophthalmic lenses, presented as a percentage and not as absolute values, were provided by a leading ophthalmic lens manufacturer operating in Portugal. According to an official report, the manufacturer in question represents approximately 55% of the national market of ophthalmic lenses.[90] This dataset comprises ophthalmic lenses that were adapted to individuals in the Portuguese territory after a prescription made by an eye care practitioner. These data don't allow to identify the methods of assessment of the refractive error or any other information about the ophthalmic lens user (sex, age, ethnicity or other).

Data were divided in two groups: single vision prescriptions and progressive/multifocal prescriptions. It included total percentage of ophthalmic lenses for each year categorized into 14 spherical equivalent ranges. Data were validated for missing or incomplete data fields.

The quantitative definitions from the International Myopia Institute have been adopted, myopia was defined as spherical equivalent refractive error ≤ -0.50 Diopters when ocular accommodation is relaxed

and high myopia as spherical equivalent refractive error ≤ -6.00 Diopters when ocular accommodation is relaxed. [76] Emmetropia was defined for those with a spherical equivalent of less than 0.50 Diopters in absolute value, regardless of whether the blur is myopic or hyperopic, and hyperopia when the spherical equivalent is ≥ +0.50 Diopters.[77]

Given the lack of absolute values, indirect estimates and a qualitative analysis of the current situation and trends on refractive error epidemiology was carried out.

3.4.3. Results

Data Characterization

Dataset from manufacturer comprises percentage values of ophthalmic lenses dispensed in Portugal between the years of 2010 to 2020 divided in single vison prescriptions and progressive/multifocal prescriptions. Total percentage values were categorized into 14 spherical equivalent ranges for both groups single vison prescriptions (table 10) and progressive/multifocal prescriptions (table 11).

SE	≤ -20.00	[-19.99; -15]	[-14.99; -10]	[-9.99; -8.00]	[-7.99; -6.00]	[-5.99; -3,00]	[-2.99; -1.50]	[-1.49; -0,50]	[-0.49; -0.01]	0,00	[0.01; 0.49]	[0.50; 1.49]	[1.50; 2.99]	[3.00; 5.99]	[6.00; 9.99]	≥10.00
2010	0,025%	0,114%	0,470%	0,611%	1,545%	7,928%	12,882%	17,322%	8,951%	3,401%	5,898%	12,869%	16,087%	10,884%	0,919%	0,096%
2011	0,030%	0,094%	0,462%	0,603%	1,471%	7,910%	13,515%	17,711%	8,988%	3,347%	5,532%	12,159%	16,241%	10,965%	0,889%	0,084%
2012	0,029%	0,095%	0,423%	0,557%	1,338%	7,396%	13,257%	18,459%	9,525%	3,473%	5,659%	12,129%	15,939%	10,781%	0,853%	0,086%
2013	0,030%	0,108%	0,468%	0,629%	1,486%	8,021%	13,383%	17,517%	8,581%	2,024%	5,656%	12,469%	16,629%	11,976%	0,991%	0,034%
2014	0,042%	0,129%	0,547%	0,700%	1,674%	8,345%	12,557%	15,649%	7,294%	3,535%	5,102%	12,027%	16,741%	14,324%	1,229%	0,104%
2015	0,046%	0,152%	0,622%	0,752%	1,832%	8,863%	12,891%	16,029%	7,431%	3,470%	5,007%	11,392%	15,842%	14,289%	1,280%	0,102%
2016	0,045%	0,154%	0,652%	0,828%	1,956%	9,396%	13,517%	16,494%	7,828%	3,670%	4,974%	10,641%	14,937%	13,562%	1,248%	0,100%
2017	0,053%	0,159%	0,664%	0,882%	2,076%	10,016%	14,042%	17,058%	8,195%	3,953%	5,145%	10,744%	14,346%	11,495%	1,060%	0,112%
2018	0,047%	0,128%	0,622%	0,804%	2,065%	10,888%	16,176%	18,853%	8,239%	5,835%	5,118%	10,419%	12,284%	7,741%	0,691%	0,091%
2019	0,030%	0,095%	0,518%	0,771%	2,013%	10,762%	16,332%	18,875%	8,664%	4,244%	5,356%	10,777%	12,534%	8,297%	0,660%	0,073%
2020	0,032%	0,149%	0,765%	1,011%	2,488%	11,744%	15,866%	18,597%	8,844%	4,017%	5,124%	10,261%	12,216%	8,031%	0,777%	0,079%

Table 10: Total percentage values according 14 spherical equivalent ranges for the non-progressive/single vison prescriptions group.

SE	≤ -20.00	[-19.99; -15]	[-14.99; -10]	[-9.99; -8.00]	[-7.99; -6.00]	[-5.99; -3,00]	[-2.99; -1.50]	[-1.49; -0,50]	[-0.49; -0.01]	0,00	[0.01;0.49]	[0.50; 1.49]	[1.50; 2.99]	[3.00; 5.99]	[6.00; 9.99]	≥10.00
2010	0,000%	0,022%	0,197%	0,332%	0,815%	4,077%	5,887%	10,473%	7,163%	3,464%	8,530%	26,643%	25,811%	6,293%	0,265%	0,028%
2011	0,000%	0,014%	0,170%	0,299%	0,752%	3,938%	5,759%	10,484%	7,158%	3,455%	8,635%	26,783%	25,957%	6,349%	0,229%	0,019%
2012	0,001%	0,015%	0,160%	0,264%	0,732%	3,911%	5,788%	10,765%	7,321%	3,511%	8,421%	26,670%	25,891%	6,291%	0,245%	0,016%
2013	0,001%	0,017%	0,139%	0,273%	0,703%	3,801%	5,714%	10,811%	7,296%	3,483%	8,354%	26,511%	26,415%	6,221%	0,240%	0,022%
2014	0,003%	0,017%	0,163%	0,282%	0,693%	3,834%	5,776%	10,936%	7,353%	3,497%	8,310%	26,194%	26,246%	6,429%	0,253%	0,014%
2015	0,001%	0,015%	0,188%	0,288%	0,710%	3,842%	5,771%	10,976%	7,456%	3,856%	8,495%	25,877%	25,812%	6,431%	0,268%	0,015%
2016	0,001%	0,022%	0,170%	0,289%	0,787%	3,973%	5,754%	11,109%	7,730%	4,230%	8,607%	25,550%	25,174%	6,289%	0,299%	0,014%
2017	0,003%	0,024%	0,205%	0,315%	0,778%	3,936%	5,828%	11,204%	7,866%	4,314%	8,602%	25,257%	24,916%	6,421%	0,315%	0,016%
2018	0,001%	0,016%	0,130%	0,272%	0,848%	4,553%	6,541%	11,733%	7,959%	4,324%	8,539%	25,040%	23,950%	5,790%	0,289%	0,016%
2019	0,001%	0,025%	0,212%	0,293%	0,833%	4,397%	6,198%	11,602%	7,885%	4,164%	8,523%	24,769%	24,464%	6,311%	0,303%	0,018%
2020	0,002%	0,019%	0,190%	0,295%	0,804%	4,074%	5,768%	11,092%	7,953%	4,270%	8,545%	24,923%	25,174%	6,569%	0,310%	0,013%

Table 11: Total percentage values according 14 spherical equivalent ranges for the progressive/multifocal prescriptions group.

The distribution of refractive error in Portugal from 2010 to 2020, for single vision prescriptions, (figure 10) resembles a bimodal curve with the majority of the observations in the category [-1.49, -0.50], in every year from 2010 to 2020.

For the progressive prescription's lenses, the distribution of refractive error in Portugal for the same years, presents the majority of the observations in an interval of two categories, [0.50, 1.49] and [1.50, 2.99], (figure 11).

The same graphic representation of the refractive error distribution, but focusing only on the chosen cut-off years of 2010, 2015 and 2020 was made to better observe variations in the distribution over the decade (figure 12).

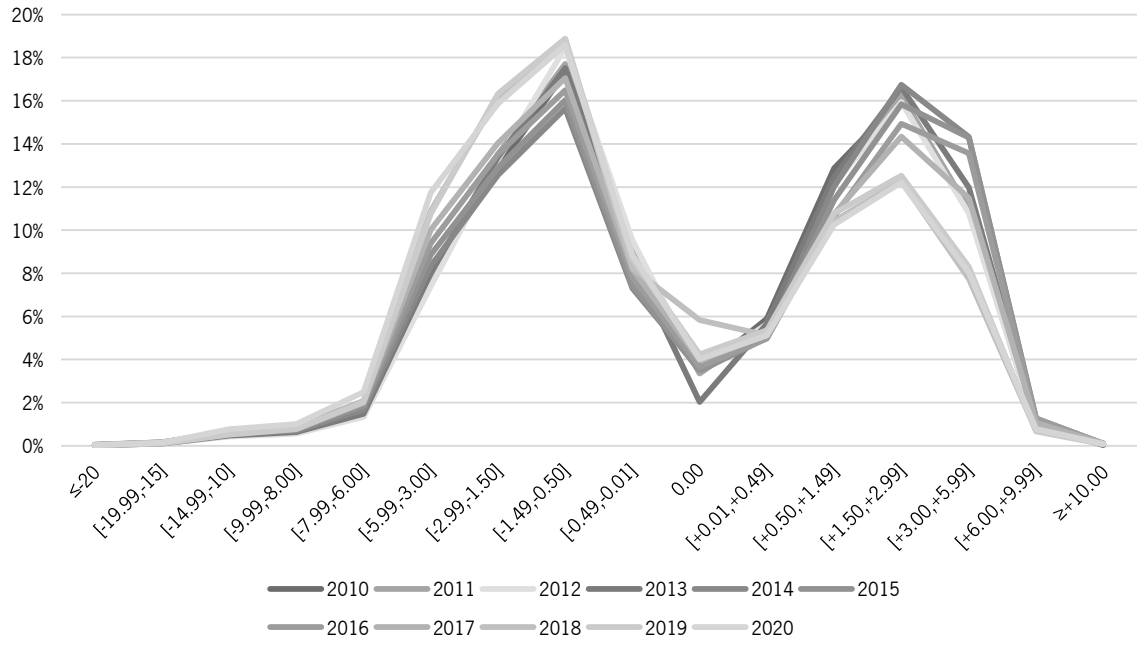

Figure 10: Distribution of Refractive Error in Portugal from 2010 to 2020 - Single Vision.

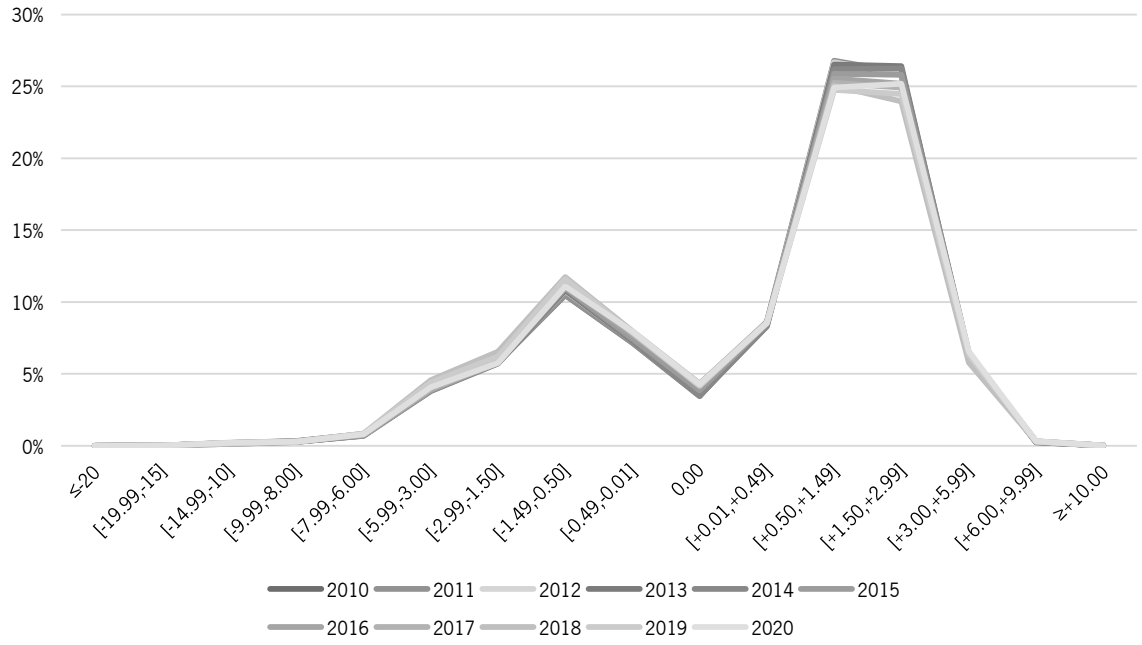

Figure 11: Distribution of Refractive Error in Portugal from 2010 to 2020 - Progressive.

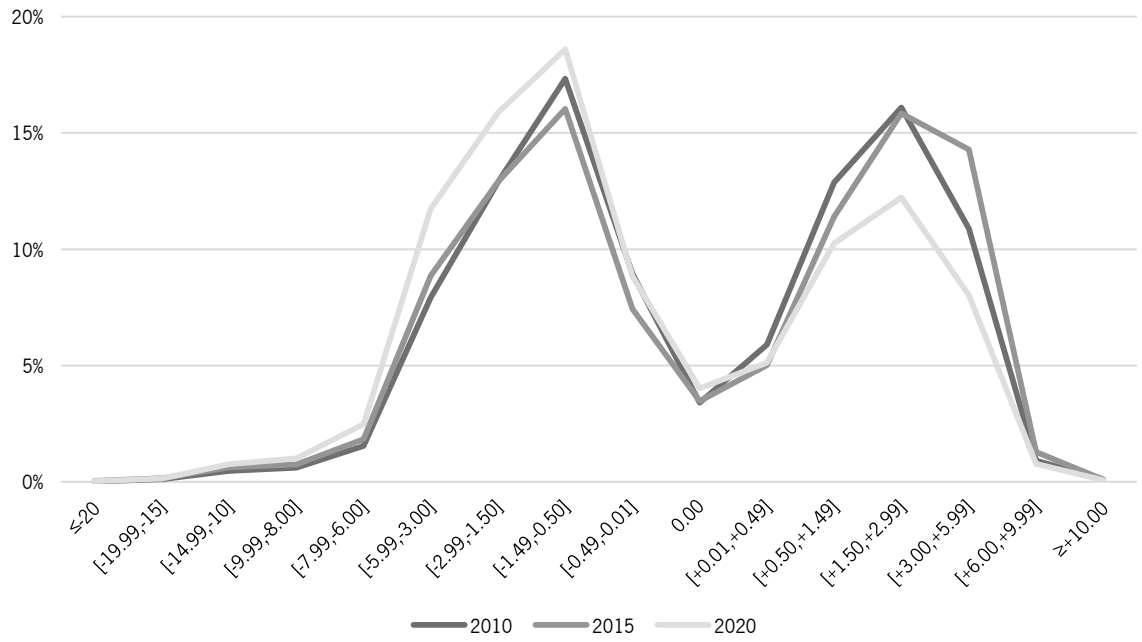

Figure 12: Distribution of Refractive Error in Portugal in 2010, 2015 and 2020 - Single Vision.

Epidemiology of Refractive Error in 2020

For an epidemiological analysis of the refractive error distribution in 2020, and given the origin and characteristics of the data, only the data set related to the single vison prescriptions were used (figure 13).

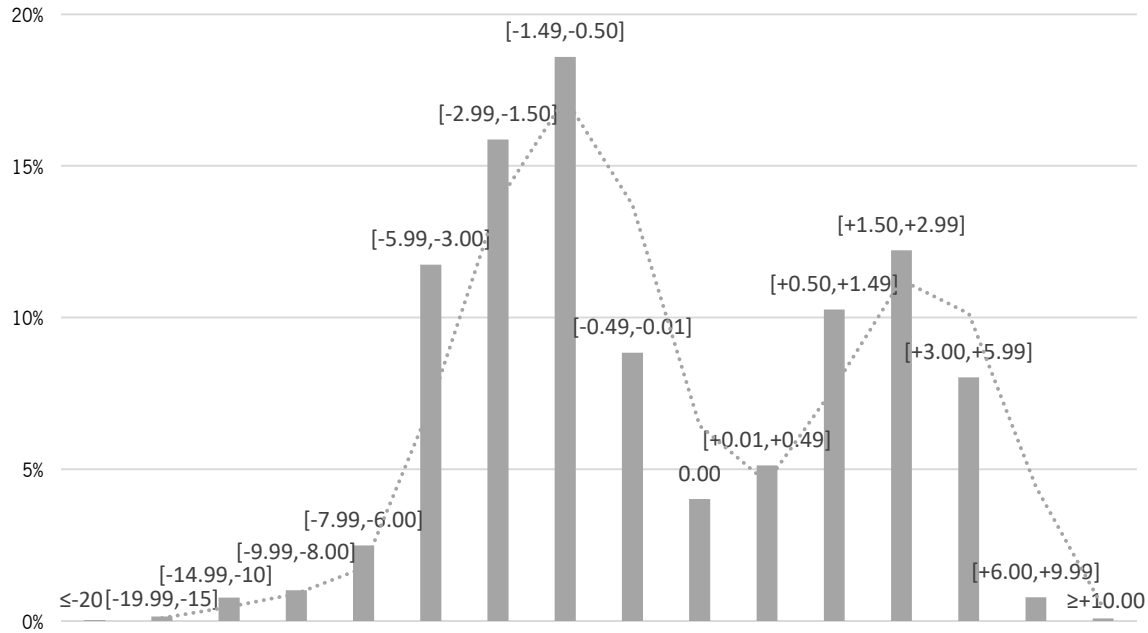

Figure 13: Distribution of refractive error in Portugal in 2020 according to single vision ophthalmic lenses prescriptions.

Trends from 2010 to 2020

For epidemiological trend analyses from 2010 to 2020, and given the origin and characteristics of the data, only the data set related to the non-progressive/single vison prescriptions were used.

Grouped percentages for each refractive error, high myopia, myopia, emmetropia and hyperopia, as previously defined, were obtained by the sum of each spherical equivalent ranges for the years of 2010 and 2020 (table 12).

	High Myopia	Myopia	Emmetropia	Hyperopia
2010	2,76%	38,13%	18,25%	40,85%
2020	4,45%	46,21%	17,98%	31,36%

Table 12: Percentage of refractive error type in the first and last years of measurement.

A graphical representation was made to analyse the trends in the distribution of refractive error in Portugal from each year, since 2010 to 2020 (figure 14).

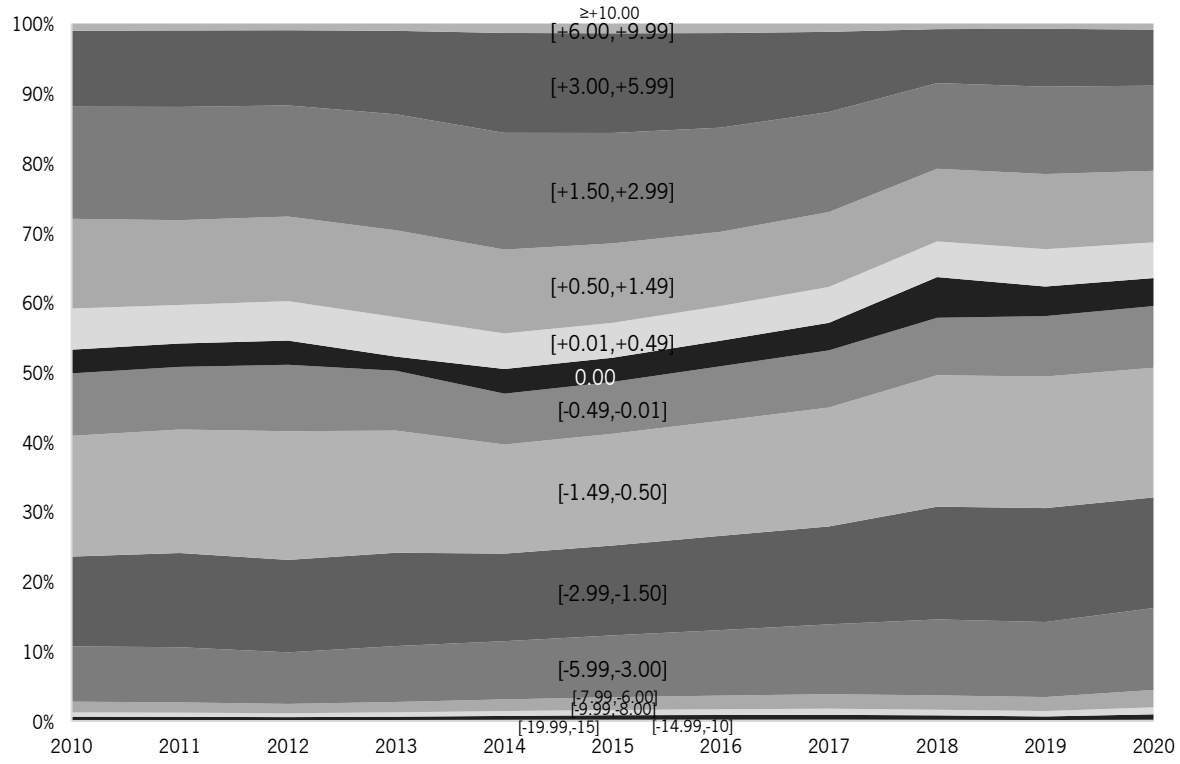

Figure 14: Trends in the distribution of refractive error in Portugal from 2010 to 2020 according to single vision ophthalmic lenses prescriptions.

A graphical representation was made to compare each one of the spherical equivalent ranges in the extremes of the decade, the year of 2010, and the year of 2020 to analyse differences and assess trends between the two extremes years of the decade (figure 15).

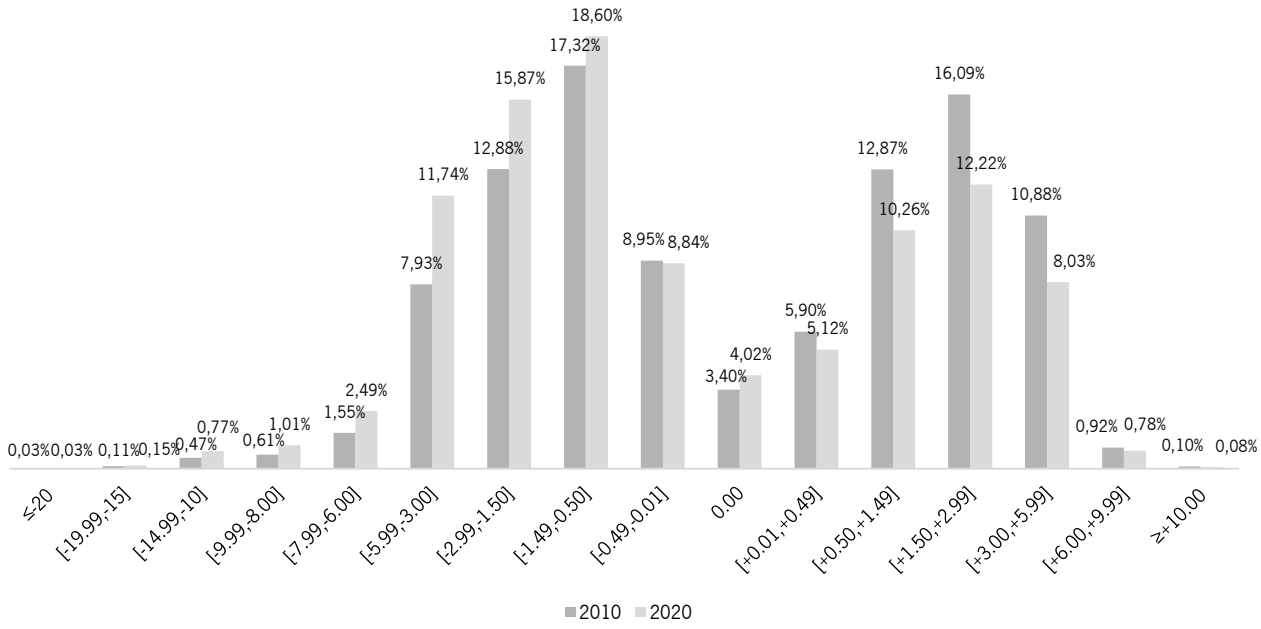

Figure 15: Trends in the distribution of refractive error in Portugal for the years of 2010 and 2020 for each spherical equivalent range according to single vision ophthalmic lenses prescriptions.

3.4.4. Discussion

This study approaches an alternative method to estimate refractive error distribution through ophthalmic lens manufacturer big data. In the absence of population-based surveys, this approach can represent a potential source of refractive error epidemiological data. [89]

However, some important limitations need to be recognized. First, ophthalmic lenses are not the only form available for refractive error correction, alternative corrections such as contact lenses or refractive surgery are becoming increasing popular, but ophthalmic lenses are undoubtedly the most common intervention for refractive error correction and the majority of contact lens wearers also use of ophthalmic lens. [5] Secondly, when using data from devices only the people with access to them are considered, which leaves everyone with an URE out of the equation. Thirdly, the nature of the data acquired does not allow conclusions about distribution by sex, age groups or other subpopulation divisions. And lastly, the method of assessment of the refraction is impossible with this methodology.

Despite that, the very large sample size that ophthalmic lens manufacturer big data represent, makes it unlikely that all these limitations have significant impact on the results.

It is also important to note that, the classic distribution curve found in refractive error studies, with the majority of observations centred near the emmetropia[91] would never be possible to observe in studies using big data from manufacturers. Data from manufacturers refer to an optical correction device prescribed assuming a certain refractive error which disregards practically all emmetropic individuals. This fact can be observed by the atypical distribution of refractive error in figures 10, 11 e 12.

According to the report Vision Needs Monitor EMEA 2019, with a sample in Portugal of 0,05% of the total population in the country aged 15 years or over, close to 80% of the respondents at some point in their life needed ophthalmic lenses and almost 70% currently use them. Knowing that the manufacturer that has provided this data holds a dominant market position in Portugal, approximately 55% we can assume that this dataset is very close to the reality of ophthalmic lens users in Portugal.

The distribution of refractive error in Portugal from 2010 to 2020 for non-progressive/single vision prescriptions (figure 10) resembles a bimodal curve with the majority of the observations in the category [-1.49, -0.50] and more oriented to the myopic prescriptions. For the non-progressive/single vision lenses, in every year from 2010 to 2020 is possible to observe a higher percentage of myopia prescriptions in relation to hyperopia, and from 2018 onwards the percentage of myopia and high myopia represent 50% of the total prescriptions made for single vision, in line with what is happening in most developed countries and in long-term forecasts.[1,27,92]

Comparing the distribution of refractive error in Portugal only between the two extreme years of the decade, 2010 and 2020 (figure 12), we can observe a shift to a more myopic population over the decade, with an increase of all the myopic spherical equivalent intervals and a decrease of all hyperopic ones. The spherical equivalent range of [-5.99, -3.00] was the one that increased the most, with an increment of 2.984% from 2010 to 2020 and the spherical equivalent range of [1.50, 2.99] was the one that decreased the most, with a reduction of 3.871% from 2010 to 2020.

In the case of the progressive/multifocal prescriptions distribution (figure 11), the majority of the observations are observed in an interval of two categories, [0.50, 1.49] and [1.50, 2.99], due to the near vision addition of the lenses. A higher percentage of hyperopic prescriptions is observed but is important to note a gradual increase in myopic prescriptions over the decade and a decrease in the same order of the hyperopic. Considering that these data refer to presbyopic individuals, usually in an

age group above 45 years old, we can infer, supported by recent scientific evidence,[81,93,94] that the new presbyopic persons that have emerged in recent years have a more myopic trend than the previous ones.

For analysing the epidemiology of refractive error in 2020 and the trends from 2010 to 2020 only the data set related to the non-progressive/single vison prescriptions were used in order to not consider presbyopia, an age-related condition that mostly affects individuals over 45 years of age.

In 2020 (figure 13), 50.66% of the prescriptions made were for myopia and high myopia correction. In the same year, 17.98% of prescriptions were for emmetropia and 31.36% for hyperopia (table 12). These data are representative of the total burden of myopia among the other refractive error and are in line with what was observed in other countries and extrapolated for Portugal.[1,6,82,95]

More concerning is the comparative analysis of the burden of each refractive error in ophthalmic lens prescriptions for the extreme years of the decade, 2010 and 2020. From 2010 to 2020 the burden of myopia increased from 38.13% to 46.21%; the burden of high myopia increased from 2.76% to 4.45%; and the burden of hyperopia decreased from 40.85% to 31.36% (table 12). Holden *et al.*, 2016, [27] estimate an increase in global myopia prevalence from 28.3% in 2010 to 33.9% in 2020, this work, with the limitations inherent to the data characteristics, allows to observe an increase in myopia from 38.13% in 2010 to 46.21% in 2020, that, in terms of the percentage increment value, is very close to the predictions.

It is possible to observe over the course of the decade (figures 14 and 15) a trend of gradual and significant increase in myopia and high myopia, which allows to anticipate the impact on public health. Trends of refractive error in Portugal in the last decade are very similar to the observed in most developed countries, [27] and myopia, high myopia included, represents in 2020 more than a half the total prescriptions made for single vision by this manufacturer. Refractive error, specifically myopia, when uncorrected or undercorrected can affect the child development, school performance, and limit future opportunities of employability and quality of life. Additionally, myopia-related ocular complications includes cataract, retinal detachment, choroidal/scleral thinning, myopic choroidal neovascularization, glaucoma, among others with high probability to cause visual impairment.[86] The burden of myopia, knowing its progression and impact, must therefore be addressed from a public health perspective, with universal and effective coverage.[5,19]

Assuming that in the future, even nations which have little myopia today will be severely affected,[27] early detection to avoid impact on the individual's development[96], as well as the adoption of preventive mechanisms for risk factors[38,39] and slowing progression[97], are measures that these data show an urgent need to adopt by the Portuguese authorities.

3.4.5. Conclusion

Despite the known individual variations in the prevalence of myopia and high myopia, according to geography, age or ethnic groups, that are impossible to estimate with the data from this study, it is possible to observe a trend of increasing prevalence of myopia and high myopia from 40.89% in 2010 to 50.66% in 2020. That increase trend has important implications for public health, in the planning of services, indicating the need to adopt promotion, prevention, treatment and rehabilitation eye care services to manage not only the myopia, but also, myopia-related complications likely to cause visual impairment. Additionally, this study allows to identify alternative sources of epidemiological data, such as manufacturers big data, and places this data as an important instrument for public health purposes.

3.5. General Conclusions of the Chapter

Findings from this chapter allows to conclude that:

i. Refractive error prevalence in Portugal is between 20 to 45% (95% CI), but more consistent sources, data and studies are needed to obtain narrower estimates.

ii. This value shows that at least 2 to 4 million Portuguese have a refractive error and that places the refractive error as one of the conditions with more burden on the health system and the national population.

iii. Myopia is the most prevalent refractive error (41.3%) and the most prevalent among the younger populations, representing a considerable burden for group ages between the 6 and 29 years old (69.3%).

iv. A trend of increasing prevalence of myopia and high myopia was observed from 40.89% in 2010 to 50.66% in 2020. It is anticipated that this shift towards the increase of myopia prevalence in the next years will continue, with important implications for public health and in the planning of services, not only to manage the refractive error itself, but also, future expected myopia-related complications likely to cause visual impairment.

v. Alternative sources of epidemiological data, which proves to be important instruments for public health purposes, were identified.

Chapter 4. Action Plan Proposal for Integration of Refractive Services into the Portuguese NHS

The concept of integration of services into NHS obey the principles of universal health coverage to ensure access and coverage to the promotive, preventive, treatment, rehabilitation, and palliative health services needed, when and where they are needed and with financial protection.

Access to health services can be dived into three dimensions: [98–100]

i. Physical accessibility: availability of quality and effective health services within reach of those who need them and with appointment/referral systems, waiting times and other aspects of service organization and delivery that allow people to obtain the services when they need them.
ii. Financial affordability: ability to pay for health services and medical devices without financial hardship. Indirect and opportunity costs, such as the costs of transportation or time away from work, are considered.
iii. Acceptability: awareness and willingness to seek care. Acceptance and behavioral insights of the individual or community can have a determinant action. A health condition, such as a refractive error, or the use of an optical device can be determined by a person or community's specific health-related actions. Understand how and why people and communities behave in their respective contexts allows the develop behavioral informed strategies. [101]

To ensure universal health coverage, health services must be physically accessible, financially affordable, and acceptable to users. Understanding these concepts, the burden of refractive error within the population, and the ongoing need of refractive error patients for services and devices, the need to frame refractive services within universal health coverage and within the NHS is demonstrated.

4.1. Portuguese Situation Analysis

4.1.1. Current Capacity of the Portuguese NHS to address Refractive Error

A situation assessment of the Portuguese NHS capacity to address refractive error was conducted. The WHO Eye Care Situation Assessment Tool served as a basis for that analysis, however more country insights were adopted based on the particular NHS and health system organization. The WHO Eye Care Situation Assessment Tool intends to support countries in the planning, monitoring of trends and the evaluation of eye care services. It provides information about the current situation, priority areas to be

addressed in strategic planning, possible activities to address gaps and baseline information for tracking capacity and performance of the eye care sector. [102]

Initially, it is important to emphasize that in the Portuguese NHS there are no specific services to address refractive error. [103] The management and treatment of refractive error occurs at the level of eye care general services, without a specific referral or list. And in this way, on the same list and in the same order of priorities, there are people with ongoing refractive error needs and people with pathologies that can cause blindness in the immediate term, such as glaucoma. Most of the refractive care delivered in Portugal occur at the private sector, divided between the private medicine sector and the optical sector, without any referral system, integration within the NHS or the national health plan. [49] Adding to that reality, eye care services available within the Portuguese NHS are almost entirely secondary care level and fully hospital-centered, providing refraction services without differentiation of care. [103] There are only two formal initiatives currently taking place at the primary healthcare level, but which in essence translate into screenings, not complying with the definition of primary care, they are the eye screening for infants/children, population-based, and the systematic screening of diabetic retinopathy. There is an assumed lack of structure and strategy at the level of primary eye care, limited to the recent screening initiatives, and for that reason there is an openness and the realization of the need to implement a methodology capable of proposing new measures and improving the system as a whole, based on a strong primary eye care structure. [53]

Eye care services, or just ophthalmology services in Portugal, the NHS hospitals are divided into three large groups, according to the technical differentiation, technology required and workforce capacity. Group I ophthalmology services covers an area of direct influence of a minimum 75 000 inhabitants with permanent daily service of basic eye care interventions such as refraction, general assessment of age-related macular degeneration and diabetic retinopathy, according to a referral protocol centralized by group III ophthalmology services, has less resources, both technological and workforce. Group II ophthalmology services are medical-surgical permanent daily services that cover all eye care interventions with the exception of oncology, transplantation, pediatric glaucoma and cataract, retinopathy of prematurity and rare diseases, they have more resources than group I. Group III ophthalmology services are responsible for all eye care interventions and for the country's eye care urgency/emergency services, having more resources, both technological and workforce, than the previous groups. [103] According to the last National Strategy for Eye Care, from 2018, Portugal had 22 group I ophthalmology services, 12 group II ophthalmology services and 5 group III ophthalmology

services. [53] It is also important to emphasize that at the NHS level the only integrated workforce is composed by ophthalmologists and orthoptists, together with nurses and other general paramedical assistants. [53]

Purely analyzing the geographic distribution of the eye care services availability within the NHS in Portugal, fundamental limitations of coverage and a centralization of services, mainly in urban areas, are identified (figure 16). Data from 2021 shows that only 3 Portuguese municipalities have more than 1 NHS eye care service and 41 have 1 NHS eye care service, which leaves 234 municipalities, especially those in the most rural and remote areas, underserved. [53,103]

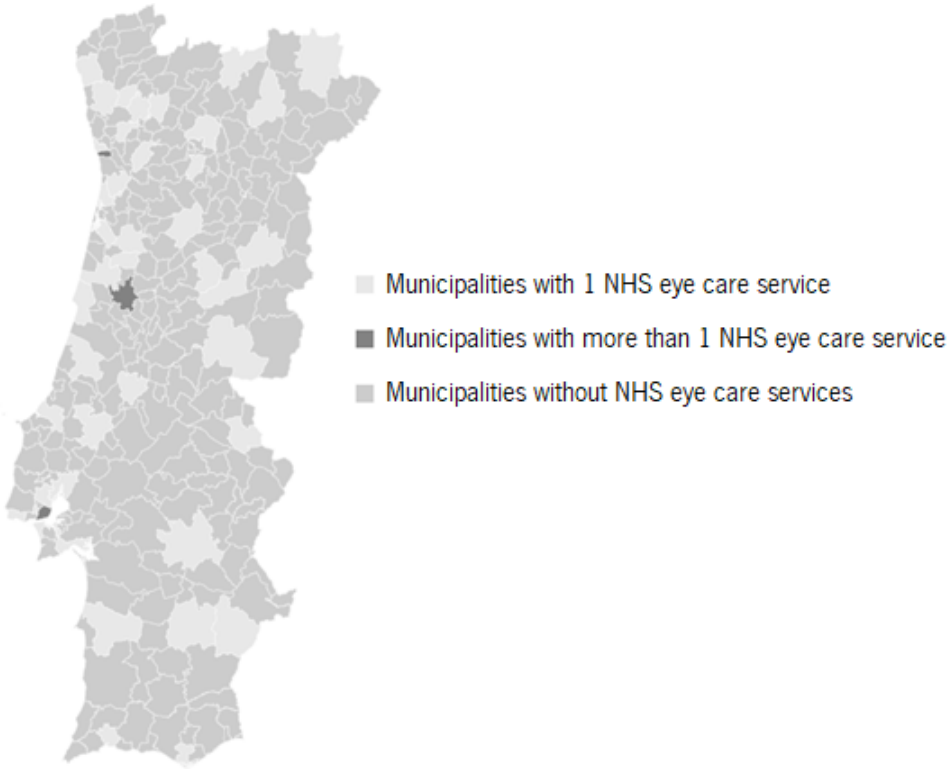

Figure 16: Total number and distribution of NHS eye care services in the country (elaborated based on official data on waiting times from the Ministry of Health) [104]

When analyzed both the geographical areas, the total population served by direct influence of the NHS eye care services and the available workforce within the NHS eye care services (table 13), a shortage in the workforce per inhabitant is immediately observed. According to the 2016 National Network of Hospital Specialty and Referral – Ophthalmology itself, the minimum ratio recommended is 1 ophthalmologist per 15 000 population. [49,103] Additionally, WHO recommends a ratio of 1 optometrist (refractionist, that is personnel with training in refraction) per 50 000 population in 2020. [73,105] There are no recommended ratios for allied ophthalmic personnel (where orthoptists are included). It is also

important to understand that these recommendations for workforce are always assessed considering the coexistence these groups of professions, ophthalmologists, optometrists, and other allied ophthalmic personnel (where orthoptists are included). However, and although in the absence of one, other(s) could address the condition and that do not represent an emerging problem, the lack or inexistence of all of them translates into important barriers in accessing services.

Health Regional Administration	Population Served	Population Density (inhabitants per km²)	Number of NHS Ophthal-mologists	Number of NHS Orthoptists	Eye Care Services - Group I	Eye Care Services - Group II	Eye Care Services - Group III	NHS Ophthal-mologists per 15 000 inhabitants
Health Regional Administration of the North	3 682 370	173,3	166	70	8	3	2	0,68
Health Regional Administration of the Centre	1 846 954	74,6	78	33	3	4	1	0,63
Health Regional Administration of Lisbon and Vale do Tejo	3 557 442	299,9	200	83	8	3	2	0,84
Health Regional Administration of the Alentejo	509 849	18,6	17	14	3	1	0 (referral to Lisbon)	0,50
Health Regional Administration of the Algarve	451 006	90,3	10	7	0	1	0 (referral to Lisbon)	2,2

Table 13: Distribution of NHS eye care services and NHS ophthalmologists (elaborated based on official data on waiting times from the Ministry of Health, the 2016 National Network of Hospital Specialty and Referral – Ophthalmology, and the 2018 National Strategy for Eye Care) [53,103,104]

In every NHS Regional Administration of the country, it is observed a shortage of eye care workforce, for ophthalmologists (ration per 15 000 inhabitants < 1) and optometrists (inexistent).

One of the consequences of not providing refractive services as a differentiate care, with a proper and functional referral system, is the extensive waiting lists for a general eye care assessment that

compromises timely delivery of care, not only for refractive error but to the numerous other conditions that are placed at the same list of priority. Between the years of 2016 and 2017, referrals from the general primary care to the hospital specialty of ophthalmology, increase from 313 941 to 327 431, showing a demand for eye care. From those, 181 824 to 223 228 were left unattended, respectively, and the median waiting time has increase from 171 days to 180 days, with a maximum of 783 waiting days for an eye care assessment. [49] More recent data, from 2021 shows that 52% of the hospitals providing eye care services don't meet the recommended response times. [104]

Centering the NHS eye care in a secondary care, ophthalmologist-only model is known to be ineffective and expensive use of eye care resources. A simple comparison with the United Kingdom ophthalmologist-optometrist model clearly evidences the Portuguese NHS shortcomings. [106] Evidence shows that the delay in the use of primary eye care provided by optometrists is associated with a greater probability of resorting to General Practitioners, as an indicator of missed opportunities to detect potentially serious eye conditions. [107]

It is also important to highlight, that as a result of not implementing the recommendations of the WHO, good practices and scientific evidence, the resilience of the system is affected and a difficult pre-pandemic situation suddenly escalates to a defiant pandemic and post-pandemic situation. [52]

Summarizing, the problems and barriers identified in the access to refractive error services within the NHS were:

1. Inexistence of primary eye care that can address refractive error at a primary care level, in a context of proximity for the population.
2. Physical barriers for accessing the services with centralization of eye care services in urban hospitals and an undifferentiated referral system with no priorities defined by conditions or severity.
3. Workforce shortage that limits the coverage of eye care services and contributes to the extensive waiting times for services to respond.

4.1.2. Current Refractive Error Services Available in Portugal

As previously described, in Portugal universal access to refractive services, and eye care services in general, is far from being assured due to the important limitations, extensive waiting times and lack of coverage of the NHS. Furthermore, the access to the prescribed optical devices is often compromised once their acquisition is fully made through out-of-pocket payments for the majority of the population.

The NHS limitations forces patients to turn to the private medical sector and commercial optical shops, with the increase in the costs and financial risks associated. In addition to the exposure to financial risk, the inexistence of specific professional regulation that defines the refractive prescriber, training requirements, guidelines and medical devices dispensing regulation, expose patients to considerable risks for public health. [49]

Governmental approved formal training in public universities, that train professionals with knowledge and competencies to provide refractive services in autonomy, are available in Portugal since 1988. [108] However, the lack of concertation between the Ministries of Science, Technology and Higher Education and Health, does not consider these professionals as a regulated health workforce.

Despite the formal academic training, optometry remains the only eye care discipline unregulated and with no legislative framework that ensures guidelines for practice.[109] The current inexistence of specific regulation of access to the optometrist profession and clinical practice of optometry, allows access and practice by people whose training and qualifications are not the minimum required for the provision of health care with quality and safety. Without the proper regulation, the quality and safety of services provided within the commercial optical shops are not ensured, and possible conflict of interest between the exercise of the profession and the commercial interests are not prevented.

Recognizing that the majority of refractive devices prescriptions in Portugal occur in the private sector and commercial optical shops, the inexistence of specific policies and regulations expose the population to considerable risks of inadequate health services provision and unnecessary financial burden, namely by inducing the demand for services and medical devices.

In light of the universal health coverage concept, the premises of access to health services according to user's needs and of protection from adverse financial consequences of out-of-pocket payments for health care are not safeguarded when analyzed the refractive error care in Portugal.

4.2. Problem Analysis and Setting Priorities (SWOT Analysis)

The impossibility of maintaining the current practices regarding refractive care, and eye care, provision in the NHS imposes a paradigmatic shift that breaks with previous overcome practices and with the permanent insufficiency in the provision of this care. It is consensually assumed and accepted that better cost-benefit practices must be implemented, but more important than that, is the requirement of

changes that protects public health, patients and professionals, that provides care where is needed, when is needed, not exposing the user to financial risks.

Scientific evidence, technical recommendations and standards for good practices, [5,110–112] as well as socio-economic impact analysis, [49] shows the same actions and solution, a solid primary care-based eye care, that covers differentiated and multidisciplinary care, duly integrated not only within the NHS but within other sectors, such as education or labour, and provided, by definition, by the optometrist. [30]

The reform of health systems and health policies has been proved to be challenging. [113] Regarding eye care, and refractive services specifically, the solution that is immediate reachable for Portugal, and unfortunately so desired by other settings, is to take advantage of the workforce and infrastructures resources already trained and existing in the country and implement policy and regulatory changes to address this condition.

Refractive error services is becoming worldwide priority, due to its prevalence, and once it is a simple, easily and cost-effective intervention, with substantial and measurable impact on the quality of life. [5,19,114] In addition to that, it's an opportunistic intervention that makes possible the periodic screening for other vision and eye conditions that can be duly address if timely detected and referred, representing health gains for the patient and efficiency gains for the health service. [107] Given the predicted increase on the need for refractive services, considering the anticipated increase in the prevalence and population and demographic variations, it's also fundamental to prepare eye care services to rapidly adapt and respond to the expected demand. [1]

An analysis of the strengths, weaknesses, opportunities, and threats - SWOT analysis (figure 17) - was made to identify the internal and external factors that can potentially facilitate or hinder the possible integration of refractive error within the NHS.

Strengths [5,19,115]	Weaknesses
▪ Refractive services duly integrated facilitates the care process of the individual as a whole and respond to the health priorities and needs. ▪ Cost-effectiveness of the intervention. ▪ Timely management of the condition and facilitate access to an optical device. ▪ Proximity to the users, enhancing access and adherence.	▪ Initial financial investment on the equipment. ▪ Need for "in-service" training and integration of the workforce. ▪ Restructure and update of the current referral system.
Opportunities [5,19]	**Threats**
▪ Possibility to detect/screen for other vision and eye conditions and timely referral to other levels of care/specialties. ▪ Expansion of the eye care services to underserved populations. ▪ Services better prepared to adapt and respond to the anticipated refractive error population needs in the coming decades.	▪ Change in the regulatory scopes of practice and competency frameworks of the eye care workforce in the country. ▪ Impact of more prescribed refractive devices in the national eye care budget.

Figure 17: SWOT Analysis of integration of refractive error within the NHS.

4.3. Resources and Action Plan for Refractive Services

Refractive services need to be properly integrated across relevant programmes, health and non-health, such as child health or healthy ageing and non-health sector such as social services, education or labor. Refractive error should be addressed on a public health perspective, enhancing equity in the access, quality of the services and effective coverage. Interventions to address refractive error were considered essential, that is, of high priority and should be included within national health services, frequently and

periodically required by the population due to the high prevalence and that benefits a large number of individuals. Noticing this, and the fact that the provision of comprehensive refractive error interventions must be delivered at the primary level of eye care, where they are most accessible to the community[30,114], evidence emerges of the need to reorient refractive services towards primary eye care within primary health care. In order to provide proposals that ensure universal access to refractive error care, with health and financial protection, this work presents a concrete recommendation, based on scientific evidence, technical recommendations and experiences from other countries. This recommendation is the integration of refractive services within the NHS.

4.3.1. Refractive Error Service Delivery – Access and Quality

Previous experiences shows that addressing refractive services in short-term programmes or in settings without regulation, compromise sustainability and service delivery. [30,114] Addressing a refractive error is not only essential for the high prevalence among the population, but also because it represents and an ongoing need that requires more than an isolated intervention. People need periodic assessments and updating of refractive devices, and that demands for sustainable services that are easy to access and of effective coverage, both in capacity and in quality.

The declaration of Alma-Ata[116], adopted by the WHO, defines primary health care as: "*the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process."* The promotion, prevention and treatment of refractive error fall within this level of care by definition and the integration into the national health service grants the sustainability and service delivery needed to ensure a long-term provision.

Sustainable service delivery in refractive error is a critical element to population health status, along with other factors, including social determinants of health. To ensure well-functioning, the country's network of refractive services duly integrated into primary care centers, should have the following characteristics: [23,24]

i. Comprehensiveness: provide not only refractive services, but also detection and screening of other vision and eye conditions and timely referral to other levels of care/specialties, through a functional referral system. Eye care promotion and prevention activities, appropriate to the needs of the target population, are also essential to raise awareness and acceptance.

ii. Accessibility: refractive services must be permanently and directly accessible to population. Delivered at a primary level, with no physical barriers of geography or exposure to financial or health risks.

iii. Coverage: refractive services must be designed to cover the entire population, with or without the condition, since this is a condition with a high prevalence, will most probably affect every person during their life cycle and represents an ongoing need for care.

iv. Continuity: refractive services must provide continuity of care not only over the lifecycle and the ongoing need, but also across the different services and conditions experimented by the individual. This highlights the need for integration within a vast system of health.

v. Quality: refractive services must be effective, safe, timely delivered and people-centered. Effectiveness and safeness are intimately linked with the regulation and policies that normalize the provision of care.

vi. People-centeredness: refractive services must be centered in the individual, and not the condition or financing. Adopt a user perspective allows services to be responsive and acceptable.

vii. Coordination: usually the primary care provider is the entry point into the health system and facilitates the route through the needed services. Coordination with the different levels of care and a totally functional referral system is essential for a well-functioning refractive service.

viii. Accountability and efficiency: refractive services must be managed to achieve core elements and address population needs with a minimum wastage of resources.

4.3.2. Refractive Services Workforce and Organizational Implementation

The distribution of the eye care workforce should be based on population needs and, in this case, on population refractive needs. To address Portuguese population refractive needs, and as response to the eye care shortage within the NHS, a new professional eye care cadre must be integrated within NHS to work along medical-surgical professionals – ophthalmologists – and the other allied ophthalmic personnel.

Worldwide, optometry has been the major provider of refractive services, Portugal included even though from a private sector setting. [117] The population of trained optometry professionals in Portugal was estimated at 1563 individuals in 2017, according to data from Portuguese Universities and the

International Agency for the Prevention of Blindness, with a minimum of academic qualifications Bachelor in Sciences. [118]

The use of the optometry workforce by the NHS is justify by the population refractive needs but has to be driven by a regulatory and policy framework that allows integration, protecting both the professional, the user of the services and the services themselves. Placing the optometrist at the primary level of care not only enhances the management of refractive error immediately without clogging the system but also allows the possibility to detect/screen for other vision and eye conditions and timely referral to other levels of care or medical specialties. [30] The use of the workforce of optometrists also represents budget savings for the government and a use of the resources invested, since this is a qualified workforce trained in governmental academic institutions, without the latter taking advantage of its competencies.

The implementation of refractive services in the NHS should occur within the already existing organizational framework, to facilitate the path of the user within the system. Since 2008 Primary Health Centers are organized into Groups, Health Centers Groups (ACeS) with the main objective of improving their performance. The ACeS are constituted by a set of functional units with administrative and technical autonomy. One of this unit, and the more complex and distinct from the others since it outlines a wide range of specialized skills, is the Shared Assistance Resources Units (URAP). URAP articulate with all the other functional units and contributes to a timely and full response, of ongoing need of care and proximity, which results into a reduction of costs, number of hospital referrals and number of complementary means of diagnosis and therapeutic, contributing to the NHS sustainability, better quality services and better health outcomes for the population. URAP are formed by different cadres of professionals to address the population ongoing needs of care, such as, psychologists, physiotherapists, oral health technicians, nutritionists, social workers, among others. [119]

The wide range of specialized skills reflected in the URAP, and the goals off a timely and full response to ongoing need of care, with population proximity and reducing the number of hospital referrals, places this unit as the ideal setting to integrate refractive services.

ACeS geographically cover the entire country (figure 18), in a logic of proximity, both in urban and rural areas, duly integrated in the community and represent the first level of care for NHS users. Data from 2012, shows 357 health centers and more than 1000 extensions, duly aggregate into ACeS, every municipality in the country has at least 1 health center. [120] Its distribution within the entire country allows to deliver care in a more efficient way, reducing the transportation expenses and work absence

losses for the user, which result in more adherence, acceptance and compliance with the intervention or care.

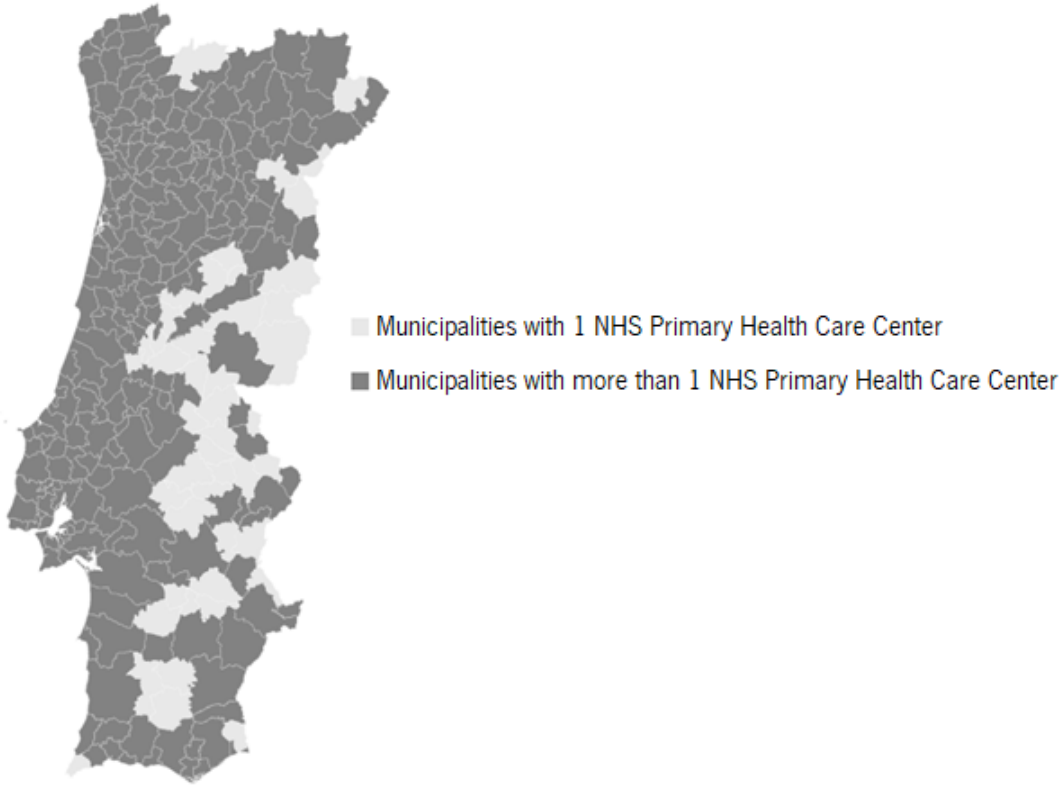

Figure 18: Total number and distribution of NHS Primary Health Care Center in the country (elaborated based on official data from the Ministry of Health). [119]

Integrate refractive services within the URAP units of the ACeS will allow to take advantage of the specific health policies of these units to cover another area of care, take advantage of the existing infrastructure and referral and access systems. Additionally, it will allow a total geographical coverage within the country, offering refractive care in the community and in a logic of proximity of the population and their ongoing needs for this type of care.

Following the minimum ratio recommended for eye care workforce per population previously approached in this work, safeguarding the geographical distances and population density, the integration of 200 optometrists within the NHS, at URAP level, would allow to address the minimum needs of refractive error at a primary level of care (table 14), complying with minimum the recommended of 1 optometrist per 50 000 inhabitants according to the refractive error needs estimated for 2020. [73,105] It should be noted that the number of ophthalmologists is maintained as the

current one, since to meet the recommended minimum ratio of ophthalmologists per population, even with the integration of optometrists, it would also be necessary to increase this eye care workforce.

Health Regional Administration	Population Served	Population Density (inhabitants per km²)	Current Number of NHS Ophthal-mologists	Current Number of NHS Orthoptists	Number of NHS Optometrists to integrate	NHS Eye Care Services – Group I, II, III	NHS ACeS	NHS URAP
Health Regional Administration of the North	3 682 370	173,3	166	70	73	13	24	23
Health Regional Administration of the Centre	1 846 954	74,6	78	33	37	8	9	9
Health Regional Administration of Lisbon and Vale do Tejo	3 557 442	299,9	200	83	71	13	15	15
Health Regional Administration of the Alentejo	509 849	18,6	17	14	10	4	4	4
Health Regional Administration of the Algarve	451 006	90,3	10	7	9	1	3	3

Table 14: Proposal for distribution of NHS eye care services, hospitals and primary care centers, and recommended NHS eye care workforce for primary eye care (elaborated based on official data on waiting times from the Ministry of Health, the 2016 National Network of Hospital Specialty and Referral – Ophthalmology, and the 2018 National Strategy for Eye Care and the BI – CPS from the Shared Services of the Ministry of Health) [53,103,104,121]

From a health-economics point of view, refractive error intervention represents one of the most highly cost-effective vision-restoring interventions, and, along with cataract intervention, would solve more than 90% of unmet eye care needs. Integration of refractive error services within the NHS will also remove one of the most important barriers in accessing those services, the financial barrier. Costs associated

with refractive services, optical devices, such as spectacles or contact lenses, or travel expenses for care prevent the population from accessing this essential health services.[18]

Also, the compensation of refractive error, vision improvement and optimization of vision functional ability, not only for people able to meet its full visual potential, but also for those with blindness or VI, leads to improvement in employment prospects, enhanced work productivity, increased household income and enhanced economic productivity of both individuals and nation.[122]

Considering the country's economic and financial situation in the past years and the sustainability of the NHS, it is imperative to guide the health systems towards the primary health care. Evidence indicates that primary centered health systems are more cost-effective, responsive to health care coverage and effectiveness, for resource monetization and equity growth.[111]

4.3.3. Action Plan Summary

Actions to be made to implement refractive services within NHS according to relevant WHO health systems building blocks must comprehend (figure 19): [123]

Governance	Workforce	Financing	Service Delivery
• To address regulatory and policy barriers. • To address policies barriers to allow the integration of refractive error/eye care services within the existing primary care infrastructures.	• To regulate and integrate a primary eye care wrokforce available and trained - Optometrists. • To implement the service within the existing primary care facilities - URAP of the ACes.	• To deliver a cost-effectiveness of the intervention. • To ensure protection against financial risk for the population.	• To address accessibility and coverage through primary care. • To address affordability and safeness through NHS integration.

Figure 19: Summary of actions to implement refractive services within the NHS.

4.4. Monitoring and Evaluation Frameworks

A factor that can facilitate the implementation of refractive services in the Portuguese NHS is the recent Portugal's favorable vote, in the WHO 74th World Health Assembly, to the endorsement of the new global eye care targets, being one of them the Effective Refractive Error Coverage (eREC). [19,20]

To address the unmet needs in eye care, all countries, Portugal included, have committed to increase in 40% the effective coverage of refractive error by 2030. That is, increase in 40% the proportion of people who have received refractive error services and have a resultant good quality outcome relative to the number of people in need of refractive error services, by the year of 2030.[19]

To achieve the target, specific objectives and indicators, adapted to the country, must be defined and adopted. A framework for monitoring and evaluation must be created, to collect, standardize, and manage information relevant to indicators of refractive condition status; determinants of refractive error (prevention, control and risk factors); and refractive services (governance, workforce, technologies and assistive products and service delivery). [5] Health information is critical to identify needs, to respond with an evidence-based approach, to better allocate resources and to design more effective services that respond to population needs. The absence of this tools often results in significant divergences between what is known and what is needed to know to improve health population.

Indicators to be considered in a monitor and evaluation framework for refractive services must collect and manage, in a periodic basis:

i. Data on the prevalence and incidence of refractive error and the cause-specific burden of this condition in vision impairment or blindness.
ii. Data on the financial coverage of refractive services and devices.
iii. Data on effective coverage of refractive error (coverage in access and quality).
iv. Data on service rate of refractive services and capacity to respond to the needs.
v. And data on workforce and infrastructure density and distribution within the country.

Chapter 5. Main Conclusions

The main conclusion from this work is the need for more epidemiological studies to obtain narrower estimates on the prevalence and incidence of refractive error in Portugal, as a periodic and standardized process, such as population-based surveys. In the absence of population-based surveys, to address this gap on the literature, this work adopted a three studies approach to have a more realistic estimate of the prevalence and to withdraw more strong conclusions: a systematic review and meta-analyse of epidemiological data of refractive error prevalence in Portugal, a cross sectional retrospective review of case records and an alternative source of data, big data from a leading ophthalmic lens manufacturer.

The meta-analysis conclusions give a closer, and conservative, value for the prevalence of refractive error among the Portuguese population between 20 - 45%, which, according to the current estimate population for the country, translates into at least 2 to 4 million Portuguese people with refractive error and the characteristics ongoing needs of this condition. This prevalence, even conservative, places the refractive error as one of the conditions with more burden on the health system and the national population, demonstrating the need to be addressed in a public health context.

Data from optometric case records from all the country territory showed that myopia represents the most prevalent refractive error, but more important, myopia is more prevalent in the younger age groups from 6 to 29 years old than the older ones, demonstrating a shift towards an increase of myopia in the next years. That trend has important implications in the planning of services, not only to manage the increase in the prevalence of myopia, but also, future expected myopia-related complications likely to cause visual impairment. This approach generates evidence at service delivery level, informing on the distribution of refractive error, frequency and ranges to expect for different age groups.

According to national ophthalmic lens manufacturer big data, that are a potential source of refractive errors epidemiological data, it is possible to observe a trend of increasing prevalence of myopia and high myopia from 40.89% in 2010 to 50.66% in 2020, and it demonstrates the probable distribution of cases that would be observed in a refractive service and the burden that myopia constitutes in the immediate future.

The prevalence of refractive error in Portugal between 20 - 45%, according to the meta-analysis, gives the picture of the **population met and unmet needs**; the epidemiological analysis of the optometric case records across various Portuguese districts shows what to expect at service level and allows **to**

plan at service delivery level at an NHS refractive service; and the analysis of the national ophthalmic lens manufacturer big data informs about the trends over time and allows **to plan and prepare service for future needs**. The results of these three studies sustain the need to create refractive services, to adopt the integrated people-centred eye care strategy to address this condition, contributing to the reduction/elimination of avoidable VI due to refractive error that contribute to greater exposure to morbidities, higher mortality rates, lower quality of life and greater risk of exposure to poverty. Additionally, it indicates the need to adopt promotion, prevention, treatment, and rehabilitation eye care services to manage not only the increase in the prevalence of myopia and high myopia, but also, the myopia-related complications likely to cause visual impairment.

The burden of refractive error within the population, and the ongoing need of refractive error patients for services and devices, as well as the responsibility to ensure universal health coverage, health services that are physically accessible, financially affordable, and acceptable to users, demonstrate the need to integrate refractive services within universal health coverage and within the NHS. An action plan demonstrate that is possible and effective to integrate refractive services into the already existing infrastructures of primary care existent in the country, and with already trained workforce with competencies for that effect.

Chapter 6. Future Work

It is currently accepted and highly recommended that eye care interventions should be people-centred, integrated into the health systems and based on strong primary health care. Also, the integration of relevant eye care data within health information systems, that is used to collect, standardize, and manage information relevant to indicators of eye care status, including eye conditions and VI, is essential for planning and strengthening the health system.

Although this work tries to answer some of the important questions regarding the prevalence of refractive error among the Portuguese population and how to address this condition in order to provide accessible, affordable, and equitable services, it only scratches the surface of the problem and much more work remains to be done.

To do so, future work should focus on standardized systematic data collection on eye care and structures capable of collecting a representative volume of data of eye care determinants, conditions, and services in an institutional and targeted manner.

6.1. Systematic Data Collection on Eye Care

Existent data on the prevalence of refractive error among the Portuguese population is scarce and very heterogeneous. Studies to estimate the prevalence of refractive error and VI in Portugal are sorely needed. Future work will pass through the ability to collect this data from population-based surveys in a standardized manner, aligned with the internationally adopted methodology, in order to allow comparisons and withdraw valid conclusions, which is critical to ensure the robustness of the process.

The adoption of the global eye care targets for 2030, which include a 40% increase in effective refractive error coverage (eREC), by the Member States in the 74th World Health Assembly (2021), will require that countries, Portugal included, report data not only related to refractive error epidemiology, but also related to services coverage, access, and effectiveness of the interventions.

Another path of future work is the systematic data collection to estimate direct and indirect costs of refractive error interventions and VI in Portugal. To strength the health systems, defining and implementing better strategies to address eye care, it is fundamental to generate scientific evidence on the costs imposed by refractive error and VI on the country.

6.2. Eye Care Observatory

The ability to collect representative volumes of data, to improve the availability and use of information and evidence on eye care/conditions status and trends for policy use, and to monitor and evaluate the implementation of national eye care strategies or plans, can only be achieved by the creation of institutional structures capable of generate, facilitate the use, and encourage exchanges based on knowledge.

Future work will also pass through the creation of a national health observatory for eye care – an Eye Care Observatory. As defined by the WHO the main functions of a health observatory should be the marshalling function, gathering relevant data sets from various sources, specific data extraction, and overall organizational flow of data; the analysis and synthesis function, transformation of data into usable knowledge; the sharing function, facilitating the exchange of information for decision support; and the networking function, ability to form partnerships and coordinate between multiple stakeholders. [124]

The development of a national eye care information and surveillance system, that uses standardized tools and instruments, aligned with all the other health areas, and with the ability to collate, report and use reliable national, and international, eye care statistics on a regular basis is essential for the adoption and adaption of strategies and interventions that better responds to the populations needs.

6.2. Financing Insights

A financial analysis on the impact of refractive error to the society and the individual is also extremely important to, not only plan effective health services, but also develop measures of financial protection of risk.

In an introduction to the theme, a very rough analysis was made using values from a comprehensive study in Singapore, considered, as Portugal, as a high-income country. Data from this study estimates that the mean annual direct coast of myopia from those aged 5 to 39 years old was 144€, 618€ for those aged 40 to 49, €803 for those aged 50 to 59 and €495 for those older than 60 years old. [125] Despite more recent evidence showing that the costs increase substantially as individual age, to adopt a conservative analysis, the previous values were adopted.

Costs are generally reported as annual costs and these costs refer only to those associated with the refractive error, that is, refractive services and optical devices.

Table 15 shows that the annual financial burden of myopia (refractive services and optical devices only), for the prevalence according to age groups in Portugal estimated in this work, his higher than a thousand million euros.

Group Age	Estimated No. of Portugal Residents 2020 [126]	Prevalence of Myopia*	Estimated No. of Myopes	Annual Cost Per Myope (converted to €) ǂ	Total Annual Cost (€)
[6-29]	2 599 327,00	69%	1 801 334	144	€259 392 039,98
[30-44]	2 002 196,00	56%	1 129 239	144	€162 610 350,34
[45-59]	2 282 811,00	24%	550 157	803	€441 776 433,15
[60-81]	2 648 569,00	15%	405 231	495	€200 589 373,22
					€1 064 368 196,69

Table 15: Estimated costs of myopia correction (refractive services and optical devices) in Portugal. * Prevalence of myopia estimated in this work. ǂ Based on data from Zheng *et al,* 2013. [125]

This are only the costs associated with the expenditure of individuals to have the service and acquire the optical devices. It is therefore important that the overall health care costs associated to myopia are evaluated in a more precise context, such as loss of productivity, loss of workdays for seeking for care or due to the condition, transportation to care centres, among other costs associated. Additionally, costs associated to the expected pathologic changes due to myopia and high myopia, as well as the impact of the resultant vision impairment are important metrics on the financial impact of myopia.

A recent systematic review of the costs of myopia correction, that considered the data of the Singapore study here mentioned, conclude that, due to the high prevalence of myopia, the annual direct cost of this refractive error correction alone far exceeded the costs of other ocular diseases including acute primary angle closure glaucoma, dry eye syndrome or wet age-related macular degeneration. In addition, without further policy measures or interventions, the short-term projected increase in the prevalence of myopia will lead to a substantial increase in the economic burden of this condition. [127]

Financial protection is one of the pillars of universal coverage and is directly affected by health financing policy. Future work on a health economic analysis of the impact of refractive error, and more specifically myopia, is therefore, essential to inform decision-makers and to plan for financial protection.

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