



# BMJ Open Trends in certifications of overall vision impairment and that due to diabetic retinopathy/maculopathy in England and Wales, 2009/2010 to 2019/2020: a retrospective database analysis

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## ABSTRACT

**Objectives** This study aims to report the trends in the certification of both sight impairment (SI) and severe sight impairment (SSI) in England and Wales during the period of 2010 to 2020, prior to the COVID-19 pandemic. The focus is on diabetic retinopathy/maculopathy as the key causative factor.

**Design** Retrospective database analysis.

**Setting** England and Wales.

**Participants** Individuals certified as SI or SSI.

**Outcome measures** Trends in certification of vision impairment in England and Wales due to any cause, with specific attention to diabetic retinopathy.

**Methods** Certifications of vision impairment made by ophthalmologists in England and Wales were recorded and copies were sent to Moorfields Eye Hospital for epidemiological analysis. All certificates completed in England and Wales over an 11-year period, from April 2009 to March 2020, were queried and analysed on an annual basis. This analysis included all causes, and where both the main cause was diabetic eye disease or where diabetic eye disease was a contributory cause among multiple pathologies. Poisson regression was employed to analyse changes in trends over time for certifications of vision impairment.

**Results** In England, from 2010 to 2020, there was a small but significant reduction ( $p < 0.001$ ) in the overall rate of certifications for SI and SSI due to any cause, from 43.4 certifications per 100 000 people to 41.7 per 100 000 people. Conversely, in Wales, an initial decline was observed, with a decrease from 50.6 to 40.1 per 100 000 people from 2009/2010 to 2014/2015, respectively. This rate subsequently increased to 51.8 per 100 000 by 2019/2020; however, this was not statistically significant ( $p = 0.087$ ). Individuals in Wales had a 9% higher certification rate compared with those in England (1.09 (95% CI 1.07, 1.10)). For diabetic retinopathy, certifications in England significantly decreased from 72.8 to 41.3 per 100 000 people over the study period; in Wales, the certification rate initially declined from 82.3 to 47.1 per 100 000 by 2016/2017 before increasing to 55.5 per 100 000 in 2019/2020. Despite this fluctuation, there was a significant decrease in certifications due to diabetic retinopathy in Wales during the study period.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study is a comprehensive retrospective analysis comparing longitudinal trends in both sight impairment and severe sight impairment certifications in England and Wales over an 11-year period (2009/2010 to 2019/2020), prior to the COVID-19 pandemic.
- ⇒ It provides a valuable comparison between England and Wales during the study period and explores possible reasons for the observed differences in trends.
- ⇒ A key limitation of the study is its reliance on the validity of the current certification and registration processes for vision impairment in England and Wales, which exhibit considerable variation both between and within national boundaries.
- ⇒ Numerous obstacles hinder the certification process, including its voluntary nature and the need for specialist or ophthalmological input, which contributes to an underestimation of the true burden of diabetic retinopathy and other causes of vision impairment in the population.

**Conclusions** The findings underscore the importance of understanding regional variations in certification rates, particularly in the context of diabetic retinopathy. Despite fluctuations in Wales, the overall reduction in certifications due to diabetic retinopathy in both regions suggests a critical need for ongoing public health initiatives aimed at preventing vision impairment linked to diabetes. However, to provide a true reflection of the burden of vision impairment and its various causes, ensuring that all eligible people are certified is a prerequisite. Continuing attempts to limit the incidence of vision impairment due to diabetic retinopathy remain a priority.

## INTRODUCTION

It is predicted that by 2050, more than 1.31 billion (1.22–1.39) people will be diagnosed with diabetes.<sup>1</sup> Consequently, the prevalence of diabetic retinopathy is also expected to increase from 103.12 million in 2020 to



160.5 million in 2045, with approximately 6% having sight threatening diabetic retinopathy.<sup>2</sup> In people with diabetes, diabetic retinopathy/maculopathy continues to be one of the most common microvascular complications, with sight loss remaining one of the greatest concerns.<sup>3</sup>

Historically, data on the number of people with severe sight impairment in England and Wales have been collected since 1851. Between 1930 and 2003, causes of blindness were recorded using a designated certificate (BD8), which required the signature of an ophthalmologist, with partial sightedness (sight impairment) included from 1950 onwards.<sup>4,5</sup> In 2005, the BD8, in England was replaced by the Certificate of Vision Impairment (CVI), followed by its equivalent for Wales (CVI-W) in 2007. In this transition, the term 'blind' was replaced by 'Severe Sight Impairment' (SSI) and 'partially sighted' by 'Sight Impaired' (SI).

Improvements in diabetes care and treatments for diabetic retinopathy alongside systematic screening in the UK have relegated diabetic retinopathy as the primary cause of sight loss in England and Wales.<sup>6,7</sup> Systematic community-based screening for diabetic retinopathy was introduced in 2003 in England and Wales to facilitate the early detection of sight-threatening diabetic retinopathy. This initiative has provided the opportunity for the timely implementation of cost-effective interventions to prevent the personal and societal burden associated with serious vision impairment. A secondary aim was to detect the presence of diabetic retinopathy at an early stage of its development when modification of putative risk factors could be implemented to prevent disease progression or even rescind the early features of retinopathy. Currently, the three most common causes of sight impairment among those aged between 16 and 64 years are hereditary retinal disorders (20.2%), diabetic retinopathy/maculopathy (14.4%) and optic atrophy (14.1%), which together accounted for almost 50% of all sight impairment certifications.<sup>6</sup>

This study aims to report the trends in the certification of both SI and SSI in England and Wales covering the period from 2009/2010 to 2019/2020. The analysis will report on the trends during this 11-year period, with a specific focus on diabetic eye disease. Comparisons will also be made between England and Wales.

## METHODS

### Certification process

With written patient consent, the CVI form is shared with the Certifications Office at Moorfields Eye Hospital, where an electronic version of the data is transferred into a database used to record diagnostic and other information for anonymised epidemiological analysis. This data is verified by members of the certification office (authors WX and AZ). Once all certifications for a single period have been collected, the database is locked to prevent any further changes. Certifications are recorded annually from April to March to align with the financial years of

the NHS, a practice established when the database was first created.

### Data extraction

All electronic certifications for England and Wales between April 2009–March 2010 and April 2019–March 2020 were queried by WX. The first analysis captured all causes of vision loss, and the second analysis focused on cases where the main cause of certifiable vision loss was diabetic eye disease or where diabetic eye disease was a contributory cause in cases of multiple pathologies, as determined by the ophthalmologist at the time of registration. Data for age, gender and ethnicity were extracted for certifications recorded between 2009 and 2019 but were unavailable for 2019–2020 due to data limitations at the time of extraction. Data for health boards in Wales were extracted for the period 2014–2020. These data could not be extracted prior to 2014 because health board details were not recorded before this date.

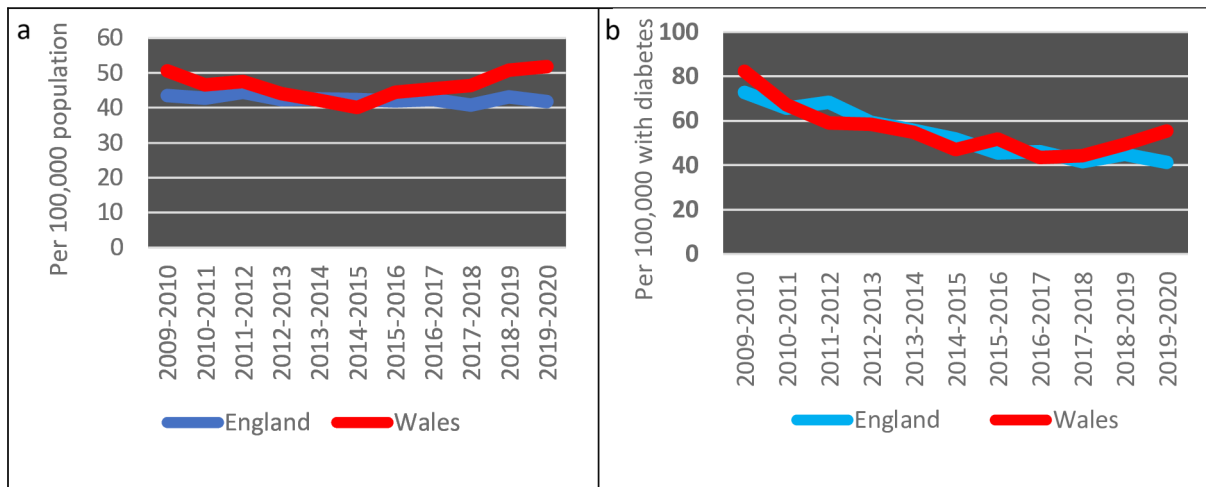
The guidance criteria for SSI certification include the following: (1) a best corrected visual acuity (V/A) in the better eye, according to the Snellen chart (LogMAR), worse than 3/60 (1.3) with a full visual field, or (2) V/A between 3/60 (1.3) and 6/60 (1.0) with severely constricted visual fields, or (3) better than 6/60 (1.0) with severely constricted visual fields, particularly the inferior field. SI classification occurs when: (1) V/A (while wearing any glasses or contact lenses) is 3/60 (1.3) to 6/60 (1.0) with a full field of vision, or (2) V/A of 6/60 (1.0) to 6/24 (0.6) with a moderate reduction of field of vision or with a central part of vision that is cloudy or blurry, or (3) V/A better than 6/18 (0.5) with a significant visual field defect.<sup>8</sup>

### Statistical analysis

The annual incidence of SI and SSI due to any cause in England and Wales was calculated using the total number of new certifications as the numerator and the mid-year population estimates from the Office of National Statistics for each yearly time period between 2009/2010 and 2019/2020 as the denominator. Additionally, the incidence of SI and SSI due to diabetic eye disease was determined using the total number of certifications where diabetic eye disease was the main or contributory cause (numerator) and the Quality and Outcomes Framework (QoF) estimates of individuals with known diabetes in England and Wales (denominator). Using both QoF and mid-year population estimates may not accurately reflect the population size at the time of certification and represents a limitation of the study. The results are presented as the combined total for SI and SSI. Poisson regression was used to analyse the trends in certifications in England and Wales over the study period.

### Patient and public involvement

Patients and/or the public were not involved in this study.



**Figure 1** Certifications for SI and SSI in England and Wales due to (a) any cause and (b) diabetic retinopathy.

## RESULTS

### Demographics of people with vision impairment (SI and SSI) due to diabetic retinopathy

The demographics of the populations in England and Wales, where the main or contributory cause of certification for vision impairment (SI and SSI) was diabetic retinopathy, are presented in online supplemental table 1). Over the study period, the median age decreased in both countries, from 67 to 62 years in England and from 68 to 62 years in Wales. In England, approximately 70% of certified individuals were Caucasian, with around 15% Black or Asian descent. In Wales, about 80–90% were Caucasian. In England, there was very little difference in the sex distribution over this study period with only a slight male preponderance most years. By contrast, Wales exhibited a greater male preponderance, which reached up to 61% during the observation period.

### Rates of certification due to any cause

During the observation period from 2009 to 2020, there was a small but significant reduction ( $p < 0.001$ ) in the rate of certifications for SI and SSI due to any cause in England, decreasing from 43.4 certifications per 100 000 of the general population to 41.7 (figure 1a). By contrast, Wales initially experienced a decrease in certifications from 50.6 (95% CI 44.1, 53.2) to 40.1 (95% CI 37.9, 42.4) per 100 000 people over the first 5 years (2009/2010 to 2014/2015). However, this was followed by a sharp increase to 51.8 (95% CI 48.6, 53.6) per 100 000 people in 2019/2020. Thus, while there was an overall increase in certifications in Wales over the 10-year period, this was not statistically significant ( $p = 0.087$ ).

People in Wales had a 9% higher certification rate compared with those in England (1.09; 95% CI 1.07, 1.10). This difference appears to be largely driven by activity in one of the seven University Health Boards in Wales (area 7), which consistently recorded higher levels of certifications throughout the study period. Area 7 exhibited a higher initial certification rate of 66.3 (95% CI 58.4,

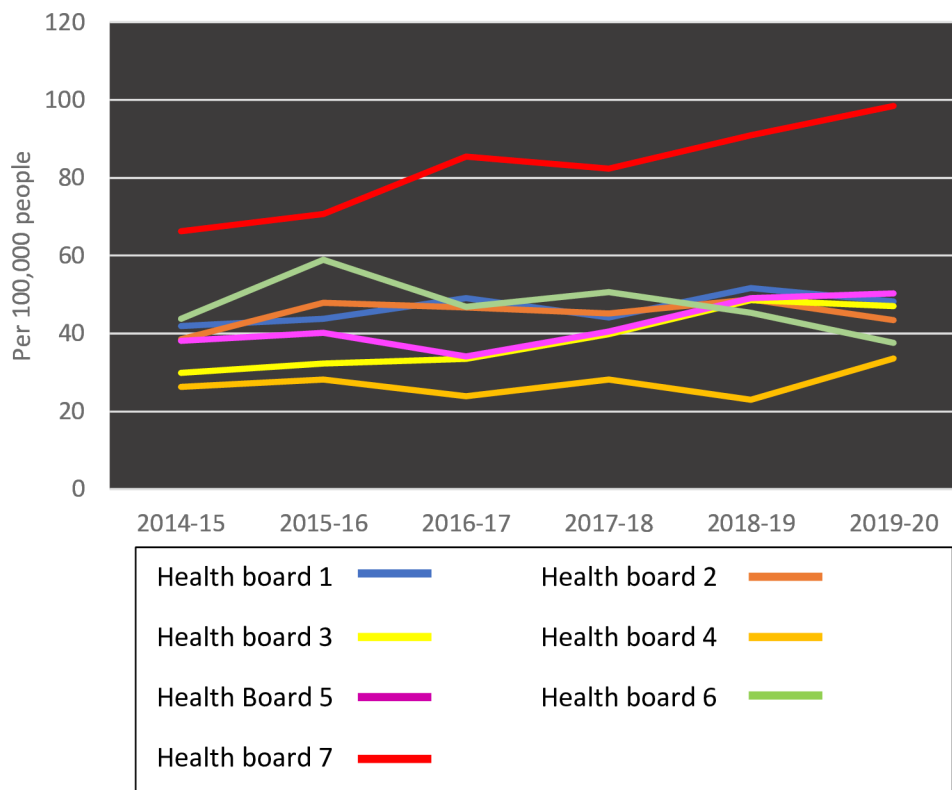
74.9) per 100 000 people, which further increased during the second half of the study period to 98.5 (95% CI 88.9, 108.8) per 100 000 people (figure 2). Two other health boards recorded slight increases, with area 3 rising from 29.9 (95% CI 25.2, 35.1) to 47.0 (95% CI 41.2, 53.4) and area 5 from 37.5 (95% CI 31.6, 44.1) to 50.3 (95% CI 43.5, 57.8) certifications per 100 000 people.

### Rates of certification due to diabetic retinopathy

In England, certifications for SI and SSI due to diabetic retinopathy saw a gradual but significant reduction ( $p < 0.001$ ) over the study period from 72.8 (95% CI 69.4, 76.4) certifications per 100 000 people in 2009/2010 to 41.3 (95% CI 39.2, 43.5) in 2019/2020 (figure 1b). In Wales, there was a more dramatic reduction (49%) in certifications due to diabetic retinopathy during the first 5 years dropping from 82.3 (95% CI 68.2, 98.6) to 47.1 (95% CI 35.7, 57.9) certifications per 100 000 people with diabetes. However, from 2016/2017 onwards, the certifications rate steadily increased, reaching 55.5 (95% CI 45.9, 66.6) per 100 000 people in 2019/2020, levels not seen since 2013/2014. Despite this increase, there was a significant overall reduction in certifications due to diabetic retinopathy in Wales over the study period ( $p < 0.001$ ). Notably, there was no significant difference between the rates of certifications for diabetic retinopathy in England and Wales.

## DISCUSSION

During the observation period of 2009/2010 to 2019/2020, England saw a significant reduction in new certifications of vision impairment (SI and SSI) for all causes of sight loss. By contrast, Wales experienced an impressive reduction in certifications during the first 5 years but subsequently witnessed an upward trend (not significant), reaching a peak for the year 2019/2020, equating to that seen in 2009/2010. The rise in CVIs in Wales appears to be largely driven by one local health



**Figure 2** Certifications for SI and SSI in England and Wales due to any cause by health boards in Wales.

board, which had disproportionately higher certification rates throughout the study period particularly in the final 4–5 years.

When considering those CVIs where diabetic retinopathy was the primary or contributory cause of vision impairment, England saw a continuous and significant decline throughout the study period. Wales also experienced an overall significant reduction; although after the initial 5-year drop, there was a modest increase in certifications from 2016/17 onwards, which did not reach the levels seen at the beginning of the study.

The increase seen in CVIs in Wales may be due to the fact that a greater proportion of eligible individuals were offered and accepted to be certified, potentially due to increased awareness by third-sector organisations and encouragement from the Royal College of Ophthalmologists. The sharp rise in certification rates observed in one University Health Board in Wales may reflect differences in access to diabetes care between the different Health Boards, although there is no evidence to support this assumption. Alternatively, the variation in certification practices across Wales may account for these trends, with some areas offering easier access to certification than others,<sup>9</sup> representing under-reporting. Geographical variation in certification practices has also been noted in previous studies.<sup>10–12</sup>

The inability to fully explain the reasons behind the increase in certifications or to determine with certainty whether this increase reflects a true rise in the incidence of vision impairment highlights the limitations of using current CVI data as an indicator of prevalence/incidence

of vision impairment and as a public health tool. Nevertheless, this is the first comprehensive retrospective study comparing the longitudinal trends in sight impairment certifications in England and Wales over an 11-year period (2009/2010 to 2019/2020), prior to the COVID-19 pandemic. The study also provides valuable insights into the different trends observed between the two countries.

A key limitation of this study is its dependence on the certification and registration process, which is known to be flawed. Variability in certification practices between and within national boundaries can lead to significant under-reporting of the true burden of vision impairment. For instance, more than half of those eligible for certification may not be certified.<sup>12–15</sup> The certification criteria focuses primarily on visual acuity, whereas vision loss due to diabetic retinopathy may be more attributed to visual field defect and even a decrease in contrast sensitivity than visual acuity itself. Additionally, the voluntary nature of the certification process and the need for ophthalmological input can serve as barriers to certification.<sup>14</sup> Furthermore, those with treatable conditions or those undergoing treatment are less likely to be certified than those with untreatable conditions.<sup>13 15 16</sup> These factors are likely to further complicate the estimation of the prevalence of vision impairment.

The National Institute for Health and Care Excellence (NICE)<sup>17</sup> advises that adults with serious eye disorders should be certified as vision impaired as soon as they become eligible. While certification is not compulsory, it facilitates access to certain state benefits and social services, depending on the level of certification (SI/SSI).

Despite these limitations, certification data have been used to assess the burden of ‘preventable sight loss’ in England through the Public Health Outcomes Framework, though this is not the case in Wales.

To obtain a more accurate picture of the burden of vision impairment in people in England and Wales, concerted efforts are needed to ensure all eligible people are certified appropriately. Such efforts would provide a clearer reflection of the impact of healthcare strategies. In Wales, the introduction of a new optometry contract under ‘A Healthier Wales and the Future Approach for Optometry Services’<sup>18</sup> may reduce barriers to certification. This contract allows qualified optometrists to certify vision impairment caused by age-related macular degeneration,<sup>19–22</sup> with the potential to expand certification to other conditions and increase access to certification.

## CONCLUSION

This study was designed to examine trends in certifiable eye disease in England and Wales with special reference to diabetes. In general, the data reflect a fall in certification of both SSI and SI in both England and Wales which was more evident in England. However, in Wales after an impressive fall in certification during the first half of the study period, there was then a gradual rise. The data also highlight the wide variation in certification rates especially in Wales with one Health Authority recording extremely high rates. This emphasises the current limitations when adopting CVI rates to reflect the burden of sight loss, especially as we are moving to a new situation where accredited optometrists will be eligible to certify individuals with SSI and SI, which will inevitably further inflate the numbers. We can only return to utilising CVIs for this purpose when the certification process is optimised, when we can be reassured that most eligible individuals have and are being certified.

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