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# BMJ Open

## Retrospective analysis of newly recorded certifications of visual impairment due to diabetic retinopathy in Wales during 2007-2015

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## Abstract

**Objective** –The aim of this study was to analyse the changes in new certifications for both sight impairment (SI), and severe sight impairment (SSI, blindness) in Wales due to diabetic retinopathy/maculopathy (DR) between 2007 and 2015.

**Research Design and Methods** – This is a retrospective analysis of annual data of new certifications for visual impairment and blindness (CVI) for England and Wales derived from the national database provided by the Certifications Office, Moorfields Eye Hospital, over a period of 8 years from 2007.

**Results** – In Wales there were 339 less new certifications for both SI and severe SSI from any cause combined from 2007-2008 to 2014-2015. The number SI and SSI combined specifically due to DR was reduced by 22 in people with known diabetes. This was a reduction of new certifications, over the observation period of 82.4 to 46.9 per 100,000 (-43.1%) with a fall in SSI from 31.3 to 15.8 per 100,000 (-49.4%), respectively. During this observation period however, there was a parallel increase in 52,229 (39.8%) persons with diabetes in Wales.

**Conclusions** – Whilst acknowledging the limitations of the certification process and the increasing numbers of persons with diabetes the incidence of SI and SSI per 100,000 population of persons with diabetes in Wales has almost halved over an 8-year period up to 2015. This may reflect the earlier diagnosis of DR and sight-threatening DR since the introduction of screening and/or improved diabetes management with timely onward referral and newer treatments.

## Article Summary

### Strengths and Limitations of this study

- A key limitation of our analysis is a consequence of the non-compulsory and inconsistent process of reporting/certification of visual loss (sight impairment and severe sight impairment) which currently requires a consultant ophthalmologist to complete a certification of vision impairment (CVI or CVI-W) rather than being population based compounded by the reluctance of patients to be registered as visually impaired/blind.
- The strength of our study relates to its nationwide coverage, unified data base, providing important epidemiological information on the trends in new certification of visual impairment due to diabetic retinopathy as the main cause, in Wales, over an 8-year period.
- An additional strength of this study is that the time period it covers is when a nationwide screening programme was introduced to reduce severe sight impairment (blindness) by the early detection and treatment of sight-threatening diabetic retinopathy and secondly raise awareness to the presence of DR when enhanced medical management can prevent progression.

## Introduction

In 2015 an estimated 415 million people worldwide had diabetes mellitus, with DR amongst its most feared complications capable of causing visual impairment and blindness (1). Therefore, the predicted global increase in diabetes prevalence to 642 million by 2040 is of considerable public health concern due to its adverse effect on both the individual concerned and society in general (2-4). Previously, in 2012 a pooled meta-analysis was carried out including 35 studies worldwide involving people with diabetes where DR was determined from retinal photographs estimated that 34.6% had evidence of any DR and with 10.2% having vision threatening DR (5). The prevalence of any DR in the our Welsh population during 2005-2009 was 32.4% with 29% non-sight-threatening DR and 3.4% sight-threatening DR (6). The increasing prevalence of diabetes is acknowledged to represent a major public health problem worldwide and DR is amongst the most feared complication, leading to sight impairment (SI) and severe sight impairment (SSI) if not detected and treated at an early stage, and is therefore prioritised on the global public health agenda (7, 8). The societal costs of SI due to DR are significant and include severe reduction in quality of life, loss of productivity and increased healthcare costs (2, 4, 9).

In its 'Action plan for the prevention of avoidable blindness and visual impairment; 2009-2012' the World Health Organisation has highlighted the importance of recording SI and SS], in an attempt to monitor the impact of various strategies to eliminate preventable SI and SSI globally (8). Recording the number of people who are SSI in England and Wales was initiated in 1851, and between 1930 and 2003 a designated certificate (BD8) was employed which required the signature of an ophthalmologist with the cause of low vision included from 1950 onwards (10-15). The BD8 was superseded in 2005 by the certificate of vision impairment (CVI) for England and later in 2007 its equivalent for Wales (CVI-W) which are crown copyright under the ownership of the government. A copy of the CVIs are sent to the Certification Office, London, for anonymised epidemiological analysis and which is funded by the Royal National Institute for the Blind (RNIB) operating under the governance of the Royal College of Ophthalmologists. Since 2012, despite their limitation,

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2  
3 certification numbers have been used in an attempt to indicate the burden of preventable sight loss  
4 and which are included in the Public Health Outcomes Framework by the Department of Health, UK  
5  
6 Government. Between 1999 to 2000 the major causes of SSI in working aged adults (between 16  
7  
8 and 64 years) in England and Wales were DR/maculopathy (17.7%), hereditary retinal diseases  
9  
10 and optic atrophy (10.1%) (16, 17). However, in a more recent analysis for 2009-2010 the  
11  
12 order of the three main causes of SSI had changed to hereditary retinal disorders (20.2%),  
13  
14 DR/maculopathy (14.4%) and optic atrophy (14.1%) (18). DR was therefore, for the first time in five  
15  
16 decades, no longer the leading cause of certifiable SSI in England and Wales, a most encouraging  
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18 trend from a public health standpoint.  
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26 In Wales a screening program for DR was launched in 2003 and by the end of 2006 all persons  
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28 known to have diabetes in Wales, aged 12 years or over, and under the care of general practice  
29  
30 located within Wales had been offered an appointment for screening. Therefore, the time period  
31  
32 covered in this analysis corresponds with the time when screening was provided on a national basis  
33  
34 implementing standardised quality assured methods to include photography and grading. This  
35  
36 retrospective analysis was conducted in order to address whether the introduction of Diabetic Eye  
37  
38 Screening in Wales (DESW) has had any impact on the level of certification for SI and SSI in Wales  
39  
40 between 2007 and 2015 by virtue of the earlier detection of DR and its subsequent management.  
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## 45 **Methods**

### 46 **Numerator**

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50 The numerator included the causes of new CVI-W of both SI and SSI for Wales were sourced from  
51  
52 the Certifications Office, at Moorfields Eye Hospital, London. Details of data entry and transmission  
53  
54 using the BD8 certificate causes of blindness recorded by Ophthalmologists and CVI forms have been  
55  
56 reported previously (18, 19). All patients provided explicit consent for certification and for  
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3 anonymised data to be sent to the Certifications Office. The number of new certifications of SI and  
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5 SSI due to diabetic eye disease (retinopathy/maculopathy) included those cases where the main  
6  
7 cause of certifiable SI or SSI was diabetic retinopathy/maculopathy and those where the main cause  
8  
9 was recorded as multiple conditions but a contributory cause was diabetic eye disease. To be  
10  
11 certified as SSI, sight assessed using the Snellen Chart, while wearing any glasses or contact lenses,  
12  
13 will fall into the following categories: visual acuity (V/A) of less than 3/60 with a full visual field, or  
14  
15 V/A between than 3/60 and 6/60 with a severe reduction of field of vision, such as tunnel vision, or  
16  
17 V/A of 6/60 or above but with a very reduced field of vision, especially if a lot of sight is missing in  
18  
19 the lower part of the field. A definition of SI requires the sight to fall into one of the following  
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21 categories, while wearing any glasses or contact lenses, a V/A of 3/60 to 6/60 with a full field of  
22  
23 vision, or V/A of up to 6/24 with a moderate reduction of field of vision or with a central part of  
24  
25 vision that is cloudy or blurry, or V/A of 6/18 or even better if a large part of the field of vision, a  
26  
27 whole half of the vision, is missing or a lot of the peripheral vision is missing. Certification for SI or  
28  
29 SSI is decided upon by a consultant ophthalmologist. Incidence data was provided for SI and SSI for  
30  
31 each year running from April 2007 to March 2015 derived from the certifications for SI and SSI  
32  
33 covering a two-year period.  
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### 39 **Denominator**

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41 Annual population estimates for Wales were obtained from the Office of National Statistics and were  
42  
43 based on the mid-year estimates. Between 2007 and 2010 the estimates were adjusted to bring  
44  
45 them into line with the official mid-2011 population estimates published in 2013 (20). The number  
46  
47 of persons with diabetes in Wales is recorded annually by the Quality and outcomes Framework  
48  
49 (QoF) in Primary Care (21). QoF is a voluntary reward and incentive programme which aims to  
50  
51 standardise improvement in the delivery of primary medical services. The estimate for the  
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53 population with diabetes for the last period of the certification timescale was used as the  
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55 denominator.  
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## Statistical analysis

The incidence of visual impairment (SI and SSI) due to any cause in Wales were calculated using the total number of new certifications and the population estimates for each yearly time period between 2007 and 2015. In addition the incidence of SI and SSI related to DR were calculated using the QoF estimates of people with known diabetes in Wales. The results are represented as the combined total (SI plus SSI), SI and SSI individually when due to either any cause or DR in the population of Wales. The percentage change in the incidence of new certifications for SI and SSI due to any cause or DR during each of the eight annual observation periods were also calculated.

## Results

Between 2007 - 2008 and 2014-2015 in Wales there was an overall reduction in new certifications for SI and SSI combined from any cause of 339 i.e. from 1582 to 1243, equivalent to 12.2 per 100,000 of the population representing a decrease of 21.4% over the 8-year observation period (Table 1). The new certifications for SI fell by 24.2% from 26.9 (95% confidence interval [CI] 25.1,28.8) per 100,000 population in 2007-2008 to 20.4 (95% CI 18.8, 22.0) per 100,000 in 2014-2015. For both parameters, a temporary and unexplainable increase was seen between 2008 and 2009 after which there was a reduction year on year for the remainder of the study period. However, new certifications for SSI have fluctuated over the observation period with a peak at 2008-2009 of 25.6 (95%CI 23.8, 27.4) per 100,000 population followed by a lesser peak during 2011-2012 before reaching a nadir of 18.3 (95%CI 16.9, 19.9) per 100,000 during the final year compared to 22.5 (95% CI 20.9, 24.3) per 100,000 during the initial year period of 2007-2008.



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3 The number of new certifications for SI and SSI combined in Wales due to DR during 2007-2008  
4 increased from 108 to a peak of 140 certifications during 2008-2009. Thereafter the numbers fell to  
5 86 certifications during 2014-2015, a reduction of 20.4% from the initial period of 2007-2008 (Table  
6 2). Similarly, there was a temporary increase in both SI and SSI during the second annual period of  
7 observation with SI certifications thereafter falling consistently from 89 to 51 during 2014-2015 a  
8 reduction of 42.7% and SSI falling from 51 to 29 certificates being a fall of 43.1% over the remaining  
9 seven years of the study. The overall reduction in SI and SSI combined, SI and SSI for the entire study  
10 period from 2007-2008 to 2014-2015 was 22.2%, 23.8% and 35.7% respectively. For the population  
11 of Wales the initial rate of new certifications in 2007-2008 for SI and SSI combined, SI and SSI was 3.6  
12 (95%CI 3.0, 4.3), 2.1 (95%CI 1.7, 2.7) and 1.4 (95%CI 1.0, 1.8) per 100,000 respectively followed by  
13 slight increase in the second year to 4.6 (95%CI 3.9, 5.4), 2.9 (95%CI 2.4, 3.6) and 1.7 (95%CI 1.3, 2.2)  
14 per 100,000 respectively and then a general trend downwards to the lowest rate of 2.8 (95%CI 2.2,  
15 3.4), 1.6 (95%CI 1.3, 2.2) and 0.9 (95%CI 0.7, 1.3) per 100,000 respectively seen during 2014-2015.  
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34 Over the eight-year observation period the number of persons known with diabetes in Wales  
35 increased by 52,000 from 131,119 in 2007-2008 to 183,348 in 2014-2015 (Table 3) representing an  
36 increase in the prevalence of diabetes in Wales from 4.3% in 2007-2008 to 5.9% in 2014-2015.  
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39 During this time, there was an increase in the rate of new certifications for SI and SSI combined, SI  
40 and SSI from the first to the second year (2007-2008 to 2008-2009) from 82.4 (95%CI 68.2, 99.4),  
41 48.8 (95%CI 38.2, 62.3) and 31.3 (95%CI 23.1, 42.4) to 100.7 (95%CI 85.4, 118.8), 64.5 (95%CI 52.0,  
42 78.8) and 36.7 (95%CI 27.9, 48.2) respectively per 100,000 persons with diabetes. Thereafter, the  
43 rate fell to 46.9 (95%CI 38.0, 57.9), 27.8 (95%CI 21.2, 36.6) and 15.8 (95%CI 11.0, 22.7) respectively  
44 per 100,000 diabetic population a reduction of 53.4%, 56.9% and 56.9% respectively by 2014-2015.  
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54 The overall reduction over the entire 8 year study for new certifications in persons with diabetes for  
55 SI and SSI combined, SI and SSI was 43.1%, 43.0% and 49.5% respectively (Figure 1).  
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## Discussion

This analysis of new certifications for SI and SSI in Wales from 2007-2008 to 2014- 2015 provides information on the changes that occurred over the eight-year observation period due to any cause and specifically DR. Between 2007 and 2015 the number of new certifications for SI and SSI due to DR fell from by 23.8% and 35.7% respectively albeit there was a slight increase in the second year in SI and a smaller increase in SII during the fifth year. In the context of the rising number of persons with diabetes (~40%) during the same period of time the proportion of persons with diabetes certified as SI and SSI combined, SI or SSI alone almost halved between 2007-2008 and 2014-2015 at 43.1%, 43.0%, and 49.5% respectively. It is acknowledged that a more prolonged period of observation prior to 2007 would have been most helpful in ascertaining the meaningfulness of this important trend in lowering of new certification rates for visual impairment in Wales since the introduction of a national DR screening service for Wales.

Currently there are a limited number of reports on the number of new certifications for SI and SSI due to DR/maculopathy. For those that do exist it is difficult to compare findings due to different methods for certifications and definitions of SI and SSI. However, recently it was reported that in Ireland there were 33 new certifications including both SI and SSI due to DR in 2007 decreasing to 29 in 2013 which equates to almost halving the risk in persons with diabetes from 45.9 per 100,000 in 2007 to 26.4 per 100,000 in 2013 (22) which is lower than seen in our population with diabetes in Wales. It is noteworthy that in Ireland prior to the establishment of a National DR screening programme DR in 2013 DR screening was performed on a limited basis by local services using different models of service provision and the analysis restricted to the 18-69 years of age population. Earlier, in Fife, Scotland the incidence of blindness due to diabetic eye disease during 1990-1999 was reported to be 64 per 100,000 population/year with diabetes(23). During the following decade between 2000 and 2009 the incidence of blindness in Scotland fell by a mean of

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3 10.6% per year from 59.7 to 23.9 per 100,000 in the diabetes population (24) which is slightly lower  
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5 than the 30.8 per 100,000 seen in our population in 2009-2010. The Scottish national screening  
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7 program for DR was implemented in 2006 midway during our study period. A comparison of the  
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9 causes of new SSI certifications in England and Wales in working age adults (16-64 years) between  
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11 1999-2000 and 2009-2010 reported a reduction due to DR from 17.7% to 14.4% as the main cause  
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13 and from 17.9% to 16.2% with DR as a main or contributory cause (18).  
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19 In our study there are a number of possible explanations as to why the number of new certifications  
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21 of SI and SSI due to DR fell during the eight-year period of observation between 2007-2008 and  
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23 2014-2015. Screening for DR was introduced in the Wales in 2003 (25, 26), along with the parallel  
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25 availability of new treatments for management of both diabetes and sight-threatening DR and  
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27 maculopathy (27-30). In addition, an increase in the population with diabetes during this period will  
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29 also contribute to this observation due to the greater awareness of diabetes and changes in  
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31 diagnostic criteria. To date, relatively few studies have reported a reduction in the prevalence of  
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33 sight- threatening DR mainly referring to persons with type 1 diabetes (31-33) again suggesting the  
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35 possible benefit of recent changes in the management of diabetes. In addition a systematic review  
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37 of 28 studies noted that participants involved from 1986 onwards had a lower proportion of  
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39 proliferative DR and severe vision loss at 2.6% and 3.2% respectively compared to 1985 and before  
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41 at 19.5% and 9.7% respectively (31). These studies suggest that the reduction in sight-threatening  
42  
43 DR could possibly be due to improved diabetes and/or ophthalmological care. In our experience in  
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45 Wales the number of people referred by the DESW to the hospital eye services with sight-  
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47 threatening DR for ophthalmological review fell from 3.4% in 2007 to 2.0% in 2015 (34). There has  
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49 also been a decrease in the volume of certifications in England and Wales especially of partially  
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51 sighted people and also there is evidence to suggest an inappropriate severe sight impairment  
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53 certification rate of approximately 20%, due to a variety of reasons (35, 36). Implementation of the  
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3 National DR screening service will have resulted in a reduction in SSI as a result of the earlier referral  
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5 and treatment of sight-threatening DR by the hospital eye services. In addition providing awareness  
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7 of the presence of DR to Primary Care indicates the need for reviewing diabetes management in  
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9 order to prevent progression of non-sight threatening DR. It would be difficult to say if one or any  
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11 one of these changes were primarily responsible for the observed decrease as it is more likely to be  
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13 a combination of these elements.  
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19 Using certifications to study rates of sight impairment is justified on the grounds of coverage and the  
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21 collection of uniform data fields and working definitions of visual impairment both partial sighted  
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23 and blindness. However, there are major limitations which are well described by others (14-16)  
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25 acknowledging the fact that certification is hospital and not population based which requires the  
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27 patient to access hospital based services in order to be seen and certified by a consultant  
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29 ophthalmologist. A substantial proportion of visually impaired persons (approximately 50%) remain  
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31 uncertified and certification is deemed inappropriate in approximately 23% (15,32,34). Patient and  
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33 healthcare professional knowledge and attitude relating to certification for visual impairment can  
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35 also have a negative impact. Understandably the offer of certification can be distressing for patients  
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37 and they may therefore need time to come to terms with this realisation as well as understanding  
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39 the important benefits certification may bring (17). Ophthalmologists can be uncertain as to when  
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41 to offer certification, which results in unnecessary delay between the diagnosis of certifiable sight  
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43 loss and the offer of certification with a bias towards SSI, permanent, non-treatable causes, and  
44  
45 those with t central rather than peripheral vision loss (37, 38). Unfortunately, blind certification  
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47 does not equate with rates of blindness. Our analysis provides data on the incidence of new  
48  
49 certifications for SI and SSI in Wales as a result of DR over an 8-year period since the introduction of  
50  
51 a nationwide DR screening service (DESW). The findings need to be interpreted acknowledging the  
52  
53 inherent limitations of the current state of visual impairment certifications where unfortunately  
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3 blind certification does not equate with blindness rates. Due to these limitations and different  
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5 definitions of sight and severe sight impairment in other countries and settings it would be difficult  
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7 to apply these findings to other settings outside of the UK.  
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12 Trends in SI and SSI certifications due to DR are clearly decreasing in Wales as in other regions of the  
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14 UK (18, 22, 24) although the reasons need to be more fully elucidated and confirmed with further  
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16 analysis over the coming years. Studies have also indicated that those persons most at risk of losing  
17  
18 vision due to DR either do not attend for eye screening and/or are not fully engaged with the  
19  
20 management of their diabetes (39-43). In order to ensure the reduced risk for sight loss due to DR in  
21  
22 Wales continues, more needs to be done to improve attendance rates for eye screening above its  
23  
24 current and stable level at approximately 80%. Studies are currently underway to explore this very  
25  
26 important question and to ensure a better uptake into the screening services in order to  
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28 accommodate this vulnerable segment of the population of people with diabetes. Increased access  
29  
30 to structured diabetes education program is another essential way to help those with diabetes to  
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32 better understand the importance of regular DR screening and the need to achieve and maintain  
33  
34 good glycaemic, blood pressure and lipid control.  
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42 In conclusion, findings from this analysis provides positive and useful epidemiological information to  
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44 assist in the future monitoring of diabetic eye disease in order to provide the basis for assessing the  
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46 benefit or otherwise of changes in the management of diabetes and diabetic  
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48 retinopathy/maculopathy. However, improvements are needed to the certification process to  
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50 enhance its value by providing reliable and meaningful epidemiological data in support of the  
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52 eventual aim of eradicating preventable vision threatening disease in the ever increasing population  
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54 of people with diabetes and the general population alike. This analysis, despite the inherent  
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56 limitations of the current process for the certification of vision impairment, highlights the  
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3 positive benefits of introducing a community based screening programme for the  
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5 early detection of sight-threatening diabetic retinopathy.  
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23  
24

### 25 26 **Ethical approval**

27  
28 All patients provide explicit consent for certification and for anonymised data to be transferred to  
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30 the certifications office. All data analysed in this study was anonymised and therefore no ethical  
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32 approval was required.  
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38 Data sharing statement - No additional data is available  
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43  
44 RT performed the data analysis and wrote and edited the manuscript. SL, RN SB and DRO all  
45  
46 contributed to the study design, interpretation of the data and revised the manuscript. AZ and CB  
47  
48 carried out the data collection and revised the manuscript. RT is the guarantor for the study and  
49  
50 affirms that the manuscript is honest, accurate and transparent account of the study being reported.  
51  
52 No important aspects have been omitted and any discrepancies from the study as planned have  
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54 been explained.  
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50 interpretation of data, report writing or submission for publication.  
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Table 1: Number of new certifications for combined (total), SI and SSI due to any cause in the population of Wales 2007-2015

<b>Visual impairment certifications due to any cause in Wales: n (per 100,000 population)</b>				
<b>Time period</b>	<b>Population</b>	<b>Total</b>	<b>Sight impairment</b>	<b>Severe sight impairment</b>
<b>2007-2008</b>	3,025,867	1582 (52.3)	814 (26.9)	681 (22.5)
<b>2008-2009</b>	3,038,872	1737 (57.2)	914 (30.1)	777 (25.6)
<b>2009-2010</b>	3,049,971	1544 (50.6)	802 (26.3)	689 (22.6)
<b>2010-2011</b>	3,098,346	1425 (46.0)	745 (24.0)	649 (20.9)
<b>2011-2012</b>	3,074,067	1463 (47.6)	703 (22.9)	721 (23.5)
<b>2012-2013</b>	3,082,400	1362 (44.2)	696 (22.6)	621 (21.1)
<b>2013-2014</b>	3,092,000	1302 (42.1)	680 (22.0)	580 (18.8)
<b>2014-2015</b>	3,099,086	1243 (40.1)	631 (20.4)	568 (18.3)

Table 2: New certifications for SI and SSI due to DR in the population of Wales 2007 - 2015

<b>Wales Certifications due to DR: n (per 100,000 population)</b>				
<b>Time period</b>	<b>Population</b>	<b>Total<sup>1</sup></b>	<b>Sight impairment</b>	<b>Severe sight impairment</b>
<b>2007-2008</b>	3,025,867	108 (3.6)	64 (2.1)	41 (1.4)
<b>2008-2009</b>	3,038,872	140 (4.6)	89 (2.9)	51 (1.7)
<b>2009-2010</b>	3,049,971	118 (3.9)	71 (2.3)	45 (1.5)
<b>2010-2011</b>	3,098,346	103 (3.3)	62 (2.0)	40 (1.3)
<b>2011-2012</b>	3,074,067	95 (3.1)	55 (1.8)	38 (1.2)
<b>2012-2013</b>	3,082,400	98 (3.2)	58 (1.9)	38 (1.2)
<b>2013-2014</b>	3,092,000	95 (3.1)	62 (2.0)	29 (0.9)
<b>2014-2015</b>	3,099,086	86 (2.8)	51 (1.6)	29 (0.9)

Table 3: New certifications for SI and SSI due to DR in those persons with known diabetes in Wales between 2007 and 2015: n (per 100,000 population)

Time period	Total with diabetes	Total new certifications	Sight impaired	Severe sight impaired
2007-2008	131,119	108 (82.4)	64 (48.8)	41 (31.3)
2008-2009	138,988	140 (100.7)	89 (64.5)	51 (36.7)
2009-2010	146,173	118 (80.7)	71 (48.6)	45 (30.8)
2010-2011	153,175	103 (67.2)	62 (40.5)	40 (26.1)
2011-2012	160,533	95 (59.2)	55 (34.3)	38 (23.7)
2012-2013	167,537	98 (58.5)	58 (34.6)	38 (22.7)
2013-2014	173,299	95 (54.8)	62 (35.8)	29 (16.7)
2014-2015	183,348	86 (46.9)	51 (27.8)	29 (15.8)

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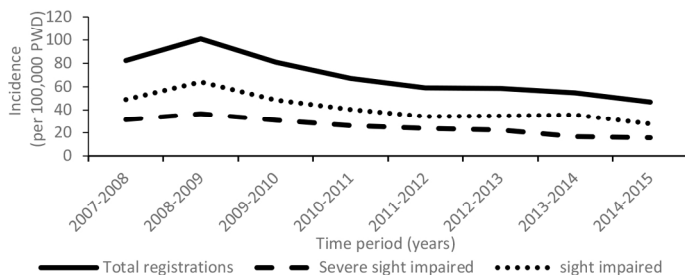


Figure 1: Total visual impairment certifications and incidence of sight and severe sight impairment due to DR in Wales (per 100,000 people with diabetes).

Figure 1: Total visual impairment certifications and incidence of wight and severe sight impairment due to DR in Wales (per 100,000 people with diabetes)

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## STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract page 1 (b) Provide in the abstract an informative and balanced summary of what was done and what was found page 2
<b>Introduction</b>		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported page 3
Objectives	3	State specific objectives, including any prespecified hypotheses page 4
<b>Methods</b>		
Study design	4	Present key elements of study design early in the paper page 4-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection page 4-5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up n/a <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls n/a <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants page 4-5 (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed n/a <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable page 4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group page 4-5
Bias	9	Describe any efforts to address potential sources of bias n/a
Study size	10	Explain how the study size was arrived at page 4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why page 5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding page 5 (b) Describe any methods used to examine subgroups and interactions n/a (c) Explain how missing data were addressed n/a (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed n/a <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed n/a <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy page 5 (e) Describe any sensitivity analyses n/a

Continued on next page



**Results**

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed table 1, table 2 and table 3 (b) Give reasons for non-participation at each stage n/a (c) Consider use of a flow diagram n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders N/A (b) Indicate number of participants with missing data for each variable of interest n/a (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount) n/a
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time n/a <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure n/a <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures page 6-7
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included 95% CI provided for incidence rates pages 6-7 (b) Report category boundaries when continuous variables were categorized n/a (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses n/a

**Discussion**

Key results	18	Summarise key results with reference to study objectives page 8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Page 10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Page 9-10
Generalisability	21	Discuss the generalisability (external validity) of the study results page 11

**Other information**

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based page 13
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\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).