Masterclass 3: Retinopathy

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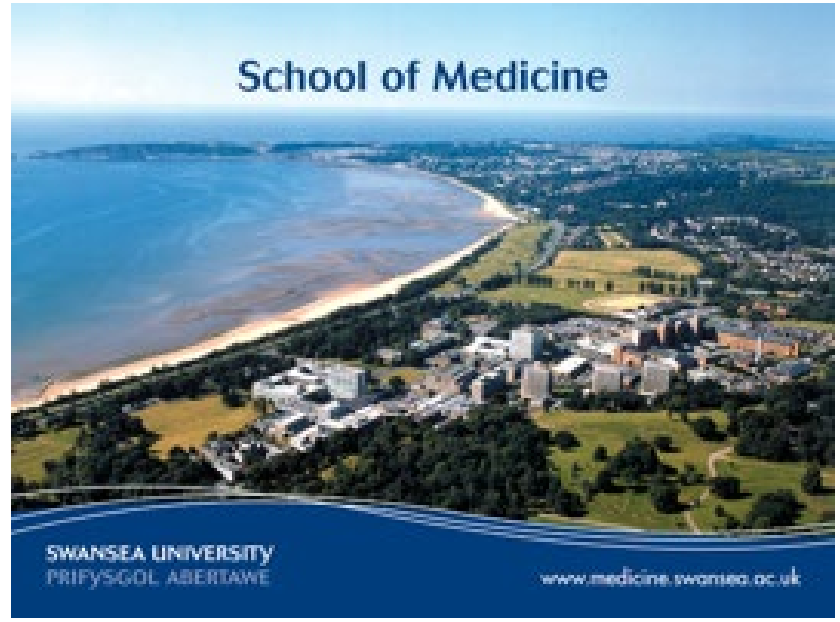
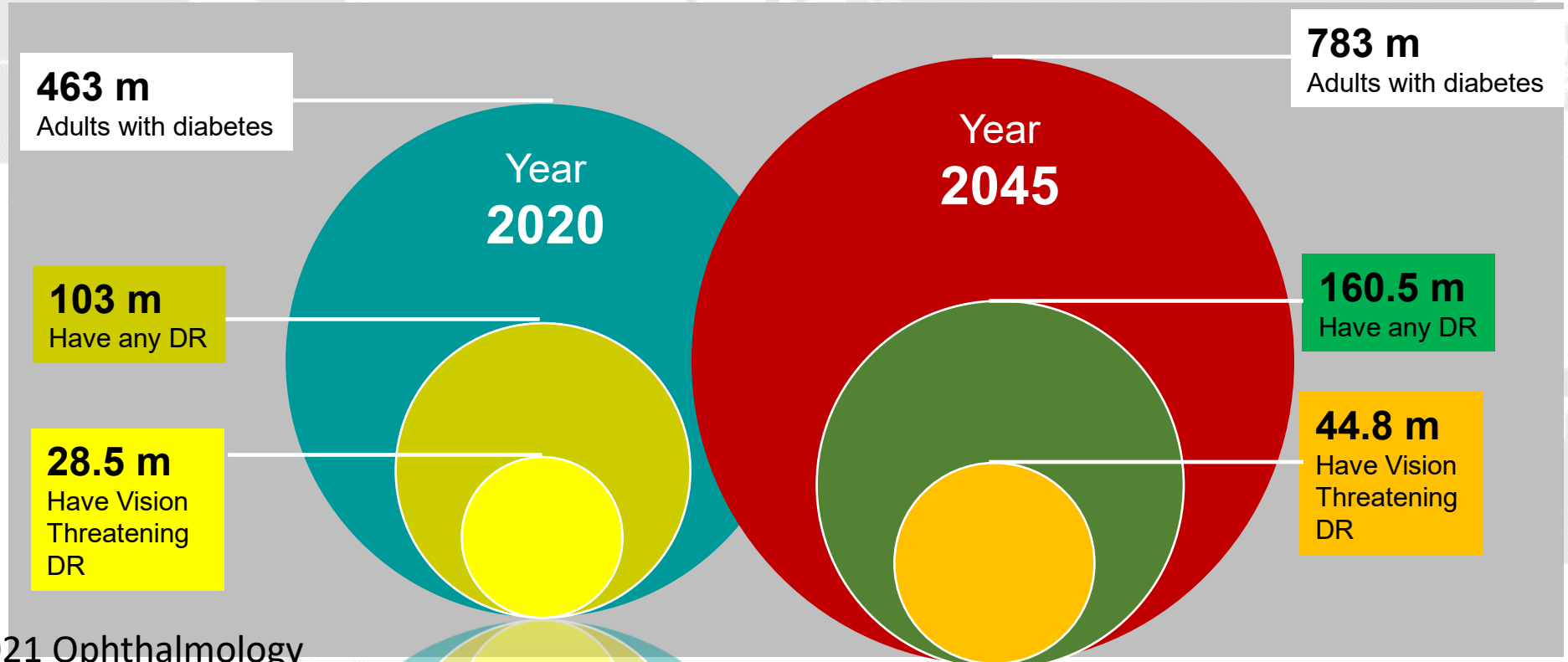
11- 2023



Diabetic Eye Health: Global Perspective:

Year	Any DR Million	Increase	VTDR Millions	Increase	CSMO Millions	Increase
2020	103 (22%)		28.5 (6%)		18.8 (4%)	
2030	129.8	+25.9%	36.1	+26.3%	23.5	+24.8%
2045	160.5	+55.6%	44.8	57.0%	28.6	+51.96%



Teo et al 2021 Ophthalmology

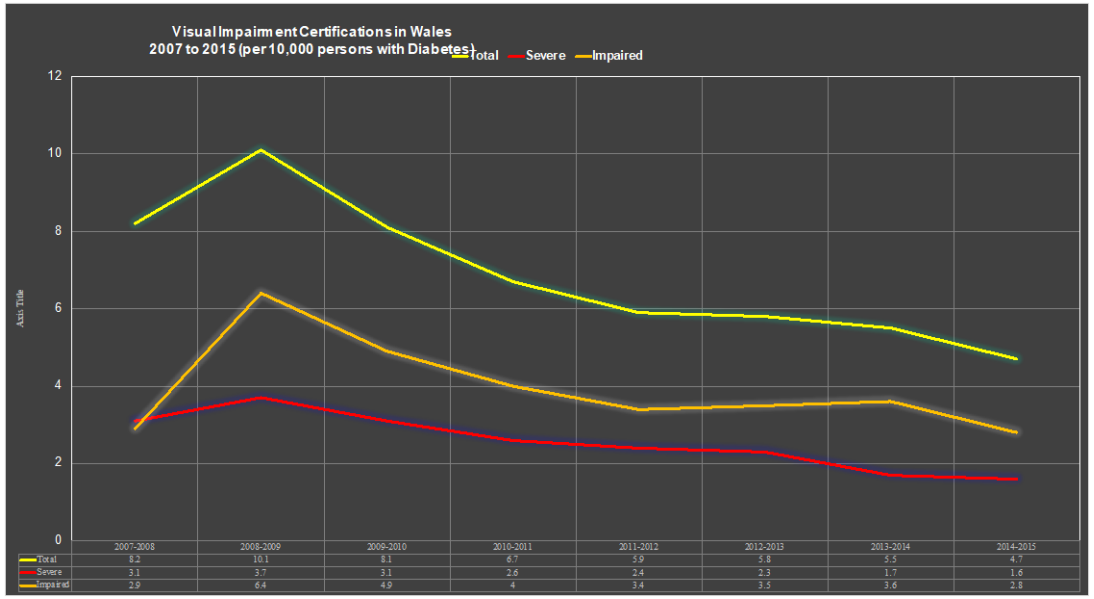
Reduction in certifications due to diabetic retinopathy

Design: Analysis of National database of Certificates of **V**ision **I**mpairment **(CVIs)** in working **age (16-64 years) population** (n=1756)

% of Total	
1999-2000	**2009-2010**
17.7	14.4
15.8	20.2
10.1	14.1
7.7	3.0
5.4	5.9

Liew et al *BMJ Open*, 2014

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

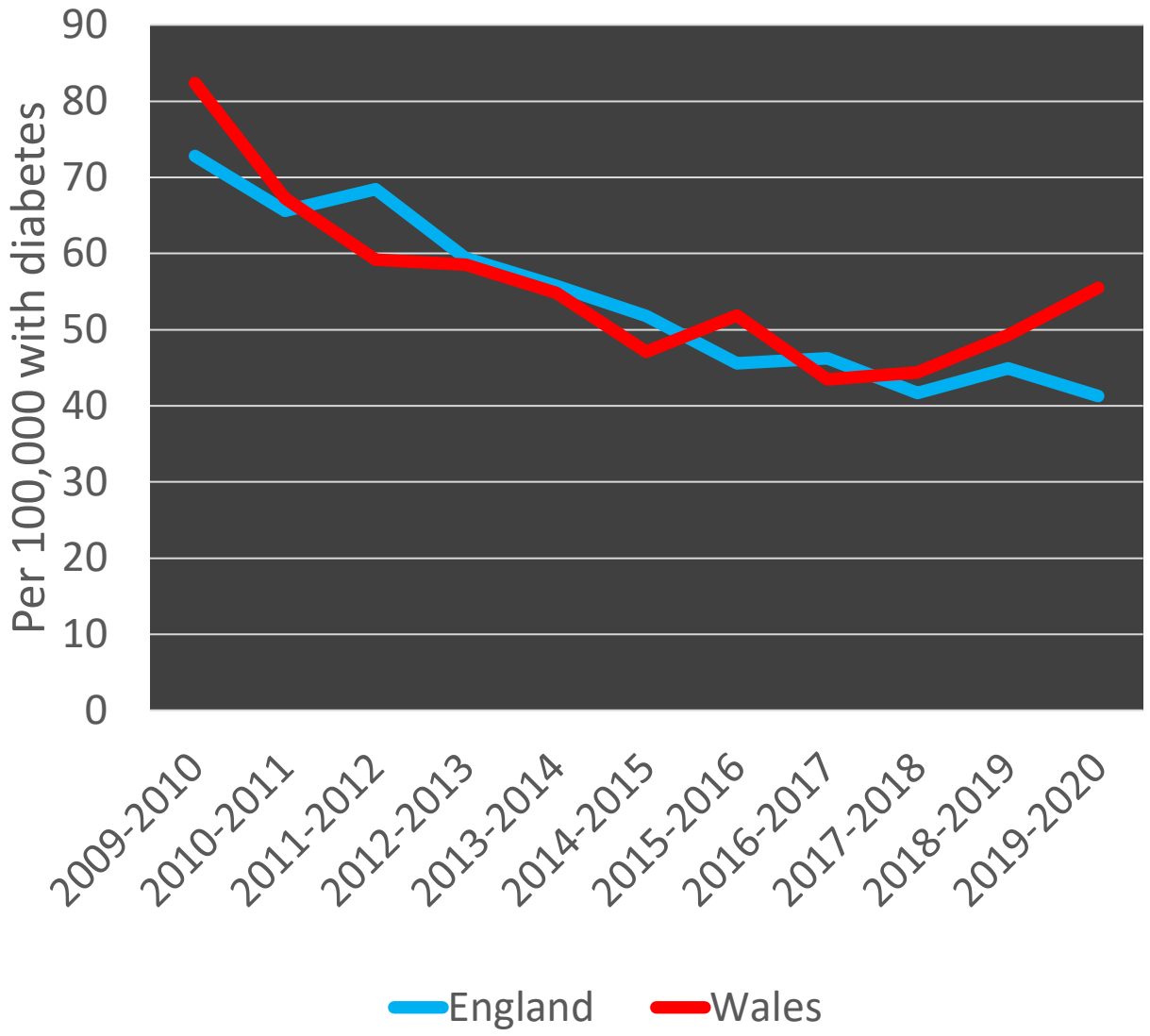


Thomas et al *BMJ Open* 2017;7:e015024.

Certifications for sight and severe sight impairment – diabetic retinopathy

- Certifications due to diabetic retinopathy per 100,000 people with diabetes
- **England:**
- Fell from 72.8 in 2009-2010 to 41.6 in 2019-20
- **Wales:**

Fell from 82.3 in 2009-10 to its lowest level of 43.5 in 2016-17
Since 2016-17 there has been a continued increase to 55.6 in 2019-20



Diabetic Retinopathy Barometer study: views of people with diabetes (4,340) and Health Care Professionals (2,329) in 41 countries

Contents available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres

ELSEVIER

International Diabetes Federation

The Diabetic Retinopathy Barometer Study: Global perspectives on access to and experiences of diabetic retinopathy screening and treatment

Cavan et al *Diabetes Res and Clinical Practice* 2018;129:16-24

Global perspectives on the provision of diabetic retinopathy screening and treatment: Survey of health care professionals in 41 countries

Cavan et al *Diabetes Res and Clinical Practice* 2018;143:170-178

28%
Never discussed eye complications with their doctor only after symptoms

63%
Present when visual problems already present, **6%** too late for effective treatment

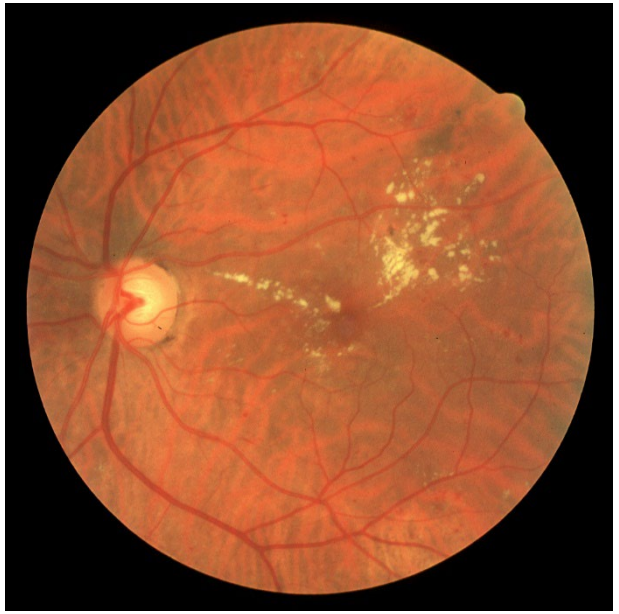
44%
Providers did not have or use written protocols for DM related vision loss

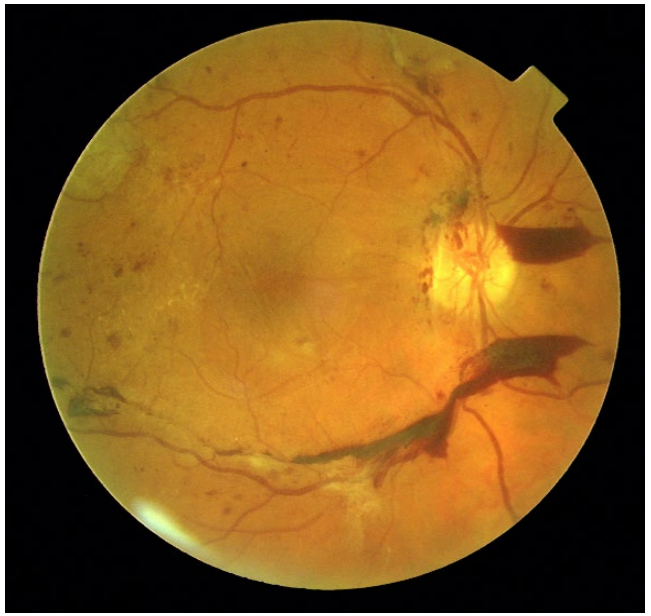
21%
Ophthalmologist had not received specific training in diagnosis or treatment of DED

20%
Vision impairment due to DR/DME made it difficult to manage their diabetes

The Global Reality

Why screen for diabetic retinopathy

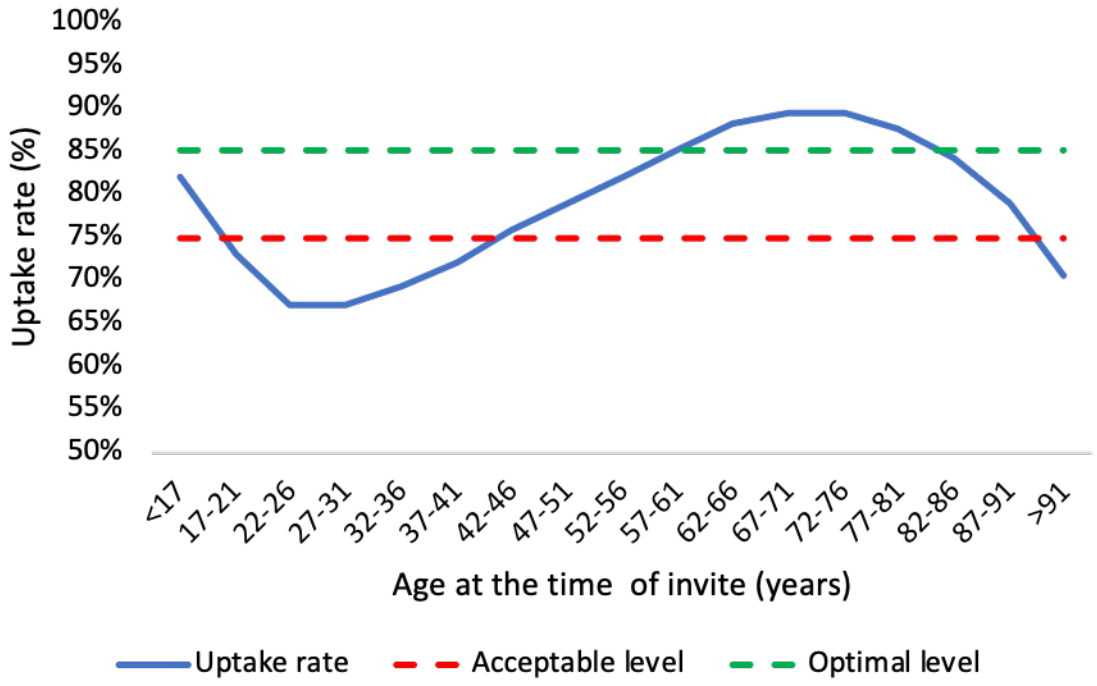




Screening for Diabetic retinopathy aims to detect sight-threating lesions at the earliest stage when treatment is most effective. This stage normally occurs before someone notices changes in their vision. Once vision changes are noticed by someone with diabetes the diabetic retinopathy is still treatable but may require more treatment than if it was detected earlier.

Attendance rates at screening for DR

- Attendance rates for retinopathy screening are high in those under the age of 17 years.
- However, they begin to fall from 17-21 years and reach their lowest rates from 22-31 years
- They begin to rise from 32 years but do not reach the acceptable screening levels until after 41 years
- They remain high until 76 years when they begin to fall again



Thomas et al (diabetologia 2021)

Repeat non-attendance at screening for DR

	Type 1 diabetes N=7067		Type 2 diabetes N= 164,788
Sex: Men Women	Removed from model	Sex: Men Women	 Reference 1.25 (1.20, 1.30)
Age: 10-17 18-34 >34	 Reference 1.51 (1.25, 1.82) 1.03 (0.85, 1.26)	Age: 10-17 18-34 35-54 55-84 >84	 3.94 (1.09, 7.42) 2.32 (1.99, 2.70) 1.39 (1.23, 1.57) 0.75 (0.67, 0.84) Reference
Deprivation: WIMD 1 (most) WIMD 2 WIMD 3 WIMD 4 WIMD 5 (least)	 1.94 (1.54, 1.82) 1.61 (1.27, 2.04) 1.29 (1.01, 1.65) 1.10 (0.84, 1.43) Reference	Deprivation: WIMD 1 (most) WIMD 2 WIMD 3 WIMD 4 WIMD (least)	 1.76 (1.64, 1.89) 1.57 (1.46, 1.68) 1.31 (1.22, 1.41) 1.19 (1.10, 1.28) Reference
Number of house moves	1.25 (1.18, 1.32)	Number of house moves	1.32 (1.28, 1.35)
Attendance at first screening	0.13 (0.11, 0.15)	Attendance at first screening	0.07 (0.07, 0.08)

Thomas et al diabetic medicine 2021

- Greatest risk of repeat non-attendance
  - Younger age
  - Those living in more deprived areas
  - Those with more house moves
- Lowest risk of repeat non-attendance
  - Those who attend the first screening appointment

Risk factors for diabetic retinopathy

Modifiable

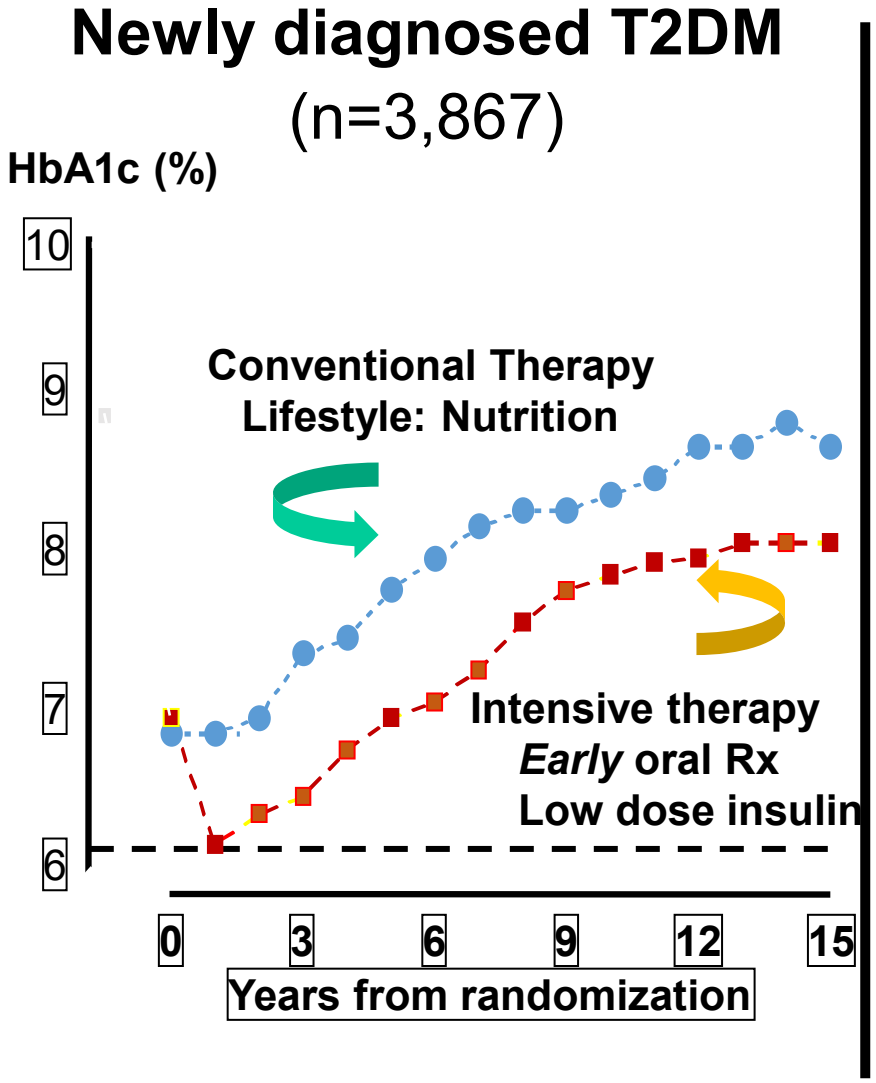
- High blood glucose
- High blood pressure
- High cholesterol

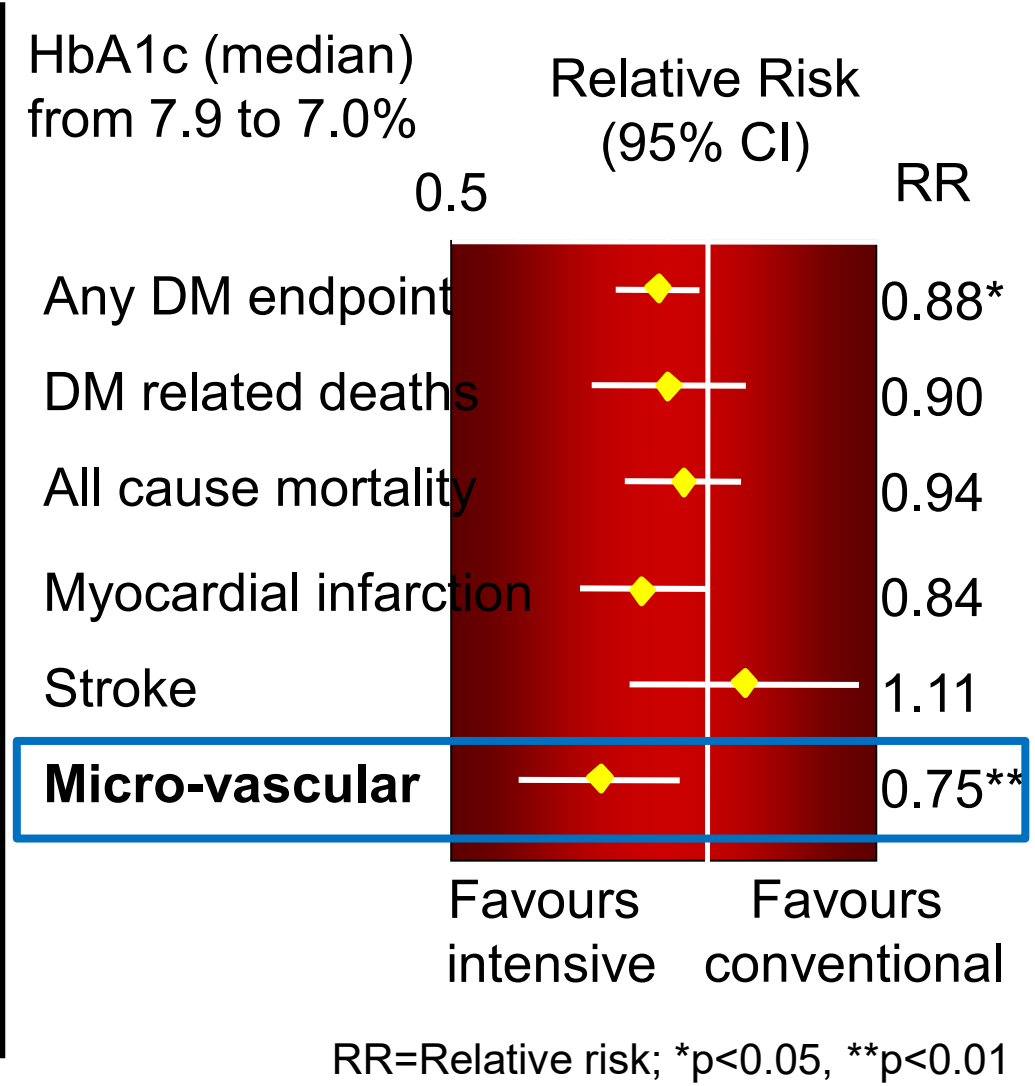
Unmodifiable

- Duration of diabetes
- Ethnicity
- Pregnancy
- Age
- Puberty
- Genetic makeup

Risk increases with multiple ‘risk factors’

UKPDS Intervention Trial: **Blood glucose management**



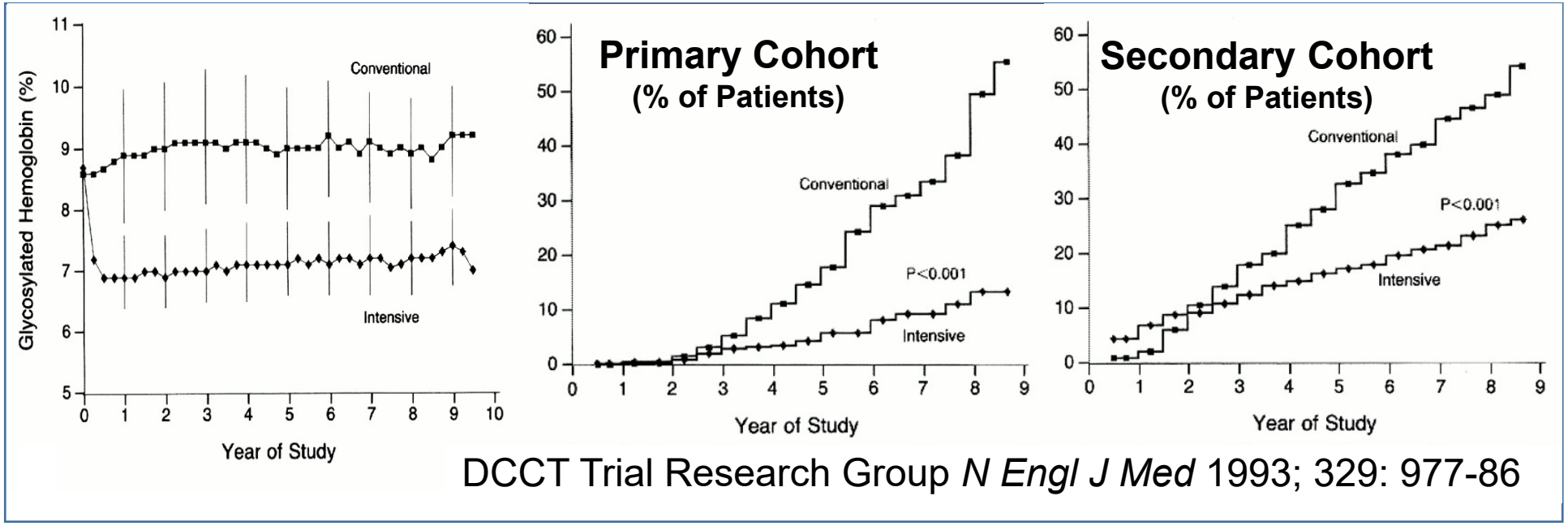


RR=Relative risk; *p<0.05, **p<0.01

DCCT : **Blood glucose management**

Primary Prevention (726) Secondary Prevention (715) over 6.5 years

Conventional Rx HbA1c 9.1% Intensive Rx HbA1c 7.2%

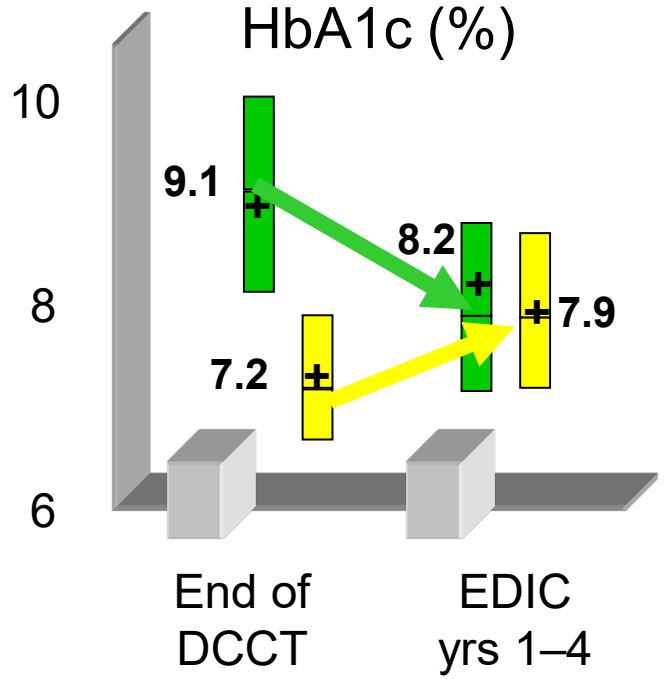


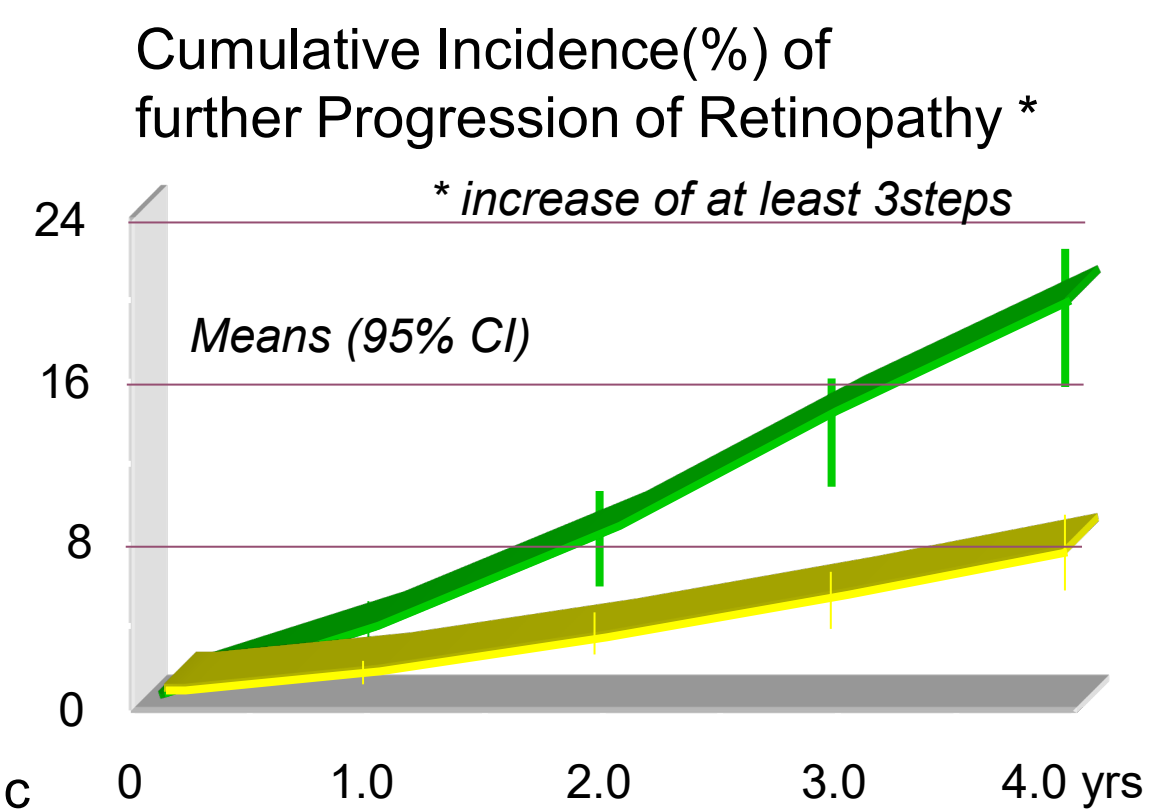
DCCT Trial Research Group *N Engl J Med* 1993; 329: 977-86

N Engl J Med 1993; 329: 977-86

DCCT : **Blood glucose management**

Epidemiology of **D**iabetes **I**nterventions & **C**omplications (EDIC)





Despite HbA1c Levels converging at 4 years ↓**75%** reduced risk of progression

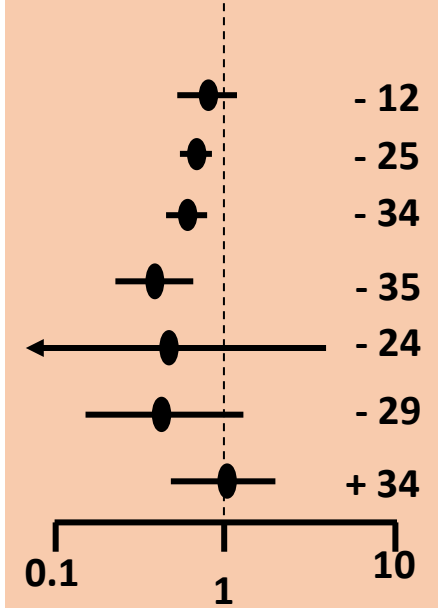
'Metabolic memory'- legacy of good control

DCCT/EDIC Research Gp
NEJM 2000; 342:381-389

UKPDS: **Blood Pressure management**

- 'Tight' <150/85 vs 'less tight' BP <180/105 mmHg
- Treatment ACEI or beta blocker over 8.4 years duration.

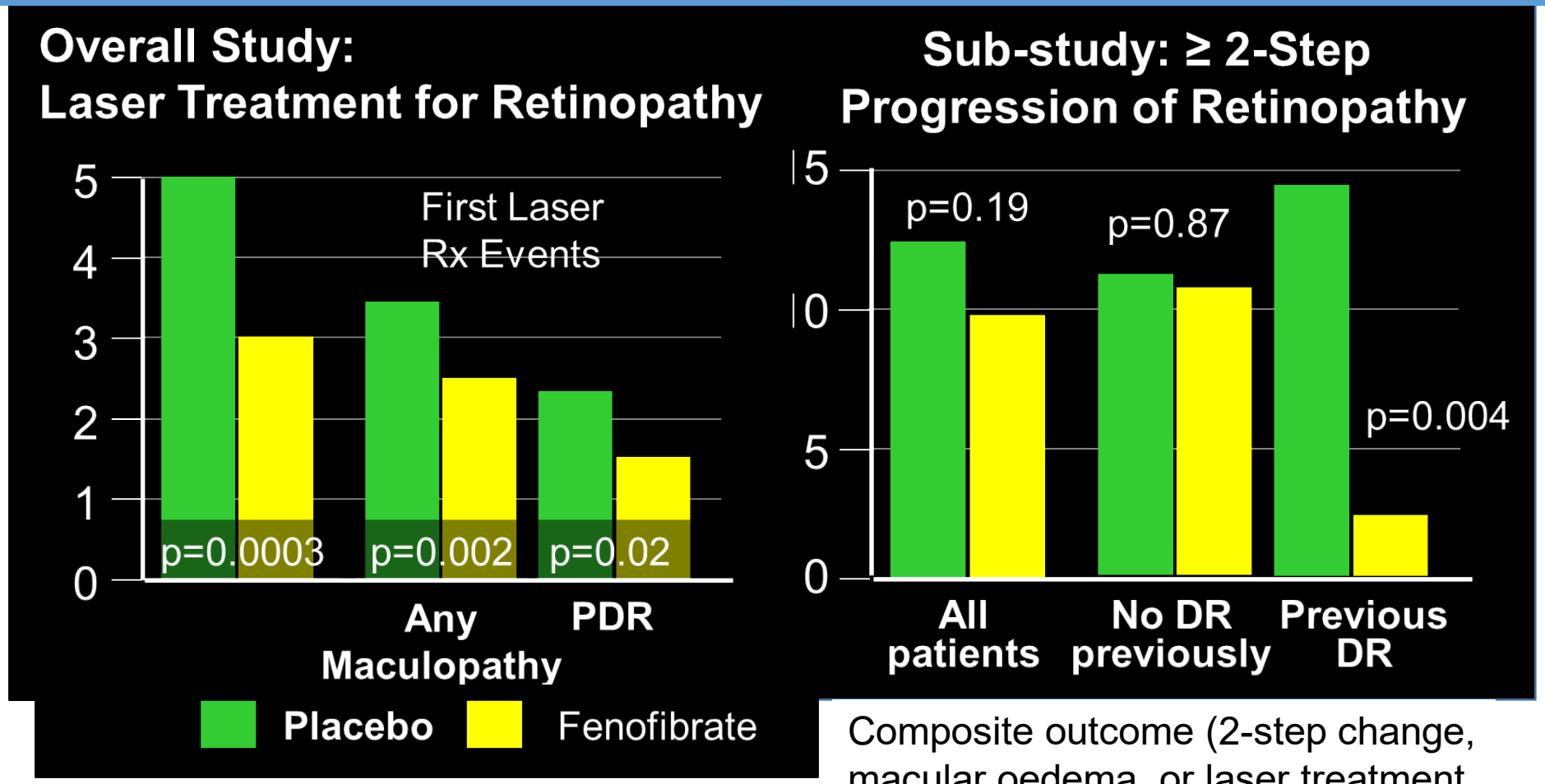
Surrogate end point	% of patients with progression: Tight control	Less tight	Relative Risk for tight control (95% CI) %	p value
Progression of DR by ≥2 steps				
Median 1.5 yrs	20.2	23.1	- 12	0.38
Median 4.5 yrs	27.5	36.7	- 25	0.019
Median 7.5 yrs	34.0	51.3	- 34	0.0038
Retinal photocoagulation	10.2	16.6	- 35	0.023
Vitreous haemorrhage	13.7	20.3	- 24	0.76
Blindness in one eye	22.4	27.2	- 29	0.34
Cataract extraction	18.6	23.5	+ 34	0.35



UKPDS 38 *BMJ* 1998;317:703-13

UKPDS 39 : *BMJ* 1998; 317: 713-20

Diabetic Retinopathy : FIELD Study (Fenofibrate)



Potential benefit for subjects with pre-existing Diabetic Retinopathy

Composite outcome (2-step change, macular oedema, or laser treatment 11.9% vs 16.1% (p=0.022)

Keech et al. Lancet 2007;370:1687-1697

Fenofibrate reduced DR Progression in T2DM

Diabetic Retinopathy : ACCORD eye study

Effects of Medical Management on DR progression in T2DM*:

*Population of **established** T2DM (2856/10,251) at high risk for CVD :

1 Glycaemia : HbA1c 6.0 vs 7.0-7.9%

2 Dyslipidaemia : Fenofibrate* + statin vs placebo + statin

*(*160 mg fenofibrate daily)*

3 Hypertension : SBP <120 vs <140 mmHg

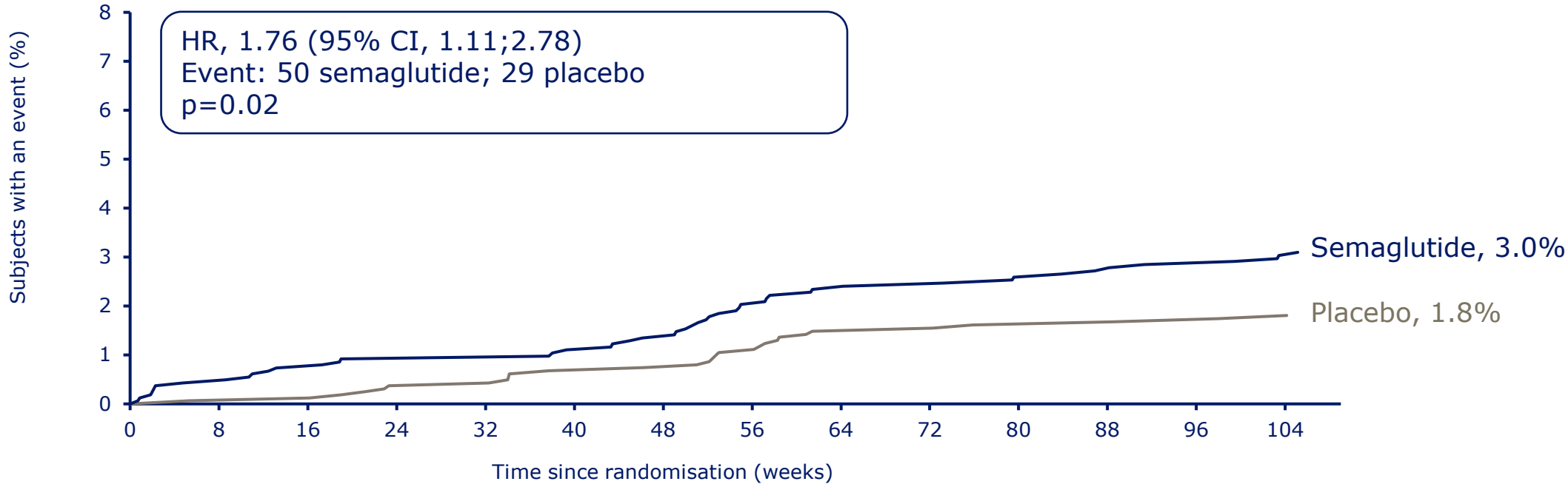
Progression of DR (%)	intensive	vs	standard	OD (95% CI)	p value
1 Glycaemia	7.3		10.4	**0.67** (0.51-0.87)	0.003
2 Fenofibrate	6.5		10.2	**0.60** (0.42-0.87)	0.006
3 Systolic BP	10.4		8.8	1.23 (0.84-1.79)	0.29

ACCORD

Chew et al, ACCORD Eye Study Group *N Engl J Med* 2010; 363: 233-244

SUSTAIN 6: diabetic retinopathy complications

TIME TO FIRST OCCURRENCE OF DIABETIC RETINOPATHY COMPLICATION



Number of subjects at risk

Semaglutide	**1,648**	**1,622**	**1,612**	**1,595**	**1,570**	**1,548**	**1,535**	**1,525**
Placebo	**1,649**	**1,636**	**1,617**	**1,605**	**1,576**	**1,558**	**1,539**	**1,530**

Kaplan–Meier plot for time from randomisation to first EAC-confirmed diabetic retinopathy complication using 'in-trial' data from subjects in the full analysis set. HR is from a proportional hazard model. CI, confidence interval; HR, hazard ratio.

Marso SP et al. *N Engl J Med* 2016;375:1834–44.

SUSTAIN 6: diabetic retinopathy complications

FIRST EVENTS

	Semaglutide N (%)	Placebo N (%)
Diabetic retinopathy complications	50 (3.0)	29 (1.8)
Need for retinal photocoagulation	38 (2.3)	20 (1.2)
Need for treatment with intravitreal agents	16 (1.0)	13 (0.8)
Vitreous haemorrhage	16 (1.0)	7 (0.4)
Onset of diabetes-related blindness*	5 (0.3)	1 (0.1)

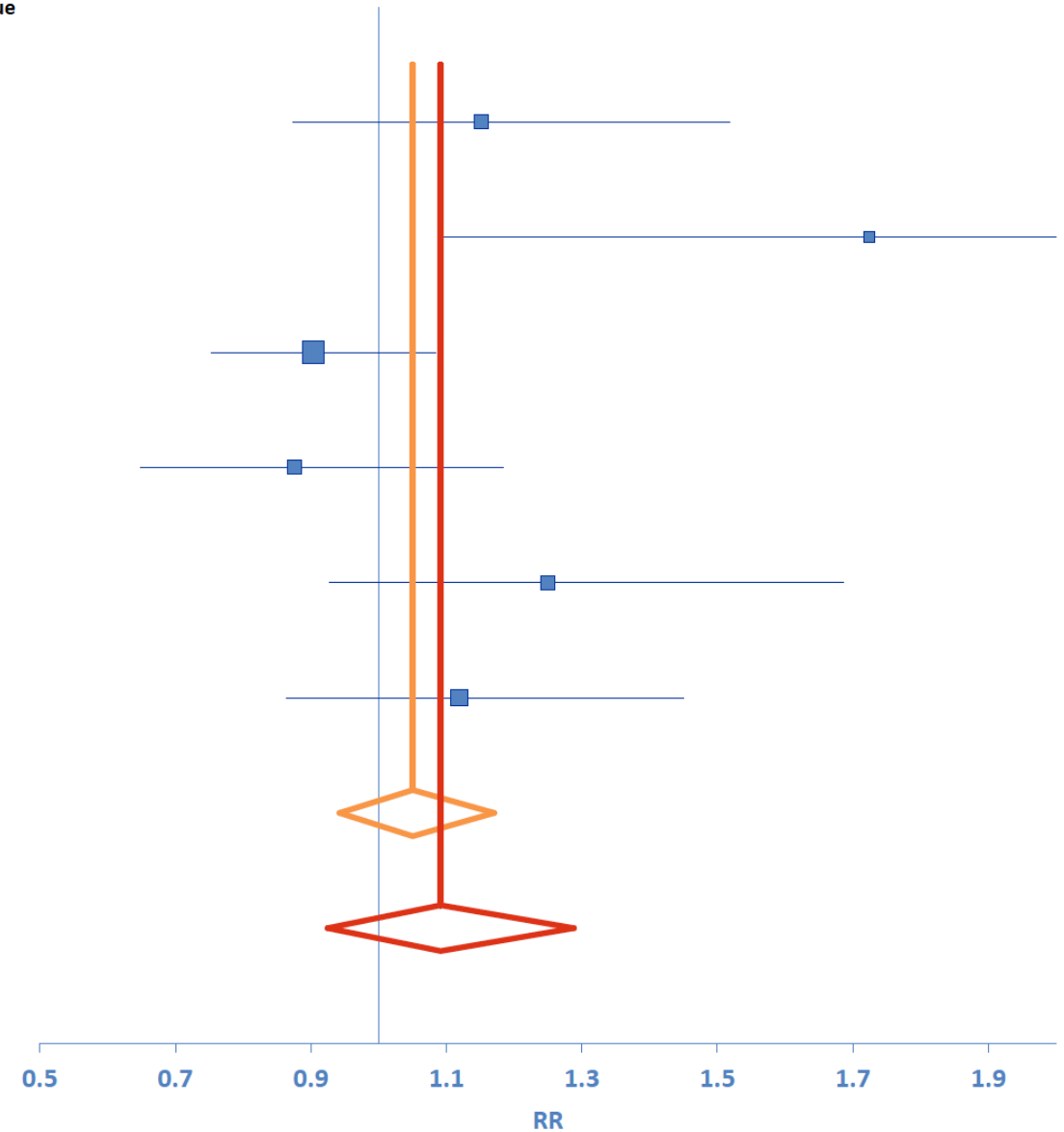
*Defined as Snellen visual acuity of 20/200 (6/60) or less, or visual field of less than 20 degrees, in the better eye with best correction possible. N, number of subjects.

Vilsbøll T et al. *Diabetes Obes Metab* 2017. doi: 10.1111/dom.13172. [Epub ahead of print].

Meta-analysis of retinopathy events in GLP-1RA cardiovascular outcome trials

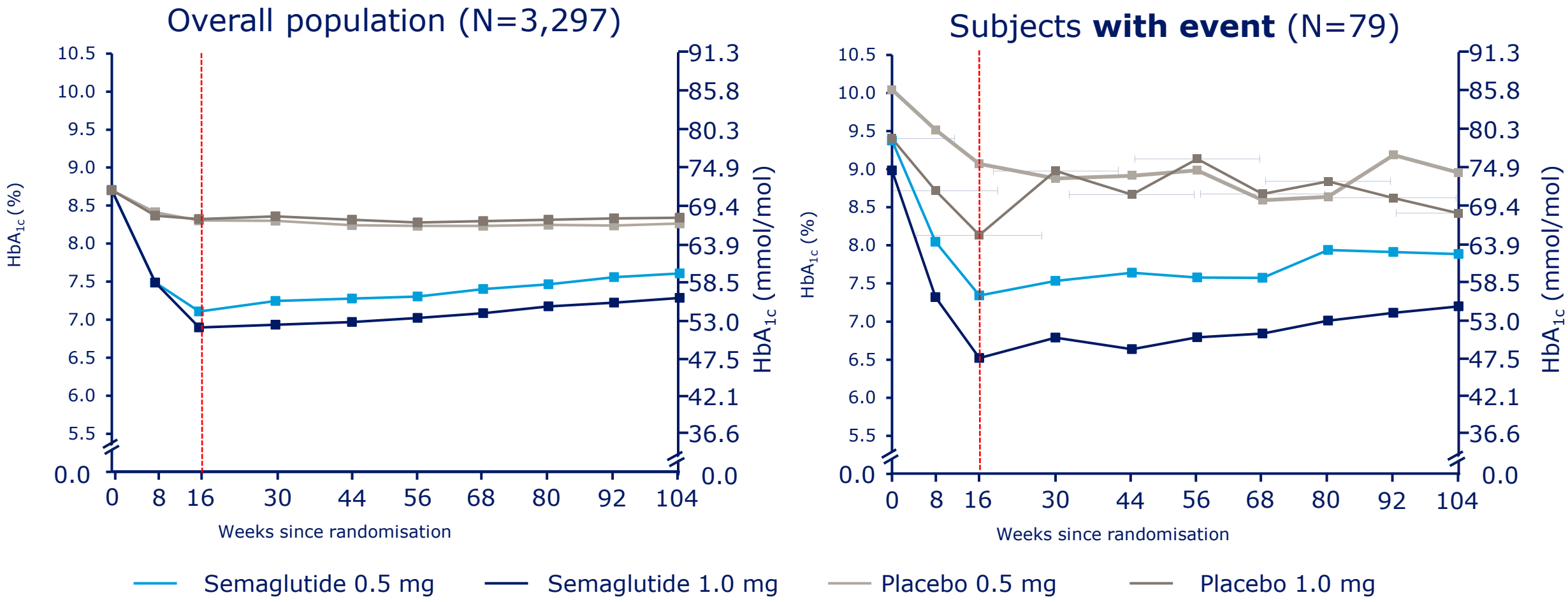
Author	Drug	Measure (CI)	P value
Marsco (LEADER) 2016	liraglutide	1.152 (0.874; 1.519)	0.316
Marsco (SUSTAIN-6) 2016	semaglutide	1.725 (1.097; 2.712)	0.018
Holman (EXCEL) 2017	exenatide	0.904 (0.754; 1.084)	0.277
Hernandez (HARMONY) 2018	albiglutide	0.877 (0.649; 1.185)	0.392
Gerstein (REWIND) 2019	dulaglutide	1.251 (0.927; 1.687)	0.143
Husain (PIONEER 6) 2019	semaglutide (oral)	1.12 (0.864; 1.451)	0.393
Synthesis		**1.092 (0.925; 1.289)**	**0.299**

$rr_{(random\ model)}$ =1.092, 95% CI; 0.925, 1.289, p=0.30
$rr_{(fixed\ model)}$ =1.050, 95% CI; 0.944, 1.170, p=0.36
I^2=53%



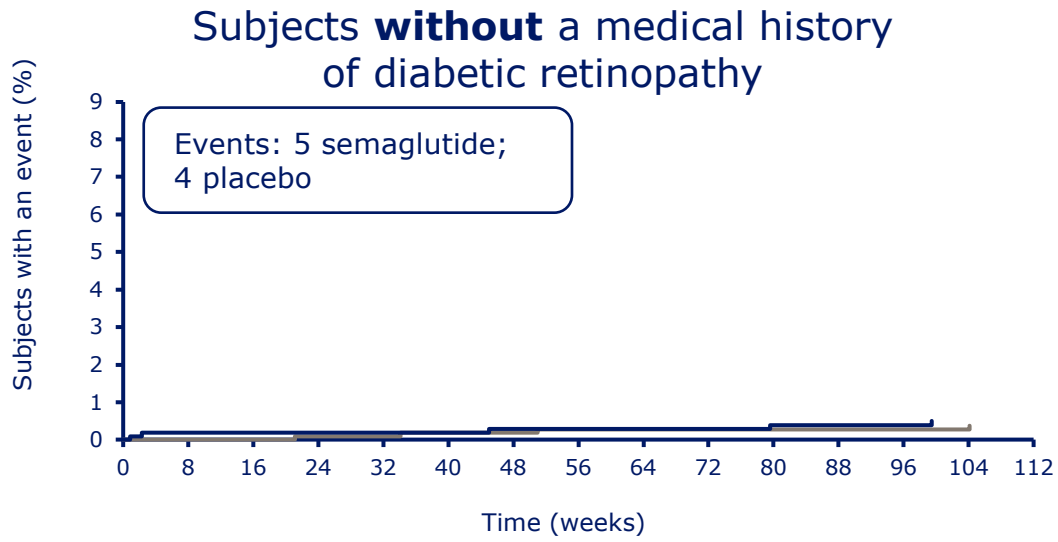
A

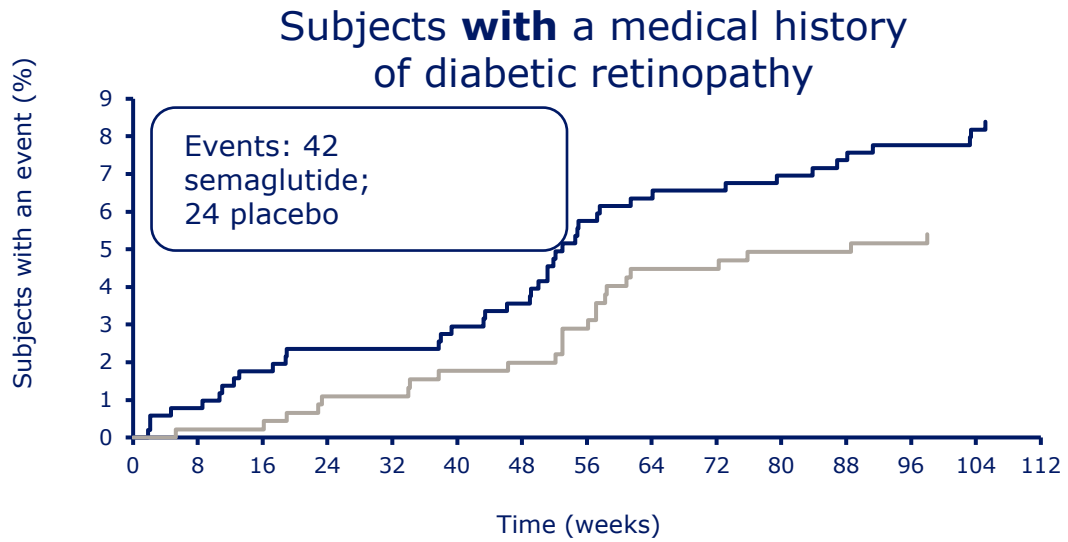
SUSTAIN 6: early HbA_{1c} reduction and diabetic retinopathy complication events



Vilsbøll T et al. *Diabetes Obes Metab* 2017. doi: 10.1111/dom.13172. [Epub ahead of print].

SUSTAIN 6: risk of diabetic retinopathy complications in subjects with medical history of diabetic retinopathy





Number of subjects at risk

Semaglutide	1023	1015	1011	1005	999	985	978	116
Placebo	1089	1083	1073	1071	1058	1045	1035	119

Semaglutide	510	498	492	483	466	460	454	54
Placebo	459	453	445	437	421	417	410	43

Semaglutide — Placebo

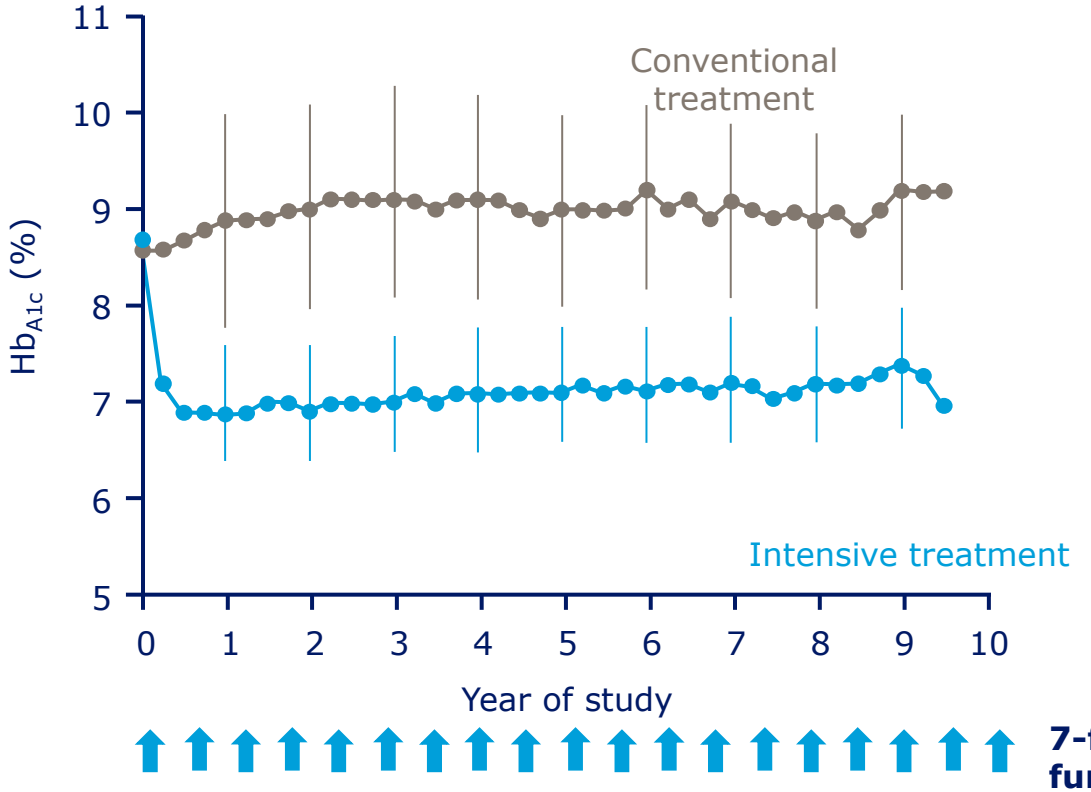
Four subjects' history of diabetic retinopathy was unknown at baseline. CI, confidence interval; HR, hazard ratio.

Vilsbøll T et al. *Diabetes Obes Metab* 2017. doi: 10.1111/dom.13172. [Epub ahead of print].

DCCT: incidence of sustained change in diabetic retinopathy in subjects with type 1 diabetes

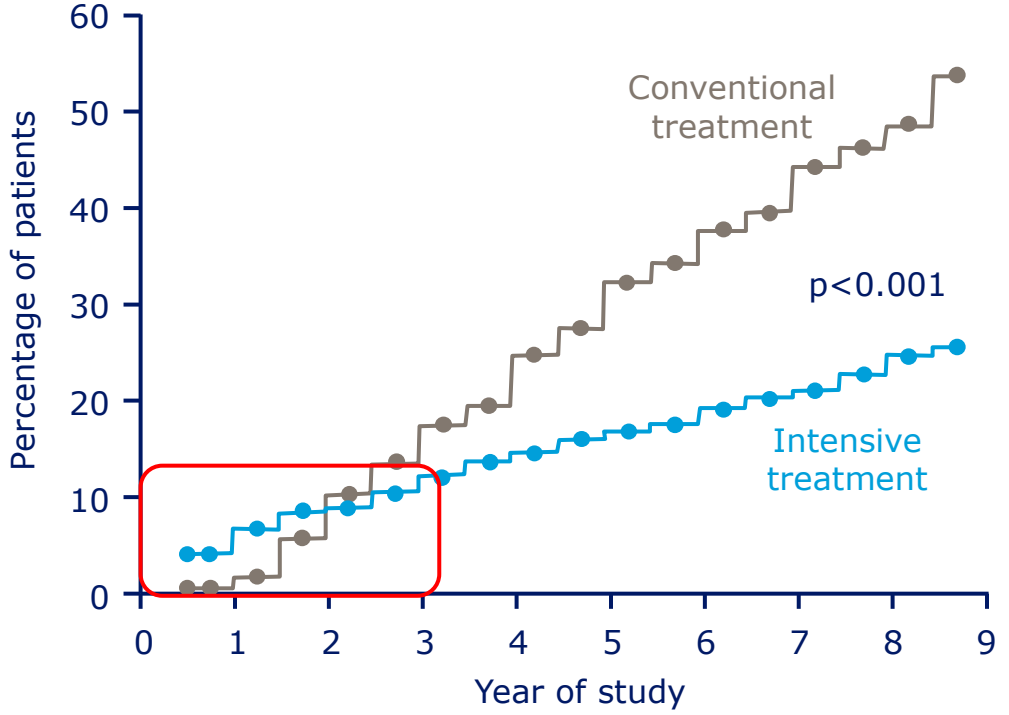
C

Measurements of HbA_{1c} in patients receiving intensive or conventional therapy (entire cohort)



change worsening on the ETDRS scale during ≥6 months

Secondary-prevention cohort – Mild DR at baseline



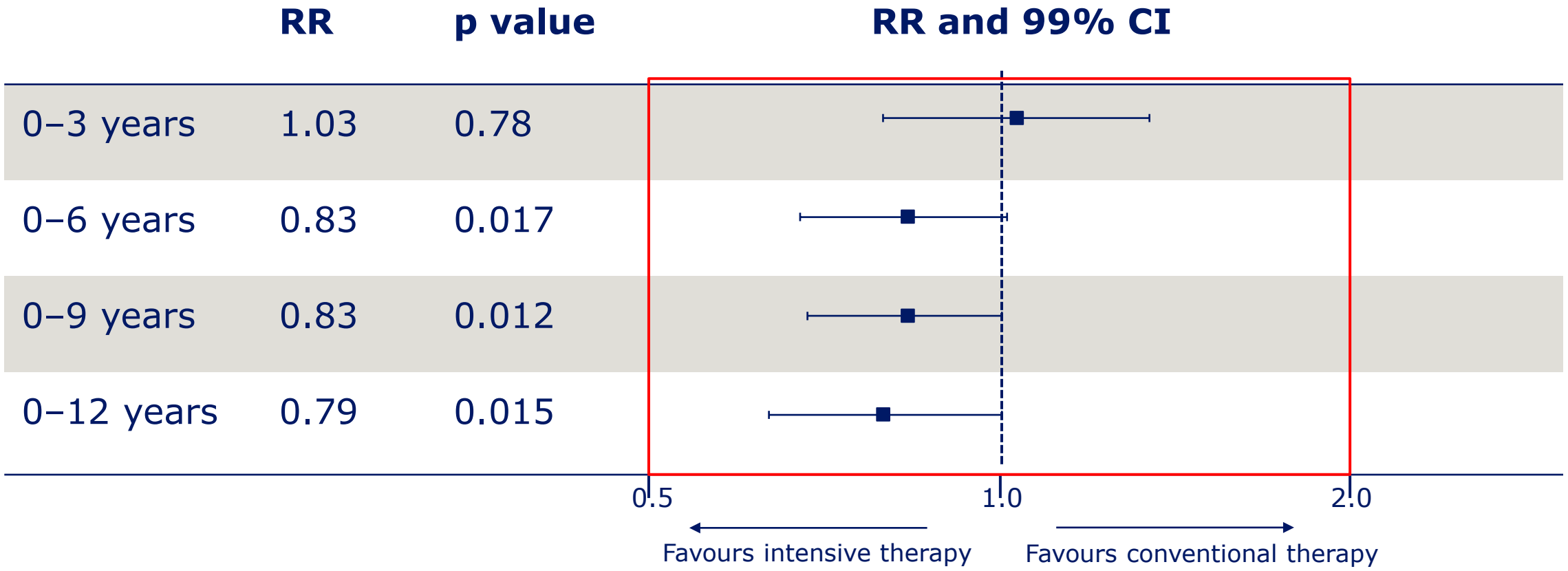
7-field stereoscopic fundus photography

DCCT, Diabetes Control and Complications Trial; DR, diabetic retinopathy; ETDRS, Early Treatment Diabetic Retinopathy Study.

The Diabetes Control and Complications Trial Research Group. *N Engl J Med* 1993;329:977–86.

UKPDS: two-step progression of diabetic retinopathy in subjects with type 2 diabetes

Relative risk of 2-step change on the ETDRS scale in subjects randomised to intensive or conventional glycaemic therapy



CI, confidence interval; ETDRS, Early Treatment Diabetic Retinopathy Study; RR, relative risk; UKPDS, UK Prospective Diabetes Study.
UK Prospective Diabetes Study (UKPDS) Group. *Lancet* 1998;352;837–53.

Metabolic Control and Progression of Retinopathy

The Diabetes in Early Pregnancy Study

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DIABETIC Medicine
DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

Research: Complications

Progression of diabetic retinopathy after bariatric surgery

R. Murphy ✉, Y. Jiang, M. Booth, R. Babor, A. MacCormick, H. Hammodat, G. Beban, R. M. Barnes, A. L. Vincent

First published: 16 February 2015 | https://doi.org/10.1111/dme.12727 | Citations: 35

SMPs for Insulin include information about diabetic retinopathy

NovoRapid® (i.aspart EU label)[1]

- Intensification of insulin therapy with abrupt improvement in glycaemic control may be **associated with temporary worsening of diabetic retinopathy**, while long-term improved glycaemic control decreases the risk of progression of diabetic retinopathy

Similar labels for:

- **Lantus®** (i.glargine)
- **Apidra®** (i.glulisine)
- **Levemir®** (i.detemir)
- **Toujeo®** (i.glargine U-300)
- **Tresiba®** (i.degludec)
- **Ryzodeg®*** (i.aspart/i.degludec)
- **Fiasp®** (i.aspart)
- **Novomix®** (i.aspart)
- **Actrapid®** (i.human)

*Not available in the UK. EU, European Union; i, insulin; UK, United Kingdom.

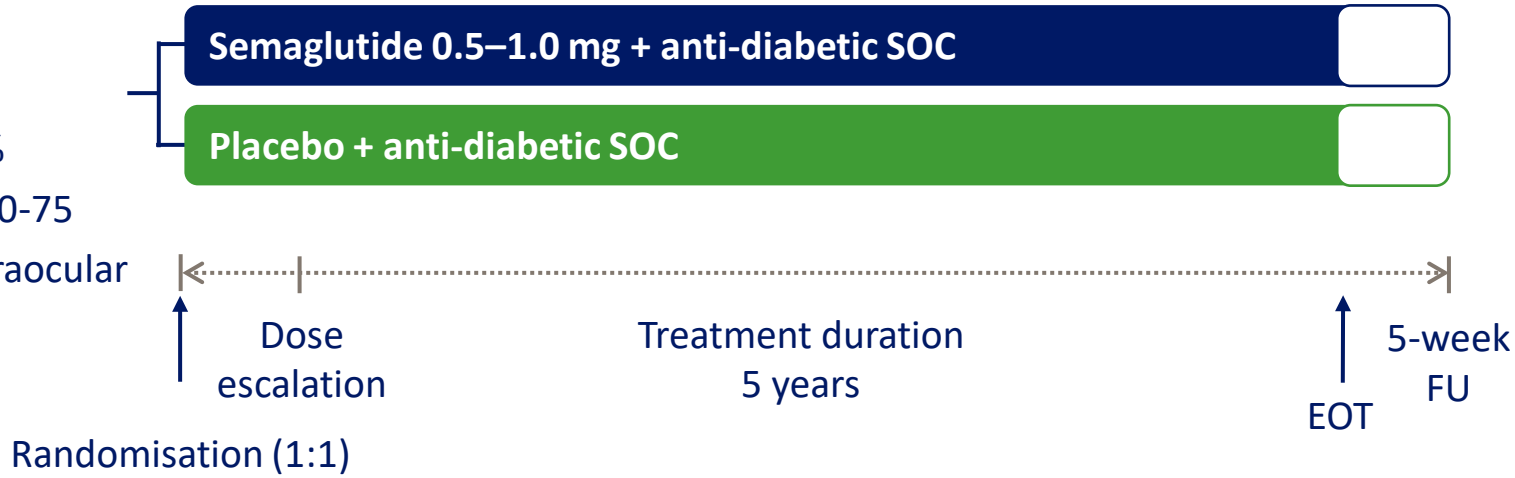
1. NovoRapid SmPC. Novo Nordisk Limited. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000258/WC500030372.pdf. [Accessed February 2018].

FOCUS: Trial design

A 5 year, randomised, double-masked, parallel-group, placebo-controlled trial

1500 participants

- ≥18 years
- T2D ≥10 years
- HbA_{1c} 7.0-10.0%
- ETDRS level of 10-75
- No ocular or intraocular treatment



Trial information

- FPFV 08 May 2019
- Randomised, placebo-controlled double-masked study
- Recruitment: 46 weeks
- Duration: 5 years

Trial objective

- To assess the long-term effects of semaglutide compared with placebo, both added to SOC, with respect to diabetic retinopathy development and progression

Key endpoints

- Primary: Presence of ≥3 steps ETDRS subject level progression at year 5 (yes/no)
- Secondary: Time from randomisation to first ≥3 steps ETDRS subject level progression or ciDME in either eye (month)

ciDME, Central-Involved Diabetic Macular Edema; ETDRS, Early Treatment Diabetic Retinopathy Study; EOT, end of trial; FU, follow-up; FPFV, first person first visit; HbA1c, glycated haemoglobin; SOC, standard-of-care; T2D, type 2 diabetes

NN9535-4352. Novo Nordisk A/S. Data on file

Diabetes ONTHENET.com

Diabetes & Primary Care

At a glance factsheet

GLP-1 receptor agonists and diabetic retinopathy

An unexpected safety signal emerged from the SUSTAIN 6 cardiovascular outcomes trial of the glucagon-like peptide-1 receptor agonist (GLP-1 RA) semaglutide, whereby increased rates of diabetic retinopathy were observed in trial participants randomised to semaglutide. This finding has, justifiably, led to a great deal of investigation and caution. This At a glance factsheet outlines the evidence regarding diabetic retinopathy in users of the GLP-1 RA class as a whole, and provides recommendations on safe use.

Initial safety concern

In the SUSTAIN 6 cardiovascular outcomes trial of semaglutide, diabetic retinopathy endpoints were reported in significantly more individuals randomised to semaglutide than to placebo (50 vs 29 participants; 3.0% vs 1.8%; *P*=0.02).[1]

Take-home recommendations

The author has adopted the following recommendations in Swansea Bay University Health Board for initiation of semaglutide (both injectable and oral), and all other GLP-1 RAs.

Caution is urged in patients with:

- Diabetic retinopathy requiring active ophthalmology follow-up (see Diabetic retinopathy factsheet for more information).
- Poor glycaemic control: HbA_{1c} >91 mmol/mol (10.5%).
- Current insulin treatment.
  - Note: In people without significant retinopathy (e.g. those on an annual review for eye screening), being on insulin or having poor control alone do not imply risk. Conversely, if a patient has gone missing to annual screening (and therefore may have active retinopathy), they should be screened before GLP-1 RA initiation.

Diabetes & Primary Care Vol 23 No 3 2021

Q&A

Diabetic retinopathy

Rebecca L Thomas, Stephen C Bain

Questions by:
Pam Brown, GP, Swansea

Q What is the difference between retinopathy and maculopathy?

"Diabetic retinopathy" describes any changes in the retina which are caused by hyperglycaemia in people with diabetes of any aetiology (and so includes people with both type 1 and type 2 diabetes). These changes include:

- Microaneurysms.
- Dot and blot haemorrhages.
- Hard exudates.
- Cotton wool spots.
- Venous abnormalities.
- New blood vessels (proliferative diabetic retinopathy).

When any of these changes occur within the macular region, it is termed "diabetic maculopathy". The macular region is an area which is arbitrarily defined (i.e. it does not have a true anatomical delineation), usually as a circle

Approximately 3% of those with type 2 diabetes (105 000 people in the UK) would have a sight-threatening form: pre-proliferative or proliferative diabetic retinopathy, or diabetic maculopathy (Thomas et al, 2015). Diabetic maculopathy is more common in people with type 2 diabetes, while proliferative retinopathy is more common in those with type 1 diabetes. The majority of those with type 2 diabetes with sight-threatening retinopathy would have diabetic maculopathy alone or in combination with pre-proliferative and proliferative retinopathy.

Q What is the significance of developing background retinopathy? What is the risk of progression of retinopathy and what are the risk factors?

After 20 years of having diabetes, approximately 80–90% of people with type 1 diabetes, and approximately 50% of people with type 2 diabetes, will have diabetic retinopathy (Yau et al, 2010). The majority of this will be background

Swansea Bay University Health Board recommendations:

Caution is urged in patients with

- Proliferative retinopathy or maculopathy requiring active ophthalmology follow-up
- Poor glycaemic management - HbA1c > 91mmol/mol (10.5%)
- Current insulin treatment

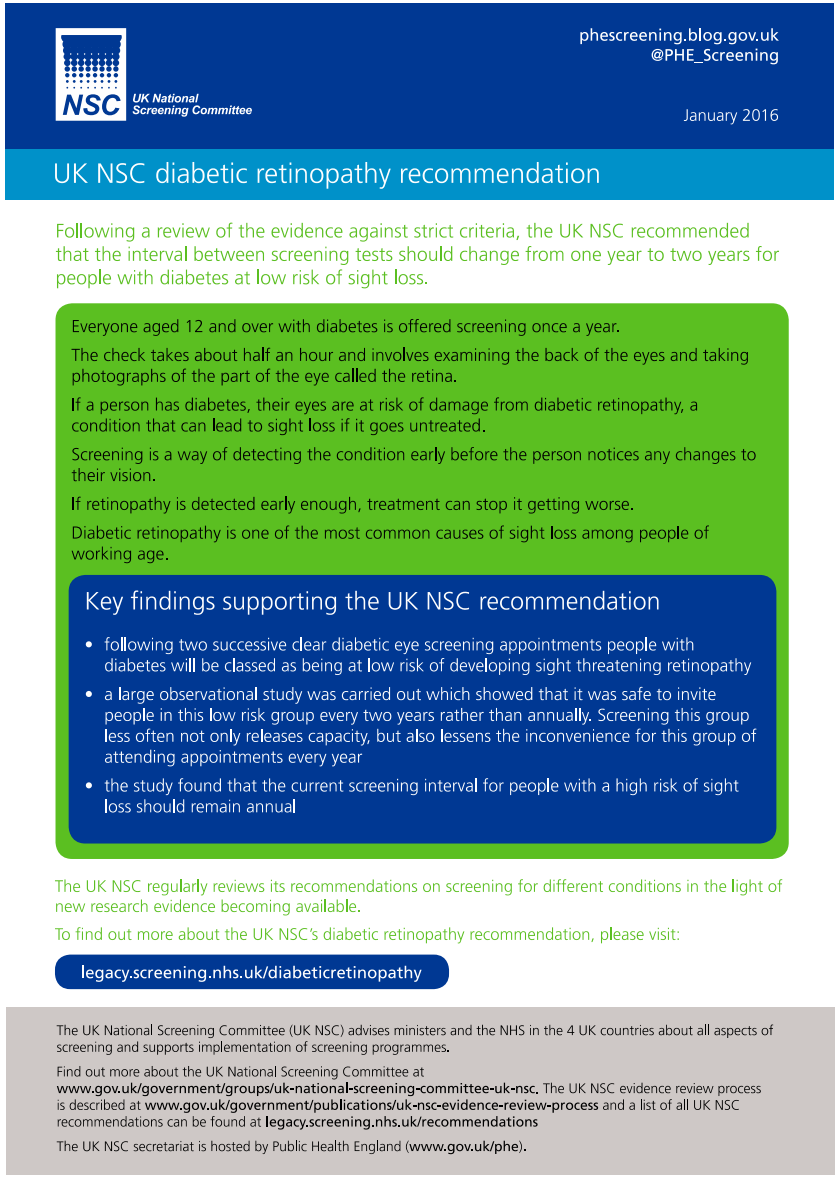
The word ‘caution’ means that the ophthalmology review should be up-to-date with no indication for on-going intervention.

Screening DESW update – Extended screening

- Scotland introduced this in 2021 to help with the backlog caused by covid-19

- England are due to begin pilot sites and role out 2023-2024

- Wales NSC approved the policy July 2022 to be implemented 2023



NSC UK National Screening Committee

phescreening.blog.gov.uk
@PHE_Screening

January 2016

UK NSC diabetic retinopathy recommendation

Following a review of the evidence against strict criteria, the UK NSC recommended that the interval between screening tests should change from one year to two years for people with diabetes at low risk of sight loss.

Everyone aged 12 and over with diabetes is offered screening once a year.

The check takes about half an hour and involves examining the back of the eyes and taking photographs of the part of the eye called the retina.

If a person has diabetes, their eyes are at risk of damage from diabetic retinopathy, a condition that can lead to sight loss if it goes untreated.

Screening is a way of detecting the condition early before the person notices any changes to their vision.

If retinopathy is detected early enough, treatment can stop it getting worse.

Diabetic retinopathy is one of the most common causes of sight loss among people of working age.

Key findings supporting the UK NSC recommendation

- following two successive clear diabetic eye screening appointments people with diabetes will be classed as being at low risk of developing sight threatening retinopathy
- a large observational study was carried out which showed that it was safe to invite people in this low risk group every two years rather than annually. Screening this group less often not only releases capacity, but also lessens the inconvenience for this group of attending appointments every year
- the study found that the current screening interval for people with a high risk of sight loss should remain annual

The UK NSC regularly reviews its recommendations on screening for different conditions in the light of new research evidence becoming available.

To find out more about the UK NSC's diabetic retinopathy recommendation, please visit:

legacy.screening.nhs.uk/diabeticretinopathy

The UK National Screening Committee (UK NSC) advises ministers and the NHS in the 4 UK countries about all aspects of screening and supports implementation of screening programmes.

Find out more about the UK National Screening Committee at www.gov.uk/government/groups/uk-national-screening-committee-uk-nsc. The UK NSC evidence review process is described at www.gov.uk/government/publications/uk-nsc-evidence-review-process and a list of all UK NSC recommendations can be found at legacy.screening.nhs.uk/recommendations

The UK NSC secretariat is hosted by Public Health England (www.gov.uk/phe).

Leese et al 2015 Diabetes Care, Thomas et al 2014 BMJ

Criteria for extended screening (LRRP pathway)

- Two previous outcome grades of R0M0 (no retinopathy, no maculopathy)
- Appointments must be at least 12 months apart
- Appointments will be no further back than 1st April 2019

Two cohorts of participants to be moved onto the new pathway

1) Prior to next appt – approx. 38,000 participants meet the above criteria and will be moved at go live date (19th June 2023)
2) Post next appt – participants who meet this criteria after their next screen from the 19th June onwards

Criteria for extended screening (LRRP pathway)

- If a participant does not attend their eye screening appointment when on the two year pathway, they will automatically be invited again one year later.

- If there are any concerns about a participant's health which may impact on their eye screening (i.e. raised HbA_{1c}), then there is an expedite process which health professionals can access. Each case is then discussed at an MDT meeting, and a participant can be invited in for screening sooner.

Key public messages for extended screening

- From June 2023, DESW will be introducing changes to the screening programme for people with diabetes who are at low risk of diabetic eye disease, based on recommendations from the UK National Screening Committee, with the time period between screenings being extended from one year to two years.
- The changes are based on robust evidence which demonstrates that it is safe for low risk participants to move to a 2 year screening pathway.
- This is not a change to save money, however it will free up appointment capacity so that those at highest risk can be seen in a more timely way.

Key public messages for extended screening

- Only those who meet the criteria for low risk will be affected by the change, all other participants will remain on their current pathway.
- The changes will take place from June 2023 and will involve moving all those participants who are eligible on to the low risk recall pathway at that time.
- Diabetic Eye Screening is important for anyone aged 12 years and over who has diabetes, as it helps to reduce the risk of sight loss looking for a condition that is treatable. Anyone invited to attend a Diabetic Eye Screening appointment is strongly encouraged to attend.

DESW Covid-19 backlog update

- Still operating with a substantial backlog following the pause in 2020 due to covid pandemic
- Currently return to screening from 79 venues (previously operated out of 137 different sites)
- Continuing to fund private venues: scouts hall, community church etc
- Rented a large mobile unit for two months and locating across 4 key geographical areas to address longest waiting participants. Currently bidding for more funding to repeat this.

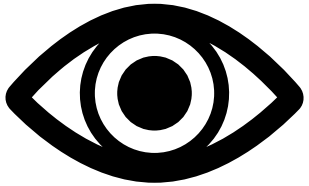
DESW Covid-19 backlog update

- Have reached 97% of pre-Covid clinic appt capacity across all Wales
- Averaging 3220 clinic appointments per week
- Six of the seven health boards in Wales have returned to at least 92% of pre-covid levels, capacity remains lowest in Aneurin Bevan UHB (only 61% appts returned)
- New registration rate is continuing to show increases from pre–covid levels, average 1,240 referrals a month over the year (112% of pre-Covid rates)
- Approximately 192,100 registered participants eligible for screening
- Currently 82,000 participants are due or overdue eye screening

DESW update

- Undertaking a programme of work with external partners to digitise referrals into DESW and possible future options for online booking for participants

Summary



- ‘A single microaneurysm is not an innocent finding.’ Prof Eva Kohner
- Glycaemic, blood pressure and lipid management is vitally important at all stages of diabetic retinopathy
- If sight-threatening retinopathy develops there are treatment options available but these have better results and less impact on vision if used early before visual symptoms occur.
- Lots of new therapies for sight-threatening retinopathy are being developed and whether they can be used earlier in the disease