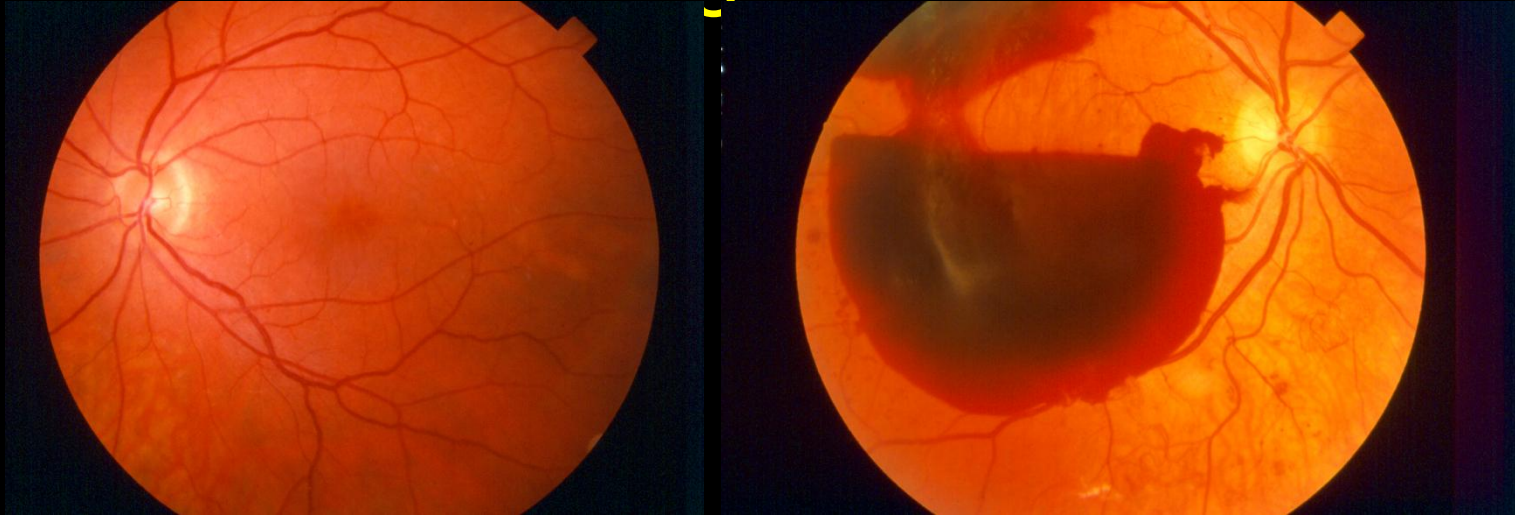


National Diabetic Retinopathy Screening and Treatment Programme



2nd NATIONAL CLINICAL PROGRAMME FOR DIABETES CONFERENCE
Croí Heart and Stroke Centre Galway, 13TH November 2015

David Keegan

National Clinical Director

The National Diabetic Retinal Screening Programme

Acknowledgements

Colette Murphy: Programme Manager

Majella Byrne: National Screening Service Manager

Alan Smith: National Screening Service Clinical Lead

Simon Murtagh: National Screening Service Finance Manager

Pat Cafferty: ex Programme Manager

Margaret Morgan: ex Clinical Lead

Robert Acheson: Clinical Lead Medical Imaging

Mark Cahill: Clinical Lead Global Vision

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Leahna Kelly

Lisa Heffernan

Gillian: IT Lead

Diarmuid Smith: ex Diabetes Clinical Lead

Ronan Canavan: Diabetes Clinical Lead

Paul Dodson: UK

Peter Scanlon: UK

Robert Johnson: UK

David Greene: Health Economist

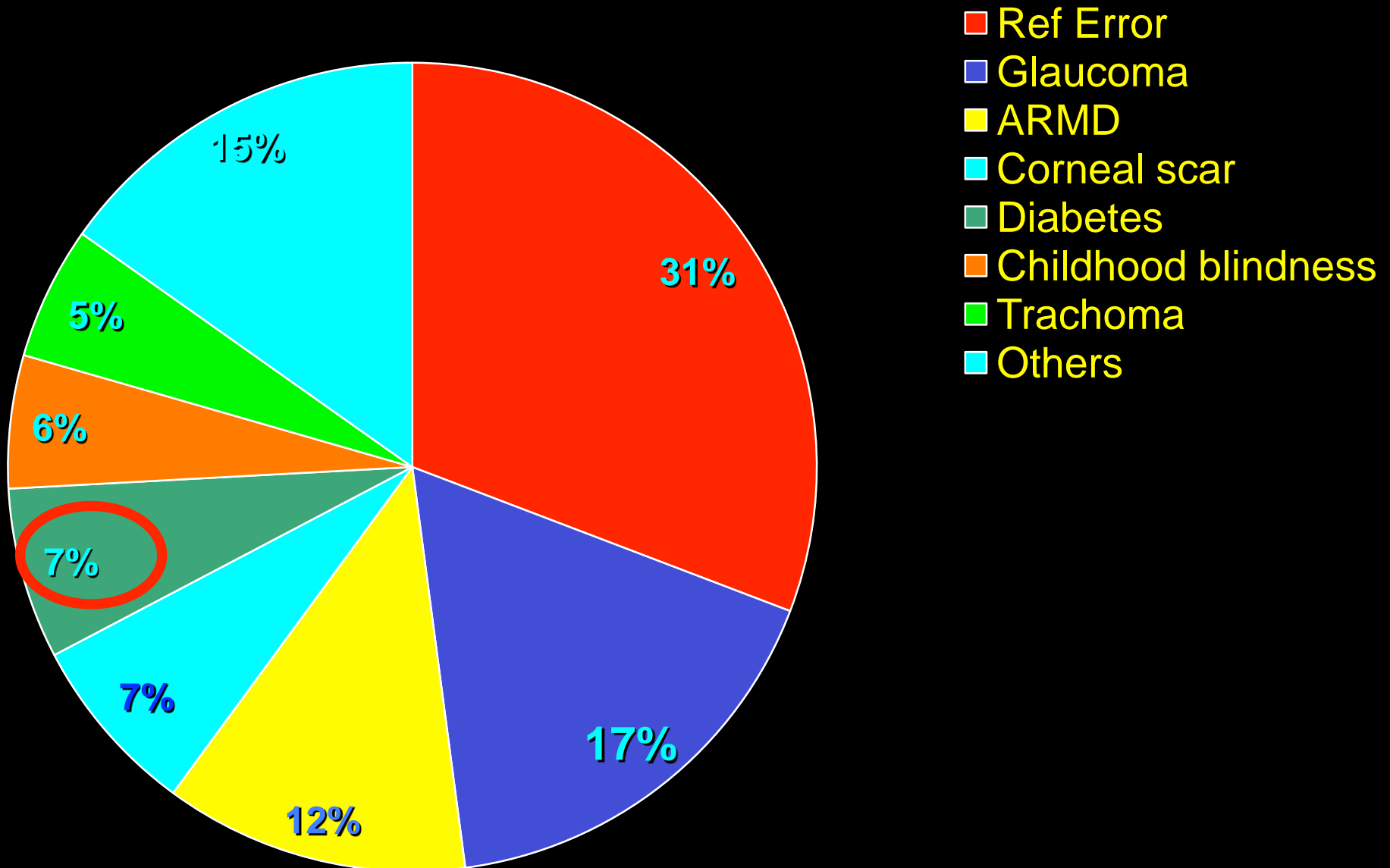
Global Vision Team

Medical Imaging Team

Call Centre Team

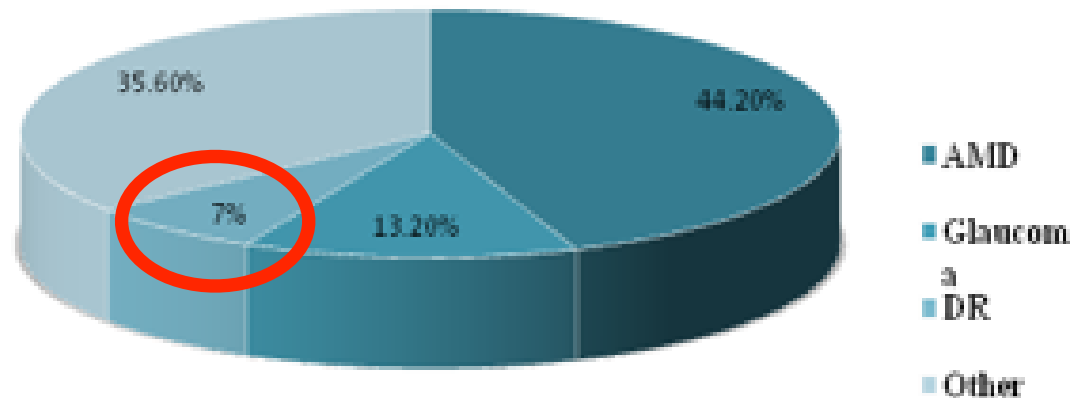


Causes of global blindness



Causes of Blindness in Ireland

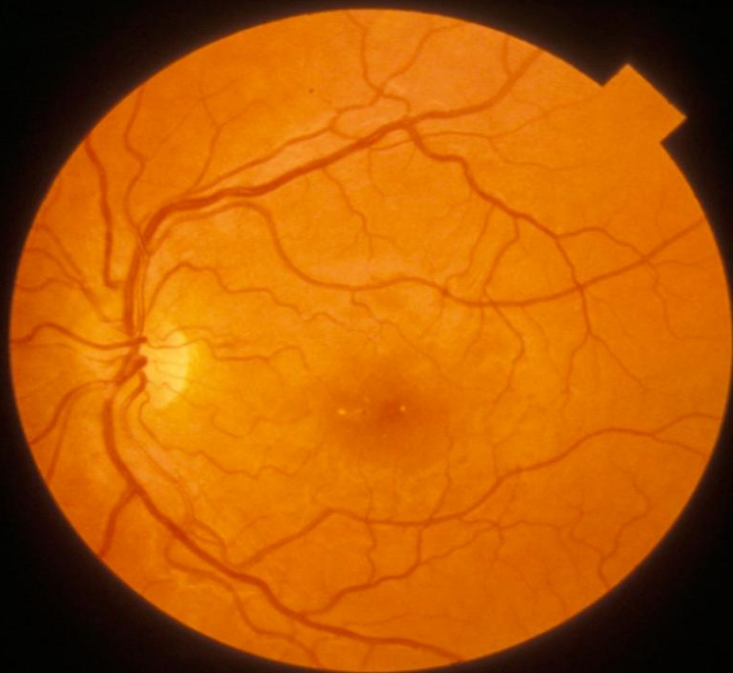
Incidence of blindness among Irish adults on the Irish Register 2003



WESDR/DRS Terminology

Maculopathy

Non Clinically Significant Macular Edema (non CSME)
Clinically Significant (CSME)



WESDR/DRS Terminology

Retinopathy

None

Non Proliferative

Mild

Moderate

Severe

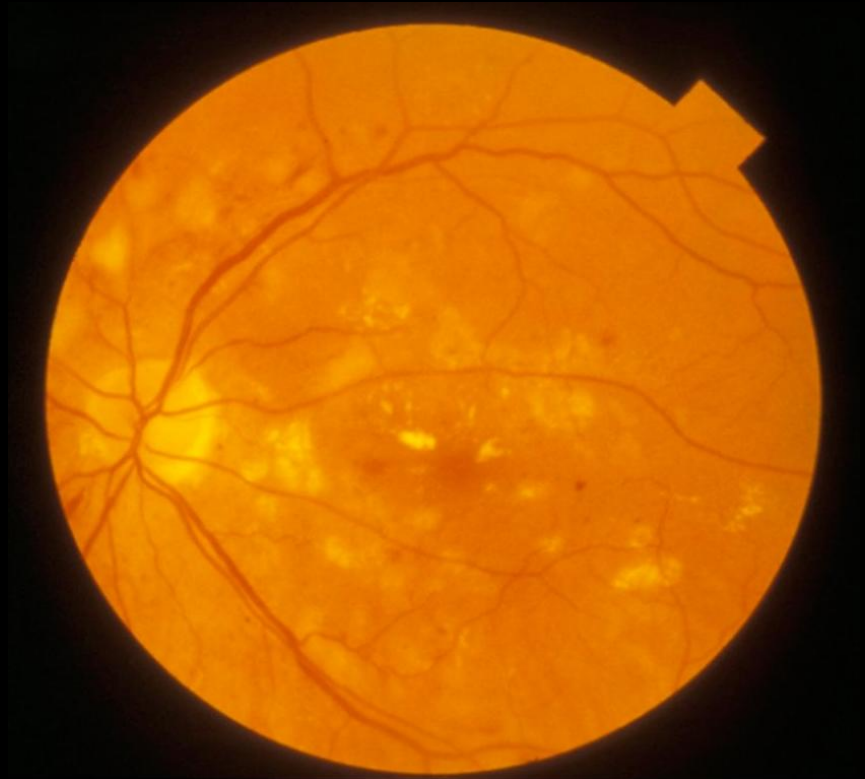
Very Severe

Proliferative

Proliferative

Low Risk

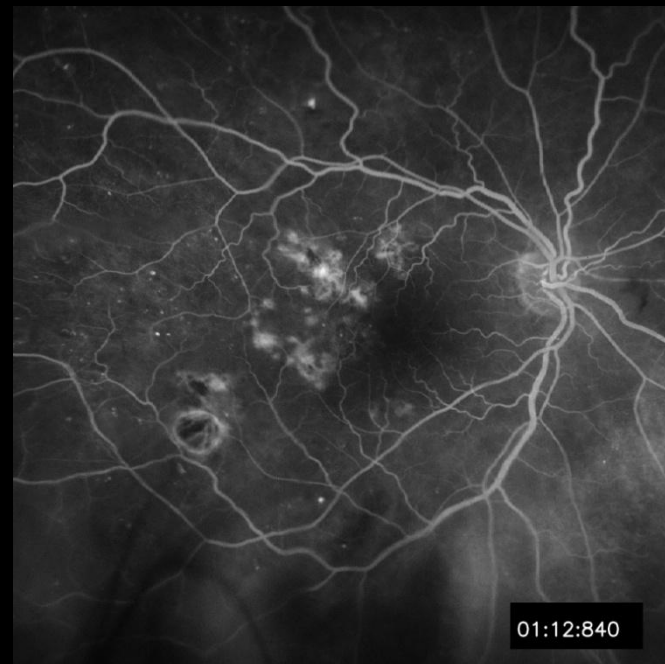
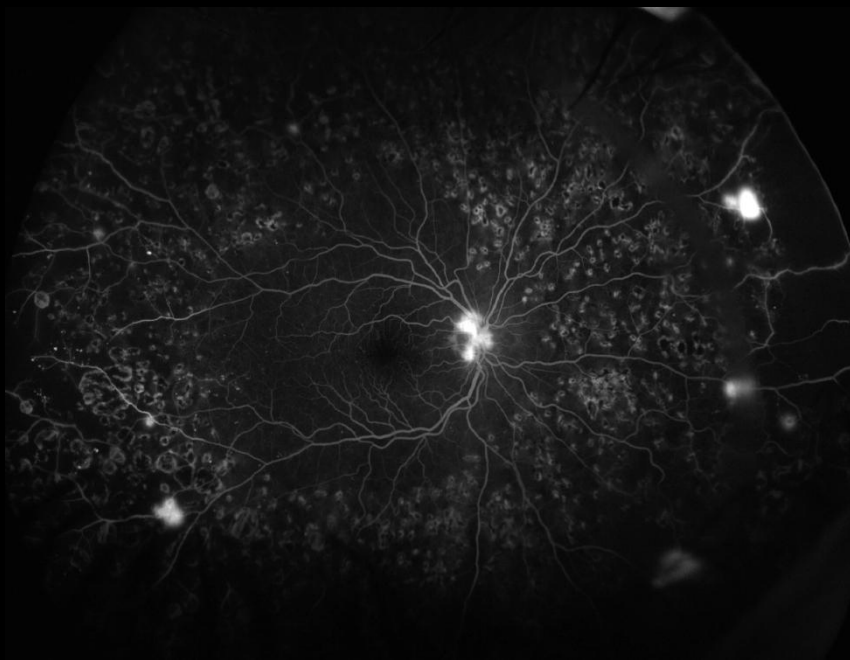
High Risk



ETDRS Overview

Established standards for treatment of
maculopathy and retinopathy

Laser was the gold standard



WESDR Overview

Risk of development of DR and Progression

Duration of Diabetes

Control of Diabetes

Associated raised BP

Ethnicity

Pregnancy

Puberty

Cataract Surgery

Challenges since ETDRS

Global growth of diabetes (to 380 million by 2025)

Epidemic proportions

Incorporation of New Technology

- Imaging

- Monitoring

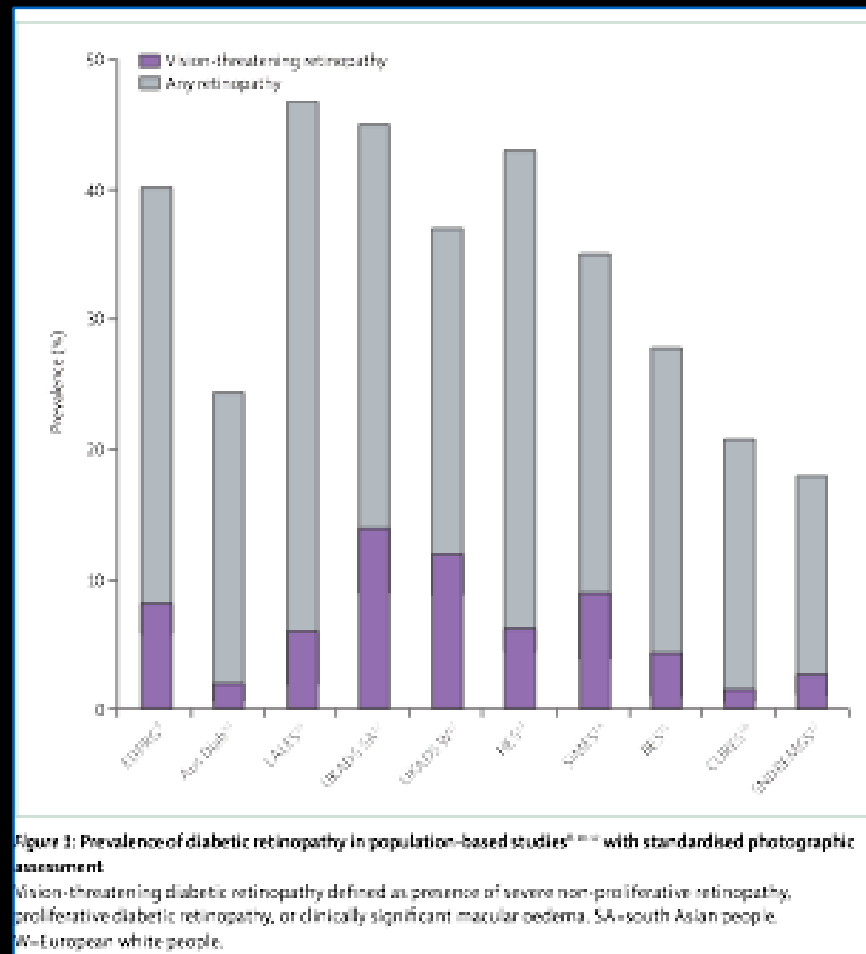
Incorporation of New Treatments

- Diabetic care

- Lasers

- Injectable

Overview of Epidemiology Studies



Delivery of DR Care in Future

Conventional approach to surveillance has been a failure in population terms (about 50% in US)

And US has a lot of ophthalmologists
(~1:20,000)

Individual access is good

Need different models

Lack of Awareness in Diabetic patients

US, Australia, UK, Malay, Ireland

Current Challenge

“Deliver highly effective evidenced based diabetes eye care to every patient at virtually any location by sustainable cost-effective means”

PaoloDaSilva, Joslin Diabetes Centre, AAO 2014

Screening

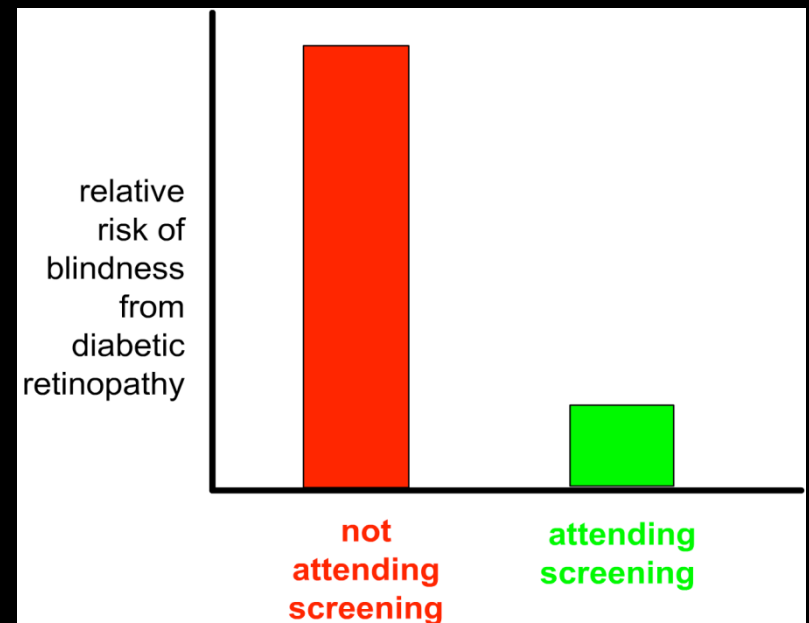
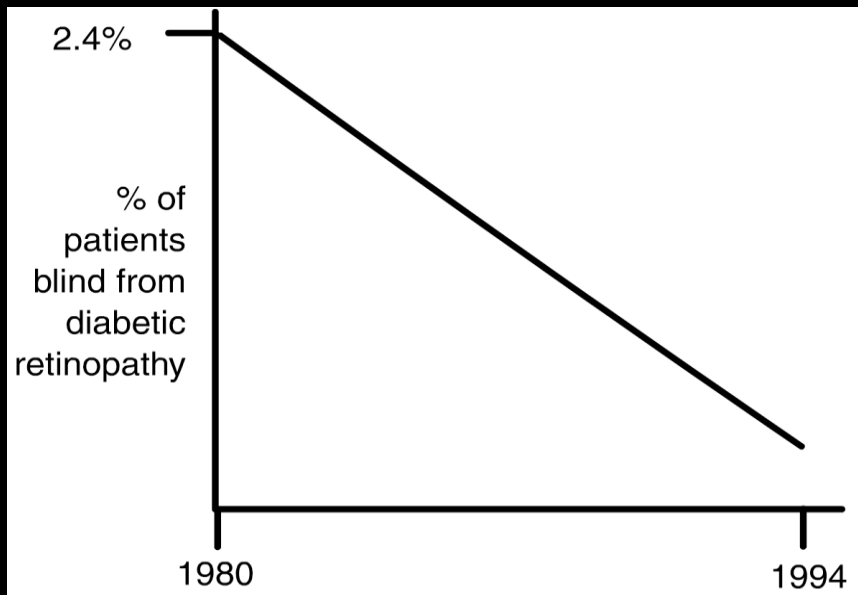
- The role of screening is to pick up pre-clinical (pre-sight threatening) disease and implement appropriate therapy.
- Screening can be performed by
 - ophthalmologists
 - endocrinologists
 - general physicians
 - GPs
 - optometrists
 - ophthalmic nurses or
 - photographic technicians (using a reading centre)..

Criteria

Box 1. Wilson and Jungner classic screening criteria¹

1. The condition sought should be an important health problem.
2. There should be an accepted treatment for patients with recognized disease.
3. Facilities for diagnosis and treatment should be available.
4. There should be a recognizable latent or early symptomatic stage.
5. There should be a suitable test or examination.
6. The test should be acceptable to the population.
7. The natural history of the condition, including development from latent to declared disease, should be adequately understood.
8. There should be an agreed policy on whom to treat as patients.
9. The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
10. Case-finding should be a continuing process and not a "once and for all" project.

Iceland Experience



Diabetes in Ireland: The Numbers: 2013

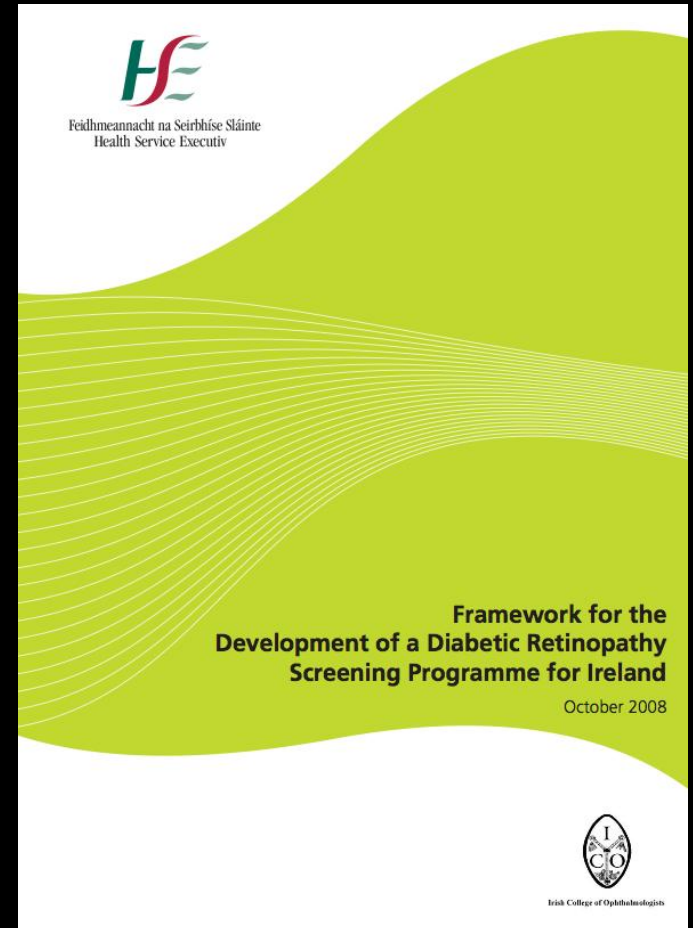
Population (Census 2011) 4.58 Million

191,000 Diabetics estimated to be in Ireland (DFI)

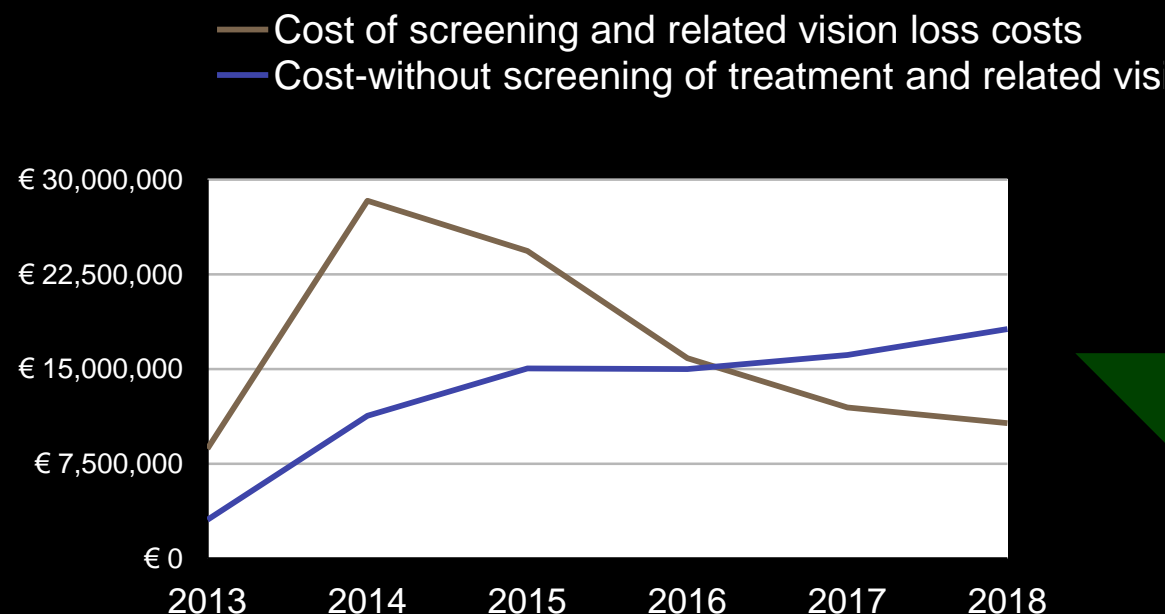
38,200 - 47,750 referrals to hospital services

5,000 - 5,700 cases of DME

3,000 - 3,820 cases of treatable retinopathy



Cost and benefits of the DR Care Programme



- Estimates are based on a 100% uptake of screening
- The current uptake in screening is under 60%
- There are currently 3,000 invitations for screening being sent per week.
- There are currently 7 designated treatment centres around the country

*The DR Care Programme is fully funded for screening and treatment nationally

	2013	2014	2015	2016	2017	2018	Total
Cost of screening and related vision loss costs	€ 8,683,371	€ 28,317,211	€ 24,338,440	€ 15,858,639	€ 11,962,585	€ 10,710,221	€ 99,870,466
Cost-without screening of treatment and related vision loss costs	€ 3,076,261	€ 11,300,734	€ 15,038,494	€ 15,008,062	€ 16,101,561	€ 18,173,224	€ 78,698,336
Incremental Cost/Savings	€ 5,607,110	€ 17,016,477	€ 9,299,946	€ 850,576	€ 4,138,976	€ 7,463,003	€ 21,172,130
Cases of blindness avoided	21	43	43	43	43	43	235
Cases of Moderate VI avoided	63	126	126	126	126	126	695
Cases of Mild VI avoided	169	338	338	338	338	338	1857

In Ireland

We estimate that 235 cases of blindness due to diabetes could potentially be avoided with the introduction of the screening programme and availability of treatment

We estimate that we will avoid ~2,500 cases of Vision impairment

The estimated economic cost of blindness of €62,270 per annum per individual

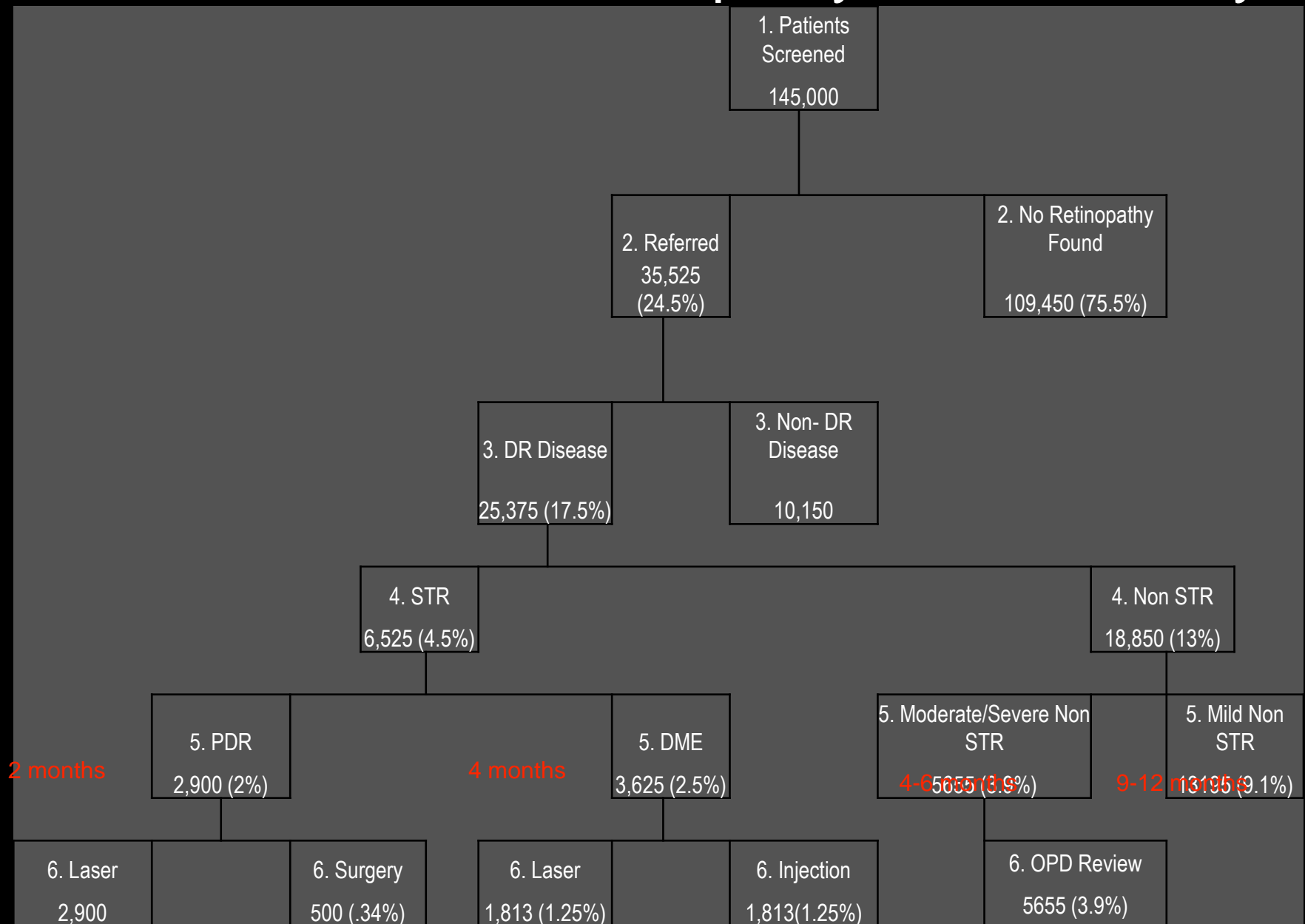
Net cost of approx €5 million over 4.5 years when the economic cost of blindness and visual impairment is taken into account

If you factor in likely impact on Vision Impairment cohort (197,000). Financial cost saving ($€1,717 \times (2,500) =$ €4.3 million over 4.5 years

Thus a NET cost of €155 per patient on Register over 4.5 years

Future projections anticipate a trend change towards a net saving after the initial cost of establishing the screening programme

National Diabetic Retinopathy Care Pathway



Impact Of Screening Programme on Treatment Caseload

Patients beginning treatment due to Screening	2014
PDR Laser ¹	1909
PDR Surgery ²	329
DME Laser ³	1197
DME injection ⁴	751
Total Number of Patients beginning Treatment	4186
Moderate to Severe Non- STR- OPD visits only-No treatment ⁵	3723

Review/OPD visits	
PDR Laser ¹	5148
PDR Surgery ²	2214
DME Laser ³	2151
DME injection ⁴	11309
Moderate to Severe Non- STR ⁵	9020
Total Number of review/OPD visits	29841

National Cancer Screening Service

- **BreastCheck – February 2000 (50-64 yrs)**
- **CervicalCheck - September 2008 (25-60 yrs)**
- **BowelScreen – November 2012 (55-74 yrs)**
- **Diabetic RetinaScreen – February 2013 (12+)**

The National Diabetic Retinal Screening Programme

- The aim of the programme is to reduce the risk of sight loss amongst people with diabetes by early detection and treatment of sight-threatening retinopathy
- Population-based, call-recall programme delivered on an annual basis
- Screening will be offered to people with diagnosed diabetes, aged 12 years and over, registered with the programme
- The programme will aim to reach a growing eligible population of an estimated 190,000+ people This is based upon 5.6% of the population having diabetes

Quality Standards

Standards for Quality Assurance in Diabetic Retinopathy Screening

First edition

Objective 5:

To maximise performance of screening test: To ensure grading is accurate

Standard	Criteria	Minimum	Achievable
1	Every registered grader to participate in ongoing training.	80% of grading staff are compliant	100% of grading staff are compliant
2	Evidence of clinical lead (or nominated senior grader) providing outcomes of the ongoing training to grading staff on a regular basis.	Completed 6-monthly	Completed 6-monthly
3	Second full disease grading for images with diabetic retinopathy or other non-diabetic eye disease outcome on first grading.	100%	100%
4	Normal images with no diabetic retinopathy which are re-graded independently as part of quality assurance.	10% of normal images re-graded	10% of normal images re-graded
5	Arbitration grading of all image sets where there is disagreement as to the grade between the first full disease grading and the second full disease grading.	100%	100%
6	Referral outcome grading of all image sets that are deemed referable to ophthalmology clinic.	100%	100%

KPI-5(1) Numerator = number of registered graders participating in ongoing training in a defined period.
Denominator = total number of graders registered.

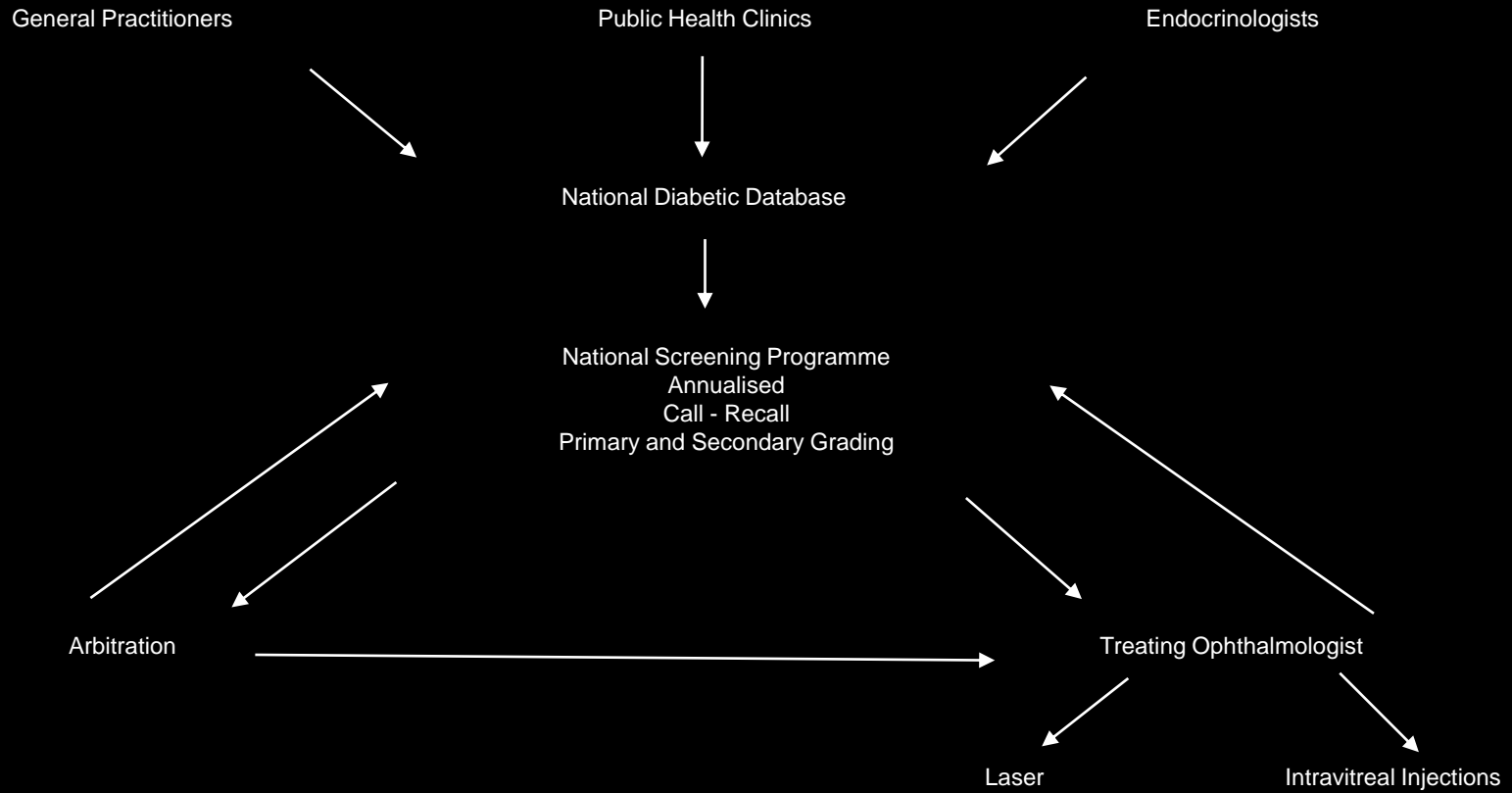
KPI-5(3) Numerator = number of image sets with diabetic retinopathy or non-diabetic eye disease in a time period where second full disease grading took place.
Denominator = total number of image sets with diabetic retinopathy or non-diabetic eye disease at first full disease grading in the same time period.

KPI-5(4) Numerator = number of images sets with no diabetic retinopathy after first full disease grading in a time period that are re-graded.
Denominator = total number of image sets with no diabetic retinopathy after first full disease grading in the same time period.

KPI-5(5) Numerator = number of image sets where arbitration grading was carried out in a time period.
Denominator = total number of images that required arbitration grading in the same time period.

KPI-5(6) Numerator = number of image sets where referral outcome grading was carried out in a time period.
Denominator = total number of image sets that are deemed referable to ophthalmology clinic following first full disease, second full disease or arbitration grading in the same time period.

Care Pathway





Diabetic Retinopathy Screening in Ireland

Diabetic RetinaScreen offers regular eye screening to people with diagnosed diabetes, aged 12 years and over, who are registered with the programme.

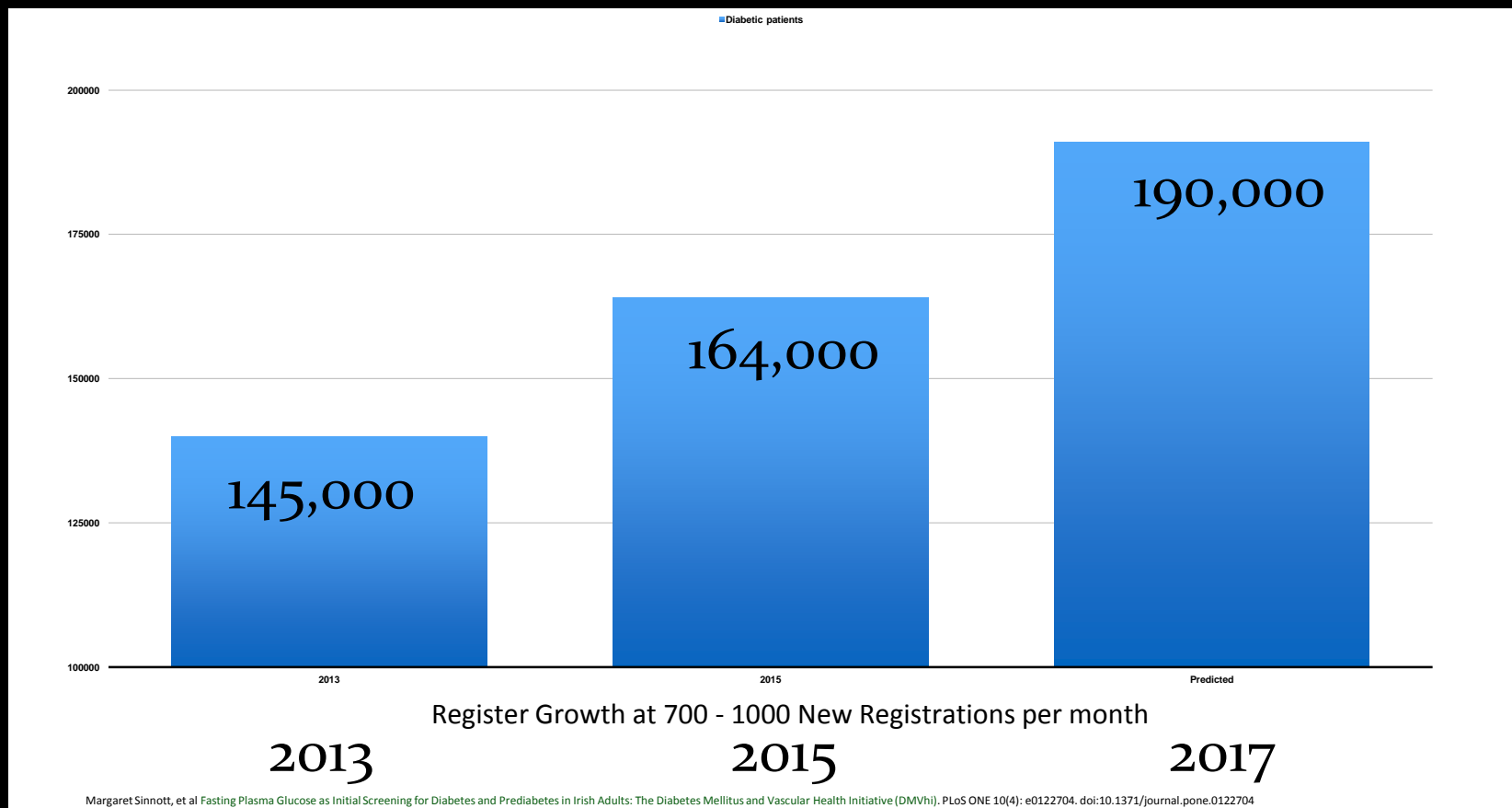
- [How can I check I am on the register?](#)
- [About diabetic retinopathy screening](#)
- [Who can take part?](#)
- [How do I take part?](#)
- [About the screening appointment](#)
- [Tips for your appointment](#)
- [Results](#)
- [I received a letter from Diabetic RetinaScreen, where did you get my details?](#)
- [Accessibility](#)

How can I check I am on the register?

You can check if you are on the register (list) by ringing Freephone 1800 45 45 55 (choose



Patient Register



Digital Healthcare

OptiMize

Search

Pre-screen

Photograph

Review

Grade

Update

Diabetes info


Drop in


Cancel

Details

View

Available grading

 Refresh grading queues

 Grade a specific patient

Arbitration

[3] High	[27] Medium	[0] Low
----------	-------------	---------


Ophthalmology Gatekeeper


[0] High	[4] Medium	[4] Low
----------	------------	---------


Slit lamp


[0] High	[1] Medium	[7] Low
----------	------------	---------

Clinical tasks


 Patient update

 Review patients


 Alert centre

 Alerts

0


 Warnings

0


 Information

0

Reporting tasks

 Advanced reports

System maintenance

 Resave images

System tasks

 Exit the application

 Log off

Maculopathy

M0 (no maculopathy)

No Maculopathy

M1 (maculopathy)



available

Retinopathy

R0 (no retinopathy)

No diabetic retinopathy

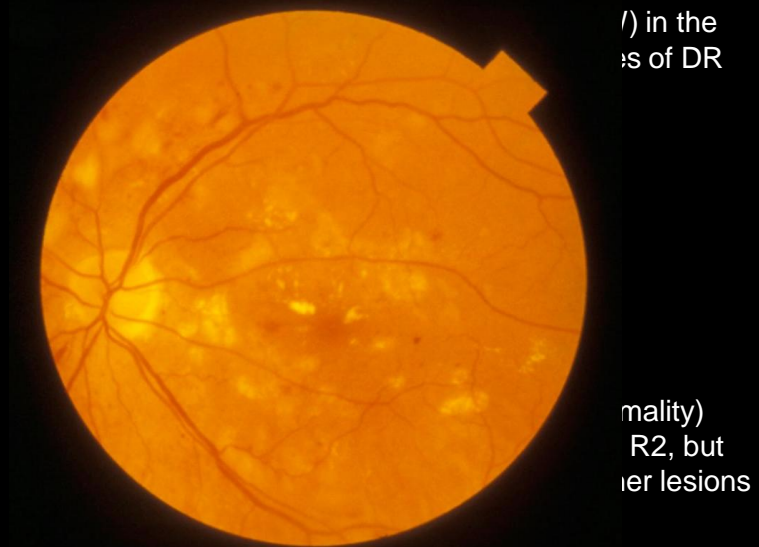
R1 (background retinopathy)

Background diabetic retinopathy (BDR)

The presence of at least one of any of the following features anywhere:

- ☐ Microaneurysms or HMa (a term used when it is difficult to tell the difference between a microaneurysm and a dot haemorrhage)
- ☐ Retinal haemorrhages
- ☐ Any exudate in the presence of other features of DR

R2 (pre-proliferative retinopathy)





Right

Left

Visual acuity

6/9 (no cor. prescribed)

6/9 (no cor. prescribed)

Image quality

Adequate

Adequate

Retinopathy grade

R2 Proliferative retinopathy

R2 Proliferative retinopathy

Advanced eye disease

No advanced eye disease

No advanced eye disease

Photocoagulation

P0

P0

Maculopathy grade

M0 No maculopathy

M1 Maculopathy

Eye conditions

▼ Comments [1]

▲ Letter notes

Outcome

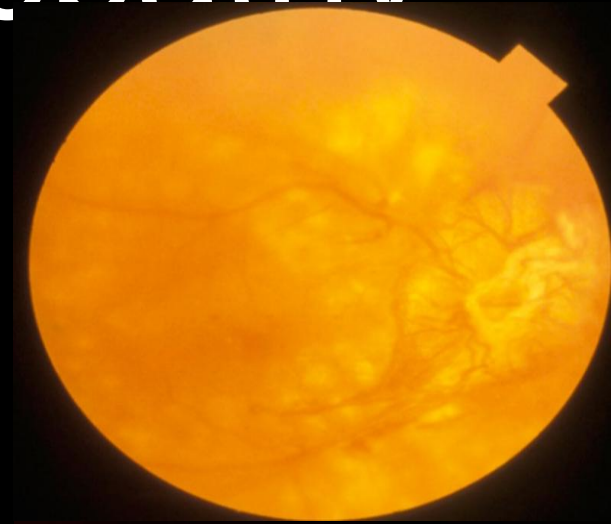
Refer to secondary grading (urgent)

Proliferative Retinopathy

R3 (Proliferative retinopathy):

R3a (Active Proliferative Retinopathy)

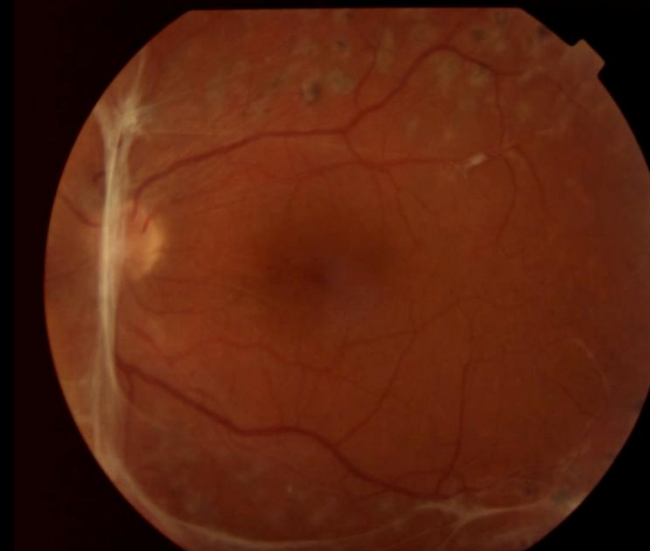
R3s (Stable Post Treatment)



following

age

eye



re

t or

retinal

laser

d

ser

ng) +

Photocoagulation

P0 (no photocoagulation)

Photocoagulation

No evidence of previous
photocoagulation (default)

P1 (photocoagulation evident)

U (Ungradeable)



Grading

If Primary and Secondary Graders Agree: **Final Grade**

If Primary and Secondary Graders Disagree, and one or both images are a referral grade (R2/R3/M1), then in most cases **Arbitration** grade is final grade

Gatekeeper: Urgent or routine referral to Hospital Eye Dept, referral for biomicroscopy at slit lamp clinic

(Future referral to **digital imaging** surveillance clinic)

Arbitration/Gatekeeper Grading

TRIAGING AT ARBITRATION GRADING

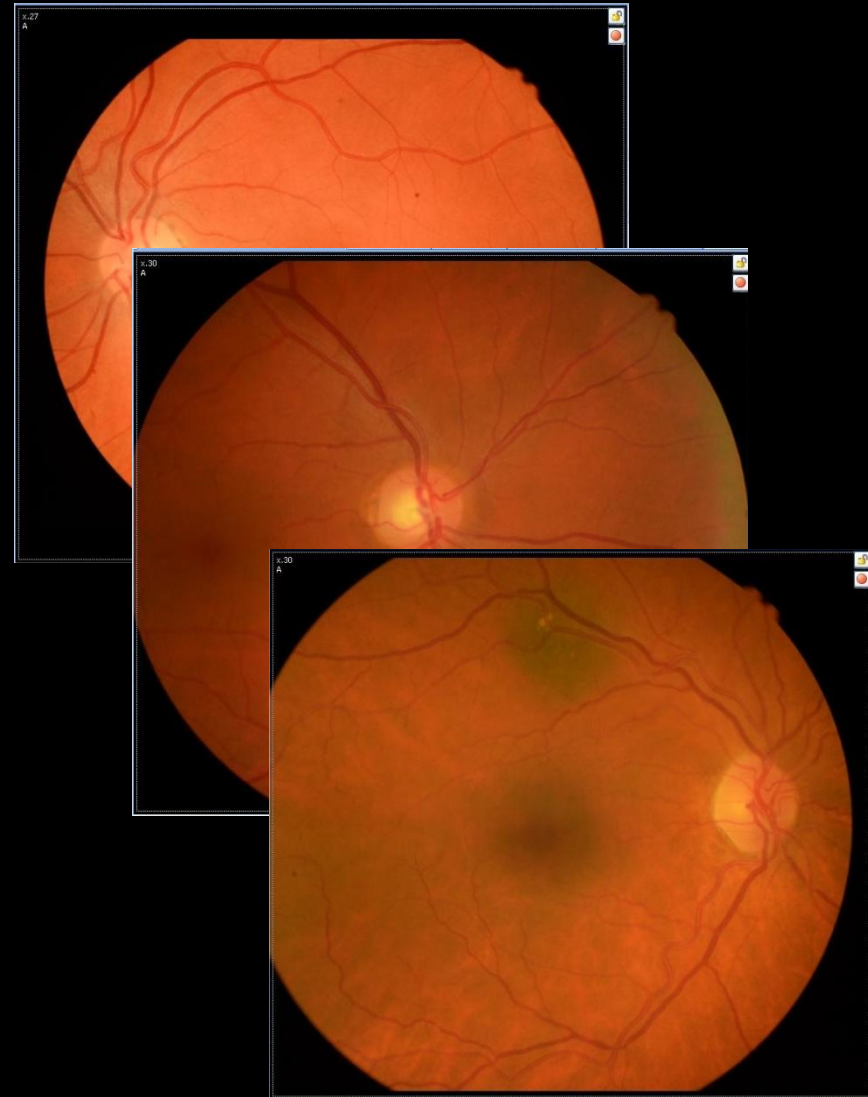
Instructions:

At the point of arbitration grading the following outcomes should be assigned. All referable outcomes will be sent to Referral Outcome Grader.

Grade Level	Outcomes
R0	Annual Recall
R1	Annual Recall
R2	Refer to Ophthalmology routine
Pregnant R2	Refer to Ophthalmology Urgent
R3	Refer to Ophthalmology Active - Urgent Stable - Soon
M1	Refer to Ophthalmology Soon
Ungradable	Technical failure
Other Pathology	See NDED list in Appendix 3
Pregnant Patients (R0, R1)	Refer to Ophthalmology Soon
P1 (Focal laser)	Refer to Ophthalmology Soon
P1 (PRP)	Refer to Ophthalmology Active - Urgent Stable - Soon

Appendix 1: Non-Diabetic Eye Disease

Description	Context/explanation	Conditions for Referral	Requires Referral
BRVO	Clinical finding of Branch Retinal Vein Occlusion of the eye	As defined	Yes
CRVO	Clinical finding of Central Retinal Vein Occlusion of the eye	As defined	Yes
BRAO	Clinical finding of Branch Retinal Arterial Occlusion of the eye	As defined	Yes
CRAO	Clinical finding of Central Retinal Arterial Occlusion of the eye	As defined	Yes
Arterial emboli	Retinal arterial emboli of the eye	As defined	Yes
Retinitis	Inflammatory disorder of the retina of the eye	As defined	Yes
Cataract	An opacity of the crystalline lens of the eye	May only be observed during slit lamp	Yes
Glaucoma	A progressive optic neuropathy characterised by a particular pattern of optic nerve and visual field damage	Refer if cup disc ratio ≥ 0.8 or if asymmetry >0.3	Yes
Age related macular degeneration	Clinical finding of Age Related Macular Degeneration	Refer if subretinal/ Intraretinal haemorrhage +/- exudate	Yes
Amblyopia	Reduced vision in one or both eyes caused by visual deprivation in childhood	First diagnosis of this condition requires referral WITH DR CHANGES	Yes
Pigmented Retinal Lesion	Clinical Finding of Pigmented Retinal Lesion	Refer lesions > 3 disc areas or pigmented lesion with overlying lipofuscin (orange pigment)	Yes
Haemorrhage Exudate	Clinical finding of Haemorrhage Exudate	See age related macular degeneration	Yes

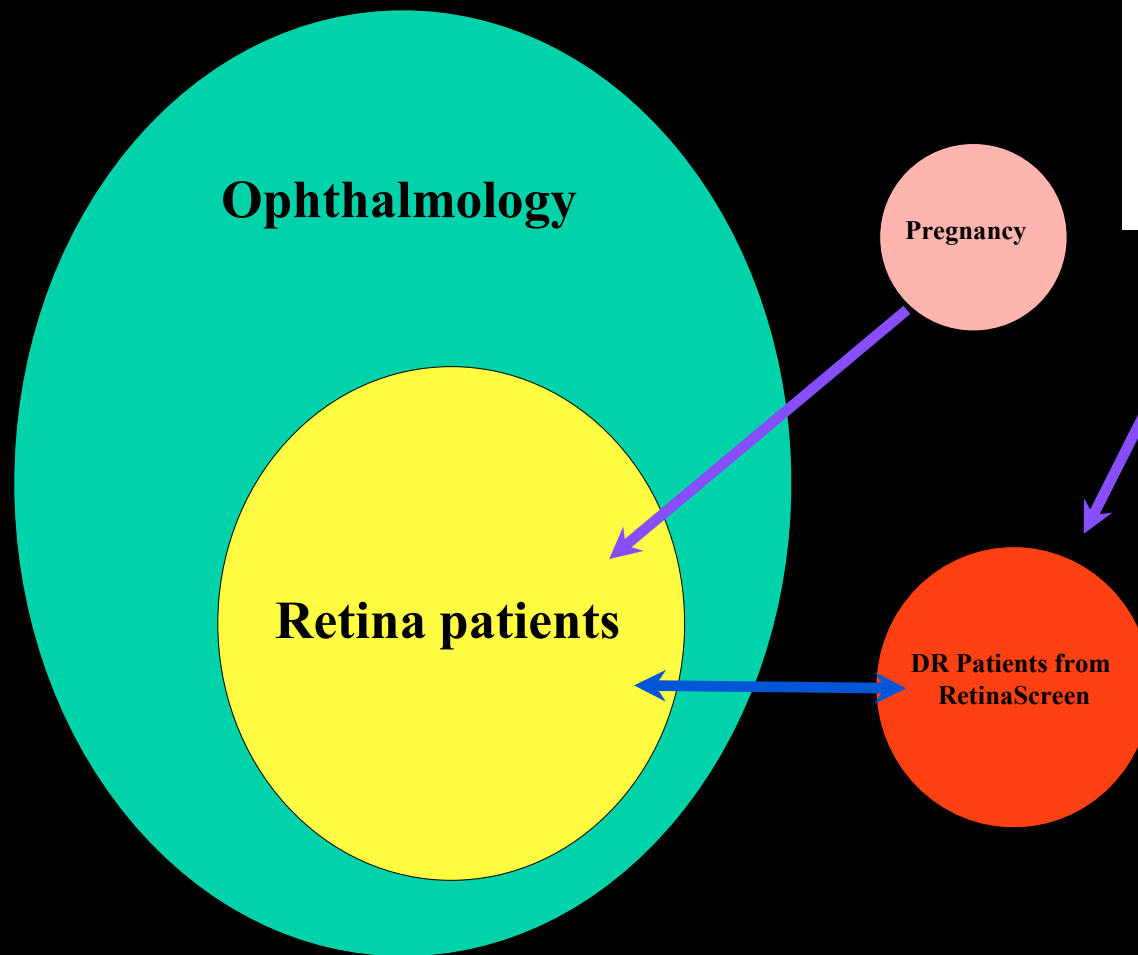


Integrated Screening and Treatment Arms

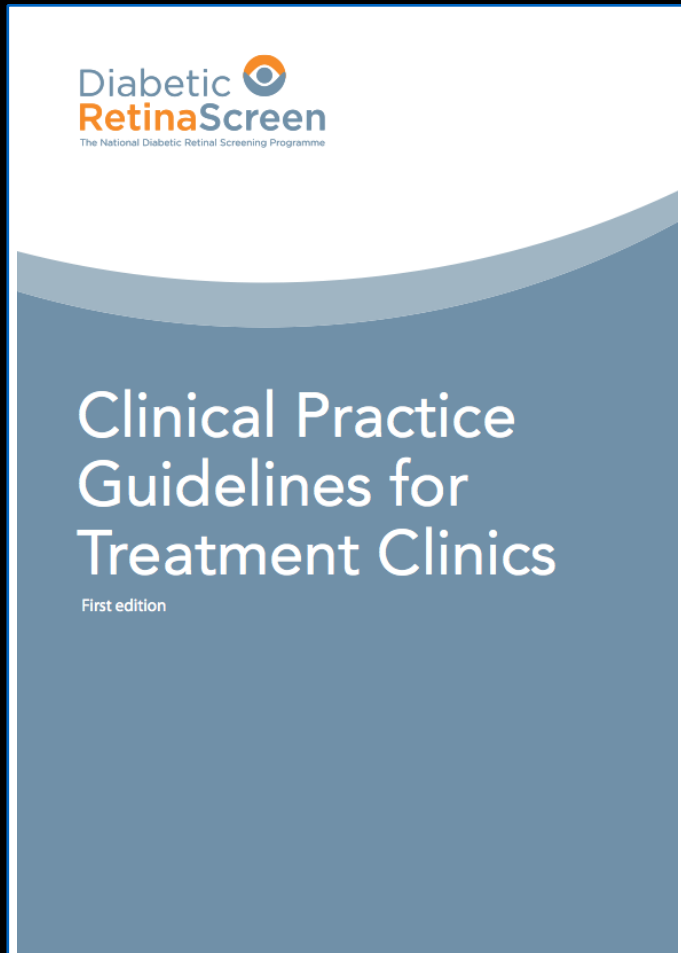
- “Looking is not Treating”
- An essential and unique aspect of Irish Programme

www.ireland-information.com

Referral Overview



Clinical Guidelines



Non Centre involving CSMO

Focal laser (as per ETDRS)

Centre Involving CSMO

if VA $>6/12$ laser obvious MAs or Observe

if VA $\leq 6/12$ use anti-VEGF

Proliferative Retinopathy

Pan Retinal Photocoagulation

Surgery

Also ERM, VH, TRD

Evidence

Ranibizumab (Lucentis,
Novartis)

READ-2

RESOLVE

RESTORE

RISE and RIDE

DRCR-Net (incl Deferred
laser)

Bevacizumab (Avastin, Roche)

BOLT

Aflibercept (Eylea)

VIVID/VISTA

DRCRNet Protocol T

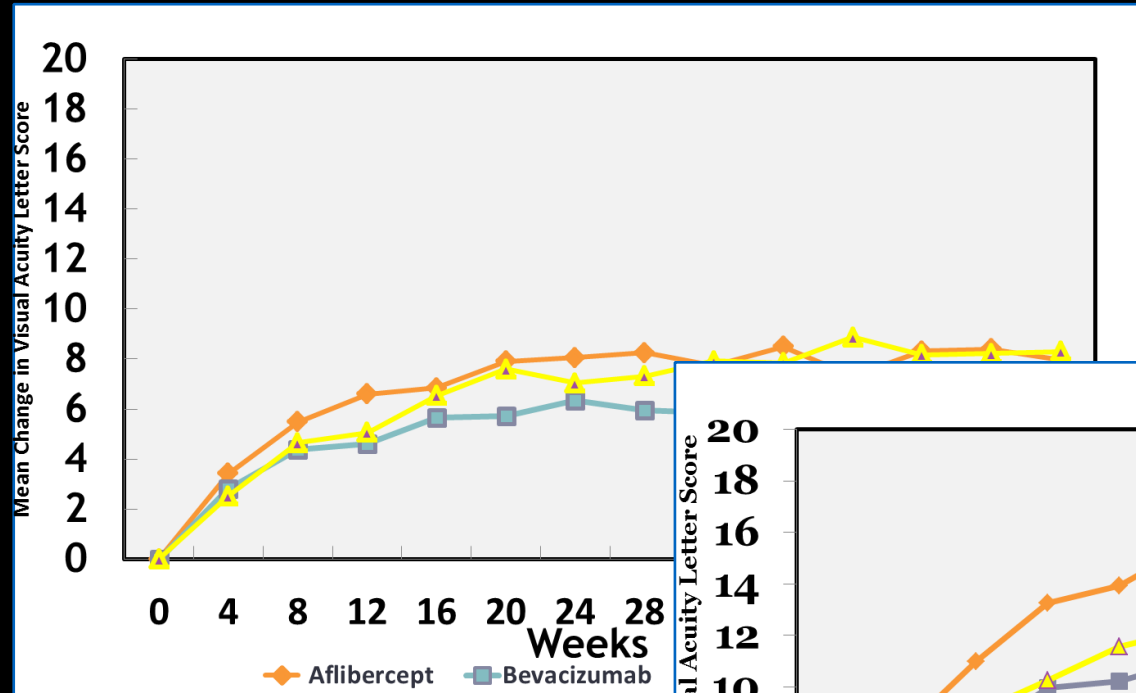
Avastin / Eylea / Lucentis

Ozurdex

Fluocinolone

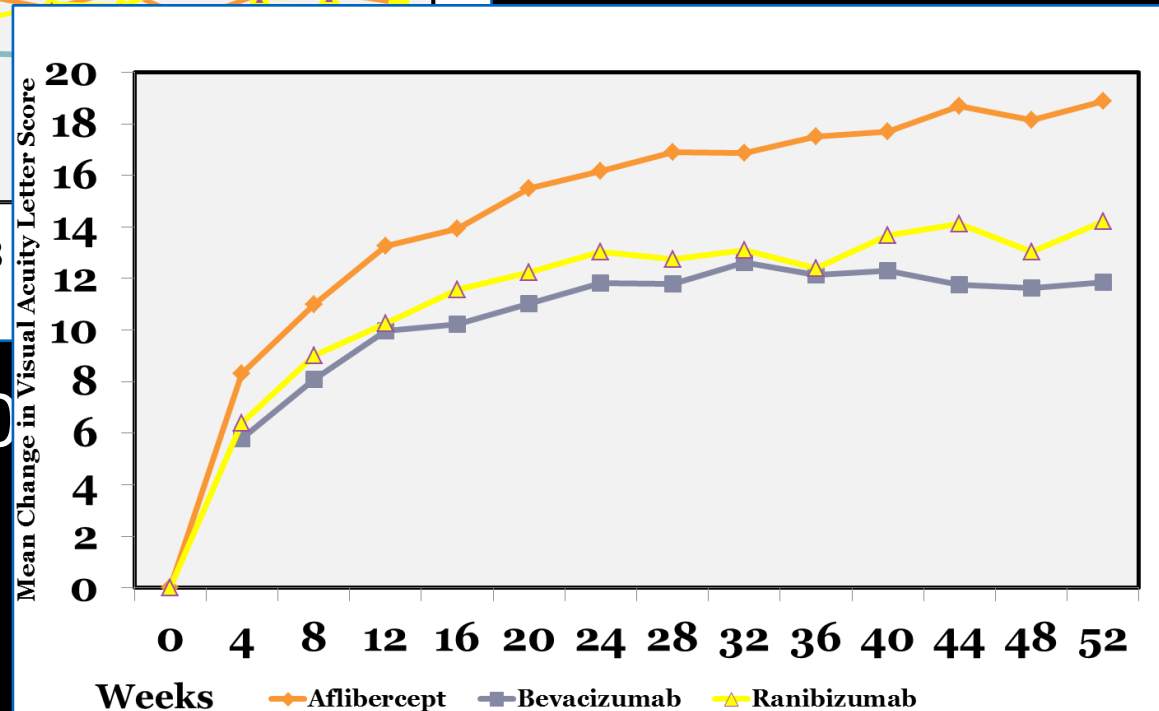
FAME study

Protocol T



< 20/50

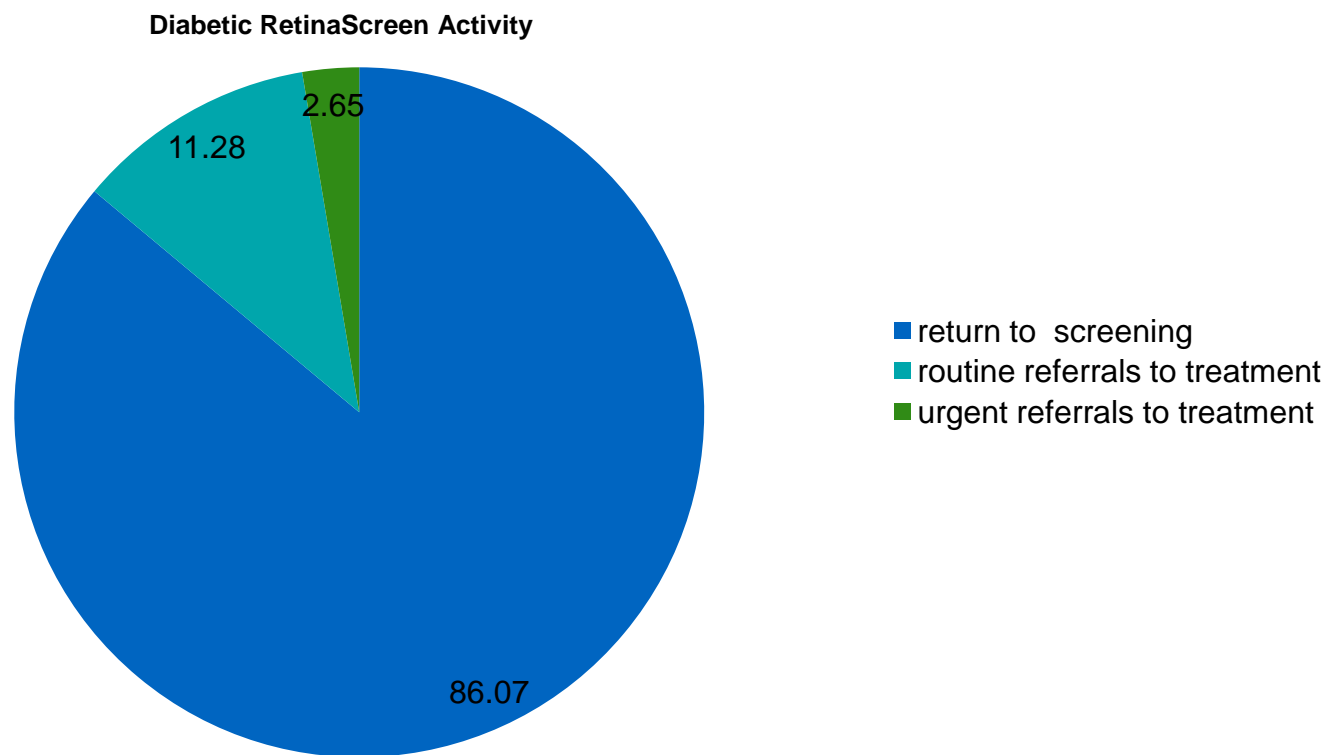
20/32 - 20/40



First Round of Screening

Diabetic Retina Screen	Totals	%
Invited	154,734	100%
Consented	76,971	50%
Attended and completed Screening	73,201	47%

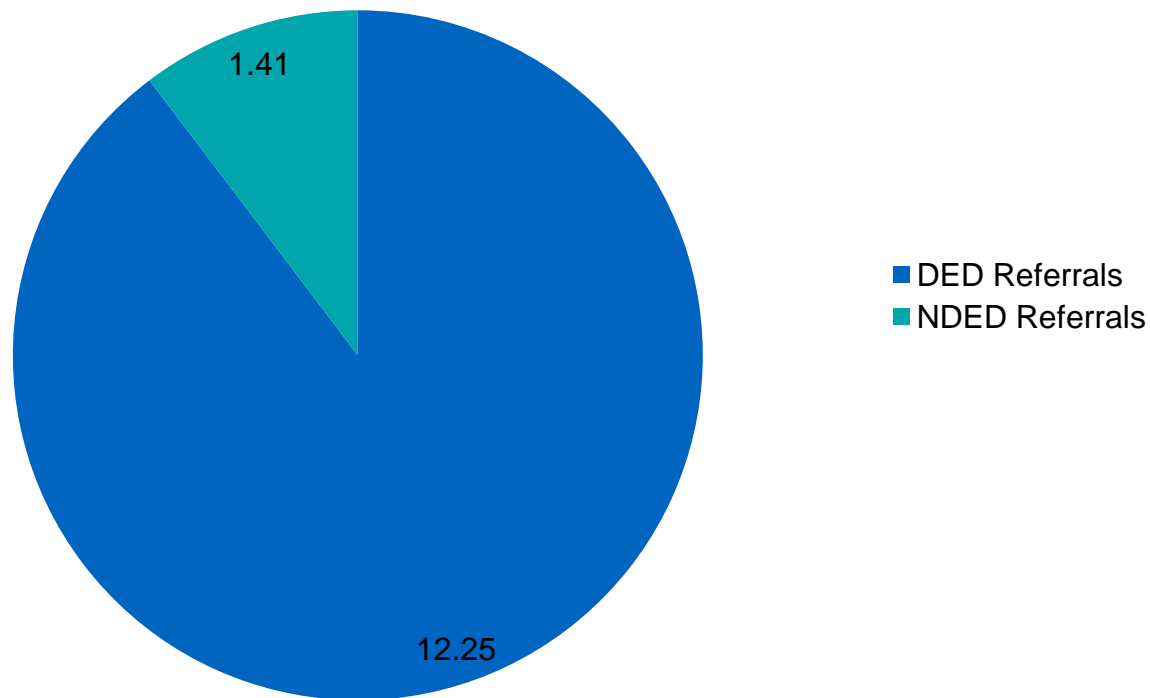
Diabetic RetinaScreen – Treatment Clinic Activity for the first screening round



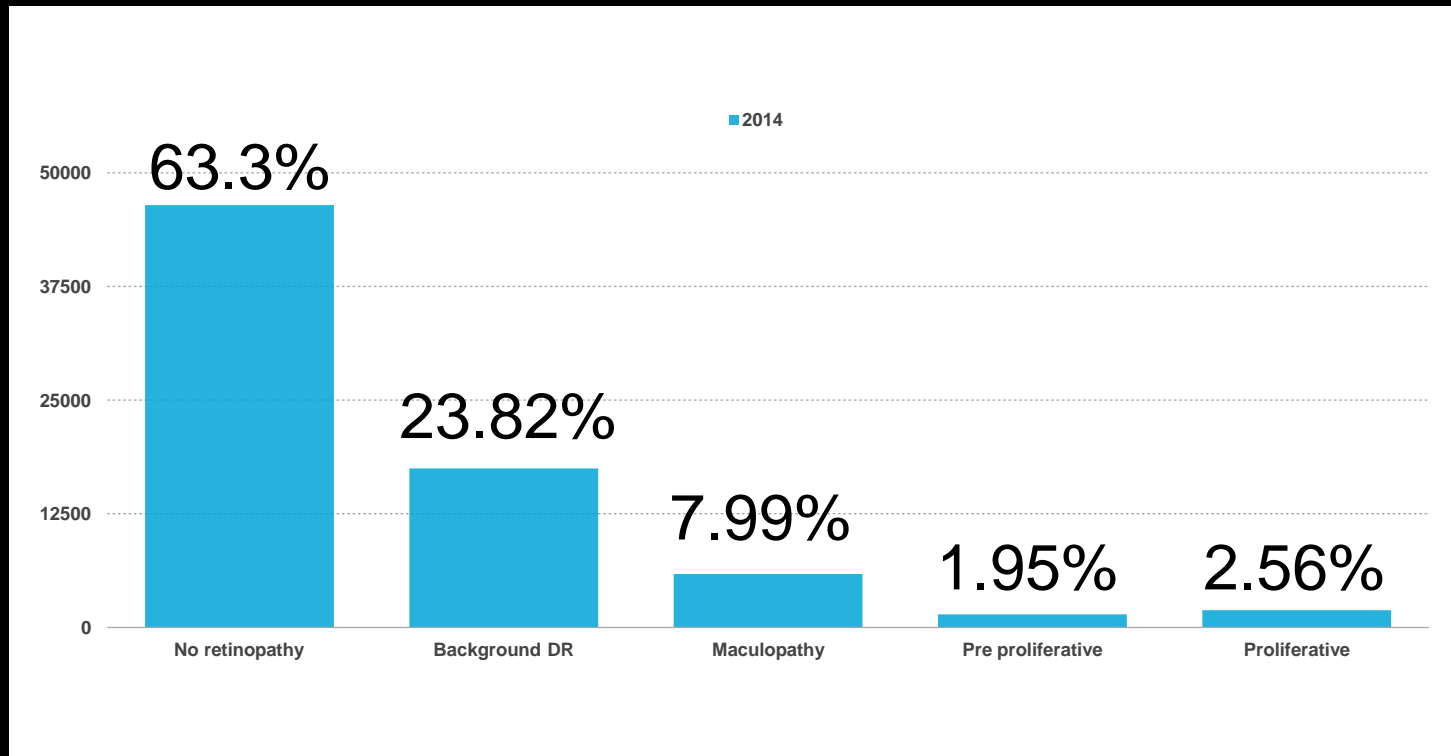
Diabetic RetinaScreen – Treatment Clinic

Activity for the first screening round

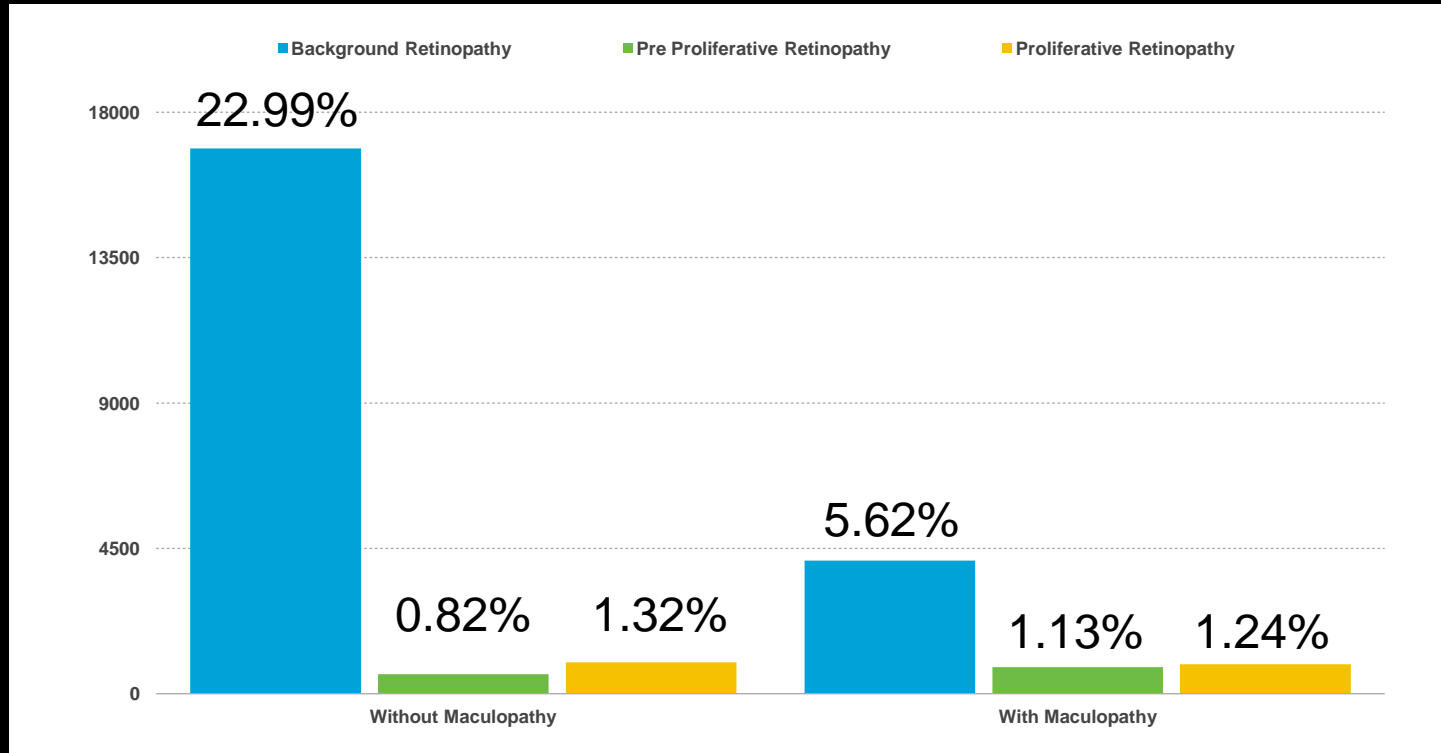
Breakout of Referrals into Ophthalmology



Breakdown of Retinopathy by Screening: 2014



Distribution of Retinopathy Identified on Screening



International Population Studies and Ireland

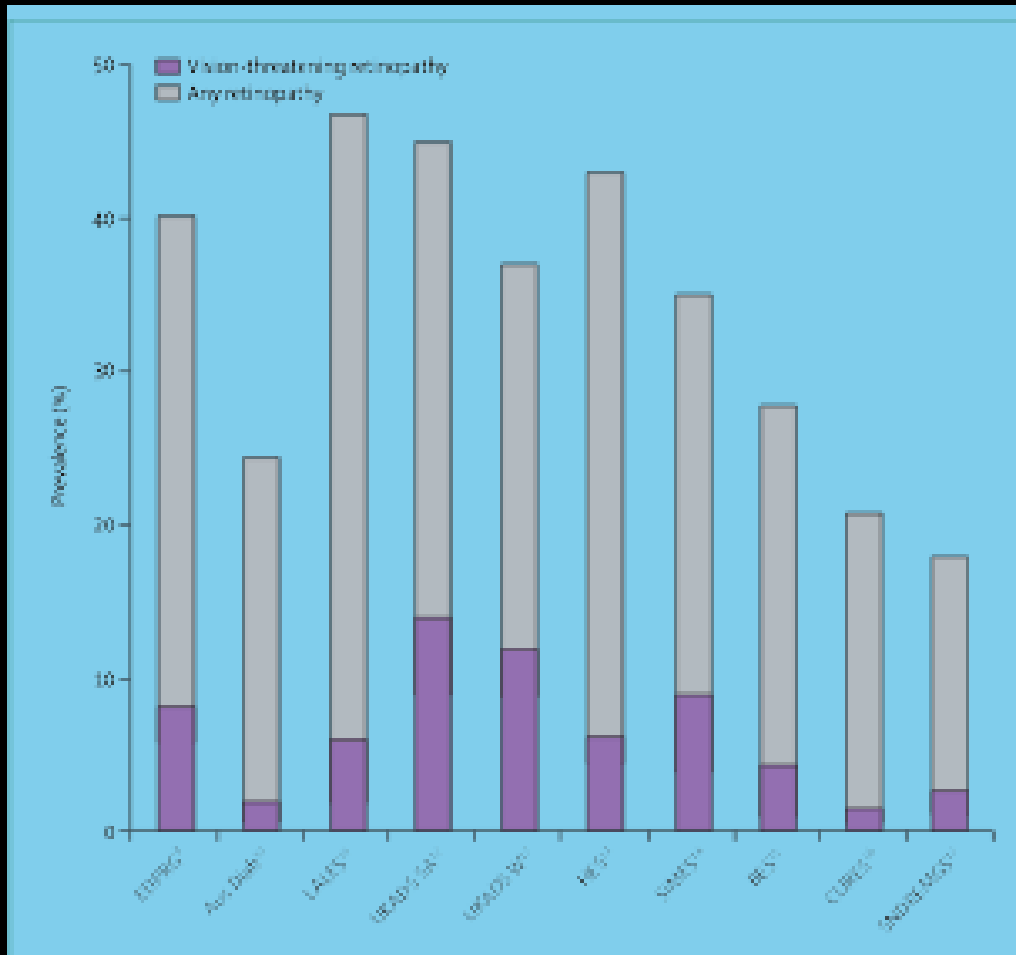
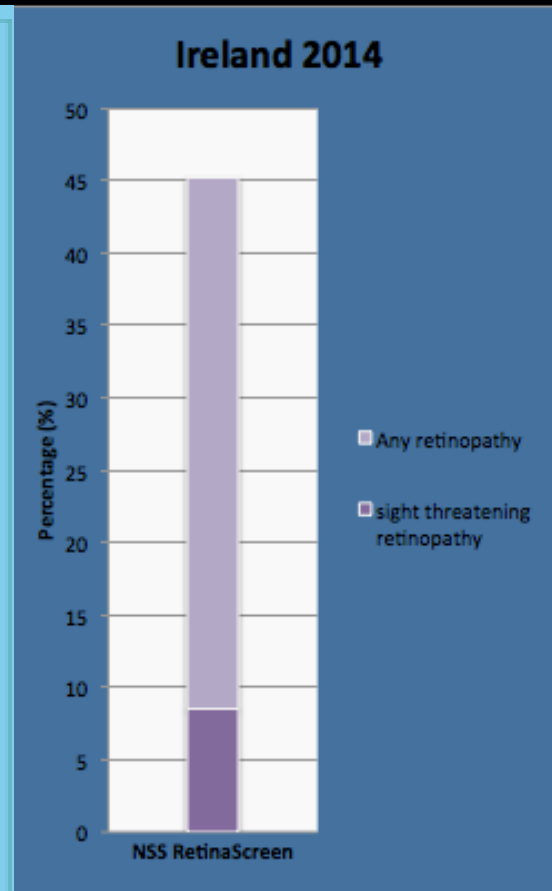


Figure 3: Prevalence of diabetic retinopathy in population-based studies⁸⁻¹⁰ with standardised photographic assessment

Vision-threatening diabetic retinopathy defined as presence of severe non-proliferative retinopathy, proliferative diabetic retinopathy, or clinically significant macular oedema. SA=south Asian people, W=European white people.



Positives of Programme

- > 73, 000 patients screened
- Equivalent to 12,000 clinic hours saved
- >8,000 referrals to treatment centres
- All patients that need treatment getting access to care

Big Picture

- Good for Patients
 - All invited
 - Access (in a timely manner) to an evidence based gold standard programme
- Good for profession
 - Investment in Irish Ophthalmology
 - New Consultant posts
 - New Medical Ophthalmology posts
 - Administrative and Nursing support
 - Capital investment (as per unit)
 - The investment from the programme is ongoing

New Technology

Imaging

Wide-field Imaging

OCT

OCT Angiography

Adaptive Optics

Automated Grading

New Treatments

Laser

Injectables

Systemic

DME: The Role of MicroPulse® Laser Therapy in the Anti-VEGF Era

AMERICAN ACADEMY
OF OPHTHALMOLOGY
VOLUME 150, NUMBER 1
JANUARY 2003

Treatment of Diabetic Macular Edema with an Inhibitor of Vascular Endothelial-Protein Tyrosine Phosphatase That Activates Tie2

AMERICAN ACADEMY
OF OPHTHALMOLOGY
VOLUME 150, NUMBER 1
JANUARY 2003

Peter J.
David
Mitchell

The Effects of Medical Management on the Progression of Diabetic Retinopathy in Persons with Type 2 Diabetes

*The Action to Control Cardiovascular Risk in Diabetes
(ACCORD) Eye Study*

Emily Y. Chew, MD,¹ Matthew D. Davis, MD,² Ronald P. Davis, MD,² James F. Lovato, MS,³
Letitia H. Perdue, MS,³ Craig Greven, MD,³ Said Genuth, MD,⁴ David C. Goff, MD, PhD,⁵
Lawrence A. Leiter, MD,⁶ Farahmarz Ismail-Beigi, MD, PhD,⁴ Walter T. Ambrosius, PhD,⁵ for the Action to Control
Cardiovascular Risk in Diabetes Eye Study Research Group⁶

Challenges

- Completeness and accuracy of Register
 - Margaret Sinnott, et al Fasting Plasma Glucose as Initial Screening for Diabetes and Prediabetes in Irish Adults: The Diabetes Mellitus and Vascular Health Initiative (DMVhi). PLoS ONE 10(4): e0122704. doi:10.1371/journal.pone.0122704
 - We are underreporting
- All invited but need to continue to improve consent uptake
- Better visibility on non-consenters
- Diabetic programme (with UCC) investigating poor attendance in Diabetics

Challenges

- Development of next Phase of Optimize
- Visibility of DRT activity
- Full staffing and organisation of treatment centres
- Implementation of guidelines
- Generation of next editions of Quality Standards and Clinical guidelines
- Publication of the outcomes of the first round of screening
- Development of strategic research partnerships



WE WILL GET THERE

