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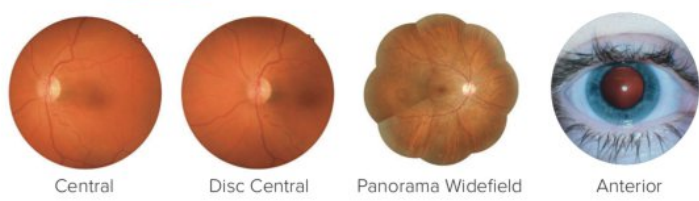
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and

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• **11th Annual Conference of the PCDS Scotland**

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• **Combined Royal Colleges Lecture :**

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• **SAS 9th National Eye Meeting**

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• **Clinical Leads Forum**

Thursday 29 November 2018

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• **Next steps for commissioning specialised services in England**

Morning, Thursday 06 December 2018

London, England

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• **6th International OCT Angiography and Advances in OCT Congress**

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• **Diabetes UK Professional Conference 2019**

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# DiabeticEyeJournal



*From the Editor*

Welcome to our September issue. In this edition we are introducing the theme of maculopathy, its monitoring and management in the Digital Surveillance and Hospital Eye Service pathway. Management and treatment of Diabetic Eye Disease is constantly improving with now commonly used Anti-Vegf agents for regression of Diabetic Macular Oedema and New Vessels. The rise in the Diabetic Population puts more pressure on Hospital Eye Services, which at times struggle to cope with the amount of referrals from retinal screening clinics. OCT modalities have therefore been steadily and slowly moving into Diabetic Eye Screening clinics and have the potential to monitor minor early maculopathies. DES Programmes screen tens of thousands of diabetic patients yearly to check their eyes for retinopathy. How can we utilise the time at the screening appointment most effectively, can the OCT scan be included - saving the number of visits to ophthalmology for the patient? This issue of DEJ will look at this possibility.

Professor Peter Scanlon from Gloucestershire Hospital NHS Trust opens with Digital Surveillance with OCT and Treatment of Diabetic Macular Oedema. His article explores questions such: Can the OCT grading criteria be standardised across all programmes and at what point do we refer our patients to ophthalmology?

In an update from the national team, John Fox, who is Senior Implementation Lead for NHS DESP, highlights what are the current national guidelines and recommendations for DESPs across the country: OCT - National Update.

Staying with our theme of maculopathy, in an article on other lesions, Tjebo Heeren and Catherine Egan from MEH NHS Foundation Trust, consider Crystalline Retinopathies which we so often see in our retinal screening clinics.

And after the main Macular theme, look at the article by Luke Rollin, Screening and Immunisation Manager NHS England North for Yorkshire & the Humber, about retinal vasculature damage and possible indicators of cerebrovascular events.

Of course there is much more that space doesn't allow us to mention, but is very much worth your attention. We hope you thoroughly enjoy this issue and as always we look forward to your valuable feedback!

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**FRONT COVER IMAGE**

OCT scan of patient with CSMO, prior and post Anti-Vegf treatment at RFH NHS Foundation Trust in London

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# Digital Surveillance with OCT and Treatment of Diabetic Macular Oedema

## Prof. Peter Scanlon

Consultant Ophthalmologist, Gloucestershire and Oxford Eye Units, Gloucestershire Hospitals NHS Foundation Trust

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Diabetes Mellitus (DM) affects more than 3 million people in the United Kingdom and its prevalence is estimated to increase to 5 million by 2025<sup>(1)</sup>. Diabetic Retinopathy (DR) is a microvascular complication of DM which is a common cause of blindness in the working age group that has been reduced in incidence by the introduction of the NHS Diabetic Eye Screening Programme<sup>(2)</sup>. The most common reason for sight impairment due to diabetes is damage to the macula, the part of the eye responsible for fine- and colour-vision.

The methodology of screening for diabetic retinopathy was assessed prior to the introduction of screening in the UK. Sensitivity and specificity of digital photography was assessed against the reference standard of an ophthalmologist's examination<sup>(3)</sup> and seven field stereo-photography<sup>(4)</sup>. Referral to hospital eye services for sight threatening DR is recommended for the presence of

- R1M1. Background DR. Maculopathy
- R2M0. Pre-proliferative DR. No maculopathy
- R2M1. Pre-proliferative DR. Maculopathy
- R3M0. Proliferative DR. No maculopathy
- R3M1. Proliferative DR. Maculopathy

Only 20% of those referred for maculopathy are listed for treatment at the first hospital visit whereas the majority of those referred for proliferative DR are listed for treatment. Those referred for pre-proliferative DR require more frequent follow up and are usually treated once they progress to proliferative DR.

The English NHS Diabetic Eye Screening Programme (NDESP) introduced surveillance clinics in 2013<sup>(5)</sup>. These are between Diabetic Eye Screening (DES) and the Hospital Eye Service (HES). These clinics were introduced to reduce referrals to HES by monitoring those in whom disease is not at treatable stage.

Some of these clinics use Optical Coherence Tomography (OCT). OCT is a non-invasive 3-dimensional imaging camera that uses light waves to take pictures of slices of the retina. The test is rapid, non-invasive and well tolerated by subjects. By acquiring a series of cross-sections it is possible to generate a thickness map of the macula. OCT equipment is too expensive to use for routine screening and there would be little point in performing OCT on 65% of people in the population who have no diabetic retinopathy.

The UK NSC annual report<sup>(6)</sup> for the 2016-17 year reported that there were 3.17 million people with diabetes known to the programme in England, screening was offered to 2.73 million with an uptake of 2.25 million (82%). Of the 2,248,277 screened, there were 9,142 referrals with urgent referrals (R3A) and 61,142 routine referrals (R2M1, R2M0, R1M1).

The majority of routine referrals would be for R1M1 and this article concentrates on the best way to manage these patients within the digital surveillance pathway and the subsequent treatment if they are found to have treatable diabetic macular oedema.

The first published report of the use of OCT in digital surveillance was by Mackenzie<sup>(7)</sup> who reported on 311 patients referred with screen positive maculopathy to a digital surveillance clinic with Topcon 3DOCT- 1000 Spectral Domain OCT read by technicians. Of the 311 patients only 144 required ongoing referral to the HES, 143 were rebooked for follow up in the OCT clinic and 24 were referred back to routine screening. In the screen positive criteria used any intraretinal cystoid space in the macular area was considered screen positive.



I introduced OCT into digital surveillance in clinics in Gloucestershire and Oxford in 2012 and my early experience was that, of 724 people with screen positive maculopathy, 426 (59%) were followed up in digital surveillance, 146 (20%) were referred to the HES, 122 (17%) were referred back to annual screening, 21 (3%) DNA'd and 9 (1%) deceased.

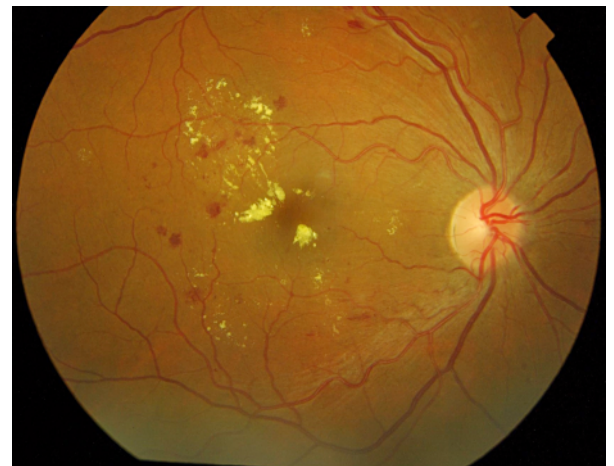
This led to a number of questions which I discussed further with colleagues who were developing grading and referral criteria for surveillance clinics with OCT in the London area:

1. Should all people with R1M1 be referred to digital surveillance or should some be referred directly to the Hospital Eye Service?
2. Would it be possible to standardise the OCT grading criteria across programmes?
3. Can one standardise the referral criteria based on the OCT grading criteria?
4. How should the grading criteria alter in the presence of other eye conditions/disease?

To answer these questions:

**1. Should all people with R1M1 be referred to digital surveillance or should some be referred directly to the Hospital Eye Service?**

The consensus view, on discussing this with colleagues in London, was that there should be direct referral from screening into the HES where on digital photography there is substantial macular exudation (>1/2 Disc area within 1 DD of fovea) and a significant drop in visual acuity (>2 lines or worse than 6/12), without receiving OCT in the screening programme.



Example:

**2. Would it be possible to standardise the OCT grading criteria across programmes?**

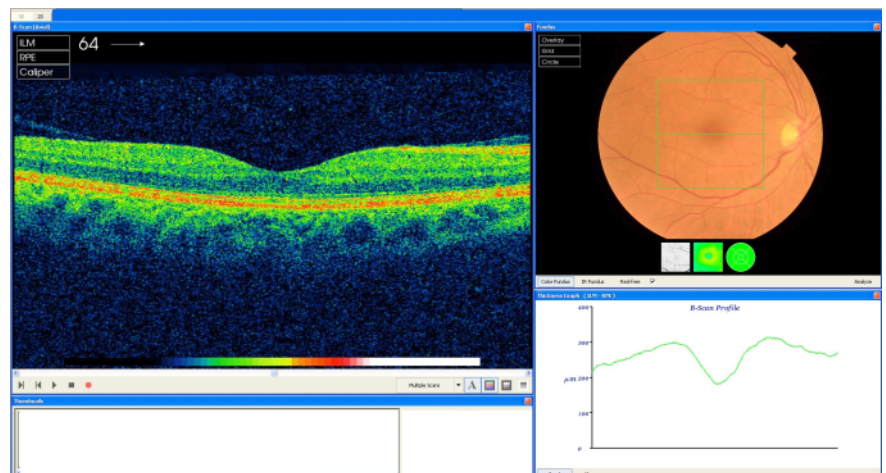
I feel that it is important that there is some standardisation of OCT grading criteria so that there can be comparisons between programmes. This should not restrict what programmes do as long as there is flexibility over outcomes.

When discussing with the London programmes, we came up with the following consensus grading criteria:

**OCT NEGATIVE** - No macular disease on OCT

- No abnormality on OCT scans

Example:

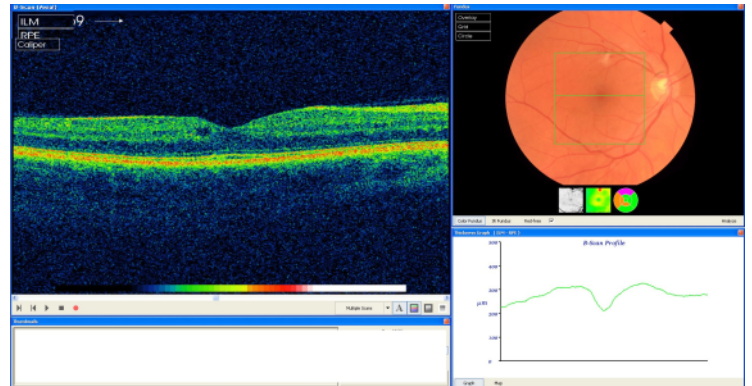


## Diabetic Eye Disease

### OCT BORDERLINE - Minimal / Borderline macular disease on OCT

- Intraretinal cystic space or spaces with no change in the ILM contour.

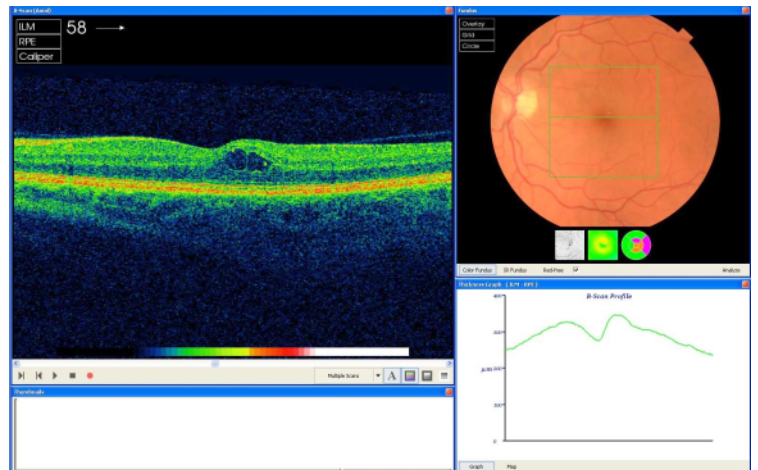
Example:



### OCT POSITIVE - Significant macular disease on OCT (see OCT examples 7-16)

- Presence of parafoveal intra-retinal cysts with a change in ILM contour, sub-retinal fluid and/or significant thickening of the retina (orange, red or white on OCT map view).

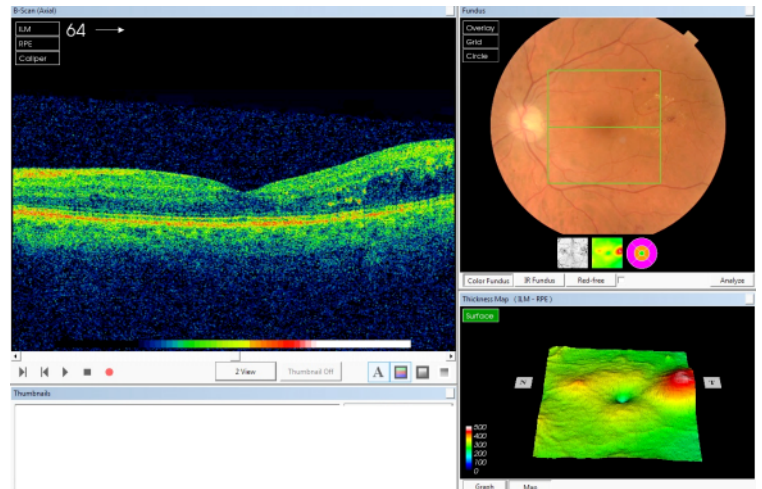
Example:



### Significant thickening can also be:

- An area of retinal thickening of greater than 1/2 disc area the edge of which is within 1 disc diameter of the central fovea

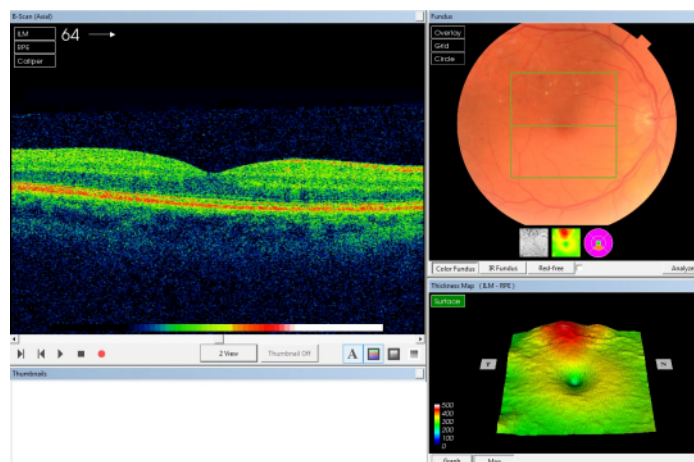
Example:





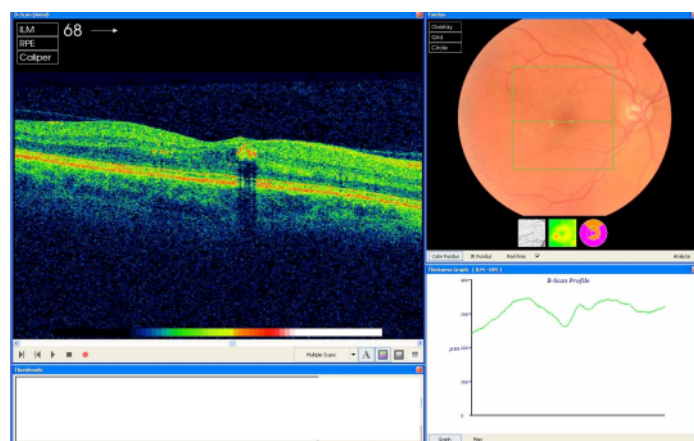
- An area of retinal thickening of greater than 1.0 disc area within the NHS DESP definition of the macula, which is that part of the retina which lies within a circle centred on the centre of the fovea whose radius is the distance between the centre of the fovea and the temporal margin of the disc.

Example:



- Any of the above associated with a change in the internal limiting membrane (ILM) contour including increased central macular thickness or loss of foveal contour

Example:



**3. Can one standardise the referral criteria based on the OCT grading criteria?**

If technicians are determining referral outcomes in digital surveillance clinics then standardisation would be required but at local level. Digital surveillance clinics with OCT need to have the flexibility for Clinical Leads to be able to manage patients according to local circumstances. For example, if the Clinical Lead is the same ophthalmologist treating the patients in the HES, he or she may keep some screen positive patients in digital surveillance clinics until they reach a stage when they would definitely be considering treatment.

A grading outcome of:

- a) R1M0 OCT negative would normally be discharged back to routine screening.
- b) R1M1 OCT negative would normally be given a 12 month review in digital surveillance.
- c) R1M1 OCT borderline would normally be followed up in digital surveillance in 3, 6, 9 or 12 months.
- d) R1M1 OCT positive would normally be referred to the HES unless the Clinical Lead made the decision to monitor the person in digital surveillance as described above.

**4. How should the grading criteria alter in the presence of other eye conditions/disease?**

There are two conditions in which the above grading criteria cannot be used because they alter the foveal contour in the early stages of the disease process:

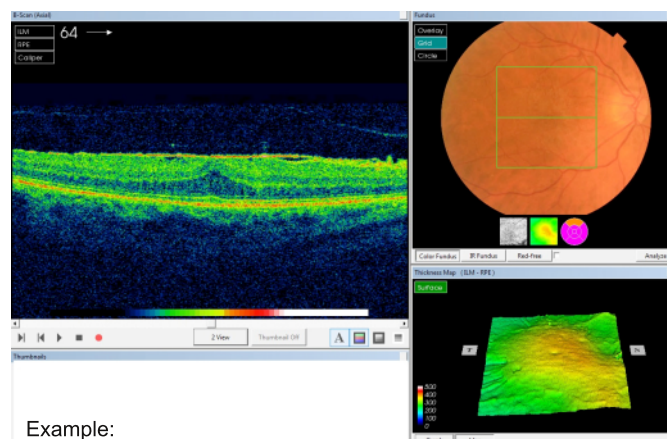
## Diabetic Eye Disease

### a) Epiretinal Membrane

Even at a relatively early stage of an epiretinal membrane with good visual acuity, there is an alteration in foveal contour.

Hence, in the surveillance clinics that I oversee, OCT positive criteria in the presence of an epiretinal membrane are defined as the following abnormalities affecting the central 1mm macular subfield:

The presence of diffuse retinal thickening or intraretinal cystoid spaces associated with a change in the internal limiting membrane contour (including increased central retinal thickness or loss of central foveal contour) and associated with a drop in VA to < 6/12 unless there is a clear reason why the vision is reduced e.g. dry AMD or known amblyopia.

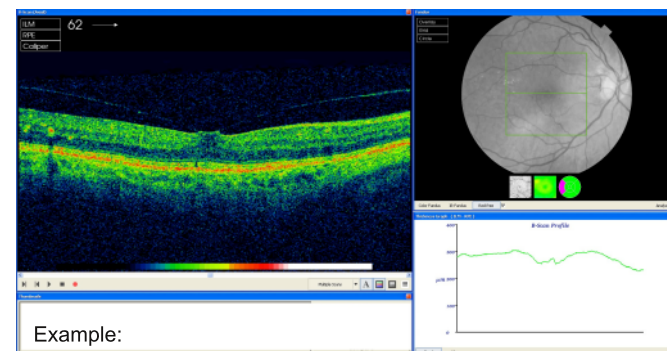


### b) Vitreomacular traction

In the example given the person was being assessed because of exudate in the macular area and was found to have mild vitreomacular traction.

If vitreomacular traction is present without any signs of diabetic maculopathy, alteration of the foveal contour cannot be used in OCT positive criteria because this occurs in the early stages of the condition.

I consider OCT positive in the presence of VMT when there is a drop in VA to < 6/12 or the development of changes that suggest that the VMT is progressing or has progressed to a macular hole such as full thickness interruption of all retinal layers unless there is a clear reason why the vision is reduced e.g. dry AMD or known amblyopia.



## Treatment of Diabetic Maculopathy Oedema (DMO)

The Early Treatment Diabetic Retinopathy Study<sup>(8)</sup> recommended treatment with laser for clinically significant macular oedema which was defined as

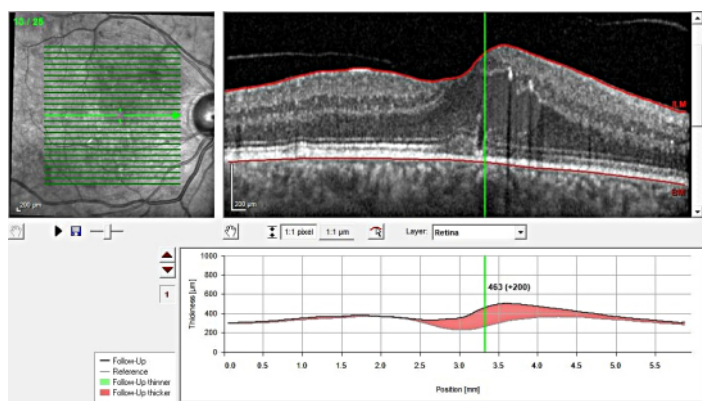
1. Thickening of the retina at or within 500 microns of the centre of the macula
2. Hard exudates at or within 500 microns of the centre of the fovea, if associated with thickening of the adjacent retina (not residual hard exudates remaining after disappearance of retinal thickening)
3. A zone or zones of retinal thickening 1 disc area or larger, any part of which is within 1 disc diameter of the centre of the macula.

Treatment with laser was possible outside but not within the foveal avascular zone because of the risk of the individual noticing a blind spot and because laser creep over time can affect the central vision at a later date.

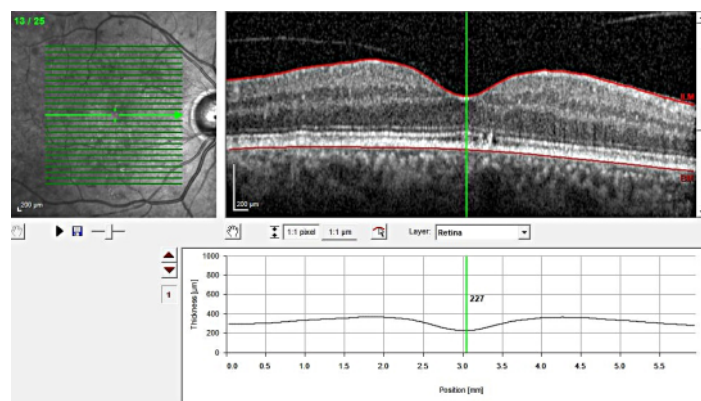
In the last 5 years, since the approval by NICE<sup>(9)</sup> of the first VEGF inhibitor for use in DMO when the centre thickness had exceeded 400 microns, they have become increasingly used for treatment of centre involving DMO. Studies using Ranibizumab<sup>(10)</sup>, Aflibercept<sup>(11)</sup> and Bevacizumab<sup>(12)</sup> have not only shown a reduction in macular oedema and an improvement in vision but also a regression in ETDRS levels. The average number of VEGF inhibitor injections required in the first year is 7-9, in the second year 2-4, and in the third 1-3 and approximately 1 injection per year in year 4 and 5<sup>(13, 14)</sup>. Side effects in a small number of patients include, endophthalmitis, raised intraocular pressure and there is a theoretical risk of cardiovascular events although this has not been found to be significantly elevated compared to control groups<sup>(15)</sup>.



Pre-treatment



Post-treatment after 3 months of VEGF inhibitor



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# Derbyshire Diabetic Eye Screening Programme – Hard to Reach Project



Derby South Team



Some of the Chesterfield North Team

## The Programme

The Derbyshire Diabetic Eye Screening Programme has a cohort of over 65,000 patients spread over a vast county. The Programme is split into 2 teams; one based at Chesterfield & North Derbyshire Royal Hospital serving the North of the county and the other based at London Road Community Hospital Derby, serving the South of the county.

This is a map of the area our screening programme covers; the North and South sections alone are huge areas and we provide screening in almost every part of the county within our base locations and at GP practices and Community Hospitals.

## Background to our Project

At the BARS 2015 conference, a Location Mapping presentation from one of the Irish Programmes caught my eye and I decided I would like to look at something similar for our North Derbyshire Service. Our North team had many discussions regarding our “hard to reach” areas and areas where we provide screening, in the hope to engage some of the harder to reach communities within the programme. The presentation at conference spurred us on to work on developing this idea.

### What did we want to do?

What we wanted to look at was:

*“Do we have adequate screening locations for all our areas and how can we engage with our local communities?”*

From Speaking with our patients, we already knew we had grey areas. These were identified as Matlock, Dronfield and the Sheffield Border, Shirebrook and the Mansfield border. My main interest, firstly, was to look at these areas, the patients and the communities falling within them to see if we could improve accessibility to the Service. This was also to promote the service to our harder to reach communities. This led to the “hard to reach” project being born. This has since also been extended into the Southern areas of the programme too.



## What have we done?

In November 2016, we were informed about an opportunity to promote our service to the farming community in North Derbyshire which coincided with our Hard to Reach Project ideas. This was a health awareness event, organised by a member of the Rural Nursing Team at the Rural Health Clinic at Bakewell Farmers Livestock Auction. The Rural Nursing Team had been working within the farming community for some years and had built a great relationship with them through the drop-in service they provide.

## Spotlight on DESP



**Our Visit to the Farmers Market 2016**

Although we do hold Bakewell & Buxton outreach clinics, patients from this community struggle to attend for all types of medical appointments. The Rural Nursing Team is there at an appropriate time and setting for this community to access. The “MOT” day was aimed at various disciplines, Physio, Podiatry and screening services and to also offer BP and cholesterol checks along with height, weight and dietary advice. We went along armed with DR information leaflets, diagrams and service information!

The drop-in service, that the nurses provided, encouraged us to investigate the possibility of being able to provide a similar service for this and other hard to reach communities. We have continued each year to attend this event to promote the service to this community.

*\*(Photo's feature Jodie Longmate, Michelle Dawes & Claire Erroch)\**

Spurred on from the first event, we were eager to look at other areas. Although in the North of the county we already provided screening in a town called Clowne, we were aware that many patients from the adjacent Shirebrook area struggled to attend for screening. A great deal of this is due to poor transport links and high levels of deprivation in this area.



**And 2017, 2018**

We were lucky enough to secure space at a Community Health Centre in Shirebrook. In February 2017, we held our first trial clinic at the Health Centre. The first two clinics were a huge success and we had such positive feedback from patients in the area. We have continued to provide a monthly screening clinic here since.

This clinic had given us links with the Community Nursing Team in this area. We were invited to attend their Health Promotion Event in July 2017, Shirebrook Health Information Point. This was a chance to promote our service to the local community, encourage attendance at screening and also gave us links with community workers in the Polish Community in this area.

The Chesterfield Royal Hospital Team has set up information events in the hospital main entrance to promote our service and talk to patients to encourage them to attend for screening.

Our Programme Board has a wonderful patient representative, Ken Smith, who has invited us to events organised by the Derbyshire Diabetes UK Group. We attended our first meeting, their AGM in April 2018 alongside other organisations such as Sight Support Derbyshire and community diabetic nursing teams.



*\*(Jodie Longmate/Cheryl Boulton)\**



\*(Jodie Longmate)\*



In May 2018, our South Team attended another Health Awareness Event at their local Indian Community Centre. Again this helped to forge links with the local community and encourage attendance for Diabetic Eye Screening.

\*(Richard Cragg, Programme Manager)\*



In July 2018 we attended our first event for the Derbyshire Task Force Disability Health Awareness Day. We had a successful day at this event, speaking to patients with Learning disabilities and their carers. It is important we engage with all areas of our community and we will continue to attend these events to promote screening and discover how we can improve our service for patients with a learning disability.

### Plans for the future

We plan to continue to attend our existing events; such as the Rural Health Promotion Event. The Shirebrook Health Information Point event, Derbyshire Diabetes UK Group events and Indian Community Centre Health Awareness sessions. We have formed a link with the local Gypsy Liaison Officer and plan to attend their next Gypsy Liaison meeting in September 2018 to provide information regarding screening to this area of the community.

Our Screening and Immunisation Co-ordinator has put us in touch with the Learning Disability Partnership Board, after a successful day in July 18 at their Task Force Health Awareness day, we plan to continue to attend these events to encourage attendance for screening. Our Screening team from both areas will be going along to this event to promote the service and encourage attendance for Screening. Our South Team are currently also working alongside one of the homeless centres in Derby City to help patients access the Screening Service.

Our work on this project has helped our Programme to engage with our local communities and hard to reach groups. We hope our work will continue to make patients aware of our service and we are continually looking at areas we can improve accessibility to the service for patients. We have achieved our initial project aim. However, I feel this will always be ongoing work, to look at where we provide screening and working with the different and diverse communities we serve to encourage attendance and help patients understand the importance of it.

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As an additional note, **Richard Cragg** (Programme Manager for the Derbyshire Eye Screening Programme and BARS council member) has also given his comments on this project:

*"The awareness projects that Jodie has written about focusses around reaching out to 'Hard to reach' patients, and also patients that come under the new inaccessible standard. Although uptake will we hope in the future be improved, our prime driver for all of this work is to educate and raise awareness. The hope for this article is that it will provide ideas for others to follow. Next week we are also attending an event specially laid on for disabled patients, and in October we will be attending the Goose fair in Nottingham to engage with the Gypsy traveller community"*

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AT THE FOREFRONT OF OPHTHALMIC TECHNOLOGY

## Community-based Optical Coherence Tomography – a year in review

Caroline Mooney, Diabetic Eye Screener / Grader, North Yorkshire Diabetic Eye Screening Programme

### Introduction

Optical Coherence Tomography (OCT) was introduced to the North Yorkshire Diabetic Retinal Screening Programme (NYDESP) Digital Surveillance (DS) clinic in 2015 to offer a community surveillance service for referable low risk R1M1 patients. All R1M1 patients were referred to the hospital eye services (HES) prior to NYDESP being able to perform OCT as part of regular digital surveillance.

DS-OCT clinics were established using the Topcon 1-Maestro combined OCT/fundus camera linked directly to the Optimise screening software (EMIS). All clinical staff are trained to use the camera and the OCT, but OCT grading of R1M1 DS patients is restricted to Referral Outcome Graders (ROG) only. A bespoke algorithm, created in consensus with local treatment centre ophthalmic consultants, was used to manage patients within DS-OCT clinics.

Some R1M1 patients were still referred from routine screening to HES at first notification of the referable disease if a face to face consultation or laser were deemed to be required, e.g. circinates larger than 1DD, poor vision/symptoms/drop in vision where oedema is likely.

It was anticipated that managing these patients within the DS-OCT pathway would significantly cut costs (compared to NHS outpatient tariffs), reduce patient numbers waiting to be seen at HES, and benefit the patient by providing convenient and accessible appointments local to the patients.

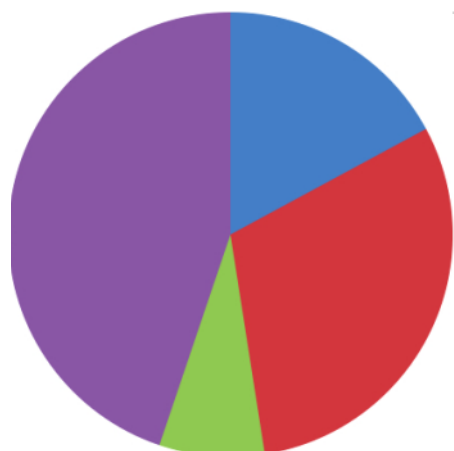
### Method

All patients who were referred for DS-OCT clinics between July 2015 and June 2016 were reviewed in 2017 for outcomes from their clinic appointments. Demographics and DNA rates were also reviewed.

### Results

477 patients were referred to the community based DS-OCT clinics between July 2015 and June 2016; 722 appointments were booked but 116 appointments were not completed due to patient non-attendance (16%).

The majority of patients cared for in the DS-OCT pathway far outweighed those who were referred to HES (Figure 1). At the first visit 18% of patients met the criteria for onward referral to HES for further assessment and possible treatment. 30% were referred back to routine screening when found not to have maculopathy, or the maculopathy had resolved. 52% remained in the DS-OCT pathway.



Patients aged 50 to 80 were at least twice as likely to be referred to HES for maculopathy when compared to patients within other age ranges, with 88% of these being male. Those who were referred for sight threatening diabetic retinopathy (STDR) into HES also followed a similar age pattern, but both genders were equally represented.

**Figure 1.** Patient pathways

- Sent to HES (18%)
- Back to annual recall (30%)
- Ongoing DS 3-month recall (8%)
- Ongoing DS 6-month recall (44%)



### Discussion

Despite being a community based clinic, the DNA rate was surprisingly high (16%). This may be because patients are still largely asymptomatic and may not understand the need for another appointment so soon after their usual annual appointment.

Attendance rates may increase if patients are made fully aware of why they are being investigated more thoroughly, the reasons for the additional testing and an approximate timescale before a decision is made. Patients are always offered the opportunity to telephone NYDESP if they want to discuss aspects of their screening. Additionally, further information explaining the need for more detailed assessment is provided in their DS-OCT appointment letter and missed appointments are always followed up by the administration team to rebook the patient. If the patient is not contactable, a senior grader phones their GP practice. This is to ensure a health care professional has a conversation with the patient to stress the importance of screening and encourage them to attend.

The lack of face-to-face consultation with the patient, at the time of grading presents some potential problems. Although results letters are standardised as per NDESP guidelines, those generated from surveillance clinics are personalised to some degree in order to provide the patient with information specific to their circumstances. In particular, this should happen if the patient is remaining within the surveillance pathway for any length of time. Nonetheless, it is not possible to provide detailed explanation of the underlying mechanism behind diabetic maculopathy. This level of detail can be found via our website.

### Conclusion

Community based DS-OCT clinic are a preferable way of confirming the presence of low risk but potentially sight threatening eye disease and monitoring for progression without sending them directly to HES. It is important to take into account the limits of screening for maculopathy in the community.



# OCT – National Update

Optical coherence tomography (OCT) is widely used in hospital eye services with many studies supporting its use for identifying and quantifying thickening of the macular. It therefore seems a natural progression to extend its use to diabetic eye screening programmes. Currently, when grading diabetic maculopathy, surrogate markers are used to predict the presence of macular oedema from two-dimensional images produced during screening. This method is found to be sensitive enough but not very specific, resulting in referrals to hospital eye services that do not require treatment.

The national service specification states that DESPs should refer patients to digital surveillance clinics who need more frequent review but do not require referral to HES. It also advises that surveillance clinics may interface with OCT assessment, which is an additional technology to that used for screening (digital fundus photography). The National Diabetic Eye Screening Programme (NDESP) grading pathway shows that maculopathy can be referred to HES or a Digital Surveillance (DS) clinic, this is decided locally. OCT is generally considered to be superior to digital photography as it produces a 3-dimensional assessment, which can reliably quantify the retinal thickening, thus refining onward referral pathway for macular oedema, but the equipment is not common in all local DESPs.

Making fundamental changes or adding additional tests to an existing screening programme must be evidence based and recommended by the National Screening Committee (NSC). This requires a robust review of evidence to support both the clinical and cost effectiveness of the proposed change. There are many studies supporting the clinical effectiveness of OCT for the detection and quantification of macular thickening. The cost effectiveness specifically for use in screening programmes has not yet been fully evidenced but it is widely believed that it would be a better use of public money to provide this level of care outside of Ophthalmology and we are currently waiting for the publication of a study which had this as a primary aim.

Currently OCT has not been recommended by the NSC to be included in the NDESP pathway and therefore is not included in any national commissioning agreements, although it has been included in some local commissioning arrangements.

We have formed a working group, consisting of experts from across the DES stakeholders including ophthalmologists, clinical leads, programme managers, quality assurance, screening and immunisation teams and commissioning to review current practice, available evidence and develop supporting guidance for local programmes. If the evidence supports implementation, we will make an application to the NSC for future inclusion.

The group are developing a best practice guidance to support programmes that already use or are planning to use OCT in their DS clinics. All DES programmes are being asked to participate in an electronic survey to identify current local practice and seek feedback on a draft pathway and criteria document. We will use this important information to advise and shape the guidance to support all programmes ensuring that the high quality and safety of our programmes is maintained.

## **John Fox**

Senior Implementation Lead

NHS Diabetic Eye Screening Programme

Young Person and Adult Screening Programmes

UK National Screening Committee/NHS Screening Programmes