

What's the vision like with Diabetic Macular Oedema?

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DiabeticEyeJournal



There are 685 BARS members who receive this Journal on a regular basis and around 200 of those make it to the BARS annual conference each September. So we thought we'd share some of the most captivating talks from the last year's Conference in this issue of DEJ with you. The most heartfelt was the talk by Leonie Watson described in the article by Phil Gardner, the BARS chair, on page 19 - 'Why does it all matter'. Why do we do what we do? Retinal Screening can prevent blindness in people with diabetes, but those who do lose their sight motivate us not to give up trying to eradicate something which so seriously affects people's lives.

Dr Elizabeth Wilkinson, the Clinical lead from North Devon Healthcare NHS Trust presented on options that we have for treating people whose sight has already been affected by diabetic macular oedema and you can read her abridged version in section on Diabetic Eye Disease.

Diabetic eye disease is a complex and progressive condition and not all of its scale can become visible by standard 45 degree field fundus photography. It isn't always possible to determine the scale of Diabetic Retinopathy progression unless we look further to the periphery by either the slit-lamp or wide-field imaging modalities. Read about the R2 refinement pathway, also presented at the Conference by Mr Hean-Choon Chen Clinical lead from Royal Derby Hospital, and how their team managed to streamline referrals to Hospital Eye Services in the most effective manner.

In the section on Other Lesions you can find out about different types of benign retina and choroid eye tumours. This article by Zine Elhousseini and Susanne Althausen from Royal Free London NHS Trust is the first part of a larger feature, the second of which will cover the malignant tumours in our September issue.

Diabetes affects almost 4 million people in the UK, and its complications cost the NHS £10 billion annually. Some of the reasons why people find controlling this condition so hard are psychological and Diabetes UK is bringing more awareness to highlight them so they can be addressed. Read how in the article by Susan Aldridge, editor of Update magazine for professionals.

We hope this gives you a nice variety of material that relates to your professional interests.

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FRONT COVER IMAGE

Private collection: Holiday photo showcasing effect on individual's vision by Diabetic Macular Oedema

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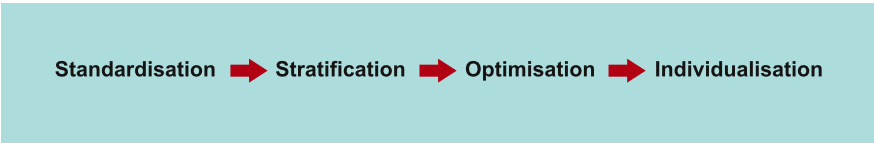
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Management of Diabetic Macular Oedema (DMO)

Dr Elizabeth Wilkinson, MA, BBChir, MRCP
Medical Ophthalmologist North Devon and Vice Chair Diabetic Eye Screening Advisory Board

This is an abridged version of her talk at the 2018 BARS Conference in Bristol.

The revered statistician, Irene Stratton, is actually the basis for most of my treatment guidance since I saw her present at one of the NDESP/RSM National Diabetic Eye Screening Conferences. She was talking about Diabetic Eye Screening but I think the central idea of moving from standardised treatment to individualised treatment works just as well for managing DMO. Standard treatment is good especially if it delivers baseline equality of access to treatment for all patients but, by treating everybody the same, there is little reflection of the variation in pathology and patients.



So, this article is really a plea to not just look at an OCT and think 400 microns central thickness let's inject but to understand what options are available for treating diabetic macular oedema and to use those to get the best possible outcomes for each patient based on their individual needs.

What are our options?

- Improve diabetic control
- Focal laser
- Anti Veg F injection (2 licensed options)
- Steroid injection (Ozurdex) – short term < 6 months
- Steroid injection (Iluvien) – long term < 3 years
- Combination

Diabetic macular oedema (DMO) is not just an eye disease. In fact, let's go further it's not really an eye disease at all – it's predominantly a blood vessel disease. And, it's part of a whole body blood disease. That's very important to remember when treating patients with diabetic eye complications because it's important to let them know that. Otherwise they will think that they have an eye problem. Why shouldn't they? They go to 'Eye Screening' then they get sent to the Eye Unit so it is up to us to join the dots for them and make sure that we are clear about the cause of their DMO. I find it very useful to show patients the OCT images of their eyes. I describe

that their blood vessels are affected by the high sugars in their blood and this makes them narrow, leak and bleed.

Option	Guidance	Benefit	Risk -systemic	Risk- local	Licence/NICE Requirements
Improve Control	NICE Type 1 and Type 2	Slow progression Protect other organs Increase lifespan	None	None	None
Laser	RCOphth	Local	None	Macular burns	None
Intravitreal Anti Veg F (3)	TA 274 (2013) TA 346	Local Short term Decrease PDR	Thromboembolic	Endophthalmitis Retinal hole Inflammation	>400um Central Retinal Thickness patient access scheme
Intravitreal Steroid (2)	TA 349 (Dexamethasone) TA301 (Fluocinolone Acetonide)	Local, longer term from 6 months to 3 years	Minimal	Glaucoma Endophthalmitis Retinal hole Inflammation ...	Pseudophakic Unresponsive to other treatments or unsuitable patient access scheme
Combination					

Table 1: Options available to most Eye Units for treating DMO.

I show them their circinates and describe them as - 'like chucking a milky coffee on the carpet – the middle is boggy and the fatty bits gather around the edge of the stain'. Most diabetic eye disease is completely asymptomatic until late so this may be the only time that patients will see what their diabetes is actually doing.

Diabetic control

There is a huge amount of very good evidence that diabetic complications are related to duration and diabetic control, by which I don't just mean the blood sugar or HbA1c but the blood pressure and fats in the blood too. The most accepted way of measuring control is HbA1c but interestingly in an audit that we carried out in my hospital (presented at BARS 2018) the vast majority, 93%, of patients did not know what their HbA1c was. That is pretty staggering when you think that it is the main measure of how likely they are to get complications and it's checked every year in primary care. We also found that those people who did know their HbA1c had significantly lower values than those that didn't. Knowledge is power! We discuss an abbreviated form of the NICE guidelines for Diabetes (Table 2) with all our new patients to give them some control over their own disease. Patients at high risk are referred directly to the Hospital Diabetes Unit.

A	Is for HbA1c, which is a measurement of the sugar in your blood. Your HbA1c should be 6.5% (48mmol/mol) to 7.0% (53 mmol/mol) or less. Ask your GP to tell you. Your day to day blood sugar should range from 4 (before meals) to 10 (after meals).
B	Is for blood pressure. This should be 130/80 or less.
C	Is for cholesterol. This should be 4 or less.
D	Is for diet. Low Glycaemic index. Try not to eat processed or white food (eg: bread, rice, pasta) and eat lots of unprocessed food and vegetables.
E	Is for exercise. Walk as much as possible.

Table 2: An abbreviated form of NICE guidelines for Diabetes, copyright ©

Patient story:

How I've done since my first appointment with you:

Thu 20/10/2016 17:53, To: Wilkinson Elizabeth (NORTHERN DEVON HEALTHCARE NHS TRUST);

'Hi Elizabeth

After my appointment with you on Tuesday [REDACTED], here is my email for you as requested. When I had my first appointment with you I was shown a picture of the back of my eye and you pointed out a leak. I can remember the exact date so please use my records to get them if needed. Together we discussed how I could reverse the damage. I was eating healthy since being told about my Diabetes to try and lose weight, but had a long way to go. I listened to you telling me to walk 10,000 steps per day and how you were not using the lifts in the hospital to walk your own 10,000 steps. I was really worried about losing my sight so set myself a target to do 10,000 steps every day. I purchased a Fitbit to count my steps and read about what else I can do. My husband and I looked at other changes to be made in my diet (and his) to help lower my sugar levels and stop the pressure in my eyes getting worse. I also read that 30 minutes per day of exercise is also very good. I started doing 30 minutes per day on a cross trainer and making sure I completed the 10,000 steps. I then joined my local gym and started running. I downloaded the couch to 5k app and started running. It has taken me longer than the app's 8 weeks but I completed the steps each week and now run regularly. I have now downloaded the couch to 10k and started working on this. I live in Bickleford and a few weeks ago ran for the first time to Instow without stopping which is about 7 miles. Since June this year I have been using the slimming world diet (if you can call it a diet). I think of it as more of a healthier way of eating and once you get your head around what and how much you can eat it's really easy to follow. I really recommend Cauliflower rice which fills you up and replaces rice with chills. It has been hard work and at first getting used to the changes was hard but well worth it. I was a size 18 and have now just bought my first size 10 jeans. I am half the person I was and feel so much better and healthy for this. My blood work is the same as the 'normal' person and the new picture of my eyes this week was normal. I am hoping that at my next meeting with Diabetic Nurse for my check up I will be taken off the last tablet I am on. Thank you once again Elizabeth for your help and the kick I needed to get where I am today. Please feel free to use this email to show others that hard work pays off. I hope it will help others. Once again thank you. Kind regards'

Focal laser

Laser treatment has somewhat gone out of fashion for the treatment of DMO but it is a very useful tool in our armoury especially for patients who have parafoveal disease. Newer lasers are kinder to the retina and less likely to cause deep, spreading burns nowadays. In fact often you can't see the laser marks afterwards. Generally we try and directly target the microaneurysms to seal them and then do a pattern of very light, non-ablative burns over the area of leakage. Laser takes a little while to start working, about 2-3 months and lasts up to a year.

The main risk with macular or focal laser is macular burns which cause a complete central blind spot. This is why we don't laser too close any more as we have other options for central fluid.

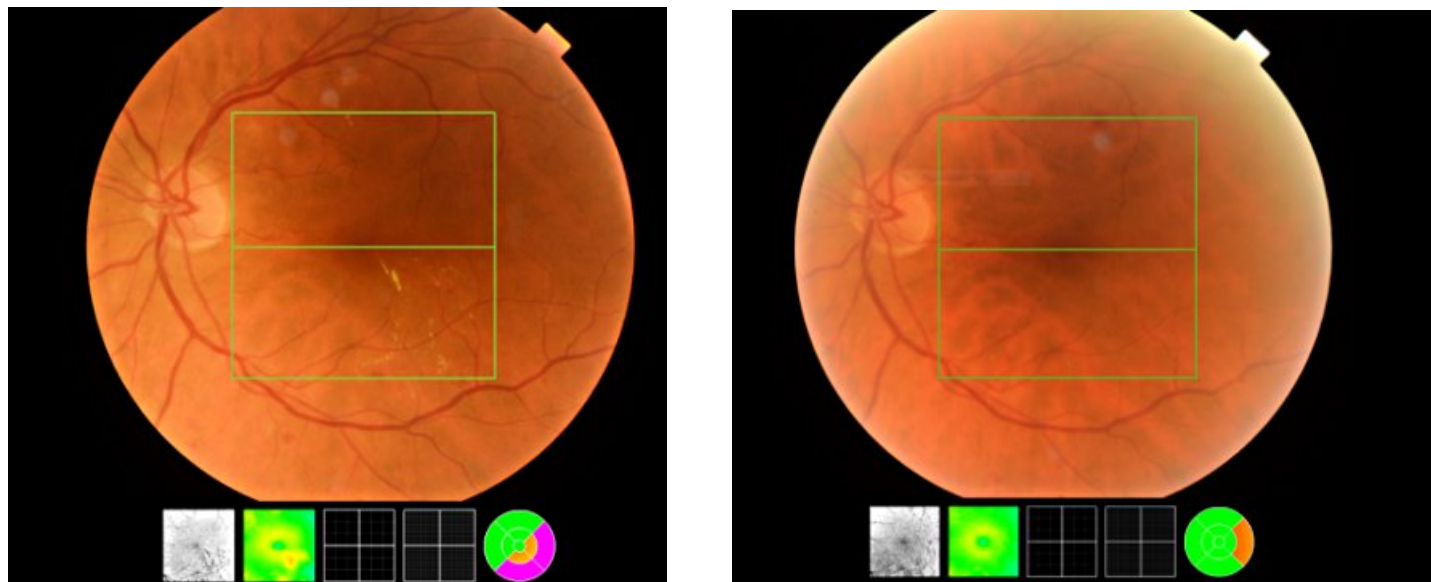
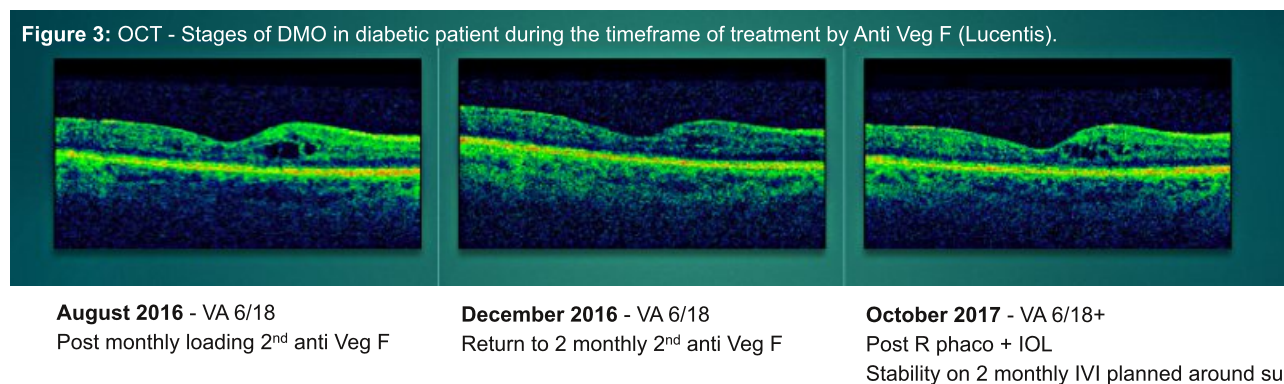


Figure: 1a) Pre and 1b) Post focal laser images taken 1 year apart.

Anti Veg F injections

We have two licensed and approved Anti Vascular Endothelial Growth Factor (Veg F) intravitreal drugs for the treatment of DMO. The criteria for their use is that there must be significant central retinal thickness on OCT scan of ≥ 400 microns and a patient access scheme for pricing. The first of these anti Veg F drugs approved by NICE was ranibizumab (Lucentis) which is given monthly after a 3 month loading phase. Aflibercept (Eylea) is given monthly for 5 months loading and then every 2 months. We know from the trial data that the first year is likely to require the most injections somewhere between 7 and 10 then the second year between 3 and 4 and less as time goes on. In fact whilst most patients fit this, as with all treatment, there is a spectrum. Some patients will need only their loading phase and no more and some will need continuous dosing. Potential adverse events are endophthalmitis, retinal tears, inflammation. There was concern about thromboembolic adverse events eg strokes and heart attacks, but as we are seeing more data this appears to be reflecting the already high risk that DMO patients have of these events. Still for at risk patients I tend to use Lucentis which has a shorter half life so may have less systemic effect.



This gentleman presented to me in 2012 which was just before we got the NICE guidance for the use of anti Veg F drugs. I have only shown his right eye because the left is amblyopic with a maximum potential vision of 1/60. This is important because if we standardised treatment, he would fit criteria but there would be no benefit to him whilst he would bear the risks and burden of treatment.

Steroid injections

There are two licensed and NICE approved intravitreal steroids that we can use in DMO. Dexamethasone (Ozurdex) is the shorter acting, lasting up to 6 months and Fluocinolone Acetonide (Iluvien) is longer acting lasting up to 3 years. The eye must be pseudophakic and unresponsive to other treatment (required by NICE). There is a risk with pressure rises and glaucoma with both but the vast majority can be treated with topical glaucoma medication. Iluvien is particularly effective in patients with chronic DMO with poor vision. It is also very useful in patients who for one reason or another cannot have treatment under topical anaesthetic as was the case with the gentleman below who has severe learning difficulties. We couldn't treat him with monthly injections as this would have been a huge burden on him so we gave him a Ozurdex in each eye, made sure he had no adverse events and then combined cataract surgery with IVI Iluvien in both eyes.

Figure 4: OCT - Stages of DMO in PDR patient during the timeframe of combination treatment by PRP and IVI Steroid.

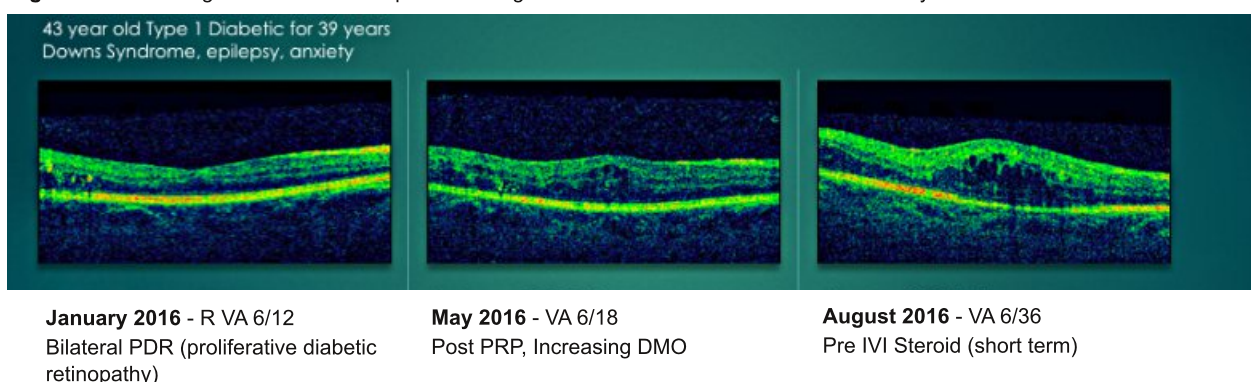


Figure 5: OCT - Stages of DMO in diabetic patient during the timeframe of treatment by Steroid.



Combination

Looking at each patient, and each eye, as individuals means that taking a combination approach is often best. Eyes will often need anti Veg F drugs and focal laser, the thought process being that if you can get the retina dry with the anti Veg F then you can target the leaking area with less ablative power more effectively. And, potentially decrease the number of injections needed. Some patients need long acting steroids and every so often an anti Veg F injection too which is often described as a rescue treatment. New evidence has shown the value of anti Veg F injections in proliferative diabetic retinopathy too so we use different combinations depending on individual needs.



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Diabetic Retinopathy R2 Audit: Plymouth DESP, EMIS Care

Sarah Eells (Screener/Grader)¹, Marc Lewis (Programme Manager)¹, Madhavi Paragati (Clinical Lead)^{1,2}

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Introduction

This is a comparative analysis of Plymouth DESP R2 referrals to Hospital Eye Services over the period of one year (31/03/2015 to 01/04/2016) with a follow up period of one year. R2 is defined by NDESP as pre-proliferative diabetic retinopathy and the presence of one or more of the following: IRMA, Multiple blot haemorrhages, venous reduplication and venous beading. Pre-proliferative diabetic retinopathy is classed as a non-urgent referral and currently needs to be seen in HES within 13 weeks from screening to appointment time. The acceptable standard at the start of this audit was 100% within 18 weeks of referral.

Purpose

To evaluate our performance regarding our R2 referrals into HES. Analysing our accuracy of grading. Looking at the comparability to HES, any missed STDR and the timescale of patients being seen.

- Did we have a close agreement rate or are we over or under grading.
- How many referred R2s did HES agree with.

Therefore, as a result asking ourselves:

- Are we referring appropriately?
- Are we missing anything?
- Also, was the first HES consultation within the required time scale.

Method

91 patients who were graded as R2 by Plymouth DESP over the one year period were included in the audit. We looked at patients demographic data, previous results and referral to appointment time. The appointment results we looked at Plymouth DESP to HES comparable R grade, comparing lesions found and the outcome after HES appointment. We also looked at the subsequent appointment looking to see if we as a programme over or under graded, or had agreed the R grade.

Results

- 91 patients graded and referred for R2 in the period of one year between 31/03/2015 and 1/4/2016 included in the study.
- None of the referrals were for Under 25, they ranged between 25-89 with the majority being aged between 56-70.
- Male was the dominant gender (57 out of 91).
- Type 2 diabetes was noted in 69 out of 91 patients.
- Age, gender and diabetes type distribution are documented in Fig 1, Fig 2 and Fig 3 retrospectively.

Fig 1— Age

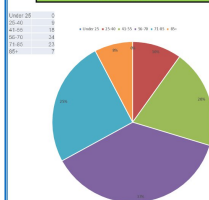


Fig 2— Gender

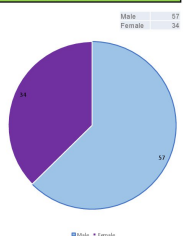
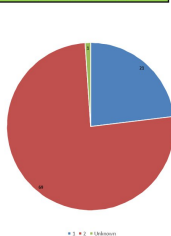


Fig 3— Diabetes type



- Duration from referral time to appointment was 82 days approximately 12 weeks. Breakdown featured in Fig 4.
- The majority of the R2 referrals were referred for Multiple Blot haemorrhages with 60, the next being IRMA with 42, Venous Beading with 12 and the least being venous reduplication with 3. But worth to note patients may have been referred with more than one lesion. Graph shown in Fig 5.

Fig 4— Referral to appointment duration

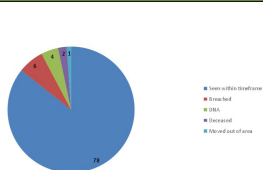
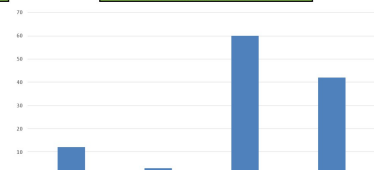


Fig 5— Referral Lesions



- At HES 50 of the patients were graded as R2, 30 were graded as R1 and 3 were graded as R3A, Fig 6.
- The three patients graded R3A at HES may have had the pathology in the peripheral beyond the realms of the standard 4 images per patient.
- On average our agreement rate with HES was 55%, we over graded 33%, under graded 3% and 9% had no information. Fig 7
- After the HES appointment, 52 were kept in HES, 32 discharged back to screening with 19 of those put on a 6 month DS review and 13 on AR. Fig 8 and 9.

Fig 6— HES grade

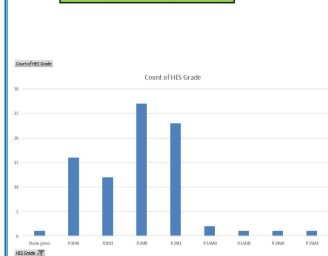
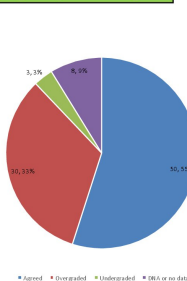


Fig 7— Agreement of R grade



Results

Fig 7—Outcome at HES

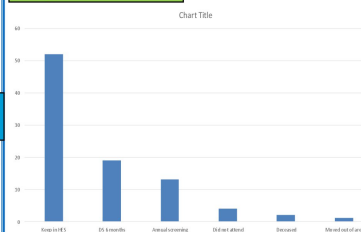
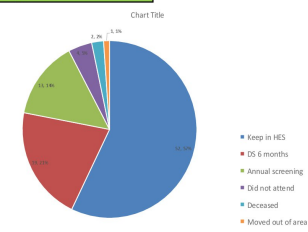


Fig 8—outcome at HES



- We looked at the patients subsequent screening after discharge.
- Of the 13 that were put on AR to see if any had STDR. 3 were found to be R1, 8 were R2, 1 was deceased and had no information.
- Of the 30 found to be over graded we found 9 to still be R2, 1 was graded R3A (originally kept in HES, DNA and screening community 18 months later and 9 remained in HES. Fig 9 and 11.
- Of those agreed R2 patients, 17 were found to still be R2. Fig 10 and 11.
- Those under graded remained in HES. Fig 11.

Fig 9

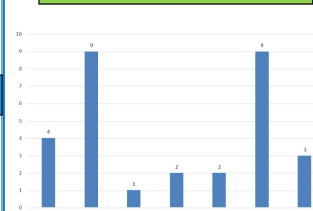


Fig 10

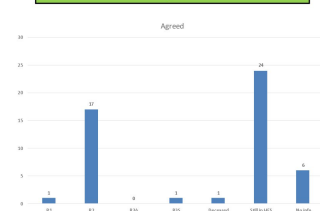
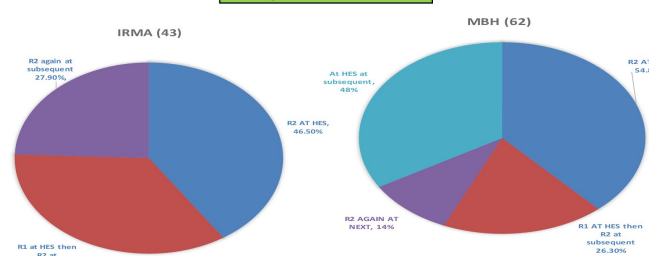


Fig 11— subsequent screening comparison

	HES Grade	Overgraded	Agreed	Undergraded
None Given		1	0	0
R1M0		16	4	0
R1M1		12	1	0
R2M0		27	5	8
R2M1		23	4	9
R3AM0		2	0	0
R3AM1		1	1	0
R3SM0		1	1	0
R3SM1		1	2	1
Remaining in HES		9	24	2
Deceased		2	1	1
NO Info		3	0	0

- The following Fig 12, is a look at the R2 lesions found, looking to see if the different grade at HES was associated with certain lesions eg. IRMA harder to see on Slit Lamp.
- 26 % of MBH featured patients were graded as R1 at HES and then 14% were graded R2 again at subsequent screening. This is compared with 40% of IRMA featured patients graded R1 at HES and then 27% of those patients were graded R2 again at the subsequent screen.

Fig 12— Referral Lesions



Conclusion

In conclusion

- The DESP-HES agreement rate for R2 referrals were at 55% (50), We over-graded 33%(30) under-graded 3% (3).
- Of the 30 over-graded at the subsequent screening 9 were graded again as R2 by the DESP. 8 patients put back on annual recall by HES were graded as R2 at the subsequent screening.
- The R3A patients remained under HES and the R3S graded patients at HES were regraded as R3S at the subsequent screening.
- The patients were seen by various different clinicians in HES, whom may have had different opinions regarding what constitutes an R2 patient.
- The mean duration from referral time to appointment time 82 days

Overall, we believe that this demonstrates that our grading was broadly in line with how the HES was classifying patients and overall our level of grading was safe in respect that there wasn't much STDR not picked up by screening.

Taking into account the lesions and what was found on the subsequent screen there is a possible difference between Plymouth DESP and HES grading of R2 with a 55% agreement rate. However, 57% remained in HES after the appointment. With regards to under-grading (3%), Plymouth DESP did miss R3A (2 patients—no suspicious R3a features reviewing the images, 1 patient—suspicious); all patients were reviewed in HES within the time scale.



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Diabetic Eye Screening: Virtual R2 Refinement Pathway

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Introduction

Patients with diabetic eye disease comprise the second largest group of patients attending the Eye Clinic. Increasing prevalence of diabetes has resulted in an increase in the diabetic eye screening population. The total number of people with diabetes globally is projected to rise from 171 million in 2000 to 366 million in 2030 ^[1]. In 2015-2016, there were almost 3.6 million people in England diagnosed with diabetes, and 2.02 million eligible people with diabetes received screening (www.diabetes.org.uk and <http://diabeticeye.screening.nhs.uk/statistics>). This places mounting pressures on the doctors in Eye Clinics to see the growing number of patients with diabetic eye disease. To better manage this increasing demand on services, more discerning processes need to be introduced to better identify those patients who need to be seen in the Eye Clinic. This will largely be the group of patients who require active treatment, rather than monitoring for the need for treatment.

It is the aim of any screening process to identify disease for which treatment is required. In order to better utilize the limited resources within hospitals, a second tier of scrutiny has increasingly been employed to increase the efficiency of screening for detecting sight-threatening diabetic retinopathy for which treatment is immediately or imminently to be required.

These referral refinement pathways aim to optimise efficiency to best utilise the limited resources of the Hospital Eye Service (HES). For example, the local M1 referral refinement pathway in Derbyshire assesses those patients identified by the screening programme by introducing a second tier of screening with an OCT (Optical Coherence Tomography) examination. With the additional information provided by the OCT, only those patients who require treatment are referred into the HES.

M1 identification in the screening programme has a high sensitivity (identifying those with disease who require treatment) but a low specificity (identifying those who do not require treatment), making the introduction of a second tier screening test, i.e. the referral refinement pathway, to improve specificity highly attractive. Treatment for diabetic macular oedema or clinically significant macular oedema (CSMO) was defined in the Early Treatment Diabetic Retinopathy Study (ETDRS) using the following criteria: retinal thickening at or within 500µm of the fovea, exudates at or within 500µm of the fovea if associated with adjacent retinal thickening, or an area or areas of retinal thickening one disc area in size, at least part of which is within one disc diameter of the fovea ⁽²⁾. The ETDRS used contact lens biomicroscopy and this was deemed to agree very closely with stereoscopic photography. Most diabetic retinopathy screening in the UK, is however based on 2-dimensional or non-stereoscopic photography and therefore surrogate criteria are used to identify possible CSMO leading to a set of M1 screen positive criteria which has a very high sensitivity but low specificity for the condition. Ocular coherence tomography (OCT) allows both objective and quantitative assessment for the presence of oedema. The introduction of OCT in the Referral Refinement Pathway for M1 disease as expected has greatly improved its specificity ⁽³⁾.

The South Derbyshire Screening Programme

The Derbyshire Screening Programme is comprised of two teams, North and South, managed by two separate Clinical Leads. The South team presently screens approximately 31000 patients per year for diabetic retinopathy (DR). This article refers exclusively to patients managed by the southern team where the overwhelming majority of patients with DR are referred to the Royal Derby Hospital. In recent years, annually the southern team identified approximately 1000 patients with M1, 250 patients with R2 and 90 patients with active R3.

M1 Referral Refinement Pathway

This pathway has been operational for approximately 8 years. Instead of a referral into the HES, all patients identified with M1 are made an appointment to enter this pathway where they are assessed with a measurement of visual acuity, repeat standard screening photographs and OCT images of the maculae are obtained. These images are assessed by either the Clinical Lead or an optometrist working within the programme.

There are 4 sessions a week where the images are captured by a member of the screening team. The images are subsequently assessed in 2 separate sessions (8 hours in total) by either the Clinical Lead or the optometrist (who have one 4 hour session each).

Currently this pathway assesses approximately 70-80 patients a week. The majority of patients are reviewed at recurrent intervals of between 6-9 months unless treatable disease is identified when they are referred into the HES, either for laser or anti-VEGF treatment.

Patients with M1 who have been treated within the HES, when deemed stable are referred back into this pathway for monitoring. Patients who no longer have M1 disease, are discharged back into the screening pathway, i.e. annual screening.

R2 Referral Refinement Pathway

This pathway was established in 2016 and has now been operational for over 2 years. Patients with R2 disease are referred into the HES not because they need immediate treatment but because of the limitations of the size of the images captured in the screening process; patients are referred into the HES for a thorough examination of their fundi, for the possibility of R3 disease outside of the area assessed in the screening images.

With the advent of wide-field photography in recent years, there is now the possibility of capturing in a single image up to 200° of the fundus. The R2 referral refinement pathway utilizes this modality to allow a more thorough examination of the fundus for R3 features photographically without the need for a slit-lamp examination of the patient.

Once identified with R2 features in screening, patients are invited into the R2 referral refinement pathway where they are assessed by measuring visual acuity, one or more wide-field fundus photograph and OCT macular examination.

The wide-field photographic system that is used in the South Derbyshire Programme is the Optos system (Optos, Dunfermline, UK) and the OCT image is performed with a Topcon scanner (Topcon, Tokyo, Japan).

The images are captured by a Healthcare Assistant and are then subsequently assessed by an Ophthalmology Consultant (Clinical Lead). The time to assess a photograph is quicker than examining a patient on a slit-lamp and arguably both technically easier (for both doctor and patient) and more effective (3). The patient's journey is much quicker and many find it a more pleasant experience. The photographs are also valuable for documentation and for the detection of progression; patients examined in the Diabetic Eye Clinic setting have no formal photographic documentation of their status.

Figures 1 - 4 are examples of Optos images obtained in the R2 referral refinement pathway.



Figure 1. Image of a right eye demonstrating multiple cotton wool spots and IRMAs.

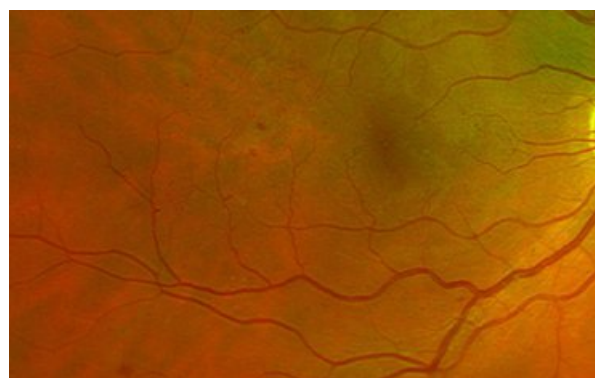


Figure 2. Magnified portion of an image of the right eye demonstrating loops and IRMAs.

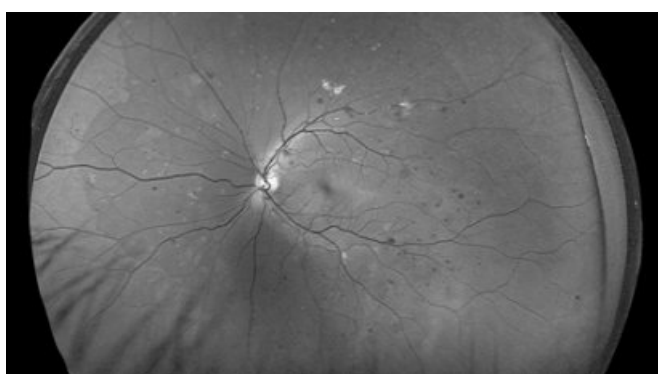
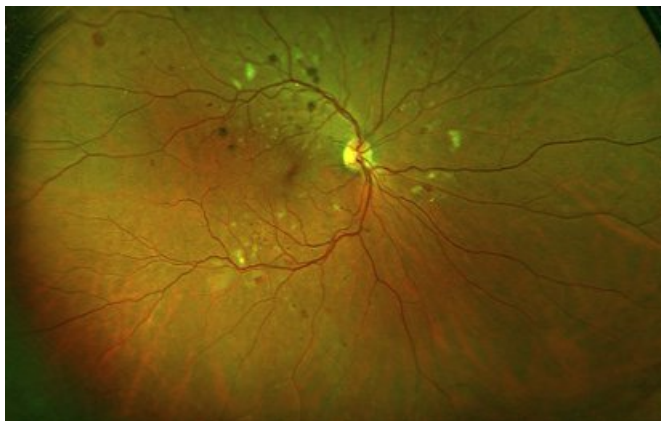


Figure 3. Comparison of a single Optos image with the images obtained during the original screening process.

The throughput of this pathway is approximately 6-8 patients in an hour, compared with 3 - 4 in a conventional face-to-face slit-lamp clinic, approximately the equivalent of a doubling of the capacity of the Diabetic Eye Clinic. This has enabled all patients who attend the Diabetic Eye Clinic to be assessed in a timelier manner. At present, 12 patients with R2 disease each week are assessed in the pathway; the majority of these patients are reviewed again within this pathway at 6-9 monthly intervals. If either R3 disease or treatable M1 disease is identified, they are referred on for the appropriate laser or anti-VEGF therapy. The results of each encounter are communicated to the patient, General Practitioner and Screening Programme.

Figure 4. Red free image demonstrating R3 disease with new vessels visible in the upper temporal quadrant.

Table 1.

Grades of diabetic retinopathy of all R2 referrals, comparing findings in a conventional clinic with slit lamp examination vs the R2 referral refinement clinic.

Diabetic Retinopathy Grade	Conventional slit lamp examination clinic (% of patients)	R2 Referral Refinement Pathway (% of patients)
R1	20.1	29.5
R2	75.4	64.1
R3	4.5	6.4
M0	45	30.8
M1	55	69.2

Table 1 presents data of all patients referred with R2, identified by the screening programme to the HES. For example, when these patients were examined on the slit lamp, 20.1% of patients had their grading downgraded to R1 as compared to 29.5% within the R2 referral refinement pathway. The Table presents data comparing the findings in the conventional slit lamp clinic for the 3 years prior to the introduction of the R2 referral refinement service compared with the detection rate in the R2 referral refinement clinic for the 2 years after its introduction. The detection rates of the various grades of diabetic retinopathy are comparable between the two systems (R1 $p=0.31$; R2 $p=0.25$; R3 $p=0.47$).

Wide-field Imaging

Retinal imaging techniques have evolved at a remarkable pace in the last two decades. Wide field imaging (WFI) and ultra-wide field imaging (UWFI) are becoming increasingly widespread. WFI refers to imaging beyond 50 degrees field area and UWFI systems can image up to 200 degrees. They are capable of imaging over 80% of the retinal surface area. They offer useful information about the vasculature in the periphery and also highlight other retinal lesions.

Wide-Field Imaging

Wide-field images can be produced through a variety of techniques. One option is to create a montage of images, which is a combination of several sub-wide field images, allowing visualization of up to 75 degrees of retina. Montaging of retinal images for the classification of diabetic retinopathy was established using the Airlie House protocol in 1968 and expanded to 7 fields in 1971 from the original 5 fields. The ETDRS group used stereoscopic colour fundus photography in 7 field photography montage as the gold standard for the detection and classification of diabetic retinopathy ⁽⁴⁾.

The first true capture of a wide-field retinal image came through using a wide-angle lens with a traditional fundus camera and most recently through using a specifically-designed wide-angle camera system. Although 7-field photography is a reliable method for assessment of diabetic retinopathy, it is a time-consuming examination requiring skilled photographers. Consequently, newer modalities are replacing 7-field imaging, particularly since the advent of ultra-wide field systems because of ease of use and wider retinal coverage.

Since the first wide-angle camera system developed by Pomerantzeff in 1975 (Equator Plus) which used a contact lens and transcleral illumination, several non-contact wide-field systems have been developed and are currently in use ⁽⁵⁾. Optos (Optos, Dunfermline, UK) introduced non-contact scanning laser technology to take ultra-wide field images. The laser uses red (633 nm) and green (532 nm) lasers which are reflected off a large concave elliptical mirror enabling large scan angles of up to 200° of the retina in a single capture. The resulting images are displayed as red only, green only and a combined red–green “false colour” image. Each image has a resolution of 2000 by 2000 pixels ⁽⁶⁾. With Optomap auto-montage, up to 97% or 220° of the retina can be imaged with the multi-capture, montaging functionality. **Figure 5** demonstrates the superior coverage provided by the Optos system as compared with 7-field photography.

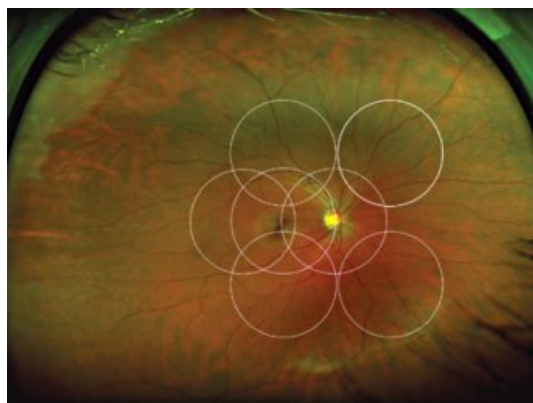


Figure 5. Overlay of 7 field montage onto an Optos image demonstrating superiority of coverage with the Optos system.

Visualization of the peripheral retina using ultra-widefield imaging has led to a new era in the assessment of retinal diseases including diabetic retinopathy. Price et al, compared diabetic retinopathy severity grading between ETDRS seven-standard field view and Optomap ultra-wide field images and found that a significant proportion of images (19%) were assigned a higher retinopathy level in the ultra-wide field view ⁽⁷⁾. Similar findings were found by Wessel et al, who reported that ultra-wide field fluorescein angiogram demonstrated retinal pathology not evident in a 7 standard field in 10% of eyes ⁽⁸⁾.

Other wide-field systems include the Eidon and Clarus 500. Eidon (Centervue, Padova, Italy) is a scanning laser ophthalmoscope WFI system which has multiple confocal imaging modalities enabling 60° field visualization in a single capture (**Figure 6**). It has an automated mode which can capture multiple 60° images and create a montage of up to 110° field. This area of coverage can be extended to 150° manually.

Clarus 500 (Carl Zeiss Meditec, Jena, Germany) UWFI is able to capture a single wide-field image of 133° of the retina which can be combined into an ultra-wide-field montage allowing visualization of 200° of the retina (**Figure 7**).

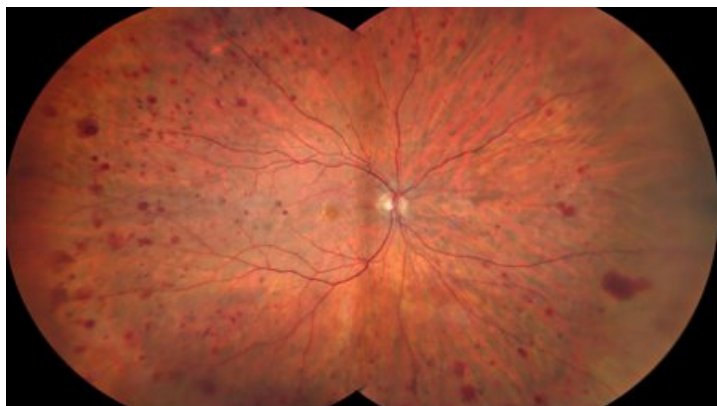
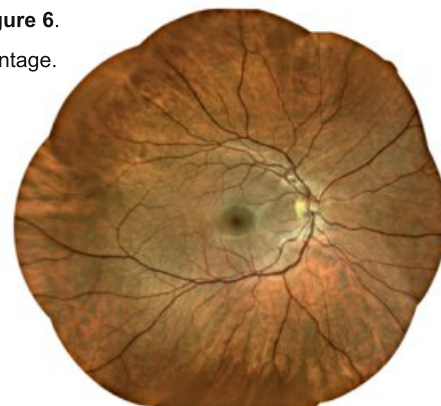


Figure 7. Clarus 500 Montage.

Figure 6.

Eidon Montage.



Limitations of the R2 Referral Refinement Pathway

The limitations of the pathway can be categorized into those related to the wide-field camera system used in the Derbyshire pathway (Optos) and non-camera factors.

The images captured with the Optos system can be limited by artefacts, the most significant of which is the intrusion of eye lashes obscuring a part of the image; this often requires the acquisition of more than 1 image with the patient directing their gaze in different directions. The Optos system, capturing images using scanning laser ophthalmoscopy, produces images which are grainy in appearance and can present interpretational difficulties particularly in the identification of finer details such as exudates; this difficulty is compounded by the large image size requiring magnification for a more thorough examination for smaller lesions. Media opacities and vitreous opacities can also significantly reduce image quality, sometimes rendering some images uninterpretable. Because of the depiction of the concavity of the retina on a flat screen, the image is distorted, particularly of the periphery of the retina.

The R2 clinic has unfortunately a relatively high rate of non-attendance (approximately 20% although this is comparable to the non-attendance rate at the Diabetic Eye Clinic). Derbyshire is quite a large county and at present the service is only at a single location in the city of Derby which may be limiting access for some patients. One of the future refinements to the programme could include setting up peripheral sites in order to improve access for some patients; these sites presently already constitute a part of the Screening Programme; this ambition is limited by the need to replicate the equipment required, i.e. Optos and OCT equipment which are of a considerable cost.

As patients do not have a face to face encounter with a doctor, there is the potential loss of an opportunity for advice to be offered to the patient regarding their retinopathy status and the role that better glycaemic and blood pressure control has to offer.

Conclusion

After over 2 years of providing the R2 Referral Refinement Pathway, no safety issues have been identified and during this time, the efficiency of the HES has been increased with the combined throughput of both the M1 and R2 pathways.

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National update

Patrick Rankin, National programme manager, diabetic eye screening programme.

It's been sometime since we talked about the health screeners diploma, but the 'new' qualification has now been with us for 3 years, so it seems timely to provide an update.

NDESP started developing the diploma in 2014 with a view to making the previous City and Guilds more adaptable to differing learning styles and less prescriptive with regards to evidencing learning outcomes. It was initially envisaged that the number of units required would be reduced from 9 to about 6 or 7, however we ended up with nearly 30 different units across diabetic eye, abdominal aortic aneurysm and new-born hearing screening programmes...not quite what we initially planned!! The main aim in developing the new qualification was to provide a nationally recognised qualification for non-professionally regulated screening professionals that would cover all the requirements for their clinical roles but also provided them with a qualification they could use for further development.

During the development we came across a number of obstacles that we needed to overcome, such as the need for CAVA qualified assessors being a requirement at the last minute, to trying to explain the qualification and assessment processes to programmes when we ourselves weren't 100% sure of the processes. There was a huge amount of work undertaken across PHE, Health Education England, Skills for Health and the local programmes to develop the qualification. We now feel it has bedded in well and programmes and learners are seeing the benefits to the more structured clinical aspect of the diploma but also the ability to assess every learner differently for their own style of learning.

Between April 2016 and October 2018, 63 learners have completed the HSD in DES and 322 are working through the qualification. Across the 3 pathways over 100 learners have successfully completed the HSD. Learners are expected to complete the qualification within 24 months, with the average time taken to be about 13 months to fully complete it. This is very similar to the time taken for the previous qualification. Assessors with a formal vocational assessor qualification are now essential to support learners working through the diploma. To date, 37 staff in DES have completed the level 3 certificate in assessing vocational achievement (CAVA) while 59 are working through the qualification. We accept that this mechanism to becoming an assessor is more time consuming than the previous process, however the CAVA training provides a structured process and nationally recognised qualification for how to assess competency.

We have been informed by awarding centres for the diploma, that some programmes are registering their learners 4-12 months following them starting work with the programme. Whilst this is a local decision, ideally learners should be registered on the diploma as soon as possible as any evidence of clinical practice must have been undertaken within the previous 4 months, so they may end up having to repeat some of the clinical competencies.

Funding for the HSD and CAVA has been available since its roll out in 2016. Public Health England (PHE) has administered the funds on behalf of Health Education England (HEE) since 2016. However, from 1 April 2019, HEE will now administer this funding themselves for 1 to 2 new screeners per each programme. Any questions about this funding should be directed to local HEE offices or php@hee.nhs.uk.

Since the launch of the HSD, PHE has produced and provided several resources to help develop and support learners and assessors in delivery of the diploma. We are developing a series of additional resources over the following months to further support local screening programmes in delivering the HSD.

The first of these is a suite of 5 short films developed in conjunction with Skills for Health. The films focus on 5 key areas of good practice that enable learners and assessors to work through the HSD efficiently, while maintaining the quality of the qualification. We expect this to be available on HEE's e-learning for healthcare website at the end of March 2019.

The next resource will also be hosted on HEE's site. This resource will focus on working through the HSD holistically and simplify mapping of evidence to numerous learning outcomes. We held a focus group meeting in October 2018 with a mix of learners and assessors. The resounding feedback we received from the focus group was for a resource that is simple to use and makes the HSD relatable to the screener's role. We anticipate that this resource will be available at the end of September 2019.

Finally, we have been holding half day HSD update sessions around the country. We have 2 more sessions to hold in central London. The sessions are 3 and a half hours long, with presenters from awarding centres and assessors from local provider programmes. Those who have attended have found the opportunity to network helpful as well as gaining top tips from others who are working through the HSD.

Any feedback, positive and constructive is always welcomed by the education and training team as all these resources and support have been developed following feedback from learners and assessors.

Pathway standards review and update

The current pathway standards were introduced into the programme in 2017 and we now have 12 months of validated data to be able to make some minor adjustments and to add some thresholds for some of the newly introduced standards. Following a consultation exercise and internal sign-off process in PHE the following changes will be made to the pathway standards in April 2019:

- The format has been changed from PDF to HTML
- Language and terminology has been updated to reflect national guidance for people with diabetes
- Pathway standard 2 (invitation for first routine digital screening appointment)
 - Screening providers that uses open appointment model have been given 7 days to send the invitation letter out to people with diabetes, the individual will still need to be seen to have the offer of an appointment with the 89-day period
- Pathway standard 3 (timely recall for routine digital screening)
 - The +/- six weeks has been amended to only include +6 weeks so that programmes aren't penalised for recalling individuals that regularly DNA early
 - -6 weeks will still be available on reports to ensure services aren't running <12monthly screening intervals
- Pathway standard 4 (timely recall for Slit lamp biomicroscopy)
 - The +/- six weeks has been amended to only include +6 weeks so that programmes aren't penalised for recalling individuals that regularly DNA early
 - -6 weeks will still be available on reports to ensure services aren't running <12monthly screening intervals
 - Thresholds will be introduced and will be reviewed again in 12 months
 - 60% acceptable
 - 85% achievable
- Pathway standard 6 (pregnancy standard)
 - To report quarterly instead of annually
 - We are aware of the difficulty of programmes achieving this standard due to the NICE guidance, software configurations and the ability to identify women who are pregnant.
 - No thresholds will be added for this standard until the data is of better quality
- Pathway standard 8 (Proportion of cohort that have DNA'd in previous 3 years)
 - Thresholds will be introduced and will be reviewed again in 12 months
 - ≤8% acceptable
 - ≤5% achievable

This review and consultation exercise highlighted a large variance across the country in what local programmes were doing within digital surveillance. Therefore, over the next 12 month we will be carrying out a full review of the digital surveillance pathways within the screening programme to ensure that it is being used appropriately and for clinically relevant reasons only.

Screening intervals update

We are still working closely with NHS England to implement 2 yearly screening intervals at some point in 2019/20. The project has unfortunately been delayed due to the complexities of the IT provision/commissioning within the screening programme. We also need to be able to demonstrate high quality grading within programmes prior to moving over to 2 yearly intervals and have been developing a new statistical derived process to do this. It is hoped that some pilot/pathfinder screening programmes can be identified in the coming months.