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ABSTRACTS

# MEETING REPORT

**Clinical Audit in Retina 2016: Summaries and discussions**

**Park Plaza, Vauxhall Road, London**

**20th April 2016**

**Chairman**: Adnan Tufail, Moorfields Eye Hospital, London, UK

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## S01
## What makes a good audit?

Audit is an important component of clinical governance; it is a quality improvement process that seeks to improve patient care and patient outcomes through systematic review against explicit criteria. A clinical audit, when done effectively, offers quality improvement assurance processes, determines compliance with clinical standards, identifies and minimises risks, and improves outcomes. In the kick-off presentation by Peter Addison, Consultant Ophthalmologist and Clinical Lead for Audit at Moorfields Eye Hospital, London, he explores what it takes to conduct an effective audit.

Clinical audits are often conducted to improve a process, to enhance a process, to ensure an improvement, or to implement a change. Every stage shown in Figure 1 is critical to conducting an effective audit. Audits should be meaningful and focus on improvements that can be made to any aspect of care or service delivery. When considering the topic for an audit, it is important to weigh up several factors, including the topic benefit and risk; evidence of quality problems; evidence available to inform standards; gravity of the problem (and can it be changed); and the potential for national audit. Further, audit projects need to have clear objectives to set benchmarks for audit teams, and a clear sense of purpose must be established before appropriate methods for audit can be considered.

After the purpose is defined, the audit team should agree on the criteria and standards that will be used in the audit. Each audit will need a set of tools (such as an electronic records management system), a team (often of doctors, nurses, other clinical staff, and managers), and time (setting deadlines for key objectives will help keep the audit on track). Often the purpose of an audit is to explore the capacity for a service, the effectiveness of a service, and, most importantly, the patient safety and efficacy outcomes.

An audit must have a standard to measure the results against. This may include national benchmark data, targets or previously published studies. The priorities of an audit also need to be defined. Audits typically are given priorities, such as external priority (e.g., The National Institute for Health and Care Excellence [NICE] requirement), internal priority (e.g. complaint or incident), service priority (e.g., service evaluation with new services like injections for neovascular age related macular degeneration [nAMD]), or clinical interest (e.g. may lead to research). The clinical interest audits, although interesting and leading to further research questions, are often the lowest priority and sometimes there is less support from within the organisation.

When collecting the audit data, it is critical to harness support from all relevant organisations. Sometimes an electronic patient record, a new database, or advanced statistics, which can be quite time consuming, will be

critical to the success of the audit. The goal should be to conduct a simple analysis that everyone in the care process can understand; however, more complex statistical analysis may be required. Once the data is collected, you may find that it does not give anticipated results, despite the background information that was used to formulate the hypothesis.

After the data is analysed and a conclusion is made, an action plan must be formulated to implement the results. The conclusion, or what was learned from the audit, should define the action plan. All clinical audit reports must have an action plan containing specific actions to address or resolve the issues identified within the audit. The plan should be SMART[1]: specific, measurable, achievable, realistic, and time-related. Whether you plan to increase capacity, conduct a re-audit, or implement a change in service, sharing the experience is also a key aspect of the action plan—this will help all stakeholders improve on future audits.

Perhaps the most challenging part of an audit is the implementation of change. Changes are often difficult to introduce, and they will take some time—teams will need to work together. This may create extra financial and/or time burden, and there may be a lack of support to achieve the proposed changes. The changes should aim to improve the service and patient pathway to improve patient experience, efficacy, and safety.

Finally, a re-audit completes the cycle, and it should be used with the same metrics as the original audit. A good audit will consider all of these factors, with priority given to external requirements and be patient focussed: patients' safety, patients' experience, and patient-reported outcome measures. This will help to establish a clear gold standard for clinical practice and lead to positive changes on a departmental or national level.

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**Disclosures:** PA declared no competing interest.

**Discussion points**

*Q. You touched on personal audit, how do you juggle your personal interests with those that are encouraged more from the trust?*
A. There are limited resources within the trust. Personal audits may not be high up on the agenda. If the revalidation date is coming up soon and deadlines are looming, then resources may be stretched. Ideally audits should be done every year in a significant area of practice; for example, personal cataract surgery audits should be done every year and they may require the cataract surgeon to conduct the process on their own; you will probably not get a lot of support from the trust. The trust will look at priorities before assigning resources.

Q. *In medical retina, the treatment of many patients is pooled. Does that count as an individual audit for revalidation purposes?*
A. We work as big teams. If your 5 year audit profile only has this type of profile, it wouldn't be sufficient. You can include it as part of it, but there needs to be balance in the audits. Given that we work in big teams, and as we scale up, we need to assess what our true contribution as an individual to each audit is. I believe we need a fair spread amongst your audits of, audits where you are the major driver and audits where you participate but do not lead.

**Reference**

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**Figure 1 [S01]:** The eight stages of an effective audit.

## S02

## Intravitreal ranibizumab (IVTR) treatment of wet age related macular degeneration (AMD) in South East Scotland: Effect on blindness rates and 5-year follow-up data

Intravitreal ranibizumab (IVTR) has been used to treat wet age-related macular degeneration (wet AMD) in Scotland since September 2007, but there are few data on the effect of IVTR on blindness rates in the population and long term visual outcomes. Vision loss has an estimated global cost of $3 trillion for the 733 million people living with low vision and blindness worldwide. One billion people worldwide are expected to experience visual impairment by 2020. In his talk, Dr. Peter Cackett reported results from their study[1] that tested the hypothesis that IVTR would reduce blind registration rates secondary to wet AMD in Scotland.

Blind registration data were obtained from the Royal National Institute for the Blind in southeast Scotland for the period 2004 to 2011 (prior to and immediately after introduction of the IVTR programme in 2007). Only full blindness data was included in this study. The total for the population was recorded, and the total for wet AMD patients was included if the terms wet macular degeneration, exudative AMD, disciform scar or choroidal neovascular membrane were used. Legal blindness was defined as a visual acuity of 3/60 (20/400) or lower in a person's better-seeing eye; or a visual acuity between 3/60 and 6/60 with severe reduction of field of vision; or a visual acuity of 6/60 or above with markedly contracted visual field. Case-notes of the first cohort of 100 IVTR patients from September 2007 to September 2012 were retrospectively analysed. Five-year follow-up data on visual acuity outcome, number of clinic visits per year, total number of IVTR injections/patient, and attrition rates were recorded.

Incidence of legal blindness from all causes decreased by 27% from 2004 to 2011 and the incidence of legal blindness from wet AMD decreased by 59% from 2004 to 2012 (Figure 1). Of 104 eyes from 96 patients (mean age 76 years 6 months; 40% male) included in the study, the mean logMAR visual acuity (Snellen equivalent) at the start of treatment was 0.60 (6/24) and after 5-year follow-up was 0.68 (6/29); this is the equivalent to a mean loss of 4 Early Treatment Diabetic Retinopathy Study (ETDRS) chart letters. The average total number of injections was 9.7.

Mean number of clinic visits are presented in Table 1. The attrition rate was 19% over 4 years, predominantly secondary to death.

These data show significant reduction in legal blindness rates secondary to wet AMD since commencement of the IVTR service in 2007. There was stabilisation of visual acuity in wet AMD patients over 4-year follow-up. This demonstrates that efficacy translates into clinical real-world practice and results in the reduction in morbidity secondary to wet AMD. Further work comparing the cost of the ranibizumab treatment versus the economic benefits of prevention of blindness will hopefully justify the high expenditure and workload in providing this service.

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**Discussion points**

*Q. How do you deal with patients dropping out of treatment over 5 years? Are these data last observation carried forward (LOCF)?*
A. The mean follow-up falls off around 4.1 years. The data are LOCF.
Chairman: Even in a clinical trial, missing data are problematic. One reason is that a patient's vision can become so bad that they don't want to continue treatment. It is difficult to answer the question, I think. But the low rate of attrition shows that overall the treatment is good.

*Q. Do people get worse when they cease treatment?*
A. From the data we have, this is difficult to answer.
Chairman: It depends on your treatment. If the natural history is getting worse, this will bias the treatment effects. Part of having a large dataset is that you can look at the data with or without certain parameters. We have approached this with the data, with all missing patients, with patients followed up the whole way through. It looks the same. There is no way to know what really happened to the patients. A simulation can only say so much.

*Q. I think this meeting is important to ask exactly this. If we only have 20% of patients dropping out this is great considering the age group. This group has very few clinic visits. You try to follow up with these patients, but most of patients will have some vision. How would you address it? Would you do a re-audit?*
A. I am not sure if we can re-audit, on this scale. We wanted to compare bias rates with visual outcomes. Despite the fact that we didn't have the same rates as published trials, I think our audit can be compared to these as a real world outcome.
Chairman: Kaplan–Meier curves are certainly another way of looking at the data and they do not depend on missing data assumptions. This would be a useful way to look at this data, indeed, but they also have their issues.

**Reference**

1. Borooah S, Jeganathan VS, Ambrecht AM, Oladiwura D, Gavin M, Dhillon B, Cackett P. Long-term visual outcomes of intravitreal ranibizumab treatment for wet age-related macular degeneration and effect on blindness rates in south-east Scotland. *Eye (Lond)* 2015; 29(9): 1156-61.

**[SO2] Table 1**: Mean number of clinic visits over 5 years

| *Year* | *Mean* |
|---|---|
| *Clinic Visits* | |
| 1 | 9.0 |
| 2 | 5.8 |
| 3 | 4.8 |
| 4 | 2.3 |
| 5 | 0.5 |

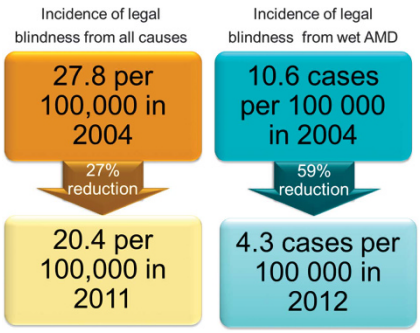


**Figure 1 [SO2].** Incidence of legal blindness registration changes from 2004.

## S03
## The UK retina electronic medical record (EMR) project

Professor Adnan Tufail described the work of the UK neovascular age related macular degeneration (nAMD) electronic medical record (EMR) users group on the treatment of nAMD in real-world settings. In these studies, data from many centres around the country recorded on an EMR device (Medisoft Limited, Leeds Innovation Centre, 103 Clarendon Road, Leeds, LS2 9DF, United Kingdom) were pooled and a national average was obtained.

Patients who participate in clinical trials are often a different demographic than the wider population; they are generally healthy, fit, and will attend clinic visits every month for 2 years. Hence, Prof Tufail and colleagues questioned whether it is reasonable to expect the kind of vision gains in a real-world setting as the gains seen in the pivotal clinical trials such as Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization in Age-related Macular Degeneration (ANCHOR)[1] and Minimally Classic/Occult Trial of the Anti-VEGF Antibody Ranibizumab in the Treatment of Neovascular AMD (MARINA)[2], particularly with regard to safety and long term efficacy.

To address these questions, Prof Tufail's team conducted an audit: (1) to provide 'real' world outcome data; (2) to provide benchmarks for therapy; (3) to show long term outcomes of therapy; (4) to guide predictive models, novel exploration of data, and future studies. The data were derived from information captured on an EMR device and the first data extraction took place at the end of March 2012 yielding data on 11,135 patients (Figure 1).

Analysis of the data immediately revealed the differences between clinical trial data and data captured in a real-world setting. For instance, one of the patients was 108 years old (mean age 79.7). In keeping with all population based studies, there was an excess of females, even if correction was made for the fact that females live longer (male $n = 4{,}071$; female $n = 7{,}062$). Overall, the

visual acuity outcomes were not as good as the pivotal trials[1,2]; however, there were fewer visits and injections. Prof Tufail suggested that clinical standards should reflect these outcomes and not the outcomes of the ANCHOR and MARINA studies.

The other argument is about case mix; baseline characteristics are likely to affect outcomes. The typical measure of visual acuity outcomes is change in vision from baseline. In this scenario, the group that looks to have achieved the greatest gains is the one with the worst baseline vision and the group that achieves the least gains is the one with the highest baseline vision. Letters gained from baseline is not a valid measure without adjusting for baseline vision because lower baseline vision will have better outcomes. Visual acuity state and not visual acuity gain is the most important factor for the patient and may be a more appropriate metric to gauge how good delivery of care is. Further, there is a high rate of second eye involvement, nearly 50%. Current treatment regimens are modelled on monocular vision. One of the advantages of having the real-world data is that we have binocular data.

The overall interpretation of these data is that treating early seems to be associated with better visual acuity state; however, The National Institute for Health and Care Excellence (NICE) does not allow for funding of treatment in patients with a vision of better than 6/12. The team generated a health economics model using data from centers that were allowed to treat better than 6/12 versus centers that were not. The data revealed that it is highly cost effective to treat early. Prof Tufail hopes that NICE will take into account the outcomes of the paper[3].

In addition, the data suggest that there is a year-on-year improvement in preventing binocular blindness and maintaining the quality-of-life measures including driving a vehicle. Many questions still remain. Other important questions to ask include: (1) what is the optimum interval for follow up of patients? (2) what is the optimum time to reactivation after a pause in treatment? (3) when can we discharge patients? Although the data give an insight into intervals of follow-up, it is a public health decision as to where the cut-off point for intervention is placed.

Prof Tufail then presented a series of studies conducted in conjunction with specialised data analysts from City University, London. These data confirmed that ranibizumb reduces the grade of retinopathy in the large data cohort. The data also allow the investigation of the interaction between cataract and intravitreal (IVT) injections. Looking at data from 65,836 cataract operations, 1,935 had undergone previous IVT. Univariate regression analyses, increasing patient age, cataract surgeon grade and number of previous intravitreal injections were significant predictors of posterior capsule rupture.

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**Discussion points**

*Q: I work in a hospital that has some sort of electronic medical record (EMR). What is the best EMR system, in your opinion?*
A: As long as you collect the data in a robust way, it should be able to be mined. However, up to this point, the only system widely available in the UK where that has been easily achievable is the Medisoft (Medisoft Limited, Leeds Innovation Centre, 103 Clarendon Road, Leeds, LS2 9DF, United Kingdom) system. We are now trying to compare data outcomes internationally and will merge data collected by different EMRs and Non-EMR repositories of data. The important part is the structure of the data, not the EMR device. We should all collect the same minimal dataset, and a group called International Consortium for Health Outcome Measures (ICHOM) have defined and published a minimum dataset for AMD that all EMR providers could utilise (http://www.ichom.org/medical-conditions/macular-degeneration/). I would argue that who and how the data are collected is a matter for the commercial environment.

*Q: How will EMR data systems improve to help better track key outcomes?*
A: EMR companies will hopefully have a core set of outcomes. You should be able to push a button and get an audit. On a personal level, the EMR system makes a great way to NOT sit down and go through notes. I don't think on a personal or trust level that data collection with an EMR is a problem. The concern is when you pool the data. Who will have access to it? How will it be controlled? What are the issues around freedom of information? I think we need to be aware of this; and handle all the data in a responsible way. If this becomes national data, we need to be extra careful; but I don't know how it will play out.

*Q: Do you think this data collection should be part of the regulatory process?*
A: I would argue that it is reassuring to the payer to know how health care providers are performing, and a clinical audit can provide this information.

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2. Rosenfeld PJ, Brown DM, Heier JS, Boyer DS, Kaiser PK, Chung CY, Kim RY; MARINA Study Group. Ranibizumab for neovascular age-related macular degeneration. *N Engl J Med*. 2006; 355(14): 1419-31.
3. Butt T, Lee A, Lee C, Tufail A; UK AMD EMR Study Group. The cost-effectiveness of initiating ranibizumab therapy in eyes with neovascular AMD with good vision: an economic model using real-world outcomes. *BMJ Open*. 2015; 5(5): e006535. doi: 10.1136/bmjopen-2014-006535

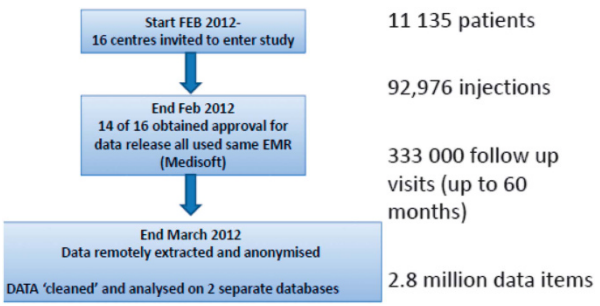


**Figure 1 [SO3]** Methods diagram for the patients and treatments included in this study.

**[SO3] Table 1**: Time of reactivation after a break from treatment at UK age related macular degeneration (AMD) electronic medical record (EMR) Dataset

| *Time to reactivation after a 6 month break* | *Time to reactivation after a 9 month break* | *Time to reactivation after a 12 month break* |
|---|---|---|
| 20th centile | 20th centile | 20th centile |
| 2.07 months | 3.69 months | 5.09 months |
| 50th centile | 50th centile | 50th centile |
| 9.62 months | 15.84 months | 22.49 months |

## S04
## Systematic program of audit in medical retina

Moorfields Eye Hospital has been running an audit program since 2011. Peter Addison, audit lead at the hospital, spoke about the benefits and learnings from the program.

Each of the services at Moorfields has 3 core audit outcomes, which are quality measures within their service; Medical retina has a very strong track record. The core audits tell us about capacity, safety, quality and interaction with other services. In addition, there are specific audits that are informed by incidents, complaints, changes in service, new procedures etc. The specific audits will often come from changes such as new treatments or the development of a particular process. This allows for specific audits conducted within the framework of the rolling core audits. Along with a regular program of audit meetings, this allows improvements to service to be implemented as needed. There are 5 opportunities a year to present these audits at meetings.

The first core audit defined in medical retina was the intravitreal endophthalmitis rate (Table 1), which is an important core audit for any unit involved in medical retina diseases. It is a good metric in terms of safety, and the gold standard was taken from the Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization in Age-related Macular Degeneration (ANCHOR)[1] trial and the Minimally Classic/Occult Trial of the Anti-VEGF Antibody Ranibizumab in the Treatment of Neovascular AMD (MARINA)[2] where 1/2000 injections resulted in intravitreal endophthalmitis.

Two key changes have occurred that have coincided with a decrease in the rate of intravitreal endophthalmitis from 1/1988 in 2009 to 1/8038 in 2014. Firstly, there was a change from predominantly doctor-delivered to nurse-delivered injections, which involved a large-scale training program, and secondly, post-operative antibiotics were no longer used. Clearly, both changes have coincided with a reduced rate of endophthalmitis so are not demonstrated as being deleterious.It is critical to have the right action plans in place to follow-up on the outcomes of a clinical audit and it is critical to present results to the appropriate audience.

The second core audit (timely treatment of diabetic patients) is based on a national key performance indicator for diabetic eye screening programmes. After implementing changes to the booking process for patients being referred urgently from diabetic eye screening programmes to Moorfields, the following referral times were obtained (Table 2). This is an example of an audit that resulted in process changes around capacity issues that led to standards being achieved when re-audit was undertaken.

The third core audit was for age related macular degeneration therapy visual outcomes standards. For the standards, we used 2 metrics: (1) percentage of patients gaining >15 letters at 12 months: >20%; and (2) percentage of patients losing <15 letters at 12 months: >80%. The data are based on sample data because, at the time of the presentation, data were not yet extracted from the electronic medical record (EMR) system for all cases. The standards were comfortably met and, in due course, they will be assessed across the whole cohort of patients.

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**Discussion points**

*Q: One thing that often happens is that people ignore the results of an audit if the result is poor; perhaps there should be a pre-prepared action plan for such an eventuality. What can you do if the standard was not met in the audit…how can we learn to just own up to it?*
A: At Moorfields, we have a committee overseeing the audit to ensure that actual outcomes are reported. The committee is in place to oversee a fair balance and rigorous thinking before doing the audit. If you work out firstly what you might find, you can proactively capture the information you will need to prove it.

*Q: How do you get other people in the department involved….people who can get things done?*
A: Having a senior clinician attend audit meetings has been very important. The clinical director for audit has been important in coordinating dissemination of the results to the whole trust. When you are in a large trust, it is important to convince the executive of the importance of the results, and therefore ensure that they support your audits.

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**[SO4] Table 1**: The rate of Intravitreal endophthalmitis over time at Moorfields Eye Hospital

| *Year* | *Intravitreal endophthalmitis rate* |
|---|---|
| 2009 | 1/1988 |
| 2010 | 1/3325 |
| 2011 | 1/5538 |
| 2012 | 1/3130 |
| 2013 | 1/3130 |
| 2014 | 1/8038 |

**[SO4] Table 2**: The performance percentage for patients followed-up over time

| *National QA Standard* | *Criteria* | *# Patients* | *Performance* |
|---|---|---|---|
| QAS 8a | Patients seen within 2 weeks of referral (target 60%) | 93/124 | 75% |
| QAS 8b | Patients seen within 4 weeks of referral (target 80%) | 114/124 | 92% |
| QAS 11.1 | Patients lasered within 2 weeks of listing (target 90%) | 43/48 | 90% |
| QAS 12.1 | Patients lasered within 6 weeks of screen (target 70%) | 44/48 | 92% |

## S05
## Retinal service evaluation can be very rewarding…..! The Calderdale and Huddersfield NHS Trust experience

There are many potential challenges to conducting a clinical audit. Rehna Khan discussed how her team of 7 colleagues developed 3 databases, produced 6 posters, and successfully applied for medical education grants to support their work. Retrospective electronic data from the Calderdale and Huddersfield NHS Trust was collected to populate the databases. One of the reports that came from the project aimed to evaluate the real world impact of choosing aflibercept *pro re nata* (PRN) or ranibizumab PRN as first line therapy in treatment naïve patients with active neovascular age-related macular degeneration (nAMD).

The goal was to harness all the resources in one focused effort and produce results within a short timeframe of 6 months.

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**Disclosures:** RK received consulting fees from Alimera Sciences, lecture fees and grant support from Novartis.

**Discussion points**

*Q: You used an external statistics company and said you wouldn't do that again. Can you please expand on that?*
A: The statistics company we hired was commercial and although they were very efficient; I felt that a lot of the information I explained was lost in translation. In the time it took to explain, I could have done the work 'in house'. I should have gone to the local university or other sources; it would have been cheaper and perhaps quicker.

*Q: Why is your team using aflibercept PRN?*
A: In our department, we felt that fixed dosing would be 'over treating' a significant proportion of patients. I don't advocate going off-label, but we observed our visual acuity results at 12 months were close to the VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW) study[1] figures with fewer injections. I don't think the commissioners would be upset about that. We were trying to avoid over treatment (our departmental audit showed 30% patients only require 3 loading injections to render their nAMD stable for 12 months). If the audit results showed that PRN was less efficacious, then obviously we would stop this practice.

*Q. When using PRN, do you have higher recurrence rate of age related macular degeneration (AMD)?*
A: The number of injections given does exceed the national average from the national intravitreal injection audit for nAMD. Based on this I would say 'no'. However I will specifically interrogate the data to explore this further.

**Reference**

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## S06
## Ranibizumab in neovascular age related macular degeneration (nAMD)—5 -Year audit data

Ranibizumab *pro re nata* (PRN) has been shown to maintain or improve visual acuity over time in patients with neovascular age-related macular degeneration (nAMD), and it is approved for use in the UK in this patient group. Priya Prakash reported the results of a study aimed to review the use of ranibizumab in nAMD patients treated in this single center.

Retrospective electronic data were analysed for patients receiving ranibizumab for the treatment of nAMD. All patients were under the care of two retina consultants and supported by a team of middle grades, nurse specialists, optometrists, and technicians. Paper audit was collected between November 2010 and November 2014 for all clinic visits, and then data were transferred to electronic medical records (EMR) systems starting in November 2014.

Patients (mean age 79.1 years) received ranibizumab PRN treatment and were then switched to the treat and extend (T&E) regimen following the update of ranibizumab licence, when clinically indicated. A total of 3736 injections were administered [first eyes ($n = 3361$)]. Nearly 11% of patients developed bilateral disease during the course of treatment. Patients received an average of 6 injections in the first year, then 3, 2, 1.5, and 1 in the following years. A total of 321 patients were treated for the 5-year period.

The mean baseline visual acuity (VA) was 54.8. The mean VA gain over time was 6.77 letters at year one, 5.6 at year two, 0.5 at year three, and 4.84 at year five (Figure 1). Further, 50% of patients achieved $>5$ letter gains, 39% achieved $>10$ letter gains, and 25% have $>15$ letters gained. The drop at year three could be caused by: (1) one patient dropped from 75 letters to Counting Fingers due to severe submacular haemorrhage and subsequently stopped treatment: (2) natural progression of the disease; (3) possible artefact as patients were transferred from paper to EMR; or (4) the subsequent increase could be due to the switch of patients from PRN to the T&E regimen in late 2014.

Ms Prakash emphasized that although not as robust as other published studies, this is the real world outcome. Switching to the T&E regimen may have influenced the outcomes, but additional research is needed.

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**Discussion points**

Chairman: In real life practice in the UK, the T&E regimen is not as effective as other countries, like Australia, where doctors are incentivised to treat. It seems that T&E forces you to treat more frequently.

*Q. Did you have any problems switching from PRN to T&E?*

A. Mainly with regards to educating the health care providers on the treatment regimens. Patients that came in to system on PRN regimens are slowly being switched but new patients are being placed on T&E. Practically, it gets more complex when 2 eyes are being treated.

*Q. I think most people will do a PRN service. Most patients will not come in every month. In the case of Australia, the clinic receives funding upon each injection. This is different than in the UK, correct?*

A. It would be great to see a survey to see how patients feel about the different treatment regimens. Is the T&E or other easier on the patient? How is it to go to the clinic, not knowing if they would receive an injection? Do they prefer to be maintained, or be rescued? We all have our own opinions. Large data on patient recorded outcomes could better inform these studies.

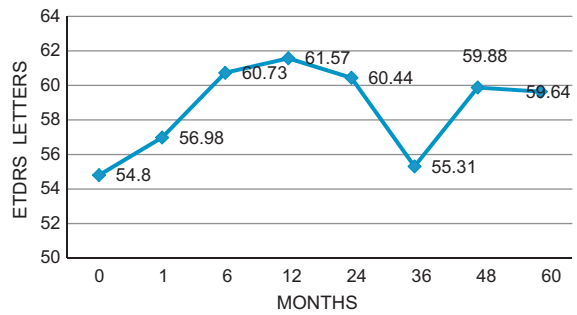


**Figure 1 SO6:** Visual acuity gain over time (in months). ETDRS = Early Treatment Diabetic Retinopathy Study.

## S07

## Diabetic macular oedema (DMO) service at Sunderland: A learning experience

Diabetic macular oedema (DMO) is a common complication of poorly controlled diabetes, which can degrade a patient's vision over time. In this session, Maged Habib shared results of the clinical audit of DMO service at a single center. This study aimed to evaluate the real world impact of ranibizumab treatment on patients with DMO.

Before the study began, Mr Habib estimated that the center received around 200 newly diagnosed patients with centrally involved DMO each year. The clinical capacity has therefore been estimated at nearly 1,600 appointments for treatment of DMO, resulting in 2 DMO clinics each week (based on monthly visits for pro re nata (PRN) treatment protocols). At that time, the team at the SEI consisted of a lead diabetic consultant, two retina consultants, senior optometrists, nurses, photographers and a retinal coordinator.

Patients received 4 monthly ranibizumab injections, and then they were monitored for follow-up. If patients showed a partial improvement (15% reduction in central macular thickness (CMT) and/or visual acuity (VA) gain > 5 Early Treatment Diabetic Retinopathy Study (ETDRS letters from baseline), then 2 additional ranibizumab injections were given. Laser was also considered after 5 months if partial improvement was maintained and stable DMO was not yet achieved (Deferred laser protocol). If complete improvement (VA ETDRS 85 letters (6/6) and / or dry optical coherence tomography [OCT]) was achieved, then injections were withheld and follow up was scheduled monthly for 4 to 6 months. If patients showed no improvement (< 15% reduction in baseline CMT and/or < 5 ETDRS letters improvement from baseline) then clinicians could switch to laser or intravitreal (IVT) steroid implant (if applicable).

Retrospective electronic data were analysed for patients receiving ranibizumab for the treatment of DMO. Patients ($n = 73$; 100 eyes; mean age 62.1 years; range 29-89) received a mean (SD) of 6.6 (1.4) injections in the first year with 10% requiring laser treatment (Figure 1). The average number of visits was fewer than expected (3.5 visits; expected 6-7) and the average follow-up out patient department appointments were higher than expected (7.5 weeks; expected 4). Mean (SD) baseline VA was 60.1 (13.7) letters and the mean (SD) baseline CMT was 472 (107.7). Mean (SD) VA and CMT changes at one year were 63.1 (16.4) letters and 326.8(90.5), respectively.

Further analysis of the results at 6 months, following the initial 4 monthly loading doses in addition to potentially 2 further injections if needed, revealed better results (Figure 2). Mean (SD) visual improvement of 5.1 (8.6) letters was reported.

Habib noted that there are lessons to be learnt from real life data; while initial VA gains were observed, results did not reach levels observed in other trials[1,2]. Further, these initial gains are not maintained with PRN dosing in real practice, and there are concerns about the timely delivery of services to patients with increased capacity demand in large ophthalmic units. This is compounded further with expanded indications for intravitreal treatments of various retinal diseases with increased burden on retinal services. Additional staff training for VA checks, involving healthcare and allied professionals, and improving the clinic capacity may improve results. This might be achieved by adopting other treatment protocols such as Treat and Extend or fixed dosing schedules or a combination of both. Further re auditing of data will explore the impact of such protocols on service delivery and clinical results.

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**Disclosures:** MH received consulting fees from Bayer and Alimera, and lecture fees from Novartis, Alimera, and Bayer.

**Discussion points**

*Q. There is a lot of variability between centers. You changed your process, and now the next step is to see if your outcome also changes. What would you expect for your outcomes?*

A. By adopting a new protocol of modified Treat and Extend schedule, we expect that our patients will be receiving their treatments in a better pre-planned timely manner with reduced demand on frequent clinic visits. We would expect that this

would maintain the macula dry to achieve sustainable VA gains at one year and beyond.

*Q. Have you looked at macular ischaemia?*
A. Yes, All patients had baseline flourescein angiogram and macular ischaemia assessed. Treatment was considered only when gross macular ischaemia was excluded and potential treatment benefit was expected.

*Q. Others have reviewed these effects. What is your opinion?*
A. We are currently analysing the effect of macular ischaemia in further details. There are different ways to quantify macular ischaemia and there are concerns about the reliability of measurements in the presence of gross oedema. Other factors to consider are ischaemia of the papillo-macular bundle as well as peripheral ischaemia. Further work to be done to assess the correlation of these factors with treatment response and visual gains.

**References**

1. Brown DM, Michels M, Kaiser PK, Heier JS, Sy JP, Ianchulev T; ANCHOR Study Group. Ranibizumab versus verteporfin photodynamic therapy for neovascular age-related macular degeneration: Two-year results of the ANCHOR study. *Ophthalmology* 2009;116(1): 57-65.
2. Rosenfeld PJ, Brown DM, Heier JS, Boyer DS, Kaiser PK, Chung CY, Kim RY; MARINA Study Group. Ranibizumab for neovascular age-related macular degeneration. *N Engl J Med*. 2006; 355(14): 1419-1431.

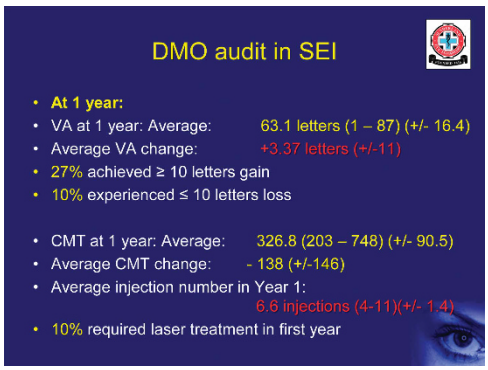


**Figure 1 [SO7]:** One-year data from diabetic macular oedema (DMO) service at Sunderland Eye Infirmary.

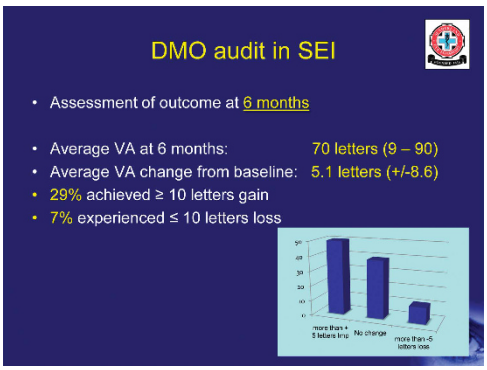


**Figure 2 [SO7]**: Six-month data from diabetic macular oedema (DMO) service at Sunderland Eye Infirmary.