

Action on AMD. Optimising patient management: act now to ensure current and continual delivery of best possible patient care

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Abstract

In recent years, there have been significant advances in the clinical management of patients with wet age-related macular degeneration (wet AMD)—a rapidly progressing and potentially blinding degenerative eye disease. Wet AMD is responsible for more than half of registered severe sight impairment (blindness) in the United Kingdom, and patients who are being treated for wet AMD require frequent and long-term follow-up for treatment to be most effective. The clinical workload associated with the frequent follow-up required is substantial. Furthermore, as more new patients are diagnosed and the population continues to age, the patient population will continue to increase. It is thus vital that clinical services continue to adapt so that they can provide a fast and efficient service for patients with wet AMD. This *Action on AMD* document has been developed by eye health-care professionals and patient representatives, the *Action on AMD* group. It is intended to highlight the urgent and continuing need for change within wet AMD services. This document also serves as a guide for eye health-care professionals, NHS commissioners, and providers to present possible solutions for improving NHS retinal and macular services. Examples of good practice and service development are considered and can be drawn upon to help services meet the recommended quality of care and achieve best possible outcomes.

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Introduction

Neovascular wet age-related macular degeneration (AMD) is a serious macular disorder resulting in progressive loss of central vision. In the United Kingdom, wet AMD accounts for more than half of all cases of registered severe sight impairment (blindness) and sight impairment.^{1,2} There are ~26 000 new cases of wet AMD each year in the United Kingdom.³ The prevalence of wet AMD is continuing to increase with the ageing population.⁴ Significant vision can be lost in a short time if wet AMD is not adequately treated,⁵ and this can have a huge impact on independence and quality of life for patients.⁶

Until 3 years ago, the only available licensed and NICE-approved treatment option for wet AMD was verteporfin photodynamic therapy (vPDT), which was only suitable for a small proportion of eyes.⁷ Patients with minimally classic and occult lesions, which account for 55–70% of all patients with wet AMD, were not eligible for treatment with vPDT.⁸ Significant advances have been made in recent years with the advent of intravitreal anti-vascular endothelial growth factor (anti-VEGF) treatment that is effective in patients with wet AMD of any lesion type.

The National Institute for Health and Clinical Excellence (NICE)-recommended treatment for wet AMD is currently ranibizumab (Lucentis[®]▼), an anti-VEGF drug that has shown superiority to

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Please note that prescribing information is available at the end of this supplement.

vPDT.⁹ The Scottish Medicines Consortium (SMC) approved ranibizumab before NICE and, subsequently, NHS Quality Improvement Scotland has advised that NICE recommendations are valid for Scotland as well. The SMC also approved pegaptanib (Macugen[®]), another licensed anti-VEGF treatment as an alternative, although this is not widely used. Ranibizumab has proven efficacy in preventing visual loss in patients with wet AMD and can also significantly improve vision in more than one-third of patients, with generally good tolerability.^{9–11} The improvement in visual acuity (VA) seen with this treatment also translates into improved patient-reported benefits in quality of life (near activities, distance activities, and activity of daily living tasks).^{12–14}

The guidance from NICE (in 2008) and the SMC (in 2007) recommending intravitreal ranibizumab treatment for all wet AMD patients, irrespective of lesion type, meant that the number of patients potentially suitable for treatment rose markedly. Furthermore, the number of clinic visits required for each patient increased because patients receiving ranibizumab require monthly follow-up (compared with every 3 months following vPDT). Many local wet AMD services in the NHS adapted to meet these increases in demand, and there have also been substantial improvements in rapid referral and fast-track processes for new patients.

Despite these initial improvements and service adaptations, limited or inadequate clinical capacity continues to threaten optimal care and access to potentially sight-saving treatment for wet AMD patients. Some NHS clinics are failing to maintain recommended follow-up intervals for patients with wet AMD. Delay in follow-up beyond the recommended interval may cause patients to unnecessarily lose vision permanently. This is important because sight impairment and severe sight impairment are associated with costs in the United Kingdom health-care system, totalling £22 billion in 2008.¹⁵ These costs include £2.14 billion direct costs (general ophthalmic services costs: £484 million, hospital expenditure: £593 million, costs associated with injurious falls: £25 million) and £4.34 billion indirect costs (including £2.03 billion informal care costs). The total costs also include £16 billion burden of disease costs, which put a monetary value on individuals losing quality of life because of sight loss.¹⁵

Increases in wet AMD patient numbers are expected to be continuous because of the long-term nature of the disease, as well as the ageing population. Pressures on clinical capacity in the hospital eye service (HES) may also be compounded in the future by new indications for intravitreal treatments and the availability of future new treatments for retinal diseases such as diabetic macular oedema (DMO) and retinal vein occlusion (RVO).^{16–18} Slow-release preparations for wet AMD are being developed, but may not be available for some time.

Furthermore, the United Kingdom has the lowest ratio of consultant ophthalmologists per 100 000 of the general population in the European Union.¹⁹

It is clear that robust and long-term retinal service models must be rolled out in order to meet the needs of local populations both currently and in the future. *Action on AMD* strongly advises that every hospital with a retinal service start this process now, so that there is no compromise later in the standard of service provision, duration of follow-up, and quality of intravitreal treatment administration. Fast-track patient referral systems from primary care combined with prompt commencement of therapy in ophthalmology care and regular monthly follow-up, as per NICE guidance and Royal College of Ophthalmologists (RCOphth) guidelines, are vital to the management of patients with wet AMD. There must be no compromise to patients' safety, efficacy of the treatment, or patient outcomes.

Key capacity issues

Modelling exercises (using national averages) have shown that the number of assessment appointments drives the need for increased capacity rather than the number of intravitreal injection appointments (unpublished data provided by Novartis). Thus, patient follow-up appointments are usually the bottleneck. This is important as the evidence shows that, with current licensed and recommended treatment, frequency of follow-up appointments for wet AMD patients must continue to be monthly and cannot be reduced without compromising patient outcomes.²⁰

It follows that a solution for many providers involves increasing capacity within follow-up clinics. In some HES facilities, pressure on optical coherence tomography (OCT) clinical imaging services is being aggravated by the increasing use of OCT imaging for other ophthalmic disorders such as glaucoma, and recent guidance from NICE requiring optic disc imaging in glaucoma patients.²¹ *Action on AMD* has identified a number of key capacity issues that are summarised in Table 1. Although these are commonly occurring issues, *Action on AMD* acknowledges that not all of these issues will apply to every clinic.

Clinical capacity issues largely fall into one of five categories, relating to the following: (1) clinic space—shared with other services or limited in physical size; (2) staffing—shortages in numbers of key staff and/or inadequacies in skills and training; (3) equipment—insufficient, equipment used is not the best available, or other clinical pressures for use of equipment; (4) support and quality—suboptimal provision of patient support or inability to carry out monthly monitoring of patients; (5) funding—business case is either inaccurate, not sufficiently long term, not agreed,

Table 1 Key capacity issues identified by *Action on AMD*, and their consequences

Issue	Consequence
<p>Clinic space</p> <p>Shared space with other hospital services and clinics</p> <p>Limited physical size of dedicated ophthalmic OPD and treatment space</p>	<p>Little scope for increased number of wet AMD patients and clinics</p> <p>Lack of space for expansion to run parallel clinics and increase patient throughput</p>
<p>Staffing</p> <p>Shortage of retinal consultants and other medical retinal staff</p> <p>Other staff shortages (eg, Eye Clinic Liaison Officer, AMD coordinator)</p> <p>Inadequacies in staff skills and training</p>	<p>Increased patient waiting times—during the clinic visit as well as waiting times for appointments</p> <p>Stressed and tired staff. Little scope for personal development</p> <p>Potential effects on clinic coordination and efficiency, auditing, general patient care and time spent with patients, and increased pressure on medical retinal staff</p> <p>Limited staff roles and responsibilities. Patient safety concerns of inferior quality care</p>
<p>Equipment</p> <p>Insufficient ophthalmic clinical imaging equipment for wet AMD patient monitoring, compounded by other clinical pressures for OCT imaging</p> <p>LogMAR VA charts not in routine use</p>	<p>OCT imaging unavailable, or unable to cope with service demands</p> <p>Delay in access to OCT imaging</p> <p>VA recorded on Snellen charts is not sufficiently accurate for low vision patients or to detect early signs of change in these patients (in response to treatment or otherwise)</p>
<p>Support and quality</p> <p>Suboptimal provision of patient support (including patient education and advice, counselling and liaison with LVA clinic, social services and other available support such as RNIB, Action for Blind People, The Macular Disease Society and local low vision societies)</p> <p>Inability to carry out monthly monitoring of AMD patients</p>	<p>Level of support and access to social care is inferior</p> <p>Patient quality of care is compromised and quality of life may be affected</p> <p>Macular disease progression may not be promptly detected.</p> <p>Suboptimal outcomes</p>
<p>Funding</p> <p>Business case for wet AMD unsuccessful or not agreed or implemented</p> <p>Business case not accurately costing the service, not sufficiently long-term or inadequate</p>	<p>Funding not available to provide the required level of wet AMD service and infrastructure</p> <p>Clinic is running at maximum capacity with no resource for expansion of service</p>

Abbreviations: AMD, age-related macular degeneration; LVA, low vision assessment; OCT, optical coherence tomography; OPD, outpatient department; RNIB, Royal National Institute of Blind People; VA, visual acuity.

or not implemented. The consequences of these issues are serious and threefold:

- Clinics run at maximum capacity with no scope for further expansion of service. They may even be unable to cope with the current patient numbers and may not provide the recommended standard of care.
- Inferior or compromised patient quality of care, which may be detrimental to patients' quality of life and disease outcomes.
- Substantial pressure on staff.

Possible approaches and key considerations: case studies

Individual wet AMD provider services differ in their structure, size, and patient population, as well as in the specific limitations of the service. Thus, it is highly unlikely that one single solution will be suitable for every clinic. Instead, *Action on AMD* believes that there are a number of possible solutions. In addition, *Action on AMD* believes that it is useful to learn from clinical service models that work. We have therefore shared some exemplar case studies here including examples where novel solutions and models have been used successfully, to illustrate that current capacity problems are not insurmountable. These case studies span a range of useful solutions and can be implemented with or without further local adaptation. For implementation of change, the key is to implement a particular model. The specifics of the roles of different professional groups will need to be defined but should not be the primary focus.

Exemplar case study: expanded roles for non-consultant clinical staff (Gloucestershire)

Gloucestershire provides a one-stop clinic service, with assessment and treatment clinics running in parallel. Non-consultant staff—particularly nurse practitioners and optometrists—take key roles, helping to maximise capacity and maintain monthly follow-up of patients.

Service structure. Initial assessment of new patients is led by optometrists and nurse practitioners who take the patient's history and perform primary examinations (including Early Treatment Diabetic Retinopathy Study, ETDRS; visual acuity, VA) and diagnostic imaging (Figure 1). All data are recorded in an Electronic Medical Record (EMR; Medisoft[®], Medisoft Limited, Leeds, UK) system. If wet AMD is suspected, the diagnosis is first confirmed at specialist clinics using fundus fluorescein angiography (FFA) before the patient is referred to the wet AMD treatment clinic. This ensures a homogeneous patient population in the wet AMD clinic and stereotyped clinical care. An optometrist undertakes refraction at presentation and annually. OCT technicians work with optometrists to collect OCT and slit lamp data. Nurse practitioners perform

LogMAR VA analysis and measure best corrected visual acuity (BCVA). Because all clinical data are recorded electronically, the retinal consultant is able to make rapid treatment decisions for new and returning wet AMD patients using the EMR. If necessary, the consultant ophthalmologist can also view previous OCT scans on the EMR and examine the patient themselves. As the nurses and optometrists gain experience, they are able to make clear 'observe' and obvious 're-treat' decisions. If intravitreal treatment is required, a second retinal specialist administers the injection, assisted by two nurses who assist with injection preparation.

If, after 18 months from first referral, a patient has not required an intravitreal injection for at least 6 months, they are moved to an optometrist-led stable AMD clinic to ease pressure on the assessment clinic.

Clinic capacity. Three assessment/treatment clinics take place per week, each comprising 40–45 follow-up assessments, 5–8 planned initial injections, and approximately 15–25 'as required' injections. Eight to ten patients are examined per session in the stable clinic, and frequency depends on patient numbers.

Key requirements. An EMR system is required, as well as networked OCT instruments. Development of nurse practitioner and optometrist skills have been necessary, to be able to perform the necessary examinations and record data in the EMR. It can also become possible for nurses to make clear 'observe' and 're-treat' decisions. For the assessment clinic, three nurses perform LogMAR BCVA and three pairs of OCT technicians and optometrists carry out OCT and slit lamp examinations. One medical retinal consultant moves between the three clinical assessment rooms. Two nurses and one other retinal doctor are required for the treatment clinic and, for the stable clinic, one hospital-based optometrist is required. There is one full-time clinic coordinator, but secretarial support is reduced as correspondence is automatically generated by the EMR system.

Learning points

Benefits	Challenges
<ul style="list-style-type: none"> • Confirmation of diagnosis by FFA prior to admission to wet AMD clinic ensures a homogeneous population, allowing standardised treatment • EMRs allow detailed audit of clinical outcomes and linking to the hospital patient information service enables patient tracking from check-in to treatment. Waiting times can also be measured at every step • Expanding the roles of non-consultant clinical staff maximises capacity and facilitates monthly follow-up 	<ul style="list-style-type: none"> • A robust business plan is required • Accurate monitoring of data and activity is required • Requires substantial clinic and waiting room space <ul style="list-style-type: none"> ○ This may necessitate moving other services • Model benefits from accurate prediction of numbers of stable patients

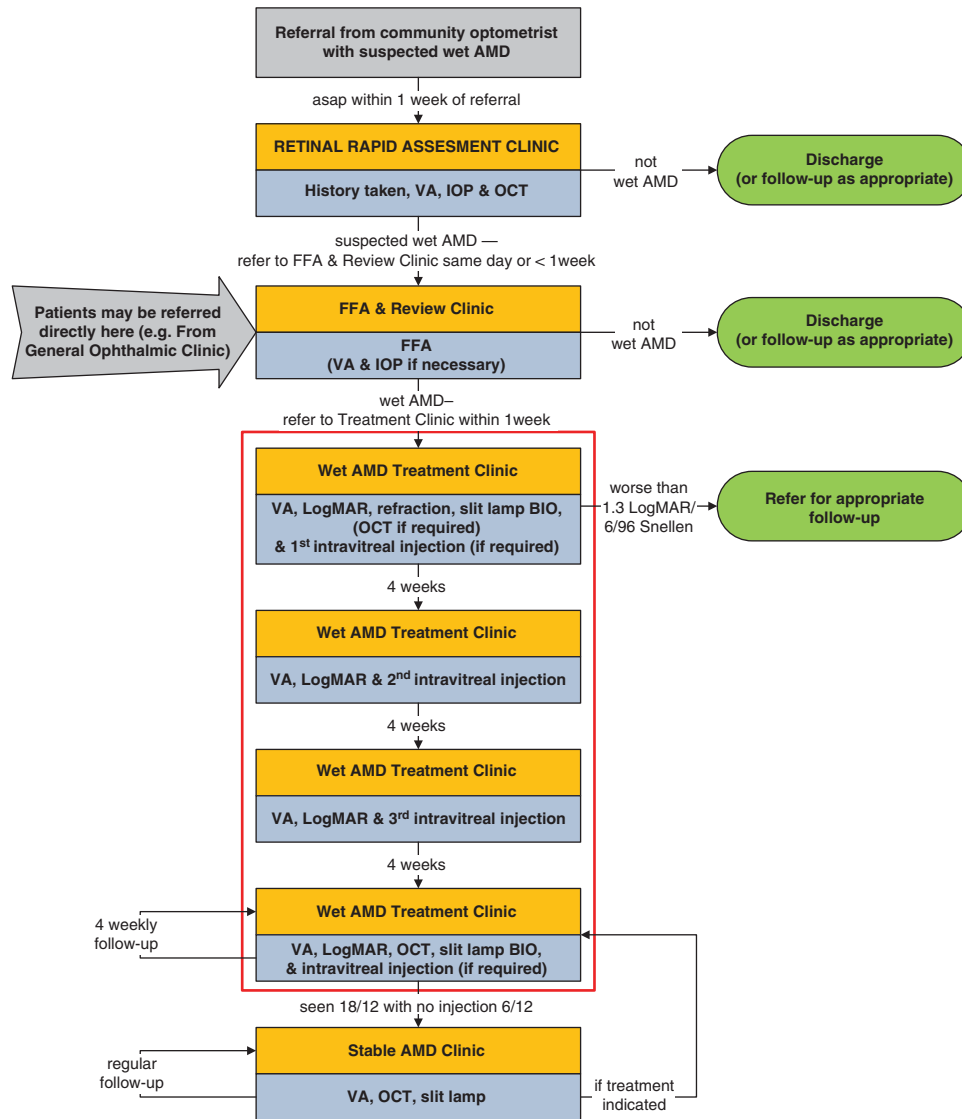


Figure 1 Patient pathway for expanded non-consultant roles (Gloucestershire example). AMD, age-related macular degeneration; BIO, biomicroscopy; FFA, fundus fluorescein angiogram; IOP, intraocular pressure; OCT, optical coherence tomography; VA, visual acuity.

Exemplar case study: The Mobile Community Eye Care Project, design and commission of a mobile eye care clinic for wet AMD (York)

The Mobile Community Eye Care Clinic (MCECC) is a purpose-built, one-stop mobile clinic, designed to increase capacity for the management of wet AMD patients. Its mobility enables it to be used at a number of different sites during the 4-week cycle of wet AMD care, abolishing the need for multiple static sites. It functions in conjunction with the hub site, which remains the diagnostic centre.

Service structure. Patients diagnosed with wet AMD at the hub site can be referred to the MCECC for follow-up and treatment. The MCECC has facilities for measuring VA, including an optometrist facility for performing initial, 12-monthly and ‘as needed’ refraction (Figure 2), as well as retinal imaging facilities (OCT), slit lamp, and intraocular pressure (IOP). If the consultant decides that treatment is needed, an initial dosing regime is initiated (doses are administered at 4-week intervals) in a dedicated treatment room. Patients at high risk of needing further treatment are followed up every 4 weeks and are suited to a one-stop service, with consultant-led

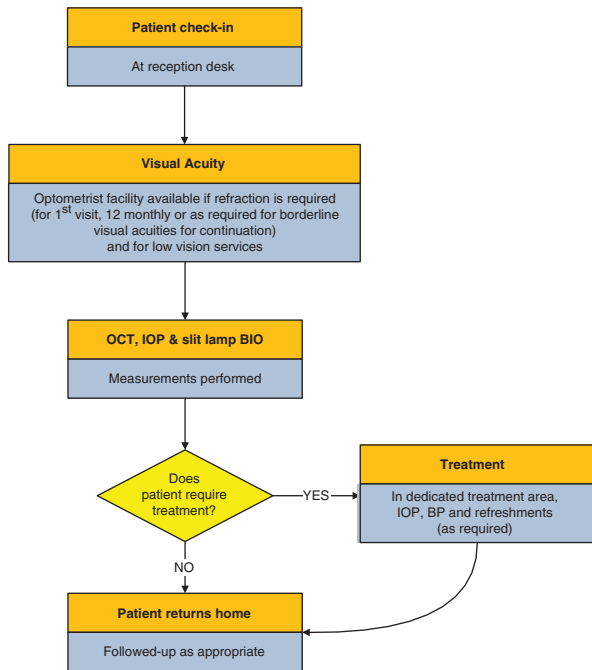


Figure 2 Mobile Community Eye Care Clinic patient pathway (York example). BIO, biomicroscopy; BP, blood pressure; IOP, intraocular pressure; OCT, optical coherence tomography.

assessment clinic and treatment at the same visit. Patients at a low risk of needing further treatment can either be assessed and treated if necessary at the MCECC or assessed by community optometrists and referred to the MCECC for treatment as a two-step process that may be more convenient for the patient.

Clinic capacity. The MCECC has capacity for two optometrists and two OCT instruments. It is estimated to be able to increase the capacity of an existing ophthalmic clinic by 40–50 patients per day.

Key requirements. The mobile clinic is assembled on site from three articulated lorry trailers. A 2.5 h assembly time and overnight/weekend relocation enable seamless continuity of the service. The MCECC is staffed by the local hospital staff, or additional staff can be offered to run the service under overall control and governance of the local HES. Contracted maintenance staff are provided (driver, management, and emergency cover), and thus local units only need to be involved in clinical management. The unit includes imaging equipment, core patient database and electronic patient records (including audit tool), disabled access, a staff room, and a dedicated intravitreal treatment clean room.

Learning points

Benefits	Challenges
<ul style="list-style-type: none"> • Additional capacity to existing services can be added quickly • Better patient experience and reduced patient travelling time • Quality of care and face to face contact is maintained • Dedicated intravitreal injection clean room and equipment • Leasing on a 4-weekly cycle enables patients to be seen every 4 weeks, removing slippage of follow-up times and reducing clinical risk 	<ul style="list-style-type: none"> • Needs to be constantly in use at single or multiple sites to be highly cost-effective • The mobile clinic comes with an additional cost per patient to the tariff • Complex to set up (design, locations, maintenance) • Expansion of staffing may be required • Provides supplementary capacity for main hub rather than replacement • Assessments by community optometrists require negotiation with commissioners for funds to follow the patient, availability of OCT facilities and an appropriate IT infrastructure

Exemplar case study: nurse-led rapid access clinics and virtual review clinics (Sheffield)

A rapid access clinic led by a nurse consultant has been set up in Sheffield. This clinic allows new patients to be triaged to the appropriate clinic on the basis of initial assessments, allowing the consultant ophthalmologist's time to be utilised more effectively. In addition, nurses also lead the photographic review clinic for returning patients, helping to relieve clinical workload of large numbers of monthly follow-up patients.

Service structure. A two-stop model allows the workload to be planned and is suitable for the urban Sheffield area, as most patients only travel short distances. New referrals are examined at a weekly nurse-led rapid access clinic, with any overflow being booked into the doctors' clinic (Figure 3). Patients are assessed, diagnosed, and triaged by the nurse and referred appropriately. Information about intravitreal treatment is given to the patient by the nurse, where appropriate. For wet AMD patients, images and notes are discussed in a weekly reporting session (virtual clinic) involving a multidisciplinary team, during which treatment decisions are made. If appropriate, patients are then booked in for intravitreal anti-VEGF treatment

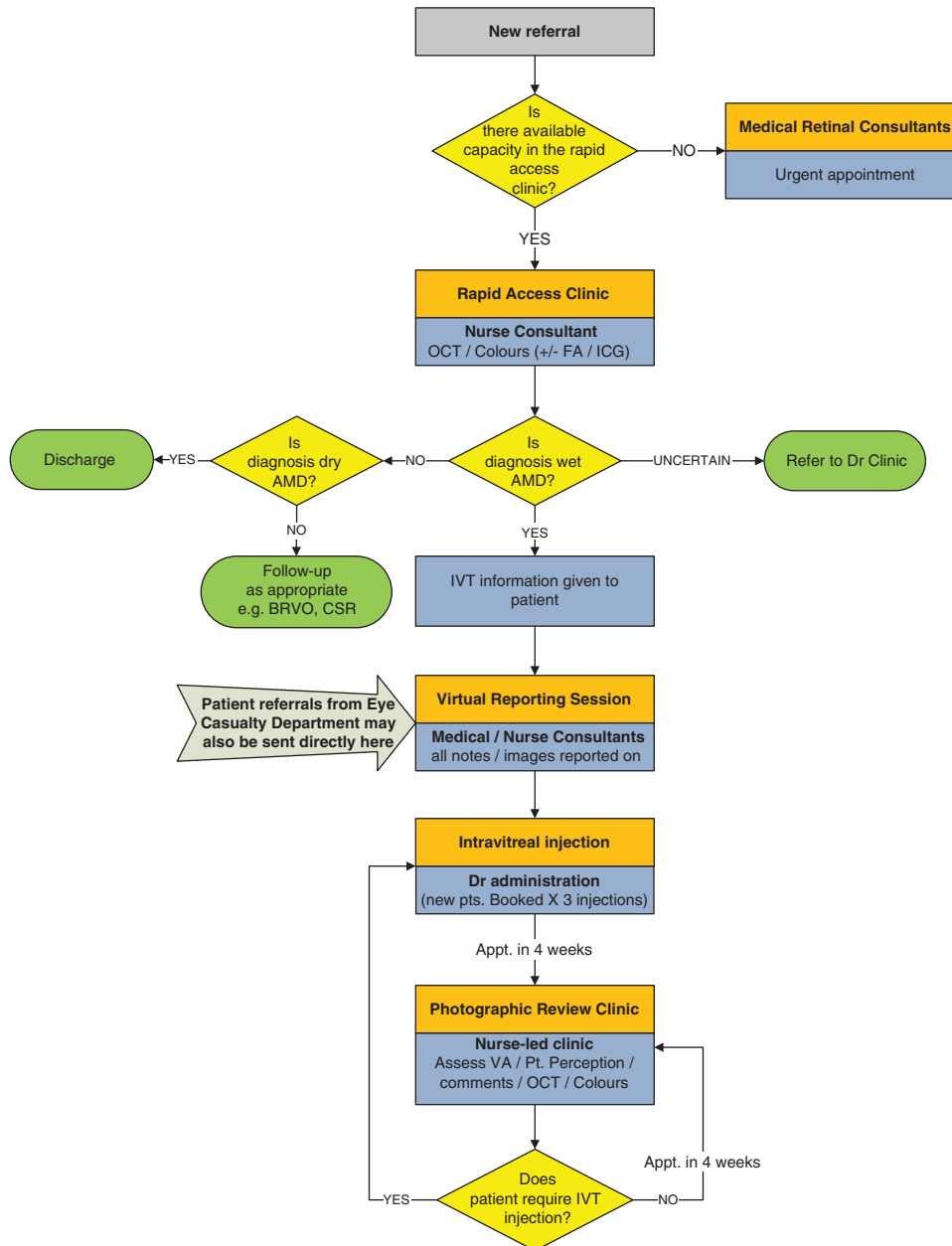


Figure 3 Nurse-led and virtual patient pathway (Sheffield example). AMD, age-related macular degeneration; BRVO, branch retinal vein occlusion; CSR, central serous retinopathy; FA, fluorescein angiography; ICG, indocyanine green angiography; IVT, intravitreal treatment; OCT, optical coherence tomography; VA, visual acuity.

by the clinic coordinator. Treatment is administered by a retinal consultant in a dedicated minor operations theatre. Four-weekly photographic reviews are carried out in a nurse-led clinic with dedicated ophthalmic imaging room and a team of ophthalmic photographers, allowing for multiple patients to be examined simultaneously. Images are reviewed by the medical consultants and nurse consultant at the weekly reporting session, allowing timely and appropriate management. Where necessary, some patients may

receive photographic review and intravitreal injection on the same day.

Clinic capacity. Three rapid access and review clinics are held per week, with a total of 35 patients assessed per week. There is a weekly capacity of 84 patients on the intravitreal injection lists and 84–90 patients in the photographic review clinics. Four reporting sessions are held per week.

Key requirements. A key requirement of this service is a senior nurse or nurse consultant who is able to lead the

rapid access clinic (including requesting medical imaging, cannulation and administration of contrast medium, diagnosis of other pathologies, talking to patients about findings, triaging, and referring to low vision assessment services or other appropriate clinic), is involved in review of retinal images at the reporting sessions (alongside the medical consultants), can list patients for treatment and re-treatment, and can prescribe anti-VEGFs. Ophthalmic staff nurses who can undertake the photographic review clinics are also required. Sheffield has four such nurses at present. Experience from Sheffield is that two AMD clinic coordinators are required to organise the clinics and intravitreal treatment lists, liaise directly with patients to ensure timely treatment, organise patient transport, data capture, and provide patients with the outcome of their photographic review.

Learning points

Benefits	Challenges
<ul style="list-style-type: none"> ● Rapid access clinic provides extra capacity for patients who need to be seen promptly and fast access to treatment ● Nurse-led photographic review clinics can help to more effectively manage the large numbers of monthly follow-up patients ● Reporting session triages patients to the appropriate clinic based on clinical findings, allowing for more efficient use of time and equipment ● Maximises individual professionals' potential 	<ul style="list-style-type: none"> ● Requires additional retinal cameras and OCT instruments, photographic staff and training for them ● Dedicated equipment and space to accommodate the optometrists ● Requires a dedicated minor operations theatre for intravitreal treatment ● Covering staff leave can be challenging, with specific challenges on covering review clinics and the reporting session

Exemplar case study: utilisation of a peripheral clinic and mobile screening (Southampton)

A peripheral clinic was originally set up to complement the Southampton Eye Unit, easing pressure on clinic space at the main hospital eye unit and resulting in a more patient-friendly service. Furthermore, a mobile assessment unit is now being developed, to provide an even more convenient service for patients and reduce transport costs.

Service structure. Initially, a peripheral clinic was set up in a large health centre, with facilities for OCT imaging and intravitreal injections. Patients were diagnosed and had their first injection at the main hospital eye unit

(Figure 4). Subsequently, they were booked for injections or follow-up at the peripheral health centre, providing a one-stop service. The service at Southampton no longer uses the peripheral clinic at the health centre. Instead, follow-up patients from three peripheral hospitals will attend a mobile assessment unit (stationed at the local hospital) for assessment of VA and OCT imaging. A medical retinal consultant at the main hospital eye unit will review the images, and, if necessary, patients will be booked for treatment at the peripheral hospital.

Clinic capacity. Southampton Eye Unit currently undertakes ~20 OCT scans per instrument per session (and has two OCT instruments), with 600–700 patients seen per month and around 300 intravitreal injections administered per month. The OCT scan van is expected to have capacity to screen 10 patients per session, and ~30 OCT images are expected to be reviewed per virtual session by the ophthalmologist.

Key requirements. The peripheral clinic required an OCT instrument, operated by a clinical photographer and an ophthalmologist to assess the patients. A second ophthalmologist performed the intravitreal injection, assisted by a nurse. For mobile assessment, in addition to the van itself, equipment and staff are required for OCT fundus imaging and VA assessment. There is a need for high-quality IT to enable large file-size images to be sent from the van to the main unit for assessment by the retinal specialist.

Learning points

Benefits	Challenges
<i>Peripheral clinic</i>	
<ul style="list-style-type: none"> ● Helped overcome lack of space at the main hospital eye unit ● Easier parking/access for patients ● More patient-friendly environment 	<ul style="list-style-type: none"> ● No facility to run large clinics ● OCT instrument was only in use 2 days per week ● A large number of personnel were required to treat a small number of patients
<i>Mobile screening van</i>	
<ul style="list-style-type: none"> ● Reduces patient travel ● Negates the cost of purchasing OCT equipment for multiple peripheral units ● Virtual clinic reduces the number of medical staff required to assess a patient at each visit ● Space constraints are overcome 	<ul style="list-style-type: none"> ● Initial investment required ● Large file sizes can affect network integration and NHS network speeds ● Current OCT instruments are built to work as a stationary unit ● Efficient booking service required

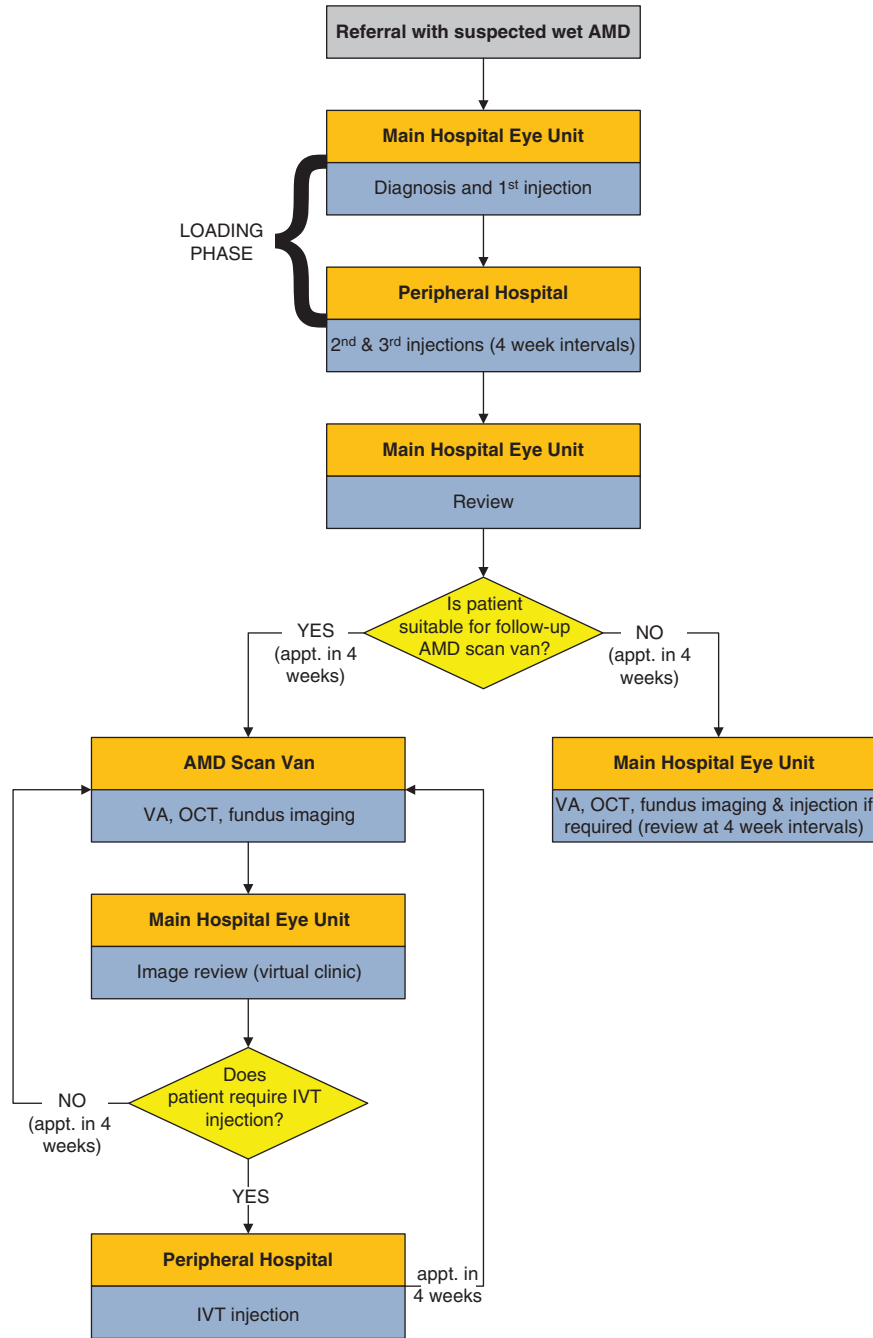


Figure 4 Hub and mobile OCT spoke model (Southampton example). AMD, age-related macular degeneration; IVT, intravitreal treatment; OCT, optical coherence tomography; VA, visual acuity.

Exemplar case study: flexible multidisciplinary approach to patient management and satellite macular clinics in the community (Sunderland Eye Infirmary)

Sunderland Eye Infirmary (SEI) uses a teamwork approach that extends the role of hospital optometrist, nursing, and health-care staff as ‘macular specialist staff’

for provision of a service in an area with higher than average incidence of wet AMD.

Service structure. All new patient referral requests are directed by rapid access referral to a named ‘on take’ medical retinal consultant who allocates the patient either to triage or directly to the AMD specialist clinic (Figures 5a and b). Triage clinics are undertaken by hospital optometrists to identify any false-positive wet

AMD referrals and redirect patients appropriately. All patients in whom wet AMD is suspected are reviewed by a medical retinal consultant, and those requiring intravitreal treatment have the choice of immediate (one-stop) treatment or joining a dedicated intravitreal injection list (two-stop). An Eye Clinic Liaison Officer (ECLO) undertakes a session simultaneous to the specialist clinic so that patients requiring support can

undergo disability assessment and visual rehabilitation during the same visit. If a patient has not required treatment for 6 months, they are followed-up in a nurse-led review clinic. When patients remain stable after 24 months from start of treatment, they are seen in an optometrist-led OCT clinic. 'Stable' patients can be seen at satellite clinics closer to their home, and a mobile OCT scanner travels to the satellite clinics.

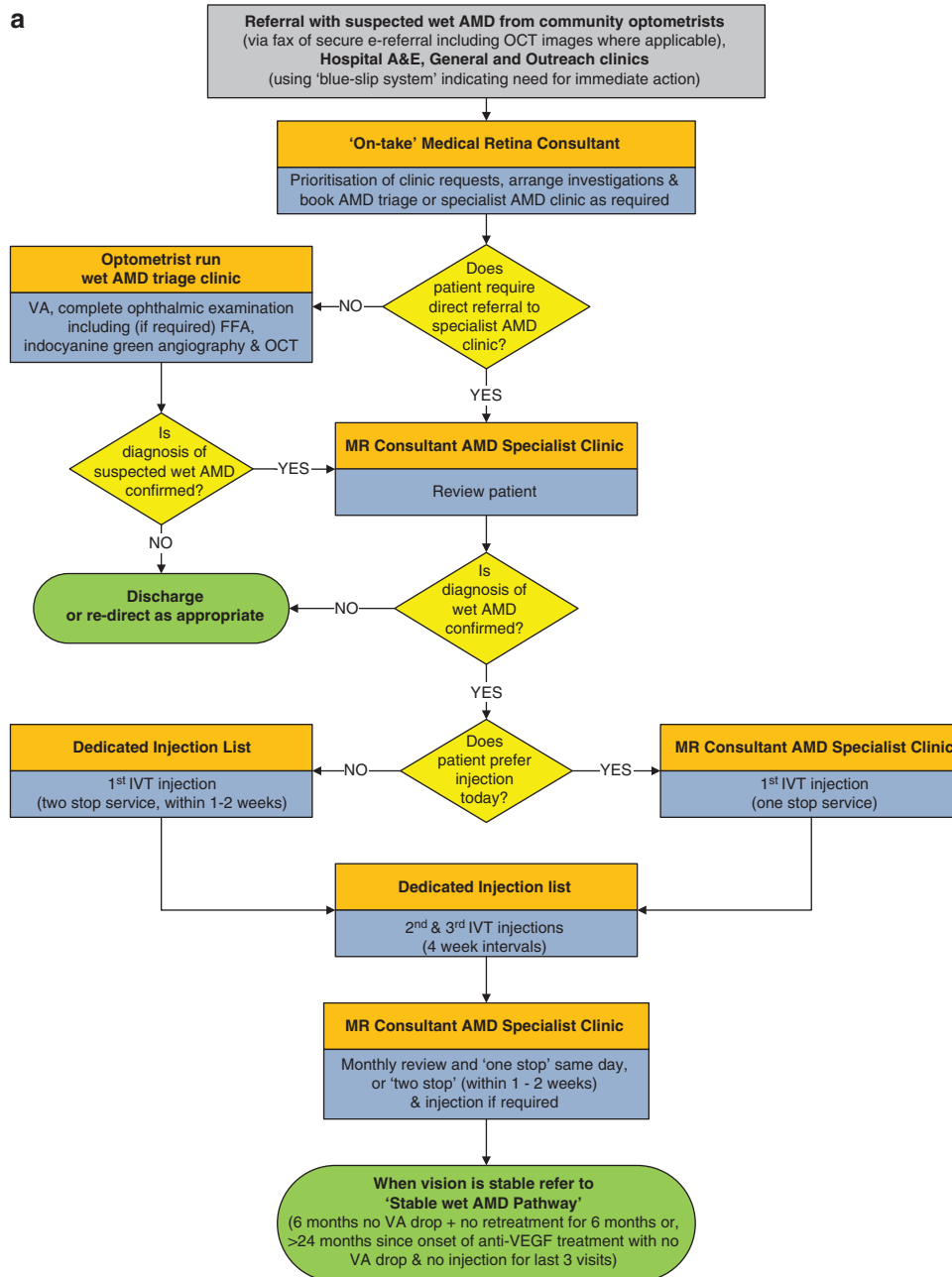


Figure 5 (a) Hub and satellite clinic spoke (Sunderland example). The pathway for newly diagnosed patients and patients with 'active' wet AMD. AMD, age-related macular degeneration; FFA, fundus fluorescein angiography; IVT, intravitreal treatment; MR, medical retinal; OCT, optical coherence tomography; VA, visual acuity; VEGF, vascular endothelial growth factor.

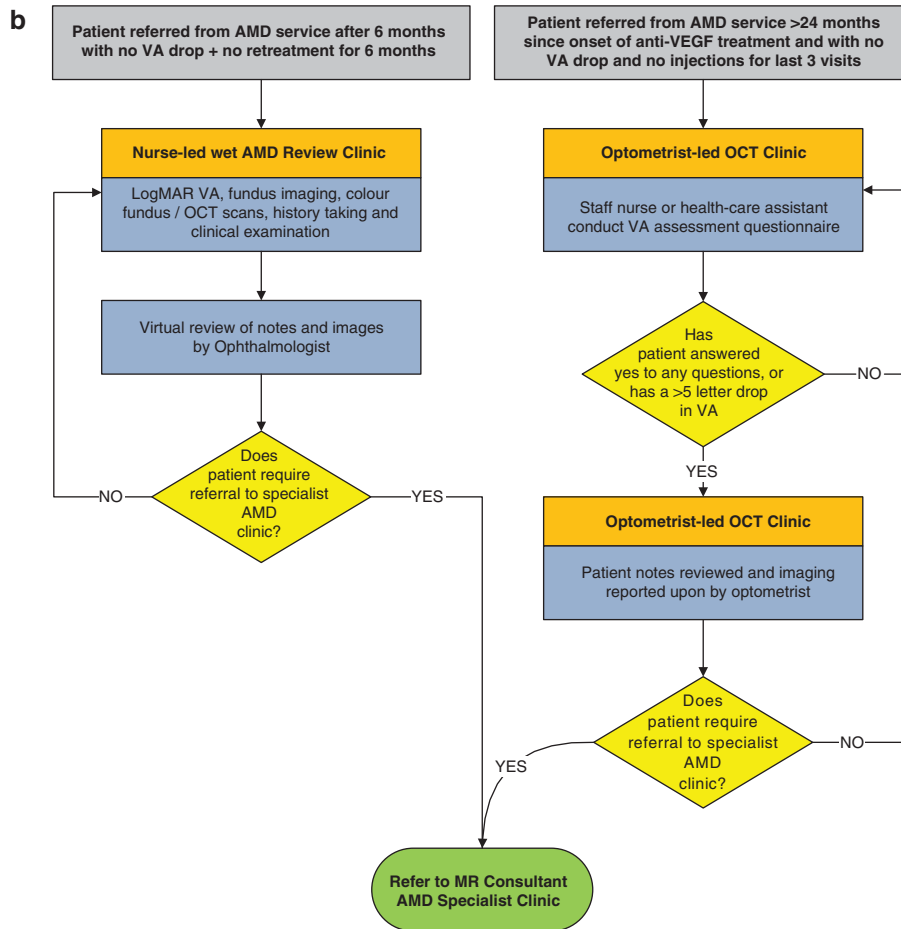


Figure 5 (b) Hub and satellite clinic spoke (Sunderland example). The pathway for patients classified as having ‘stable’ wet AMD. AMD, age-related macular degeneration; MR, medical retinal; OCT, optical coherence tomography; VA, visual acuity; VEGF, vascular endothelial growth factor.

Clinic capacity. In all, 15–20 patients are examined at each of 2 weekly triage clinics. The AMD specialist clinics are run six times a week each with capacity for 8 new patients and 24 follow-up patients, and 17 injection slots. In addition, five dedicated injection lists per week increase throughput with 15–20 injections per session. Each week there are up to three nurse-led AMD review clinics with 15 patients each and two optometrist-led OCT review clinics with 30–35 patients each.

Key requirements. Good teamwork is vital to provide patients with the best health care, and the SEI Macular Unit staff are flexible in their roles, to ensure efficient and effective delivery of the treatment. The staff comprises three medical retinal consultants, two general ophthalmologists, three optometrists, four macular specialist nurses, two health-care assistants, an ECLO, two medical photographers, a macular secretary/AMD coordinator, and three reception staff. A dedicated macular unit consisting of a nursing assessment area, imaging suite, preparation rooms,

and injection suite has been established for the macular patients.

Learning points

Benefits	Challenges
<ul style="list-style-type: none"> ● Implementation of AMD triage clinics, nurse-led review clinics and optometrist-led OCT clinics have helped maximise capacity ● Specialist clinics have enabled consultants to focus on complex macular pathology and high-risk patients ● Dedicated Macular Unit and satellite Macular Clinics in the community have increased capacity as well as convenience for patients 	<ul style="list-style-type: none"> ● Need to identify, train and retain appropriate staff to undertake FFA and OCT ● Covering staff leave has been a challenge ● Expansion of service requires expansion of the clinical area to maintain increase in throughput ● An appropriate business case is required for addition of satellite macular clinics ● A mobile OCT scanner is required

Exemplar case study: e-referral link between community optometrists and hospital eye clinics (Fife)

In the autumn of 2010, the Scottish Government announced a £6.6 million investment in a new IT scheme linking community optometrists and eye clinics within hospitals across all of Scotland.²² The link was based on a successful pilot scheme in NHS Fife and allows optometrists to send clinical images of patients with potentially serious eye problems (such as wet AMD) directly to ophthalmologists, enabling them to decide on the same day whether the person needs a hospital ophthalmology appointment. Future development of this service is expected to reduce the time between patients visiting the optometrist and receiving an appointment from the HES and lead to fewer unnecessary hospital attendances.

Service structure. In the previously published pilot study,²³ patients visiting one of three optometry practices with existing non-mydriatic cameras were charged a small fee for fundus photography, and the images were forwarded by email to the HES using NHSmail (www.nhs.net), accompanied by the electronically redesigned referral form (Figure 6). Each referral was assessed by a consultant ophthalmologist whose telemedicine assessment was based solely on the information and image provided in the referral. The decision for requiring or not requiring an appointment within the HES was communicated to the optometrist by email, and to the patient and GP by letter.

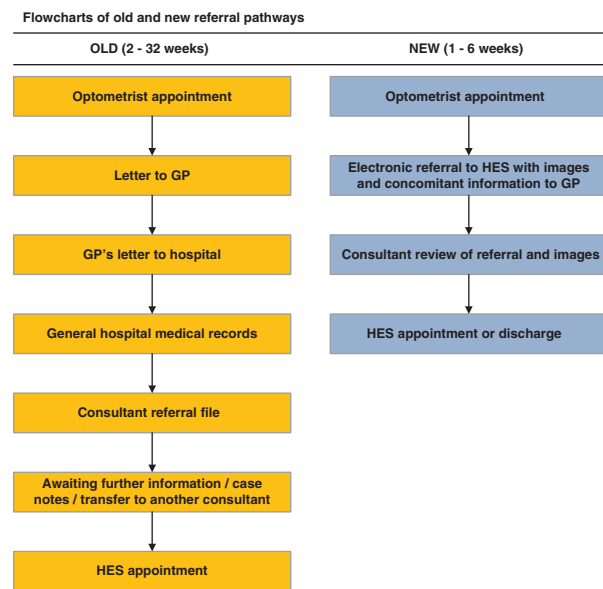


Figure 6 Telemedicine with community imaging (new vs old Fife patient pathways). Adapted from Cameron *et al.* with permission from the Nature Publishing Group.²³ GP, general practitioner; HES, hospital eye service.

Clinic capacity. In an 18-month trial, 346 patients were examined. Of these, 128 patients (37%) were found not to require an HES appointment, considerably easing the burden on the hospital eye unit. The potential cost savings of such a scheme are estimated to run into several hundred thousands of pounds per annum for individual hospital trusts.²³

Key requirements. Suitable quality retinal imaging cameras for community optometrists are required. High-quality IT equipment is also required, as well as special approval to send large files containing confidential clinical information via NHSmail. An appropriately designed e-referral form is necessary to ensure that all relevant information is captured in primary optometric care for accurate decision-making by a remote secondary-care specialist.

Learning points

Benefits	Challenges
<ul style="list-style-type: none"> ● Reduces waiting times from optometrist visit to HES appointment ● One-stop service (the right patients are sent to the right clinic) ● Reduces the number of unnecessary HES appointments and fewer non-macular patients are seen ● Improved productivity of NHS resource <ul style="list-style-type: none"> ○ Frees up space in HES ○ Potential for cost savings ● Reduces 'did not attend' rates ● Greater patient satisfaction 	<ul style="list-style-type: none"> ● Good cooperation and communication of HES with GPs and optometrists is fundamental to success of the scheme (including training for optometrists) ● Some risk of clinical oversight may be associated with dealing with purely electronic images and information

Exemplar case study: telemedicine pilot project with OCT image transfer from community optometry to ophthalmologist; teleophthalmology (Salford/Bolton)

In the first phase of a pilot project, a community optometry practice in Salford forwarded consecutive e-referrals with attached OCT images of retinal patients to a consultant ophthalmologist based at Royal Bolton Hospital NHS Foundation Trust. These cases received rapid referral telemedicine advice and triage or teleophthalmology.

Service structure. In a pilot study, 43 retinal patients were assessed during the period June 2010–June 2011. The OCT images of patients' retinæ were captured and stored locally by the optometrist and then forwarded

using NHSmail (www.nhs.net) as JPEG files to the hospital consultant ophthalmologist (Figure 7). Patients were charged a small fee for the enhanced imaging. In the pilot project, the consultant ophthalmologist typically responded within 24 h by remote telemedicine working. The next phase of the pilot study aims to secure funding to expand the service to wider eye conditions and make OCT imaging available to potential participants who may be unable to pay for community optometrist OCT imaging.

Key requirements. OCT imaging in primary care requires equipment, as well as skill in taking and transmitting appropriate images by the community optometrist. In addition, the secure email transfer and centralised data storage systems between different health-care providers need to be compatible. For roll-out of this model, relevant primary and secondary, private and NHS health-care practitioners require access to NHSmail or N3 connection to enable secure patient data transfer. A dedicated NHSmail inbox for receipt of all electronic referrals at Trusts may be of benefit, but would need to be supported by appropriate resourcing, to provide continuous management of electronic referrals. For further details on this exemplar case study, see Kelly *et al.*²⁴

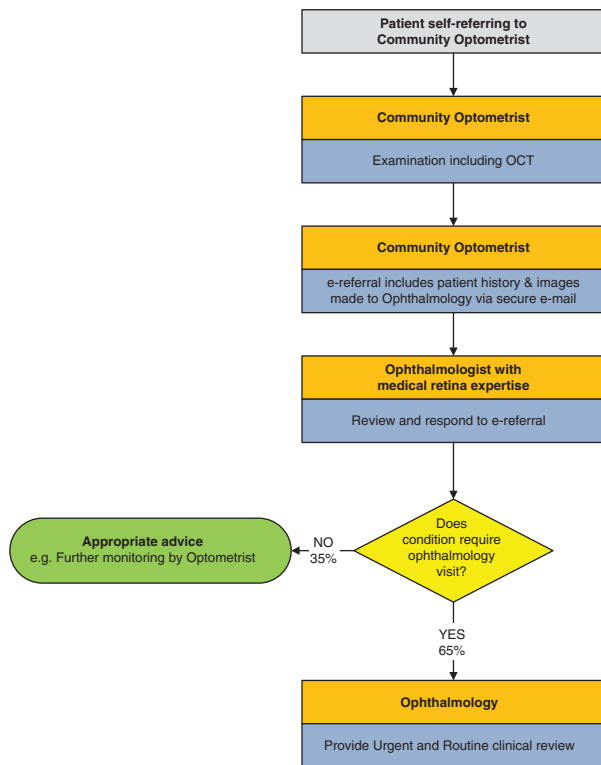


Figure 7 Community OCT telemedicine (example from Salford/Bolton). OCT, optical coherence tomography. Reprinted from Kelly *et al.*²⁴ Copyright 2011, with permission from Dove Medical Press Ltd.

Learning points

Benefits	Challenges
<ul style="list-style-type: none"> ● Enables rapid referral telemedicine advice and triage or teleophthalmology ● Reduces waiting times from optometrist visit to HES appointment ● Reduces the number of unnecessary HES appointments and fewer non-macular patients seen ● Improves productivity of NHS resource <ul style="list-style-type: none"> ○ Frees up space in HES ○ Potential for cost savings 	<ul style="list-style-type: none"> ● Ensuring that participating individuals/ organisations have appropriate OCT scanning and viewing equipment and adequate training ● Self-pay cost of OCT scanning in primary optometric care may prohibit some patients in the community from experiencing these associated benefits: NHS funding for OCT imaging in primary care and development of an NHS tariff for OCT e-consultation would be beneficial ● Consistent selection of the most clinically appropriate retinal images by the optometrist and consistent provision of clinical assessment information to support the images is important <ul style="list-style-type: none"> ○ May benefit from agreement of a protocol/criteria for selection of images and development of a bespoke electronic form, based on the GOS 18 form ● The size of OCT images rapidly filled NHS email in-boxes. Full video file transmission may be problematic

Service innovation, summary of approaches

Possible approaches to the various key capacity issues are summarised in Table 2. Overall, the general considerations for each of these potential solutions include costs, staff retention and morale, staff training and competency assessment, availability (of space, staff, or equipment), staff leave of absence, management of complications (eg, safety), and patient acceptance. Other challenges and considerations that are specific to each

Table 2 Summary of possible approaches

Possible approaches	Key benefits	Specific challenges and considerations
<p>Space</p> <p>Separation of wet AMD patient treatment from other retinal or non-retinal ophthalmic patients</p> <p>Use of other spaces (eg, mobile units or underused existing health-care space such as private hospitals, polyclinics or GP clinics)</p> <p>Decentralisation of services to local district general hospitals, or decentralisation of other services into peripherals (eg, glaucoma)</p> <p>Reorganisation of existing clinic footprint and space</p> <p>Virtual clinics (eg, use of community optometrists/other health-care professionals for OCT imaging, or mobile OCT machines)</p>	<p>Wet AMD service no longer competes with other services for space and/or time</p> <p>Separation of patients referred with suspected wet AMD from patients who are undergoing the initiation phase of injections and monthly follow-up allows treatment and assessment clinics to be predictable and efficiently organised</p> <p>Wet AMD service no longer competes with other services for space and/or time</p> <p>Provides additional space for wet AMD service</p> <p>Relieves pressures on space in the hospital service</p> <p>May be more convenient for patients</p> <p>More efficient use of existing space</p> <p>Reduces capacity issues within the hospital service (see also staff and equipment)</p> <p>Increases access for patients as optometric practices are normally in conveniently accessible locations—particularly relevant in more rural areas where patients may have substantial journey to hospital</p>	<p>A ‘clean room’ is required for intravitreal injections for wet AMD</p> <p>Ensure continuity of mobile unit availability throughout the year (eg, adverse weather, breakdown) or consider alternative cover</p> <p>Consider convenience for patients</p> <p>Dedicated clean room (for injections) required</p> <p>Assumes staff and equipment are available for the new service</p> <p>Space, appropriate staff and equipment must be available in the peripheral service</p> <p>Most ophthalmic footprints are operational at full capacity in working week-time hours</p> <p>May require funding for equipment and/or clinic renovation</p> <p>Electronic transfer of ophthalmic images from the community for review at the hospital can be problematic, due to IT issues, but is possible. Some optometrists are now getting NHS email accounts, which enable secure electronic transmission of patient information. However, if large file sizes are being transmitted, investment in N3 connections may be required</p> <p>Appropriate viewing stations and clinical governance arrangements may be a challenge</p> <p>Placement of virtual clinics in the right place in the patient pathway is critical for success</p> <p>OCT instruments are expensive and optometrists receive no capital funding for such a purchase</p> <p>A tariff for OCT imaging in optometric care and telemedicine services needs to be developed</p>
<p>Staffing/staff skills</p> <p>Appropriate utilisation of staff to best suit their skill set (eg, efficient utilisation of consultants’ time)</p> <p>Recruitment of middle-grade (non-consultant) medical retinal staff to assist the consultant</p> <p>Adoption of alternative staff (eg, hospital optometrists, ophthalmic nurses or health-care staff) for a range of tasks from LogMAR VA testing and OCT imaging to retreatment decision-making</p>	<p>Staff time is utilised more efficiently</p> <p>Higher patient throughput possible (eg, more intravitreal injections per session)</p> <p>Consultant time is freed up and can be used more efficiently</p> <p>The consultant is still involved in the diagnosis and treatment decision-making, but not every patient needs to be seen by the consultant at every visit, thus freeing up consultant time</p> <p>Pressure from large number of follow-up patients is relieved</p>	<p>Consider staff morale and personal development (eg, repeated administration of injections may be considered boring)</p> <p>Consider annual leave/staff cover</p> <p>There is a severe UK-wide shortage of middle-grade ophthalmic medical staff</p> <p>Assumes funds available</p> <p>Depends on individual staff expertise and skills locally</p> <p>Need for consultant to be involved in decision-making process at vital points in the patient pathway remains</p> <p>Requires IT networking for good information flow to speed up consultant decision-making</p> <p>Consider regular designated reporting sessions and triage sessions in medical staff job plans and including telemedicine tariffs</p>

Table 2 (Continued)

	Possible approaches	Key benefits	Specific challenges and considerations
	Stratification of patients by risk of progression, whereby 'low risk' patients attend virtual clinics in the community or within the hospital eye service	All patients are reviewed monthly and risk of an undetected deterioration is minimised At follow-up visits, specialist staff time is used more effectively to assess only higher risk patients	Availability of LogMAR VA testing and OCT imaging and fundus photography is vital for these patients who are considered at low risk of progression An accurate prediction of the proportion of 'stable' patients is key
	Employment of a wet AMD clinic coordinator	Clinics are run efficiently and patient appointments and referrals are managed effectively	Assumes funds available Appointee must have good understanding of all issues (patient as well as service) in order to be effective
Equipment	Use of suitably trained community optometrists for OCT imaging in the community	Removes the need for additional OCT machines within the hospital service	Electronic transfer of images for review at the hospital (see 'space' section above) and Information Governance Purchase of community OCT equipment and networking. OCT instruments are expensive and optometrists receive no grants for their purchase Access to NHSmail, N3 connections, satellite broadband, or PACS by community optometrists
	Mobile OCT machine	Provision of off-site OCT services in community centres or in district hospitals who do not have ophthalmic services	Needs additional staff to undertake OCT Purchase of OCT equipment and remote networking infrastructure Access to NHSmail, N3 connections, satellite broadband, or PACS Remote and off site back up of images
	Electronic Medical Record system	Improves the speed and consistency of decision-making in AMD clinics and delivers detailed audit of clinical outcomes Allows service re-design to improve the efficiency of AMD clinics	Developing a business case to justify the extra investment
Quality assurance	Provide patients with emotional support at clinic or referral to external counselling, peer support or emotional support services as required	Towards best possible standard of care for patients	Patient motivation
	Complete Certificate of Visual Impairment (CVI) registration as appropriate to ensure that patients whose sight has deteriorated to registration level have access to a social care assessment	Patients who require support are assessed by Social Services and have a better chance of being referred to other local support services	Development and roll out of electronic CVI
	Employment of Eye Clinic Liaison Officer (ECLO)	ECLOs can deal with most of the patient requirements outside the treatment itself, including low-level emotional support and signposting to daily living support services, which is crucial for a smooth transition from health to social care Specialist staff time within the hospital service is used more effectively to see only higher risk patients at follow-up	Assumes funds and suitable personnel available NHS Trusts liaison with social services and third sector
Management planning and business case development	Provide monthly monitoring for all wet AMD patients, but tailored according to patient characteristics and local model adopted	Ensures adequate funding for future developments and takes into account any necessary future expansion of the service	It is essential that monthly monitoring is provided for all patients—lower risk does not mean no risk
	Develop a robust business case that is both realistic and long-term and includes ECLO funding and where necessary a low vision service	Greater chance of business case approval and obtaining funds for expansion of service	Consider likely future indications for intravitreal therapy and any other future developments Accurate costing of the service is important and vital Capacity pressures are generally predictable
	Write a business case that is impactful	Facilitates auditing, reduction of administrative time and also facilitates evaluation/prioritisation of patients	Business case must be evidence-based, concise, and realistic Communicate to hospital and Trust management teams the value of appropriate management of wet AMD in terms of income and patient benefit Requires appropriate IT systems Cost
	Electronic patient medical records		

possible approach are also described in Table 2 and are drawn from the case studies and expert experience. Whatever the specific problem areas that need to be addressed, effective stakeholder engagement must inform the approach chosen, including engagement with patients and patient organisations.

Conclusions and summary

Wet AMD services in many parts of the UK NHS are under pressure and often running to maximum capacity. It is vital that services continue to adapt locally to meet current and future demands, so that they may continue to provide the best care possible for patients with wet AMD. There is evidence from patient safety reports from the NHS and in a survey undertaken by RCOphth that capacity has been problematic, at times, in the HESs in the United Kingdom.^{25,26} Failure to maintain the recommended follow-up interval can cause patients to unnecessarily lose vision permanently, with a consequent burden on health and social care.

Action on AMD aims to assist eye health-care professionals and NHS commissioners and providers rise to the challenge of increasing wet AMD rates and provide access to optimum care for these NHS patients. *Action on AMD* strongly advises that every hospital with a medical retinal clinic evaluate their wet AMD service and, wherever necessary, implement modifications to ensure that the best possible quality of care is currently provided, and continues to be provided into the future. We are aware of pockets of good practice and service development.

In accordance with the government's pledge to support the NHS in providing high-quality and patient-centred care, the Quality, Innovation, Productivity and Prevention (QIPP) programme aims to ensure that all money spent in the NHS is used to bring the most benefit and quality of care to patients. The Quality Standards Group of RCOphth has produced a self-assessment tool for a number of clinical services, including wet AMD. This tool indicates whether a department is currently providing an acceptable standard of patient care and can be used as a quality improvement tool to show where the service is under stress. *Action on AMD* supports such an approach that could be applied to pinpoint which of the potential solutions presented here would best improve the quality of patient care in any particular clinic.

Importantly, we have presented here a number of potential solutions that experience has shown to improve quality, effectiveness, and productivity, and thus increase capacity. The examples provided can be implemented in whole, in part, or in principle, at a local level, and our key recommendations are summarised in Table 3. For implementation of change, the broader principle of

adopting a particular model is more important than the specifics of which professional group to use. In our opinion, services for wet AMD patients require clinical leadership, and, in our opinion, ophthalmologists with expertise in the management of wet AMD must be supported by appropriately trained staff, equipment, and clinical space. Although investment may be necessary to modify existing services, this can be outweighed by the provision of better quality care that meets the needs of patients, increased productivity by maximising the use of experienced clinicians, and additional revenue to be invested in the HESs. Importantly, we would also expect cost reductions in the long term in sight support services (both health and social care) as more patients retain vision with better clinical outcomes.

Conflict of interest

Mr Amoaku chaired the Scientific Committee of the Royal College of Ophthalmologists from 2007 to 2011, and currently chairs the College's Medical Retina Service Provisions Subcommittee, and the VISION 2020 UK Macular Interest Group. He is a member of the Scientific Research Committee of the Macular Diseases Society. He has received educational travel grants from Allergan, Novartis Pharma and served on Advisory Boards for Allergan, Bayer, Novartis, and Pfizer for which he has received honoraria. He has participated in clinical trials sponsored by Novartis, Pfizer, and Bausch and Lomb, for which his institution has received funding. His institution has also received research grant funding from Allergan and Novartis. He has received lecture fees for speaking at the invitation of Allergan, Bausch, Lomb, and Novartis. Susan Blakeney is Optometric Adviser to the College of Optometrists and to the Primary Care Trusts in Kent and Medway. She is also a director of BP Eyecare Ltd, which has received consultancy fees from Novartis Pharmaceuticals UK. Mary Freeman has received an honorarium for supporting an annual symposium on AMD for nurses and allied health-care professionals, and for advisory consultation from Novartis Pharmaceuticals UK. Sheffield Teaching Hospitals NHS Trust conducts clinical trials sponsored by Novartis Pharmaceuticals UK. Richard Gale is Chairman of The Eye Site Clinic Ltd and Mobile Healthcare Accommodation Ltd, and has received educational grants from, and advisory consultation for, Novartis Pharmaceuticals UK. He has received lecture fees for speaking at the invitation of Abbott and Novartis. York Teaching Hospital conducts clinical trials sponsored by Novartis Pharmaceuticals UK. Simon Kelly has attended advisory consultation board meetings and educational travel support with Allergan, Novartis, and Pfizer. He has received lecture fees from Novartis. The Royal Bolton Hospital NHS

Table 3 Action on AMD key recommendations

Key recommendations	Comments and considerations
1. Appropriate funding and resources must be made available now that treatment is possible	Wet AMD is a serious and rapidly progressing degenerative eye disease that can cause blindness if inadequately treated and managed
2. There should be no compromise in the standard of service provision, or quality or frequency of intravitreal treatment administration	Fast track referral systems, prompt commencement of intravitreal therapy and regular monthly follow-up as per NICE guidance and RCOphth guidelines are vital components of wet AMD patient management
3. Continued evaluation and adaptation/redesign of local wet AMD NHS service is required	To increase capacity to meet current and future demands. Action must be taken now in order to ensure services that provide the quality of care that has been set out by NICE and RCOphth for all patients with wet AMD.
4. Recruitment	Recruitment of additional consultant staff, or middle-grade (staff and associate specialist grade) medical retinal staff to provide assistance for consultant medical retinal specialists has been identified as a key element of any approach to tackle existing capacity problems. Optometrists and senior nurses can be trained to perform assessments.
5. Prioritisation/stratification of patients	In line with local and regional service designs. Matching the service model to the stage of the patient journey can be helpful (eg, one-stop model for patients likely to require treatment and two-stop model for patients for whom treatment is considered unlikely to be necessary)
6. Virtual clinics	To free up capacity issues within the hospital service. Ophthalmology medical staff may not need to examine every patient, as long as they are still involved in the decision-making process at vital points in the patient pathway. Face-to-face patient contact can be undertaken by suitably trained and supervised nursing and optometry staff. Consideration can also be given to enhance roles for other staff such as optometrists, orthoptists, and medical imaging staff.
7. Use of other community spaces such as mobile units, polyclinics or GP clinics	To relieve problems of inadequate hospital space and to bring care closer to home
8. Multi-disciplinary clinics—staff training and development, flexible role, and appropriate use of staff	To best suit the individual's skill set. Consideration should be given to extending the role of nursing and other health-care professionals
9. Use of community optometrists for monitoring 'stable' patients (patients at low risk of requiring treatment)	Requires appropriately connected OCT instruments in the community setting in addition to OCT instruments and/or viewing software in the Ophthalmology Departmental setting. Also requires appropriate training of community optometrists in OCT imaging and NHS Information Governance
10. Electronic referrals from community optometrists	May be worth investment, in order to make triaging more timely, efficient and better quality. Pilot projects using, eg, retinal photography image transfer in Scotland have been of merit. Patients have often had, however, to self-fund such imaging in optometric care
11. Electronic medical records	To improve auditing capabilities, reduce administration time, and enable easier assessment of patient records and prioritisation of patients
12. Employment of an Eye Clinic Liaison Officer	To guarantee a holistic service that takes account of the emotional support needs of patients and helps secure a smooth transition from health to social care and other support services as required

Foundation Trust is involved in clinical research sponsored by Novartis and Allergan. Barbara McLaughlan has no conflicts of interest to declare. Her former institution, RNIB, received limited unrestricted educational grants from Novartis. Deepali Varma has attended advisory board meetings for Novartis and Allergan. Sunderland Eye Infirmary has participated in clinical trials sponsored by Novartis Pharmaceuticals UK and Allergan UK. Rob Johnston is the Medical Director of, and is a shareholder in Medisoft Limited. He has received lecture fees and travel grants for speaking at the invitation of Novartis Pharmaceuticals UK. He received consulting fees from Bayer in 2011. Debendra Sahu has received educational grants and

advisory consultation from Novartis Pharmaceuticals UK and Allergan Ltd UK. Southampton General Hospital NHS trust conducts clinical trials sponsored by Novartis Pharmaceuticals UK.

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Appendix

Action on AMD members

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Some of the *Action on AMD* members are also members of eye health organisations and charities. However, opinions expressed within this document are those of the individuals and do not represent the opinions of any organisations.

Lucentis[®]▼ (ranibizumab) ABBREVIATED UK PRESCRIBING INFORMATION

Please refer to the SmPC before prescribing Lucentis 10 mg/ml solution for injection.

Presentation: A glass single-use vial containing 0.23 ml solution containing 2.3 mg of ranibizumab (10 mg/ml).

Indications: The treatment in adults of neovascular (wet) age-related macular degeneration (AMD), the treatment of visual impairment due to diabetic macular oedema (DMO), or the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).

Administration and dosage: Single-use vial for intravitreal use only. Lucentis must be administered by a qualified ophthalmologist experienced in intravitreal injections under aseptic conditions. The recommended dose is 0.5 mg (0.05 ml).

For treatment of wet AMD: Treatment is given monthly and continued until maximum visual acuity is achieved; ie, the patient's visual acuity is stable for three consecutive monthly assessments performed while on ranibizumab. Thereafter, patients should be monitored monthly for visual acuity.

Treatment is resumed when monitoring indicates loss of visual acuity due to wet AMD. Monthly injections should then be administered until stable visual acuity is reached again for three consecutive monthly assessments (implying a minimum of two injections). The interval between two doses should not be shorter than 1 month.

For treatment of visual impairment due to either DMO or macular oedema secondary to RVO: Treatment is given monthly and continued until maximum visual acuity is achieved; ie, the patient's visual acuity is stable for 3 consecutive monthly assessments performed while on ranibizumab treatment. If there is no improvement in visual acuity over the course of the first three injections, continued treatment is not recommended. Thereafter, patients should be monitored monthly for visual acuity. Treatment is resumed when monitoring indicates loss of visual acuity due to DMO or macular oedema secondary to RVO. Monthly injections should then be administered until stable visual acuity is reached again for three consecutive monthly assessments (implying a minimum

of two injections). The interval between two doses should not be shorter than 1 month.

Lucentis and laser photocoagulation in DMO and in macular oedema secondary to BRVO: When given on the same day, Lucentis should be administered at least 30 minutes after laser photocoagulation. Lucentis can be administered in patients who have received previous laser photocoagulation.

Before treatment, evaluate the patient's medical history for hypersensitivity. The patient should also be instructed to self-administer antimicrobial drops, 4 times daily for 3 days before and following each injection.

Children and adolescents: Not recommended for use in children and adolescents because of a lack of data.

Elderly: No dose adjustment is required in the elderly. There is limited experience in patients older than 75 years with DMO.

Hepatic and renal impairment: Dose adjustment is not needed in these populations.

Contraindications: Hypersensitivity to the active substance or excipients. Patients with active or suspected ocular or periocular infections. Patients with active severe intraocular inflammation.

Special warnings and precautions for use: Lucentis is for intravitreal injection only. Intravitreal injections have been associated with endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear, and iatrogenic traumatic cataract. Monitor during week following injection for infections. Patients should be instructed to report symptoms suggestive of any of the above without delay. Transient increases in intraocular pressure (IOP) within 1 h of injection and sustained IOP increases have been identified. Both IOP and perfusion of the optic nerve head should be monitored and managed appropriately. Concurrent use in both eyes has not been studied and could lead to an increased systemic exposure. There is a potential for immunogenicity with Lucentis, which may be greater in subjects with DMO. Patients should report an increase in severity of intraocular inflammation. Lucentis should not be administered concurrently with other anti-VEGF agents (systemic or ocular). Withhold dose and do not resume treatment earlier than the next scheduled treatment in the event of the following: a decrease in best corrected visual acuity (BCVA) of ≥ 30 letters compared with the last assessment of visual acuity; an intraocular pressure of ≥ 30 mm Hg; a retinal break; a subretinal haemorrhage involving the centre of the fovea, or if the size of the haemorrhage is $\geq 50\%$ of the total lesion area; performed or planned intraocular surgery within the previous or next 28 days. Risk factors associated with the development of a retinal pigment epithelial (RPE) tear after anti-VEGF therapy for wet AMD include a large

and/or high pigment epithelial retinal detachment. When initiating Lucentis therapy, caution should be used in patients with these risk factors for RPE tears. Discontinue treatment in cases of rhegmatogenous retinal detachment or stage 3 or 4 macular holes.

There is only limited experience in the treatment of subjects with DMO due to type I diabetes. Lucentis has not been studied in patients who have previously received intravitreal injections, in patients with active systemic infections, proliferative diabetic retinopathy, or in patients with concurrent eye conditions such as retinal detachment or macular hole. There is also no experience of treatment with Lucentis in diabetic patients with an HbA1c over 12% and uncontrolled hypertension. There are limited data on safety in the treatment of DMO and macular oedema due to RVO patients with prior history of stroke or transient ischaemic attacks. Since there is a potential risk of arterial thromboembolic events following intravitreal use of vascular endothelial growth factor (VEGF) inhibitors, caution should be exercised when treating such patients. There is limited experience with treatment of patients with prior episodes of RVO and of patients with ischaemic BRVO and CRVO. Treatment is not recommended in RVO patients presenting with clinical signs of irreversible ischaemic visual function loss.

Interactions: No formal interaction studies have been performed. In wet AMD, adjunctive use of verteporfin photodynamic therapy (PDT) and Lucentis in an open study showed an incidence of intraocular inflammation following initial combination treatment of 6.3% (2 of 32 patients). In DMO and BRVO, adjunctive use of laser therapy and Lucentis was not associated with any new ocular or non-ocular safety findings.

Pregnancy and lactation: Women of childbearing potential should use effective contraception during treatment. No clinical data on exposed pregnancies are available. Ranibizumab should not be used during pregnancy unless the expected benefit outweighs the potential risk to the foetus. For women who wish to become pregnant and have been treated with ranibizumab, it is recommended to wait at least 3 months after the last dose of ranibizumab before conceiving. Breast feeding is not recommended during the use of Lucentis.

Driving and using machines: The treatment procedure may induce temporary visual disturbances, and patients who experience these signs must not drive or use machines until these disturbances subside.

Undesirable effects: Wet AMD Population: Serious adverse events related to the injection procedure included endophthalmitis, rhegmatogenous retinal detachment, retinal tear, and iatrogenic traumatic cataract. Other serious ocular events among Lucentis-treated patients included intraocular inflammation and

increased intraocular pressure. The safety data below includes all adverse events suspected to be due to the injection procedure or medicinal product in the wet AMD trial population. **Very Common:** Intraocular pressure increased, headache, vitritis, vitreous detachment, retinal haemorrhage, visual disturbance, eye pain, vitreous floaters, conjunctival haemorrhage, eye irritation, foreign body sensation in eyes, lacrimation increased, blepharitis, dry eye, ocular hyperaemia, eye pruritus, arthralgia, nasopharyngitis. **Common:** Anaemia, retinal degeneration, retinal disorder, retinal detachment, retinal tear, detachment of the retinal pigment epithelium, retinal pigment epithelium tear, visual acuity reduced, vitreous haemorrhage, vitreous disorder, uveitis, iritis, iridocyclitis, cataract subcapsular, posterior capsule opacification, punctate keratitis, corneal abrasion, anterior chamber flare, vision blurred, injection site haemorrhage, eye haemorrhage, conjunctivitis, conjunctivitis allergic, eye discharge, photopsia, photophobia, ocular discomfort, eyelid oedema, eyelid pain, conjunctival hyperaemia, cough, nausea, allergic reactions, hypersensitivity, and anxiety.

DMO and RVO Populations: Ocular and non-ocular events in the DMO and RVO trials were reported with a frequency and severity similar to those seen in the wet AMD trials with the addition of urinary tract infection, which was found to be 'common' in the DMO population.

Product-class-related adverse reactions: There is a theoretical risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors. A low incidence rate of arterial thromboembolic events was observed in the Lucentis clinical trials in patients with AMD and DMO and RVO, and there were no major differences between the groups treated with ranibizumab compared with control.

Please refer to the SmPC for full listing of all undesirable effects.

For UK: Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Novartis Pharmaceuticals UK Ltd on (01276) 698370.

Legal category: POM, **UK Basic NHS cost:** £742.17
Marketing authorisation number: EU/1/06/374/001.

Marketing authorisation holder: Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex RH12 5AB, UK. Full prescribing information, including SmPC, is available from Novartis Pharmaceuticals, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR. Telephone: 01276 692255; Fax: 01276 692508.

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