Macular degeneration (MD) stakeholder workshop notes

Scoping group 1

Dr Waqaar Shah, Macular Degeneration Committee, Chair of Committee – facilitator

Stephen Duffield – NICE Technical Analyst – note taker

What are the 3 main issues that need to change in clinical practice?

The group discussed the need to define when it is important to stop treatment for wet age related macular degeneration. The stopping rules for injection treatment are not clear. It was asked whether NICE are going to do any quality of life assessment on impact of treatment as patients often do not feel the benefit of their treatment and yet they are required to receive regular invasive injections into their eyes. The group felt strongly that the guidance should be patient-centred (treat patients not the results of OCT scans).

When asked if NICE also need to produce guidance on when to start treatment the group felt that the existing guidance on when to start anti-angiogenic therapy was well defined. Criticism on technology appraisal (TA) 155 was received because the group felt there was not enough information on how to manage patients before starting treatment. As a result, those around the table thought better guidance on the monitoring of these patients who are not yet eligible for therapy should be given.

Education for patients and healthcare professionals was thought to be an area which required great improvement. There is a lack of knowledge of the different treatments that are available and a concerning lack of knowledge of the urgent referral pathways for wet age-related macular degeneration (AMD) among healthcare professionals working along the patient pathway. Access for various types of treatment for instance verteporfin Photodynamic therapy was also discussed.

Should the scope be restricted to age-related macular degeneration?

The group was in complete agreement that it should.

Population groups that required specific considerations

This group were happy that the term cognitive impairment sufficiently included dementia and learning disabilities.

Groups suggested for specific consideration included patients in whom one eye is already affected as these patients are at higher risk and may require closer monitoring. The group agreed with the inclusion of those with low socio-economic status.

Chronic illness was suggested as another subgroup for specific consideration (other chronic illnesses), as chronic illness can increase the burden on patients and other factors may need consideration such as poor diet and accessibility problems. This wording would cover diseases such as diabetes and obesity that could affect management but are not specific to this condition.

Population groups that would not be covered in this guideline

Myopia was suggested amongst the conditions not to be addressed by the guideline. One stakeholder raised that there is another TA available on the treatment of pathological myopia.

The group also felt that NICE needed to stipulate that “choroidal neovascularisation secondary to other causes” Would not be addressed.

The key areas to be included in the scope

There was discussion around the problems faced by the lack of optical coherence tomography (OCT) availability in high streets and that patient referral pathways needed defining. The group felt that there is potential for optometrists to become part of a triage type system in order to take the burden off of the retinal clinics and allow for more efficient referral pathways with fewer delays. When asked the question as to whether an optometrist could safely diagnose wet AMD, or rather safely rule it out/diagnose dry AMD, the group felt that they could but that it is a matter of being trained (and the availability of validated diagnostic tools). The importance of robust training and professional competency was raised and whether this should be put into the scope. Mark Baker clarified that NICE would not normally provide guidance on training and competency. It was suggested we could recommend the best diagnostic test for the triage and diagnosis and assume the competency/training of the person using such a test instead. There is recent evidence showing that findings of OCT technologies and angiographies still vary significantly and that this would have to be taken into account.

The group felt that NICE needed to look for evidence on the effectiveness of different referral models. Does a certain pathway result in an improvement in patient outcomes? And what are the different levels of training and competency within these models of service organisation.

Training and competency also effects the treatment and monitoring sections of the pathway and the group were also interested in who should be responsible for monitoring and review.

Technologies for monitoring were suggested as an area of inclusion in the scope.

The group discussed prevention strategies in this guideline to improve the onset of AMD. Mark Baker suggested that we do not necessarily need to look for evidence on

the primary prevention of macular degeneration since none of them had been proven to work and it is not within the remit of NICE to address screening issues (i.e. targeting high risk populations for prevention strategies). Smoking is an important risk factor but has plenty of existing guidance that can be cross referred to.

It was mentioned that in terms of slowing the progress of the disease behaviour there was not consistency in practice about who receives such preventive strategies. Mark Baker noted that even if none of these strategies work it would be useful to review the evidence in order to make “Do Not” recommendations. One stakeholder thought that this could be a useful area for health economics and value for money considerations. Mark Baker was in favour of changing the wording from “primary prevention” to “reducing the risk.”

The group felt it was appropriate not to include access to first line services within the scope of the guidance.

Outcomes of interest

One stakeholder made NICE aware of the COMET initiative- Core Outcome Measures in Effectiveness Trials Initiative and the development of core outcome measures for AMD.

Some stakeholders wanted to know the outcome of proportion of gainers and losers of visual acuity (vision) but it was also noted that stability (not getting worse) can be a good outcome.

The incidence of sight registration was also suggested and the group agreed that this would also be useful for public health. More useful, however, would be to say who was ELIGIBLE for CVI registration since many patients may choose not to apply and many are not offered or given the information that would help them register.

It was also noted that the number of letters on visual charts can be important (varies from 5, 10 to 15 letters). Most trusts use LogMAR, this may need to be agreed.

A few members of the group suggested removing reading speed from the list of outcomes of interest as it was cumbersome to record and had great variability between patients and day to day.

The group felt that there was some unnecessary overlap between the listed outcomes and how these may be recorded in the study literature.

Draft review questions, Service organisation

The group felt that we needed to look for evidence on the effectiveness of different referral models and triage systems and their effect on patient outcomes. The

different models of training and competency within these models of service organisation could also be examined. In order to address this issue two new review questions were suggested as additions to the existing draft review questions:

1) What is the effectiveness of different models of service organisation for the diagnosis of patients with suspected age related macular degeneration.

2) What is the effectiveness of different models of service for the ongoing care of patients with diagnosed age related macular degeneration

The group liked the questions on how soon a person should be diagnosed and treated and added that we should be considering

a) The ideal timing

b) The maximum delay

Draft review questions, Prevention/Diagnosis

One stakeholder felt the wording around “tools for assessing the risk” and “tools for confirming the diagnosis” could be clearer. Do we want to split the questions into diagnostic tools that are useful for triage, confirming the diagnosis and for directing treatment?

The group discussed if there was any point having a question on who is high risk for developing AMD if there are no useful interventions to target this population. But knowing which patients were high risk could be useful for directing monitoring frequency and risk of progression between stages.

Draft review questions, Treatment and monitoring

It was suggested that it would be useful to have a question on not just how often people should be monitored but also who should perform this and what is the effectiveness of home monitoring? This could especially be useful for guiding monitoring of the unaffected eye in high risk patients.

Other

The group were interested in the existing TAs and what could and could not be recommended. Mark Baker stated that we would not be changing existing TAs.

One stakeholder asked whether existing interventional procedures guidance (0IPG) were now obsolete or would be updated? The group were asked to consider the IPG’s and whether these would require updates or would be obsolete. IPG 272 and IPG49 were both suggested for updating. Mark Baker said that we would have to liaise with the IPG teams to ask permission.

Guideline committee composition

The groups felt that pharmacist was an unnecessary inclusion as there were really only two drugs to be discussed and none of these would be given by a pharmacist in practice.

MB suggested that the ophthalmic Public Health specialist could be demoted to co-opted expert for inclusion only in the relevant question.

The group were eager for the inclusion of more representatives of the patients. One stakeholder pointed out that our patient representatives would likely be elderly and may struggle to reach every meeting therefore a greater representation would also make logistical sense. The group agreed that this representation should include

1) a patient

2) a carer

3) A member of a patient organisation (could also be a patient themselves)

4) A local manager from an acute care setting

It would also be useful if we could get one patient with experience of “dry AMD” and another “Wet AMD.”

Scoping group 2

Dr Alexander Foss, Macular degeneration guideline committee member - facilitator

Stephanie Mills, NICE Project Manager – note taker

What are the 3 main issues that need to change in clinical practice?

- The group was asked about the 3 main issues in clinical practice they would like to change for Macular degeneration. The following issues were stated:
    - Rehabilitation and improvement of low visual aid services
    - Developing pathways for referral and management between different services
    - Clarifying the role of optometrists in monitoring and review of people with macular degeneration
    - Genetic testing and identifying at risk groups

Should the scope be restricted to age-related macular degeneration?

- The group was asked whether the focus on age-related macular degeneration was appropriate.
    - It was felt that macular degeneration increasingly affects older people with dementia and that this could be listed explicitly as a subgroup for consideration. Cognitive impairment was not favoured as a way to express this.
    - There are difficulties stopping treatment in older people and within the population with macular degeneration more widely.
    - Some group members thought there were people younger than 50 presenting with classic symptoms of age-related MD and that age 50 seemed an arbitrary cut-off which could introduce a barrier to treatment.
    - The exclusion of late presenting staghardt's disease was questioned as this can often be a differential diagnosis.
    - The group came round to the idea that focussing the guideline on age-related MD was preferable because it would not be possible to account

for every individual in the guideline and that those with rare conditions were likely to be under specialist care.

Population groups that required specific considerations

- The group were asked if any subgroups for special consideration were missing from the scope. The following suggestions were given:
    - People with dementia had already been raised
    - To separate out particular manifestations of the disease (?)
    - People with learning disabilities
    - Those with multi-sensory loss (such as hearing too)

The key areas to be included in the scope

- The group were asked about the key areas to be covered by the scope and if these were appropriate.
    - The group felt all the areas included were needed
    - Stopping rules for therapy and also for length of follow up were felt to be needed
    - Salvage therapy and guidance on changing therapy if something is not working was felt to be needed.
    - How community optometrists are involved in the care pathway and service organisation in the community.
    - Timelines for treatment were felt to be critical
    - Discussion centred around whether the pathway in the guideline started too late and whether NICE should be looking at how to get people to access treatment. The group were questioned about how this might convert into an action for health and social care professionals. There was recognition that this would be more public health territory. Patient education was agreed to be very important and that more general awareness of deteriorating vision was needed.
    - Guidance on the role of diet, lifestyle and nutritional supplements would be of benefit.

- Urgency of follow-up for macular degeneration and emergency care to rule out problems with drusen were mentioned as potential areas for inclusion.

- Genetic testing and risk identification were felt to be important.

Outcomes of interest

- The group were asked about the outcomes section in the scope

    - Capturing rate of progression of geographic atrophy was felt to be important

    - Traffic accidents should be removed because the data would not be captured in any meaningful way and clinicians do not have the authority to revoke driving licenses.

Other issues

- Other issues were discussed:

    - The group reinforced how important smoking cessation was and felt the guideline should cross refer to recommendations on this.

    - There were comments on the ambiguity of Technology Appraisal (TA) 155 and questions about how NICE would be able to undertake writing the guideline if the lack of clarity around this TA could not be dealt with. Prevention and early treatment resounded strongly amongst the stakeholders. The group were advised that it was not possible to change the TA's. The group advocated that criteria for discontinuation of treatment should be developed and that the threshold for treatment of 6/12 was too high in TA155. They felt that when the evidence was looked at, the TA may come to contradict evidence on early treatment to prevent greater progression of disease which a committee would then want to recommend in a guideline.

Guideline committee constituency

- The group suggested the following roles as part of the guideline committee constituency:

    - Medical ethicist (probably as a co-opted expert)

    - An extra patient/ carer member

    - A Geneticist

- A Social services representative

Scoping group 3

Dr Susan Spiers, NICE Associate Director – facilitator

Hugh McGuire, NICE Technical Adviser – note taker

What are the 3 main issues that need to change in clinical practice?

- Capacity
- Equipment
- Referral pathway
- Stopping protocols for anti—VEGF's (high priority as currently only stop if there is 'permanent structural damage)
- Treatment delays (High priority)
- Referral information (High priority)
- Community workforce and how to interact
- Timing of anti-VEGF (in terms of staging)
- Advice on prevention
- Information on low-vision services and when to offer this
- Social care involvement
- Patient adaption strategies to maintain independence (visual aids etc)
- Threshold for anti-VEGF treatment
- Service organisation and 'shared care arrangements'
- Transfer from clinical care to supported care (eg transition or palliative care type approach)

Should the scope be restricted to age-related macular degeneration?

The group did not like 50 year cut off, preferred it to be called age-related MD (AMD) as this would allow treatment in those with AMD in their 40's

Population groups that required specific considerations

Not overly keen on using ethnicity as a subgroup

Diabetes / obesity

Mentioned those with myopia, also those who already have AMD in one eye or in only eye

Those with Dry-AMD as this is a risk-factor for progression to wet AMD

Population groups that would not be covered in this guideline

General agreement with the population groups currently stated.

The key areas to be included in the scope

- Social care involvement
- More interest in specific vitamins and minerals rather than multivitamins
- Patient adaption strategies to maintain independence (visual aids etc)
- Service organisation and 'shared care arrangements'
- Transfer from clinical care to supported care (eg transition or palliative care type approach) or exiting clinical care
- Certification
- Submacular haemorrhage
- Communication across care providers eg Asda, Tesco optometrist to ophthalmologist
- HCP education
- Most appropriate (accurate) conversion factor between acuity charts

Outcomes of interest

Visual disability may be better than visual acuity

Response

Non-attendance

Audit data such as time to treatment etc

Draft review questions

Add in stopping after switching

Equality issues

People in care homes

Guideline committee constituency

2 optometrists - 1 community and 1 hospital

1 commissioner of adult social services

Low vision aid specialist (co-opted expert)