Patient/carer organisation statement template

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: [redacted]

Name of your organisation: Royal National Institute of Blind People and Macular Disease Society

Are you (tick all that apply):

- an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)

[redacted]

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. **Advantages**

(a) The technology is expected to dissolve the macular oedema caused by the retinal vein occlusion and as a result improve visual acuity and reduce vision distortion in patients with the condition. This improvement in vision starts to occur within a week, much faster than any benefits seen with the current laser treatments.

(b) Short-term and long-term benefits

The short-term impact on a patient's quality of life will depend on whether there is second eye involvement from retinal vein occlusion or vision loss due to other causes as well as the extent to which the patient's ability to carry out everyday tasks is affected by monocular sight loss. With an aging population, the chance of developing visual impairment is increasing. For example, the prevalence of glaucoma rises from about 2% in 40 year olds to 10% in 75 year olds. The chances of developing other sensory deficits, e.g. hearing loss, also increase, and may further impair an individuals' ability to function. Even when only affecting one eye, there is a significant amount of distress and anxiety associated with a sudden loss of vision in one eye, and this can also affect a patient's quality of life.

We have spoken to four patients with macular oedema secondary to central retinal vein occlusion (full case study attached) who took part in the trial of ranibizumab for macular oedema secondary vein occlusion who all reported significant improvements to their vision.[1] For one of the patients (Case study A, aged 46) this was particularly important since his sight problem was having a negative impact on his ability to do his job, which requires the use of handheld computers.

[1] Three of these are attached as the fourth one did not come back to us in time to confirm that he was happy for his individual case to be attached to this submission.

In addition, one of the case studies stated that she much preferred the ranibizumab injections to laser treatment, which she had experienced as unpleasant and uncomfortable. This highlights the fact that even laser is not always a pain-free experience, and there is a proportion of patients who find it difficult to tolerate.

Long-term, the benefits for patients are likely to be magnified since retaining sight in the eye affected by RVO may become a major factor in their quality of life should they develop a condition such as dry age-related macular degeneration (AMD). Since retinal vein occlusions and AMD share some risk factors this is not unlikely. At this point a decision to treat the original retinal vein occlusion will have additional benefits since the patient will not have to rely on successful treatment in his or her remaining eye to prevent blindness.

To illustrate the impact that retinal vein occlusion can have on a person's life please find attached the case study of a woman (case study D) who lost her sight to central retinal vein occlusion in one eye and developed dry age-related macular degeneration in the other. Since she was unable to receive treatment for her retinal vein occlusion and since she has the dry, untreatable, type of AMD, she is now registered partially sighted and still inexorably progressing towards further sight loss. We are also attaching the case study of an 86 year old man (case study E) who lost his sight due to retinal vein occlusion nine years ago, he subsequently developed it in his second eye and also has a number of other eye conditions. Both of these patients were severely affected by the disease because they either had at the time, or later developed, sight problems in the second eye. They are lucky to have the support of sighted spouses without which their situation would be much bleaker.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. **Disadvantages**

All patients felt that the benefits of the treatment outweighed the disadvantages. However, one patient found the procedure extremely unpleasant because he had a phobia of needles and his

eye looked sore and raw following the treatment. Apart from the effect on him he mentioned that this had been upsetting for his partner. All patients mentioned the fear of an injection as a disadvantage that could deter people from having the procedure, although after the initial injection, this fear lessened significantly and did not prevent the patients undergoing further injections.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

The four patient interviews we conducted indicate that the usefulness of the technology is not in question but there are different degrees of acceptance of the mode of administration.

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

The treatment does not work differently in different groups of patients. However, patients who receive it early are likely to benefit most since their sight will not have deteriorated as much as in patients who receive the treatment later, and those treated late may already have suffered from a degree of irreversible damage to their vision. Also, comparatively, patients with CRVO will benefit more than those with BRVO because the former do not have effective treatment alternatives.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

There are a number of alternative available treatments for macular oedema in BRVO with grid laser photocoagulation the most commonly used in patients whose visual acuity is less than 6/12 for three months. In addition, intravitreal triamcinolone is used in

both types of RVO. However, this is not licensed for use in this condition and the manufacturers have stated that it is contra-indicated for use in the eye. Arteriovenous sheathotomy is not widely used and evidence for the extent to which bevacizumab (the unlicensed alternative to ranibizumab) is being used in this indication is poor, as is evidence for its safety and efficacy.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

For CRVO the new technology has the advantage of being an alternative licensed treatment available with clear evidence of its safety and effectiveness. For BRVO the advantage is that patients can receive treatment immediately and do not have to wait for three months to see whether the macular oedema resolves without intervention. Since not all patients experience improvement in their vision it is important to treat as early as possible. This then also leaves the option of rescue laser treatment if necessary.

The dexamethasone implant (Ozurdex), licensed for RVO, may be contraindicated in some patients (e.g. those with a history or family history of glaucoma or raised eye pressure) highlighting the importance of an alternative licensed treatment.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them.

The main disadvantage to current standard practice is the need for more frequent visits to hospital eye clinics for monitoring and treatment purposes.

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

No comments. The patients we interviewed were part of the clinical trial.

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

This treatment is not yet being used widely on the NHS.

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

Deramo et al, 2003: Vision-related quality of life in people with central retinal vein occlusion using the 25-item National Eye Institute Visual Function Questionnaire. Arch Ophthalmol/Vol 121, September 2003.

This article shows the way retinal vein occlusion can impact on a person's quality of life. Although quality of life is most strongly associated with visual acuity in the better seeing eye the study also shows lower scores in a number of areas for patients without second eye involvement.

Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

Depending on the outcome of the NICE appraisal of dexamethasone intravitreal implants patients may be able to choose between two effective treatments leaving room for patients and their consultants to discuss the best treatment option. This should further improve the chances of patients avoiding unnecessary sight loss and associated risks of falling due to

decreased depth perception. Their long-term chances of avoiding bilateral blindness will also be increased.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

This would depend on the outcome of the appraisal of dexamethasone for the same condition. If neither were to be approved for use on the NHS this would lead to inequity in access to sight-saving treatment since only patients able to afford private treatment would benefit from the new treatment(s). Furthermore, it would increase the use of the unlicensed alternative bevacizumab which has not been trialled sufficiently in this indication, and whose safety is being questioned increasingly following the release of CATT trial data on the comparative effectiveness of ranibizumab and bevacizumab for use in age-related macular degeneration. From a patient perspective that would be an unsatisfactory outcome.

Are there groups of patients that have difficulties using the technology?

No

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

We would urge the Committee to consider the loss of utility due to monocular vision but would also like to emphasise the importance of treating monocular eye disease because of the considerable risk of patients developing eye disease in the second eye as they grow older. Apart from the devastating impact of sight loss on the individual, sight loss is also associated with considerable costs to the NHS, Social Services and Society. Robust research

commissioned by RNIB in 2009 suggests that this amounts to £2 billion in direct costs and £4 billion in indirect costs and although most of this is associated with bilateral vision loss allowing a patient to lose their sight in one eye significantly increases their risk of experiencing partial sight or blindness due to the same or other conditions in the long run.

We recognise that the utility of treating visual loss in a worse seeing eye has not been well characterised, but it is important to recognise that this lack of evidence is not evidence of a lack of effect. Further research into the utility of treating a worse seeing eye is needed. In the meantime, we urge the Appraisal Committee to take account of NICE's 2008 Citizens' Council report, which advocated consideration of factors other than just the ICER to avoid unethical decisions and mentioned the issue of second eye treatment as one example.