Professional organisation statement template

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: Philip Helliwell

Name of your organisation
British Society for Rheumatology

Are you (tick all that apply):

- Yes a specialist in the treatment of people with the condition for which NICE is considering this technology?
- Yes a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc.)?
- other? (please specify)

What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

Clinical guidelines for the use of anti-TNF drugs have been developed using exemplary methodology (Kyle et al. Rheumatology 2005;44(3)390-7) and, these are currently under revision (revision expected by the end of 2010). The guidelines clearly state that anti-TNF drugs should only be used for active arthritis where treatment with at least two 'conventional' DMARDs has failed either due to intolerance or inefficacy. The guidelines do allow for the treatment of oligoarticular (less than 5 joints) disease but as yet do not acknowledge cases of refractory enthesitis and dactylitis, and cases where spondylitis predominates (the latter deferring to the ankylosing spondylitis guideline committee).

As previously advised these drugs should only be used under specialist supervision in secondary care. There is some variation in the availability of these drugs throughout the UK with some areas having better provision than others, despite previous NICE guidance. The variation appears to be due to fiscal reasons rather than clinical variation in practice.

As previously advised the treatment of psoriatic arthritis should usually be multidisciplinary and with the involvement of two specialities (rheumatology and dermatology). Treatment of the joints and the skin should be inseparable in this condition. Patients all request a treatment that works equally for the joints and the skin. Fortunately this is often the case for anti-TNF drugs.

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

The licensed conditions and rules surrounding the use of golumimab are, as far as I am aware, identical to the conditions for using other anti-TNF drugs. There is a theoretical problem with the rule for continuing or stopping the drug as the arthritis specific global outcome measure of disease activity recommended is the PsARC – this is an non-validated tool developed for use in a trial of sulfasalazine. The problem in this context is (a) it has not received appropriate validation (b) it is likely only relevant to cases of polyarticular psoriatic arthritis (c) the placebo response rate using this measure can be as high as 40%. Nevertheless, it has been used satisfactorily in the UK for some years now.

The clinical trials of golumimab have mainly used cases of psoriatic arthritis with polyarticular disease. While this is the most frequent sub-group (65%) of psoriatic arthritis it does neglect the other sub-groups and makes extrapolation to these other groups problematic. Nor are some of the distinctive manifestations of the disorder (such as dactylitis and enthesitis) given sufficient emphasis to be sure that the technology is effective for them. On the other hand including cases of predominantly polyarticular disease is appropriate as this is the sub-group with the worst prognosis. The use of non-validated outcome assessments is also a feature of these studies, although further work by the GRAPPA group has shown many of these measures, which were developed for use in rheumatoid arthritis, can function in polyarticular psoriatic arthritis.

Of interest and of some slight concern are anecdotal reports of people developing psoriasis de novo when given anti-TNF drugs. This has been

described in patients with rheumatoid arthritis given antii-TNF drugs but also worsening of existing psoriasis can occur. This appears to be a class effect. Current strategies for screening for latent tuberculosis seem to be effective but they can add substantially to the indirect cost of the product.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

Not at the moment

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

As with the provision of other anti-TNF drugs, departments administering these treatments would need to have a specialist nurse practitioner in post, an appropriately staffed day case unit and the facilities of 'health care at home' (this varies by locality) would also be required for drug delivery and home care support. However, since these facilities are already in place additional resources would not be required.