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: Eleanor Korendowych

Name of your organisation : British Society for Rheumatology

Are you (tick all that apply):

- 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)? yes
- 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.)? No
- 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.

Patients with PsA are treated predominantly by Rheumatologists in secondary care as the majority require disease modifying drugs (DMARDs) to reduce inflammation and help prevent joint damage. There is a limited evidence base for the traditional DMARDs (methotrexate and sulphasalazine) but clinical practice suggests efficacy with both these agents. Methotrexate but not sulphasalazine also improves psoriasis. There is better evidence to support the use of leflunomide (Kaltwasser et al Arthritis Rheum 2004;50 (6):1939-50) which appears to be efficacious for both the skin and joints. More rarely azathioprine and ciclosporin can be used but these are limited by a relative lack of efficacy and toxicity.

There are no apparent clinical variations in practice across the UK and most clinicians will be confident in the use of the standard DMARDs. There are published guidelines for the treatment of PsA produced by GRAPPA (group for research and assessment of PsA and psoriasis) (Ritchlin et al Ann Rheum Dis 2009:68:1387-94).

Since the approval of etanercept, infliximab and adalimumab by NICE, treatment of PsA refractory to traditional DMARDs has been greatly improved. These agents all have excellent quality studies providing evidence of efficacy for both the joints and the skin as well as improvement in quality of life and radiological damage. There are published British guidelines for the use of anti-TNF therapy (Kyle et al Rheumatology 2005;44 (3): 390-397). At the time of publication only etanercept was licensed in the UK for PsA so this guideline is currently being updated (EK and PH are on the committee) and is expected to be completed at the end of 2010. There are also guidelines published by the British Association of Dermatology (BAD) (Smith et al BJD 2009; 161: 987-1019 which contain reference to the management of PsA and comprehensively review the evidence base. It is vital that the management of patients with PsA attends to both the joints and the skin ideally by joint working of rheumatologists and dermatologists and involvement of the multidisciplinary team.

There is some variation in availability and use of the anti-TNF agents throughout the country sometimes due to financial pressures and sometimes due to lack of local

expertise in the management and assessment of severe PsA. It is recommended that assessment for initiation and continuation of anti-TNF therapy in PsA should be performed in a centre with specialist expertise. The assessment requires training of specialist nurses but most centres will already have put this in place.

With regards to subgroups, most of the publications have focused on polyarticular disease and less is known about the response in patients with oligoarticular disease or where the clinical pattern is predominantly spondyloarthritis, enthesitis or dactylitis. Clinical experience would suggest efficacy in all these areas.

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?

Golimumab would appear to be comparable to the other licensed and NICE approved anti-TNF agents. It is administered as a monthly subcutaneous injection which will appeal to patients and will provide an alternative when the other agents have led to side effects or have proved ineffective.

Commencement should be governed by the same rules that apply to the other agents (ie failure of 2 DMARDS and the presence of 3 tender and 3 swollen joints). At the moment the PsARC (PsA response criteria) is used to assess efficacy at 3 months. Although there are some short-comings of this measure (highlighted in Dr Helliwell's report) it works well in clinical practice and is probably the best measure currently available. However there is a need for a better outcome measure which is currently in development. Currently patients with few joints involved are poorly served as the assessment tool is more suited to those with a polyarthritis. The impact on a person's life from having only a few joints involved can be high particularly if those joints have a significant impact on activites of daily living eg knees, hands.

The 24-week results of the golimumab in PsA trial (Kavanaugh et al Arthritis Rheum 2009; 60(4): 976-986 suggest comparable efficacy and side effect profile to the other 3 NICE-approved anti-TNF agents. Further longer-term data (104 weeks) was presented at the British Society for Rheumatology meeting in April 2010. The outcomes measured were appropriate: the primary outcome was the ACR20 which was also used as the primary outcome in the other anti-TNF trials (IMPACT2 also used the PsARC). There was also assessment of the nails and entheses which both responded to treatment. I have not yet had the opportunity to use golimumab in the clinical setting but would not foresee any problems extrapolating the evidence into clinical practice and feel the population utilised reflects the majority of cohorts with PsA (albeit somewhat biased towards a polyarthritis subgroup. The safety data seem comparable to the other agents and the longer-term data presented at the BSR revealed no additional concerns.

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)?

The resources needed to support this medication should already be in place (specialist clinics, specialist nurses / allied health professionals, national delivery and support service (healthcare at home or equivalent).