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: Chris Deighton

Name of your organisation NICE RA Management Guideline Development Group

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? √
- 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.)? √ Clinical Advisor to the NICE RA Management Guidelines
- 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.

The National Audit Office Report demonstrated that there is tremendous variation in the quality of care provided for people with RA in the NHS. NICE RA Clinical Management Guidelines were published in February 2009, and the NAO report illustrated the shortfall in high quality care in most parts of the country. Practices do differ between consultants and clinical teams, but the NICE RA Management Guidelines have been well-received and are regarded as providing an evidence-based set of recommendations for what constitutes optimal care. The current alternatives to golimumab include the other established anti-TNF therapies. There does not seem to be much to choose between the established anti-TNF drugs and golimumab from my reading of the published studies. An advantage is that golimumab is administered subcutaneously, which is preferred by most patients, and once every four weeks, which is less frequent than the other two established subcutaneous anti-TNF drugs (etanercept and adalimumab). The anti-TNF drugs are used in patients with very active disease that has failed to respond to other conventional disease modifying drugs (DMARDs). The search for biomarkers to identify patients who will not respond to conventional DMARDs and need to go onto biological therapy promptly remains a holy grail for rheumatology. The advantages and disadvantages of golimumab in different sub-groups of RA are similar to those of established anti-TNF drugs. These drugs should be given in specialist care units used to dealing with biological therapies, and their administration and monitoring undertaken by experienced nurses. The technology is not currently available on the NHS.

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 subcutaneous administration once every four weeks has advantages over other anti-TNFs. Similar to other anti-TNFs it is likely to be administered with methotrexate where it is not contra-indicated, in order to improve efficacy.

The British Society for Rheumatology (BSR) has published a Guideline on eligibility to go onto biological therapy, and to stay on the therapy thereafter (http://rheumatology.oxfordjournals.org/cgi/content/full/keq006a/DC1?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=deighton&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT). In summary, the most important element of these recommendations argues that the current eligibility criteria are pitched inappropriately high, and the paper provides evidence-based arguments for reducing the DAS28 from the current 5.1 to 3.2. The BSR argue that the new criteria should be applied to all appropriate first line biological therapies.

The published trials approximate to UK practice, though eligibility criteria are usually pitched at a lower level than those currently used in the NHS. However, the majority of people recruited would fulfil eligibility criteria to go onto anti-TNF in the NHS. The most important outcomes are decreasing disease activity, improving function, enabling the patient to stop other treatments such as analgesics, anti-inflammatories and steroids, improved quality of life, restoring or maintaining independence from relatives, friends and the state.

The Health Assessment Questionnaire (HAQ) is a measure of functional ability that is translated into utility scores and then QALYs, but this has limitations. In early disease the HAQ is determined mainly by inflammation, whereas in established disease it is more related to damage to joints which is much less amenable to being improved by drug intervention. The HAQ also does not measure important aspects of the quality of patients' lives, such as pain, fatigue, depression, and ability to work. The

rheumatology community needs to work on ways for improving current health economic models in collaboration with NICE, and the quality of the data that goes into these models, particularly on long-term morbidity and mortality outcomes of the disease.

Side effects for anti-TNFs are few in clinical practice, but these drugs still need to be used with caution. Increased risk of infection, and particularly latent granulomatous disease like TB, need to be monitored closely. The side effect profile of golimumab is unlikely to differ from other established anti-TNF therapies. Large observational databases around the world continue to be vigilant for emerging problems with long-term use of anti-TNF therapies, but to date no major signals have emerged on the greatest concerns. Chief amongst these is the possibility that anti-TNF might amplify the already increased risk of malignancy that patients with severe RA are already known to possess. With the exception of skin cancers which patients and their carers need to watch out for, there is no consistent evidence to date to suggest increased risks for other malignancies.

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.

I am not aware of any such information.

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)?

If NICE approved the use of golimumab, it would provide further choice for professionals and patients in prescribing anti-TNF therapy, but little extra training would be required, as existing expert nurses could provide similar advice and educational materials to those that are already used for other established subcutaneous anti-TNFs.