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: [redacted]

Name of your organisation

Royal College of Nursing (Rheumatology Forum)

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)?
- 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.*

There are several STA currently under review for the treatment of Rheumatoid Arthritis (RA) and previous guidelines that support care for RA.

These include:

1. The NICE RA management guidelines (2009)
2. Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor (part review of NICE technology appraisal guidance 36, review of NICE technology appraisal guidance 126 and 141)
3. BSR Guidance on treatment with anti-TNFa therapies (2009)
4. Kennedy T., McCabe C., Struthers G., Sinclair H., Chakravaty K., Bax D., Shipley M., Abernethy R., Palferman T. and Hull R. (2005) BSR guidelines on standards of care for persons with rheumatoid arthritis. Rheumatology 2005; 44:553–556 doi:10.1093/rheumatology/keh554 Advance Access publication 3 February 2005. Guidelines
5. Chakravarty, H., McDonald, T., Pullar, A., Taggart, R,. Chalmers, Oliver S., Mooney J.. 7, Somerville M., Bosworth A., and Kennedy T. Guidelines BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatologists (2008) K. 10 on behalf of the British Society for Rheumatology, British Health Professionals in Rheumatology Standards, Guidelines and Audit Working Group in consultation with the British Association of Dermatologists
6. Certolizumab pegol for the treatment of rheumatoid arthritis. This guidance was developed using the NICE single technology appraisal process. NICE technology appraisal guidance 186 Issue date: February 2010
7. Rituximab for the treatment of rheumatoid arthritis. This guidance was developed using the NICE single technology appraisal (STA) process. Issue date: August 2007 Review date: July 2010

8. Schoels M et al (2010) Evidence for treating rheumatoid arthritis to target: results of a systematic literature search. Ann Rheum Dis: 69: 638-643

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 reviewer for this technology has not had any personal experience of using this therapy at the moment. The submission is purely based upon the evidence reviewed. The key factor will be how the therapy fits into the current treatment pathways or which specific patients will benefit from this therapy. Also key will be how this guidance fits alongside others being reviewed by NICE at present for patients with RA.

Golimumab appears to have best therapeutic benefit at 24 weeks and is administered by subcutaneous injection – which increases the patient's independence but at a reduced cost of resource and manpower to the NHS. It appears in evidence reviewed to date, to be optimal with methotrexate as frequently seen in other biologic therapies.

The side effect profiles in the documents reviewed appear to be similar to other biologic therapies particularly anti-TNFa therapies (although it is early days in the sense of research versus routine clinical practice).

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 aware of any others except to recommend reviewing the European League Against Rheumatism meeting from 2009 and the papers to be presented (June 2010) meeting and reviewing posters at American College of Rheumatology meeting 2009.

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 main concern is the time frame for measuring efficacy and how this will fit into routine clinical practice. The six month time frame is helpful in many respects with other reviews of biologics but may have an additional cost analysis burden.