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

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.)? **Member**
- 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.*

Current treatment includes 5 self injectables and 2 infusion treatments. There is some variation on prescriber preference and also a shared decision process for the self injectables. There are ABN guidelines for prescribing self injectables. The process is usually managed by the nurse specialist post prescription. The self injectables will remain an alternative treatment to the technology.

There are subgroups who are non responders to current treatments and also those who have aggressive highly active MS. Those with concomitant conditions such as cardiac disease, family history of skin cancer etc may be an at risk group. Also those who have significant cognitive issues may be at risk of poor compliance and the need for repeated screening when re-starting treatment.

Setting will require facility for base line pre screening but this could be in any clinical setting, on going surveillance will need to be monitored by clinical specialist. Education and clinical support should be provided to any generalist involved in the process.

Relevant current guidelines include NICE Guideline 8 and ABN guidelines on prescribing disease modifying therapies.

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 technology will still have the issues of concordance and side effect risk. Although ease of use (oral) is incomparable to self injection the subtle cognitive problems of the patient group will impact on concordance. There are implications for additional specialist screening including dermatology, respiratory and cardiac testing/screening. Discontinuation will be in those who have an adverse event or are non responders who continue to deteriorate or have very poor compliance which incurs repeated re-screening.

The evidence is promising and with extensive trials for this technology. The most important outcomes have been a significant reduction of acute episodes and slowing of accruing disability. The technology is also well tolerated.

The side effects have the potential to be significant and scrupulous screening will ensure the risk is minimised. The treatment has the potential to improve the quality of life for many patients as they will not have to self inject. Many will still need support and education to ensure robust concordance.

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.

No additional source to add except that this technology is also being trialled in those who have primary progressive MS; a group who traditionally have been without hope. This has to be a good step forward.

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 implication of the technology would be a new use of current resources, rather than additional resources, such as cardiac and respiratory equipment for screening. It would also require additional training of specialists, particularly specialist nurses who should remain responsible for managing surveillance and ongoing monitoring. NICE guidance will be crucial to ensuring shared understanding amongst patients, service users and specialist/generalist staff about the importance of side effect/adverse event risk.

NICE guidance will be crucial for the specialist who will be managing the process of post prescription care and support and for the GP who has limited knowledge or experience of managing MS treatment options.

There will be an increasingly complex range of treatment options to deliver a bespoke treatment plan for individual patients. This will give a bewildering range of

decisions to be made both by the clinician and the patient. NICE guidance will be essential to ensure a good and lasting decision is made.