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.)? **RCN 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.*

Cystic Fibrosis (CF) care is multidisciplinary and is treated within the national guidelines for caring for adults and children with CF. We are aware that there is significant geographic variation. Postcode prescribing has been a problem historically, especially with high cost of medications on the market.

There is minimal variation of healthcare professionals' opinion in the UK as to what the current practice should be.

Other comparators could also include an oral mucolytic known as acetylcysteine. Mannitol provides an alternative to current treatment options and we recognise that patients respond differently to different interventions.

We are not aware of specific sub groups who have different prognosis from a typical patient. We, however, know that there will always be individual differences and with genetic variation, some patients with a different classification genetically may fair worse or better than others. Non–adherent populations are thought to deteriorate faster.

The technology should be directed by the specialist teams who work in conjunction with primary and secondary services. Patient information and training by the specialist teams on the use of this technology would be helpful. Education and training on the new product should be given to other professionals.

The National CF trust Guidelines and Standards of Care (2001) provide useful resource and good source of information for healthcare professionals caring for people with this condition.

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?

This appears to be a simple technology, which the majority of people should be able to use. If the cost of the therapy is within reason, there would be no reason for it not to be used in preference to the current nebulised option (rhDNase). It may also be more palatable to take than hypertonic saline, as the taste at the back of the throat seems more acceptable (this is a common complaint from those patients taking hypertonic saline).

Overall, patient acceptability and tolerance of the medication will dictate its use in practice. Different patients will choose different treatment options which improve or control their symptoms and improve QOL.

CF treatments will always run in a set order to achieve maximal efficacy, this again will depend on patient tolerance and adherence.

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?

We are not aware of any adverse effects. However, we are aware that some patients do not tolerate the medication and have bronchospasm. We note that it was only trialled in patients with a specific lung function measure/value and we are not aware of the benefit for those who were above the range studied.

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.

From the studies done, it would appear that mannitol is safe to take and well tolerated with minimal adverse events (Chest, 2008; Respirology, 2005).

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)?

We are not aware of any specific extra resources required to facilitate the implementation of this technology. We consider that specialist staff would be able to train patients and carers to use this technology.

As with all new medication patients would need to be reviewed on a regular basis. The NICE health technology guidance should clarify all of the above and support the use of the product in practice.