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: Dr Lynn Hirschowitz

Name of your organisation: Royal College of Pathologists

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.)?
- ✓ other? (please specify):

  Specialist gynaecological pathologist representing the Royal College of Pathologists.

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 no specific guidelines about treatment for this small and diverse group of patients with advanced disease. There seems to be wide variation in treatment and treatment options are limited by prior administration of chemo and/or radiotherapy. Implications with regard to implementation of this technology require scrutiny/comment by clinical oncologists and specialist nurses, particularly in relation to current practice, treatment options, risks and benefits of the proposed technology and prognosis.

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?

This is outwith my field of expertise and is best commented upon by specialist oncologists.

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

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)?

Best addressed by specialist oncologists.

Comments on final scope and matrix documents re: STA of topotecan for the treatment of recurrent and stage IVB carcinoma of the cervix

These are the same documents that were circulated before the first meeting of NICE related to this STA. With regard to the scoping document, the appraisal objective is clearly stated and the contents of the document are succinctly written and factually accurate.

As a specialist gynaecological pathologist I have had the experience of being a member of three different gynaecological oncology multidisciplinary teams over the past decade, and can confirm that there are no national guidelines or generally accepted management strategies for patients with recurrent or advanced/stage IVB cervical carcinoma, which, unfortunately, not infrequently affects young patients with young families. Treatment of recurrent or advanced disease is also affected by any previous chemo and/or radiotherapy such patients may have received. I support any intervention which is likely to lead to improved outcomes in this small group of patients, but specialist gynaecological oncologists are best placed to assess the efficacy, risks, benefits and cost effectiveness of implementing these treatment modalities.

With regard to the matrix document this provides a comprehensive list of all consultees and commentators to ensure that all potential issues related to equality will be addressed.

Dr Lynn Hirschowitz
Consultant Specialist Gynaecological Pathologist
December 17th 2008