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 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) Clinical virologist

What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS?
Available therapies include interferon, and nucelos(t)ide analogue reverse transcriptase inhibitors.
Is there significant geographical variation in current practice?
Not able to answer this from my own experience
Are there differences of opinion between professionals as to what current practice should be?
Management of chronic HBV infection is complex. The relative roles of IFN and NRTI-based therapies in managing an individual patient may not be clear.
What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?
This is well summarised in the Final Scope document
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?
Not aware of any evidence for this
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)?
Management of chronic HBV infection is complex. With an increasing number of alternative effective drugs, this complexity will only increase. I believe treatment decisions should be made in specialist clinics with appropriate experience – either based in hepatology or infectious diseases.
There will be an increasing need to monitor the efficacy of anti-HBV drugs by viral load measurement, which is a fairly routine assay available in most diagnostic virology laboratories. Likewise, there will also be an increasing need for resistance testing, which is currently provided by very few specialist laboratories.

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?
I am unable to answer this question. I am not aware of variations.

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.
AASLD guidelines – Hepatology 2007; 45: 507-539
This contains an extensive review of all relevant published data.

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?

I am aware of very little clinical experience of the use of telbivudine or entecavir in the management of chronic HBV infection in the UK. Thus, there is nothing to add other than data that have appeared in the literature.

As mentioned earlier, the development of these new forms of therapy should stimulate the need for easily available viral resistance testing services.

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.

None to report

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)?

Allowance should be made for the increased costs of viral load monitoring and drug resistance testing as more patients with chronic HBV ifneciton are treated with nucleos(t)ide analogues.