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:
Diane Parry

Name of your organisation

Welsh Assembly Government

Are you (tick all that apply):

a specialist in the treatment of people with the condition for which NICE is considering this technology?
Chest Physician and Lung Cancer lead, University Health Board, Cardiff

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.)?

Lead Clinician South East Wales Network Lung Cancer Advisory committee

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.

Non small cell lung cancer is the commonest form of lung cancer in the UK accounting for approx 80% of new cases diagnosed. Unfortunately patients in the UK tend to present with advanced disease and are not suitable for treatment with radical intent. Patients presenting with stage 3 and 4 and of good performance status (WHO score 0,1) are suitable for first line chemotherapy with a combination of cisplatin and a one other drug - usually gemcitabine, vinorelbine, docetaxel or paclitaxel . Where the histology is adenocarcinoma pemetrexed is recommended in combination with a platinum based drug. Thiis is in line with NICE guidance.

In patients who do not respond to first line treatment or who relapse, 2nd line treatment with docetaxel is usually offered.

Recently NICE have issued guidance that Pemetrexed can be used for patients with non squamous histology as maintenance treatment provided their disese has remained stable after first line treatment. If pemetrexed was used first line however, pemetrexed cannot be used as maintenance treatment.

In essence this means that most patients with adenocarcinoma will receive pemetrexed as first line treatment and are not eligible subsequently for treatment with maintenance therapy subsequently.

Erlotinib is recommended by NICE for use as second line treatment as an alternative to Docetaxel provided it's cost equals that of Docetaxel. It is not recommended as third line treatment.
The NICE guidelines are used as above but there are no guidelines for the use of Erlotinib as maintenance therapy in the UK.

Erlotinib is an oral drug that is generally well tolerated and may have a role as maintenance treatment in patients not suitable for pemetrexed maintenance . It has been shown in previous studies that Erlotinib is more effective in specific sub groups of patients - in particular, those exhibiting EGFR mutation, adenocarcinoma histology and females.
However the recent 3 Saturn study has shown improved outcomes for patients with advanced non small cell carcinoma whose disease is stable after 4 cycles of platinum based doublet chemotherapy treated with maintenance Erlotinib

maintenance therapy.

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 do not have the full results of the 3 saturn study to hand but am aware that it has shown an overall improvement in survival of 23% (12 months versus 11 months with placebo) and improved progression free survival. I do not have the data regarding quality of life that could be extremely relevant to this group of patients. In reality the numbers of patients suitable for this treatment will be relatively small – likely less than 1000 per year for England and Wales and so the treatment would not necessarily incur major implications for funding.

The advantages of this technology are the potential for survival for a group of patients with an appalling prognosis and for whom there is very little hope and it's relative ease of administration as an oral medication. It can be given in an out patient setting and requires less intensive staffing resources than intravenous regimens. It provides a treatment option for patients who have received pemetrexed platinum drug regimen treatment first line and who are stable after 4 cycles of treatment. In addition the 3 Saturn results have shown benefit irrespective of EGFR mutation status. It has relatively few haematological side effects with relatively less requirement for inpatient admission to deal with complications of treatment.

Disadvantages include side effects of rash and diarrhoea most commonly but previous experience has shown that these are generally well tolerated by patients.

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.

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)?

This treatment would need to be delivered within the auspices of a Multidisciplinary Lung Cancer service. Since all Lung cancer care is coordinated through these services it would become an integral part of the work of the team. Since this is an oral treatment it would not have major implications for the delivery of care and it is likely that treatment would be in an OP setting . I can see no reason why the technology could not be put in place within 3 months. There is the potential for the development of Nurse led clinics to support this technology in line with National Lung cancer Nursing aspirations. There may be the requirement for a degree of training if this service model was pursued but this would not pose a significant resource implication. However, these clinics would be parallel to Consultant clinics and would enhance capacity and team working in lung cancer services ultimately.