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: Alison Jane Birtle

Name of your organisation British Uro-Oncology Group

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)

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.

Transitional cell cancer of the urothelial tract is treated according to the stage of disease. For patients with early non muscle invasive bladder cancer, treatment is usually surgical with removal of the tumour and with instillation within the bladder of chemotherapy if the tumour is of high grade. Intravenous chemotherapy is not used in this patient group.

For patients with non metastatic muscle invasive bladder cancer, radical cystectomy or radiotherapy is considered. Intravenous chemotherapy with cisplatin based regimes is often used prior to definitive surgery and may be used subsequently. Vinflunine is not being considered in the group of non metastatic patients.

For patients with metastatic bladder cancer, there is general agreement that first-line platinum-based chemotherapy improves survival and symptoms.

There are guidelines at national level through the British Uro-Oncology Group and the European Association of Urology for all of the above indications.

The proposed technology of vinflunine is being considered in the second line setting of metastatic urothelial TCC that has progressed on platinum-based regimes. There is no consensus about the type of chemotherapy used in this setting. There are no randomised data comparing one agent against another. Some clinicians will use paclitaxel weekly in this setting based on phase II data. There are no established guidelines for this patient group.
This technology is not current being used in the UK outside of clinical trials. It would be given in specialist oncology clinics in secondary care, with site-specilaised oncologists experienced in the treatment of urothelial malignancies and of chemotherapy management.

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 evidence base for Vinflunine stems from the first randomised study of second-line chemotherapy for patients with metastatic urothelial cancer (Bellmunt et al JCO 2009:27). 370 patients were randomised to receive chemotherapy plus best supportive care (BSC) or BSC alone. Patients were not stratified for performance status which is a criticism of the study as fitter patients may have derived a greater survival advantage from chemotherapy. There was a statistically non significant median 2 month survival advantage in the vinflunine + BSC arm with a 12% reduction in the risk of death. Progression-free survival was also improved. The treatment was well tolerated with febrile neutropenia in 6%.

In a UK population, patients may be different to those in the pivotal trial. The trial did not stratify for performance status which is key. Many of these UK patients are unfit for any form of chemotherapy in the second line setting . Those that are considered for treatment are in general fitter and the survival advantage may be different in this group but the data for this group is not available by subgroup analysis. In the study 34% of patient in the BSC alone arm eventually received chemotherapy and this will have introduced bias into the results, ie BSC alone may have had better results than if none of the patients in this arm had received active treatment. There is clearly an unmet need for this patient group who are fit enough to receive treatment and have an expected survival of 6-9 months.

In the Bellmunt study, the patient population itself may have been of poorer prognosis than those potentially eligible in the UK, as 80% of patients had progressed within 6 months of prior chemotherapy., none of which was given in the neoadjuvant or adjuvant setting. This latter group of patients are different to those patients who receive first line chemotherapy for newly diagnosed metastatic disease. The Bellmunt study therefore reflects a population concentrating on the key issue of second-line chemotherapy for metastatic disease, wherein patients were metastatic at time of treatment with first-line chemotherapy.

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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)?

There would be no additional training required for experienced chemotherapy units and site-specialised oncologists, other than familiarity with the scheduling and side-effect profile. This is in accordance with the use of any new agent or agent in a novel setting.

Patients with metasatic bladder cancer progressing on first line chemotherapy occupy significant amount of resource in primary and secondary care, with frequent admissions for treatment of pain, anaemia, and urological complications. The cost of these admissions is significant and should be borne in mind when assessing the cost benefit of a new technology such as vinflunine which may improve quality of life and survival in an appropriately selected patient population