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], RCP registrar submitting on behalf of:

Name of your organisation: NCRI/RCP/RCR/ACP/JCCO

Comments coordinated by [redacted] and [redacted] our nominations for the clinical expert roles

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.)? ✓

  Professor Johnson and Dr Marcus are chairs of the NCRI Lymphoma Clinical Studies Group and the NCRI Low Grade Lymphoma Sub-Group, respectively.

- other? (please specify)

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

Follicular lymphoma, which has not been previously treated and has advanced beyond a single lymph node site, is treated with combination chemotherapy and Rituximab (the subject of NICE guidance TA110, September 2006). There is an almost universal pattern of eventual recurrence, and at recurrence the standard treatment is with further combination chemotherapy and Rituximab, followed by maintenance Rituximab (the subject of NICE guidance TA137, February 2008). This pattern of practice is widely accepted in the UK, with few variations.

A national randomised trial (PACIFICO, ISRCTN99217456) is currently in progress for older patients (over 65) to test the standard R-CVP (Rituximab, Cyclophosphamide, Vincristine, Prednisolone) chemotherapy against R-FC (Rituximab, Fludarabine, Cyclophosphamide). In this study all patients will receive maintenance Rituximab in first remission.

Rituximab is generally administered in specialist chemotherapy clinics within designated cancer units. Some units have used private sector domiciliary chemotherapy providers to deliver the treatment in patients' homes. Services are already in place for delivering Rituximab maintenance in second remission as per TA137.

The advantages and disadvantages of the technology

Maintenance Rituximab is already widely used and well tolerated by patients with follicular lymphoma in second remission. It is given by intravenous infusion once every 8 or 12 weeks, for a maximum duration of 2 years. The principal toxicity in this setting is a slightly increased rate of viral infection. The most common manifestation is with viral chest infections, but there are also reports of reactivation of Herpes zoster, and rare cases of progressive multifocal leukoencephalopathy related to Jakob-Creutzfeld agents.

There is emerging evidence of the efficacy of Rituximab for the maintenance of first remission, from a large international randomised trial (PRIMA, NCT00140582), which involved centres in the UK. This trial included 1202 patients from 25 countries and reflected current UK practice closely, although Doxorubicin was included in the chemotherapy in a higher proportion of cases than is the generally done in the UK. There was a significant improvement in progression-free survival in the group given RItuximab maintenance (82 vs 66% at 2 years, Hazard Ratio=0.50, 95% Confidence Interval 0.39 to 0.64), an effect which was retained irrespective of the baseline prognostic characteristics of the patients, their initial chemotherapy or the degree of response to it, in planned sub-group analyses. Follow up was too short to demonstrate any difference in overall survival, an analysis which in any case is likely to be confounded by the high response rate to subsequent treatments in this type of lymphoma.

If the results of the PRIMA study are accepted then the use of Rituximab maintenance will move from second to first remission. This is likely to increase the numbers of patients receiving it, since there is attrition between first and second remission, but it may result in less use of second line chemotherapy if a higher proportion of patients remain in first remission.

Any additional sources of evidence

The critical data is that which was presented as an oral paper at the American Society of Clinical Oncology in June 2010 by Dr Gilles Salles.

Implementation issues

If the use of maintennce Rituximab in first remission for follicular lymphoma is approved, it is likely to be widely applied, but its use in second remission as previously approved will decline. There will therefore be some increase in the administration of maintenance Rituximab, requiring additional staff and facilities to cope with the workload.