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 General Practitioners

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)

I am a general practitioner who treats patients with the condition for which NICE is considering the technology. I am an expert in the clinical evidence base for the treatment of the condition for which the technology is being considered.

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?

There is a well established alternative technology, allopurinol. Although well established there are few data on its effectiveness on reducing the incidence of recurrent gout. I am not aware of any regional, or professional variation in its use, it is easily available at low cost. There are well recognised, potentially serious, adverse events associated with use of allopurinol; these are probably rare. There is some evidence that it is not used to its greatest effect in the management of gout in that many patients are not taking an adequate dose of this.

Other alternative drugs, currently available, for prevention of recurrent gout are sulfinpyrazone, colchicine, or oral NSAIDS. All of these have a less satisfactory adverse event profile and there are few empirical data to support their use.

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?

Some patients are unable to tolerate allopurinol, and for some patients there are concerns about its use because of poor renal function, or who have had and treatment related adverse event. These patients may benefit from availability from an alternative drug being available. It may also be particularly appropriate for those with tophaceous gout

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)?

Primary care, no additional professional input needed over current technology

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 guidelines on both the diagnosis and treatment of gout from EULAR. AN appropriate evidence based methodology has been used to develop these. However the evidence base underpinning the treatment recommendations is weak. These do not cover the new technology. There are also Quality of care indicators that have been developed in a robust manner, although again the evidence base is weak and they do not specifically apply to the new technology

Zhang, et al. EULAR evidence based recommendations for gout. Part I: Diagnosis. Report of a task force of the Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). Ann.Rheum.Dis. 65 (10):1301-1311, 2006.

Zhang et at EULAR Evidence based recommendations for gout - part ii management: report of a task force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). Ann.Rheum.Dis. doi:10.1136/ard.2006.055269, 2006

Mikuls et al Quality of care indicators for gout management. Arthritis Rheum. 50 (3):937-943, 2004

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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?

The evidence so far indicates that Febuxostat is superior to a standard dose of 300mg of allopurinol at reducing serum urate. I am not aware of evidence comparing it with a dose of allopurinol of up to 900mg per day, or indeed on the effect of titrating the dose of febuxostat.

Although superior to allopurinol in reducing the studies I am aware of do not show that febuxostat of recurrent gout over the first year of use. A benefit was only found in a post hoc analysis of the final 4 weeks of follow-up in the relevant trial. In the early follow up period participants in the febuxostat had more attacks of recurrent gout than those in the allopurinol group. This may be because co-prescribing of NSAID to prevent gout flares was not continued for long enough. If febuxostat is introduced there will be a need for co-prescribing of NSAIDs or colchicine for the first few months of treatment. If NSAIDS are used there may be a need for further co-prescribing of acid suppressant drugs to prevent NSAID related adverse effects. This is similar to how allopurinol is currently used.

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.

Since the evidence so far does not demonstrate febuxostat to be superior to allopurinol at reducing recurrent gout, indeed the evidence can be interpreted to suggest that it is inferior to allopurinol in this respect over the short term it use shodl probably be restricted to those who have failed to get an adequate reduction in serum urate (to < 0.36mmol/l) on a full dose of allopurinol or whom are unable to tolerate allopurinol

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?

The population in which febuxostat has been tested is likely to be different from that seen in UK primary care, the location where its use will be greatest. In particular few patients managed in UK primary care have tophaceous gout so benefits in reducing size of tophi may not be directly applicable to UK primary care. However, there are no reasons to believe that that the results relating to urate lowering and recurrent gout could not be applied to a UK population. The use of urate as a surrogate outcome is accepted in studies of urate lowering drugs, I am aware of extensive discussions in the American FDA on this subject which are available from their website. However in this case there is at least one study with gout as an outcome. My view it is these that should in the first instance it is these data that should be used to informed this assessment. Although the data on its effect on serum urate can be considered as useful secondary data

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 not aware of any substantial data on adverse effects. My only observation here is that although this was not statistically significant that in the published trial with recurrent gout as an endpoint that four participants in the febuxostat groups died compared to none in the allopurinol group.

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.

I am not aware of any such data

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)?

Implementation of this technology will be straightforward. No new skills or resources will be needed to prescribe and monitor febuxostat use