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: *British Society of Gastroenterology*

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.

There are currently no national guidelines for the management of constipation. As such treating chronic constipation, and the symptoms associated with it, is empirical and varies between institutions and even between individuals in the same institution. The quality of clinical trials for the vast majority of laxatives is poor, explaining the problems itemised above. Treatment centres around use of laxatives, anti-spasmodics, fibre supplements and complementary options (especially probiotics).

It is possible that the drug will be used for some particular groups with refractory symptoms, such as those with neurogenic bowel dysfunction or the elderly. The pharmacokinetics and trial evidence suggest that these groups should nnot be at greater risk.

The drug will initially be primarily used after recommendation by secondary or tertiary care specialists. Long-term prescription will obviously require primary care involvement.

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 mechanism of action of this drug means it represents a new class of compound, that is an alternative to the existing laxative options. It remains to be seen how many patients are able to use it as an alternative to laxatives as opposed to being in addition to these agents. It is to be stressed that dietary and lifestyle modifications, followed by laxatives should be used before prucalopride is considered.

With regard to testing, although the drug does work primarily on transit, I do not believe additional formal assessment of whole gut transit is required prior to prescription of the drug in these refractory patients.

The three published trials undertaken for regulatory approval were of identical design, and enrolled patients at the severe end of the spectrum. They had mostly (>80%) been exposed to laxatives, and were uniformly unhappy with their response to laxatives. About half the enrolled patients had a bowel action only once in two weeks prior to treatment. As such, the modest-appearing proportion (25%) who met the primary end-point is less modest when it is recognised that the end-point was normalisation (≥ 3 bowel actions per week) of bowel frequency. Improvements in quality of life are more reflective of the factors that patients hold as important in managing this chronic problem.

There is a major incidence of adverse events with prucalopride. Seemingly these are most marked in the first day of treatment, but it does seem clear from each of the studies that headache is a significant problem. Diarrhoea is also more frequent, but is often an "adverse effect" that patients don't mind; headache however could have a significant negative impact on quality of life.

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.

Nil I can think of that is relevant.

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)?

I don't believe any additional training of prescribers is required: adherence to the licence should be sufficient. If the drug stops use of prescribed laxatives in >25% of patients (as suggested by the clinical trials) this could result in substantial savings. With almost £50 million spent per year on prescribed laxatives, this could *represent a significant cost reduction, depending on the price tariff of the drug.*