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: [redacted]

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.

Chronic constipation (CC), otherwise known as functional constipation, is one of the functional gastrointestinal disorders and is extremely common. Many sufferers do not consult making it hard to estimate the prevalence, although it probably lies somewhere between 10-20% of the population with women being affected more than men (ref). It is defined as the presence of two or more of the following on a reasonably regular basis: infrequent bowel movements (<3/week), hard stools, straining, a feeling of incomplete evacuation, a sensation of anorectal blockage and the need for manually aided evacuation (ref). CC is a heterogenous condition in which the underlying pathophysiological mechanisms are not entirely clear although, from a management point of view, it is useful to think of it under two broad headings. Firstly, as some form of abnormal motility affecting transit and secondly, as a problem with the process of defaecation which is sometimes referred to as dyssynergia (ref). The latter often appears to have a 'learned' component and, therefore, may be amenable to behavourial therapy, such as biofeedback, whereas it seems logical to assume that motility problems are much more likely to respond to pharmacological interventions. It goes without saying that constipation due to structural causes or medication should not be included under the CC umbrella.

In many sufferers CC is a mild condition requiring very little in the way of medical assistance. However, in a substantial minority the condition is much more severe and because CC is so common, even a small percentage of the totality represents a large number of individuals. In these people severity is grossly underestimated and in secondary care for instance, patients can go

for one, two or even three weeks without opening their bowels and in such cases the problem is often accompanied by severe bloating and the passage of foul smelling wind. Patients often complain of headaches and extreme lethargy, frequently commenting that they feel they are being poisoned by their accumulated faeces. Quality of life can become progressively eroded to the extent that it has been shown that both the physical and psychological components of quality of life can be as bad as that of patients with rheumatoid arthritis, diabetes or inflammatory bowel disease (ref). Not surprisingly functioning at work or socially is impaired and relationships are also often adversely affected.

It is a sad fact of life that in Europe there have been no new medications for the functional gastrointestinal disorders for over 25 years and CC is no exception. Thus management currently has to depend on the use of laxatives in conjunction with advice on lifestyle and diet. It is important for patients to recognise that breakfast stimulates the gastrocolonic reflex and, therefore, should not be missed in patients with CC. Similarly, it is important not to defer defaecation which is something that women tend to do as well as missing breakfast. Exercise and adequate fluid intake make sense from a general health point of view although there is not enough data on its effect on constipation to advocate these specifically for CC. It is traditional to advise patients to increase their intake of fibre but the results from most clinical trials do not offer a great deal of support for this advice and certainly if it does not appear effective it is worth suggesting a decrease in fibre especially of the insoluble variety (ref). A good therapeutic principle for any functional gastrointestinal disorder is to try various options but not persist if they do not appear to lead to any improvement after a reasonable period of time. This rule also applies to the use of laxatives and it is perfectly reasonable to try preparations such as senna, bisacodyl or polyethylene glycol in order to judge which one suits a particular patient. They can also be reassured that these preparations do not damage the bowel in any way and it is far more preferable to take a low dose on a regular basis rather than intermittently inducing a catharsis. Another important point is that, at least in the more severe cases, the medication has to be used regularly on a long term basis and the hope that the bowel habit will somehow become restored to normal is not realistic. Just like in a patient with hypertension, if the medication is discontinued, the blood pressure usually goes up again.

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?

See above

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.

See above

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)?

Unfortunately, laxatives are not effective in everyone or the results of their use are so unpredictable or violent that their continuing consumption is incompatible with leading a normal life. It is in this latter group, where laxatives have failed, that I would anticipate trying prucalopride as these individuals are desperate for some help and we badly need something extra to offer them.