Professional organisation statement

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Primary Care Trusts (PCTs) provide a unique perspective on the technology, which is not typically available from the published literature. NICE believes it is important to involve NHS organisations that are responsible for commissioning and delivering care in the NHS in the process of making decisions about how technologies should be used in the NHS.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Short, focused answers, giving a PCT perspective on the issues you think the committee needs to consider, is what we need.

About you

Your name: Richard Lee

Name of your organisation (if applicable):

Please indicate your position in the organisation:

East Lancashire Health Economy New Drugs Pharmacist, providing advice and evaluating evidence to help assess the place of new drugs, and whether they should be commissioned by primary and secondary care before NICE guidance is available.

- commissioning services for the PCT specific to the condition for which NICE is considering this technology?
- a specialist in the clinical evidence base that is to support the technology (e.g. participation in clinical trials for the technology)?
- 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 in 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?

We have approved the use of varenicline locally in the following circumstances;

- ***Varenicline should only be prescribed on the direct advice of a smoking cessation adviser.***
- **Patients presenting to their GP requesting varenicline should be referred to a smoking cessation adviser to help the patient choose the most appropriate smoking cessation product. This may not be varenicline.**

- **Varenicline should be used where the use of nicotine replacement therapy (NRT) is not tolerated, ineffective or inappropriate. Varenicline has not been compared with NRT, although it has been shown to be superior to bupropion (Zyban®).**
- **Smoking cessation, with or without pharmacotherapy, has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly.**
- **There is no clinical experience with varenicline in patients with epilepsy. Patients should be advised of this, and explicit consent should be obtained if they wish to receive varenicline.**
- **Varenicline should only be used within its licensed indications, and prescribed for smokers who commit to a target stop date and who smoke >10 cigarettes (or equivalent) per day.**
- **The smoker should be offered regular follow up and advice to aid smoking cessation at at least 2 weekly intervals through the smoking cessation service.**
- **An initial supply should be for 2 weeks using the 'starter pack'. This can then be followed up by a second 2 week supply at the full dose. A third and fourth prescription of 4 weeks supply should be issued only if the smoker demonstrates a continuing attempt to stop smoking. The GP will be contacted at these points to confirm that these further prescriptions should be issued and that the patient is still being followed up by the smoking cessation service.**
- **Patients should only be treated for an initial 12 week course of varenicline until further NICE guidance on the cost-effectiveness of an additional 12 weeks treatment is available. In addition, there are no current criteria to select which patients should receive an additional 12 weeks therapy.**
- **At the end of therapy patients should be advised to taper the dose rather than abruptly stop therapy, as there is some evidence of an increase in smoking rates and withdrawal symptoms following abrupt withdrawal.**
- **For example, instead of the last week of 1mg twice daily dosing, this could be decreased to 1mg in the morning for two weeks, then stop. [This regime is not based on trial data, but on pharmacokinetics & ease of use]**
- **The concomitant use of varenicline and NRT/bupropion is not recommended.**

To what extent and in which population(s) is the technology being used in your local health economy?

- is there variation in how it is being used in your local health economy?
- is it always used within its licensed indications? If not, under what circumstances does this occur?
- what is the impact of the current use of the technology on resources?
- what is the outcome of any evaluations or audits of the use of the technology?
- what is your opinion on the appropriate use of the technology?

Potential impact on the NHS if NICE recommends the technology

What impact would the guidance have on the delivery of care for patients with this condition?

Currently most localities have some way of delivering the Nice appraisal on bupropion. Locally we have used this mechanism to deliver varenicline – ie through the smoking cessation team who counsel all the patients who are suitable for this. It has taken the place of bupropion locally and we are using it as a our second line treatment where patients have previously tried NRT, but have failed for whatever reason. However, it is the support that is required to help smokers give up that is

logisitically difficult to deliver. We haven't gone down the route of issuing this on PGDs yet, as it is a new drug, but consider this a possibility in the future. In addition, independent nurse prescribers are in a good position now to prescribe this, although it would be helpful for NICE guidance to specifically mention the ability of all independent prescribers being able to issue prescriptions for this drug.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional resources (for example, staff, support services, facilities or equipment)?

Hasn't required significantly increased resources locally as it is taking the place of bupropion, but over time clinic times for seeing patients on either varenicline or bupropion will have to increase. If it is allowed as a first line treatment either on par with NRT or prior to NRT, then this will have a significant impact on the service. We would have to allow GPs to prescribe to patients without access to the smoking cessation service.

Need to know from NICE whether patients HAVE to have smoking cessation counselling during the course of treatment, or whether counselling at the beginning, and then opportunistically throughout the course will be acceptable.

Can you estimate the likely budget impact? If this is not possible, please comment on what factors should be considered (for example, costs, and epidemiological and clinical assumptions).

Would implementing this technology have resource implications for other services (for example, the trade-off between using funds to buy more diabetes nurses versus more insulin pumps, or the loss of funds to other programmes)?

Depends on how the varenicline is issued. If it is prescribed by GPs to patients, then this will come out of the GPs overall prescribing budget, and over a population would have less of an impact. If however smoking cessation teams issue varenicline on PGDs, or community pharmacist do this, then a separate budget within the PCT will have to be set up to purchase the varenicline. This is sometime seen as a barrier to issuing on PGD, it is sometimes easier to issue through GPs prescribing budgets.

Would there be any need for education and training of NHS staff?

We have provided a couple of hours training on varenicline to smoking cessation advisers to allow them to advise clients about this. This seems to be sufficient.

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology

Should patients with epilepsy be offered varenicline? This needs to be explicit. We currently ask them to sign a consent form declaring there is no experience of use in epileptic patients, but that the patient feels the benefits from stopping smoking is outweighed by this risk.
How should people who have conditions not specifically included in the phase III trials be treated – should we stick purely to the licence and offer them varenicline. Or

should we be more cautious?
Should community pharmacists and other issue this new drug on PGD? It is a black triangle drug, and unless NICE specifically advises the NHS to allow it to be issued on PGD most organizations will not allow this initially. This also applies to independent prescribers, although they can technically prescribe, should they? Are they to be encouraged to do so?
Will the manufacturer be asked to consider applying for a OTC licence so it can be bought from a pharmacy without a prescription.
If an additional 12 week course is to be offered, strict criteria to select patients should be made available to the NHS to select patients. We currently don't offer an additional 12 weeks due to the paucity of evidence.
Should NRT be offered as the first line product of choice, or should varenicline be offered as the first line product of choice. Aware that trial data looking at NRT and varenicline is due and this should be considered to guide this choice. Moving to varenicline first line is a large step, but if the evidence supports it, it should be welcomed. Many PCTs have not approved varenicline locally as there is no comparison against NRT.
How should patients who suffer N&V be managed? Should they be offered an anti-emetic first (this would prevent use on PGD as they would also need an anti-emetic on PGD), or should they be moved to the lower dose? How long should you wait before reducing the dose, and should they remain on the low dose for the remainder of the treatment?
When should patients be offered retreatment with varenicline? With 1 month? Within 6 months?