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Subject: NICE and pegylated interferon

Here is the final version of the press release announcing a consultation on NICE's work programme from April 2003 onwards. Pegylated interferons for treatment of hepatitis C is one of the treatments proposed for appraisal by NICE.



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NEW NICE WORK PROGRAMME GOES OUT FOR CONSULTATION

New drugs for breast cancer, pain relief for Multiple Sclerosis & Alzheimer's disease and treatments for hepatitis c patients are being considered for referral to the National Institute for Clinical Excellence (NICE). The treatments are part of a proposed seventh wave of topics which may be looked at by NICE following a consultation which starts today and lasts for one month.

NICE was set up in 1999 to help tackle the postcode lottery of prescribing - where treatments are available in some areas and not others. It is also speeding up the uptake of clinically and cost effective new treatments by issuing clear, evidence-based guidance to the NHS on the use of drugs and treatments. From December 2001 Health Authorities and Primary Care Trusts have had to provide appropriate funding for NICE recommended treatment.

Stakeholders who will consult on the new work programme include representatives from the pharmaceutical industry, and patient and professional groups including the Royal Colleges, Macmillan Cancer Relief, Age Concern, the British Heart Foundation, the Multiple Sclerosis Society and the Stroke Association.

The drugs and treatments that are recommended to be referred to NICE for appraisal will be part of the new work programme that will start from April 2003. NICE will then issue guidance to the NHS putting forward their recommendations for each individual drug or treatment.

Health Minister Lord Philip Hunt said:

"This latest suggested work programme shows our commitment to tackling postcode prescribing and raising the quality of care for patients. It contains the first assessment of medicines for pain relief in Multiple Sclerosis which use cannabis derivatives. Medical Research Council (MRC) funded trials supported by the Department of Health and the Royal Pharmaceutical Society have been set up to assess the use of cannabinoids in multiple sclerosis and post-operative pain. Results are expected at the end of 2002 and NICE will use these results in its appraisal of these drugs."

"If these pharmaceuticals are licensed for medical use, it is of critical importance that NICE guidance is in place for the clinicians who will have to make decisions about their use."

"NICE is not just assessing new technologies, but also providing guidance on those currently in use in the service. Appraisal of hormonal treatments for breast cancer and SPECT for cardiac imaging could provide the NHS with evidence based guidance on how both the existing and new technologies should be used."

"This is the continuation of the already far reaching work programme which NICE has undertaken, which has provided real benefits for patients with a range of diseases including cancer, heart disease, diabetes and Alzheimer's disease. We estimate that NICE's work on drugs to treat breast and ovarian cancer is already benefiting around 9000 women at a cost to the NHS of £30 million. The Institute's guidance on drugs for diabetes should benefit over 72,000 patients a year at a cost to the NHS of £14.5 million. NICE's guidance on anti-dementia drugs will help to tilt the balance of specialist services towards earlier diagnosis, benefiting around 15,000 people this year at a cost to the NHS of £12 million."

The treatments to be looked at as part of the consultation are:

- Hormonal treatments for early breast cancer
- Cannabinoids for Multiple Sclerosis
- New pharmaceutical treatments for Alzheimer's disease and for non-Alzheimer's dementia
- Pegylated interferons for hepatitis c
- Single photon-electron computed tomography (SPECT), -an imaging technique for the diagnosis of heart disease
- Drug eluting stents which may reduce restenosis (arterial blockage) following angioplasty
- Clopidogrel and dipyridole for secondary prevention of atherosclerotic events (narrowing of the artery walls due to a build up of fatty deposits)
- Newer hypnotic drugs for the treatment of insomnia
- Nutritional supplement feeding vs modified oral feeding in adult patients with advanced diseases
- Percutaneous endoscopic gastrostomy (PEG) feeding
- New treatments for venous leg ulcers and for diabetic foot ulcers
- Prehospital intravenous fluid therapy in trauma

Notes For Editors.

1. Further details of the proposed work programme:

Cancer

Hormonal treatments for early breast cancer

Breast cancer is a major source of morbidity and mortality, with 35,000 new cases and 13,000 deaths each year in England and Wales. Hormonal treatments for early breast cancer can be used as an enhancement therapy to surgery, radiotherapy or treatment with cytotoxic drugs to delay recurrence of the disease. Hormonal treatments are generally well tolerated and may be preferable if clinically appropriate, because the side effects are much milder than those of cytotoxic therapy. A NICE appraisal would give authoritative advice on clinical and cost effectiveness, complement the recent series of appraisals on cytotoxic drugs and address any existing inequality of access to these treatments.

Neurology and other long-term conditions

Cannabinoids for MS

Cannabis derivatives are currently undergoing clinical trials for the treatment of various conditions including management of pain relief in Multiple Sclerosis. A decision whether one or more of these products will be licensed for official medical use is likely in 2004/5. If the drugs do receive a licence the NHS will require timely and clear guidance on the clinical and cost effectiveness of these treatments.

Older people

Nutritional supplement feeding vs modified oral feeding in adult patients with advanced diseases.

Nutritional feeds are used for a range of patients in both the community and in hospital. Nutritional feeds may be used as a supplement to conventional food, to increase calorie intake or to provide particular nutrients of patients who are still capable of feeding themselves and for some patients commercial feeds, administered either by tube to the stomach or by intravenous drip are the sole source of nutrition. There has been a significant increase in the use of nutritional supplement feeding in recent years and some evidence of both inappropriate use and of underuse. NICE guidance could establish a firm basis for its cost-effective use in both primary and secondary care, by advising on its role in patients who are still capable of deriving at least some of their nutritional requirements by conventional feeding.

PEG feeding

About 45% of patients with stroke suffer from dysphagia (inability to swallow). Conventionally, such patients are fed by a nasogastric tube (a tube passing down the nose to the stomach). Percutaneous Endoscopic Gastrostomy (PEG) feeding is an alternative approach involving feeding through a tube which goes through the abdominal wall directly into the stomach. PEG feeding is less irritating and may be more cosmetically acceptable to patients than nasogastric feeding and there is some limited evidence that it results in better nutritional intake and weight maintenance. There is evidence of inequity of provision and uncertainty over appropriate indications. NICE guidance would address these issues.

New pharmaceutical treatments for Alzheimer's disease

Alzheimer's disease (AD) is the most common form of dementia in the UK, affecting about 340,000 patients. Of these around 150,000 have the most severe form of AD. New pharmaceuticals are in development for moderate to severe AD and there is some evidence that they may show clinical effectiveness comparable to that of the cholinesterase inhibitors for mild to moderate AD. This is a frequent condition, severely limiting the quality of life for sufferers and imposing a heavy burden on carers. Guidance from NICE would help to ensure equitable uptake if the evidence shows that treatment is clinically and cost effective.

New drugs for non-Alzheimer's dementia

Apart from Alzheimer's disease the other two most common forms of dementia are Lewy body dementia and vascular dementia. They are estimated to account for 25% and 20% respectively of the total UK prevalence of dementia, i.e. about 120,000 and 90,000 respectively. A number of pharmaceutical treatments are currently in trial for possible use in both vascular dementia and Lewy body dementia. Guidance from NICE would help to ensure equitable uptake if the evidence shows that the treatments are clinically and cost effective.

New treatments for venous leg ulcers

Venous leg ulcers are a major cause of morbidity in older people with an estimated prevalence of 47-125,000. A number of new treatments have been developed to help promote healing in both of venous leg ulcers and diabetic foot ulcers. A variety of methods are in use, but healing rates at one year after treatment, vary from 25% to 70%. A number of new treatments have been developed and NICE guidance would help to promote consistent and cost-effective uptake of these treatments.

Infectious diseases

Pegylated interferons for hepatitis C

Hepatitis C is a common blood borne virus that causes acute hepatitis in about 20% of those infected and chronic hepatitis in about 85%. It is estimated that between 200,000 and 400,000 people in England and Wales are infected. The current treatment of choice is combination therapy with ribavarin and interferon alpha, or interferon alpha monotherapy for a minority of patients who cannot tolerate ribavarin. "Pegylation" is a chemical technique which reduces the rate at which the body clears interferon alpha and increases its effectiveness. Pegylated interferons can therefore be given once a week via injections rather than 3 times a week for the conventional version. Two products using this technique have been developed, Viraferon and Pegasys, and there is evidence suggesting that both products may be of superior efficacy to conventional interferon alpha. Guidance from NICE would ensure consistent uptake across the NHS if the new treatments are shown to be clinically and cost effective.

CHD

Coronary imaging

SPECT (Single Photo-electron Computed Tomography) is used to test for the position of any defects in the blood supply to parts of the heart. SPECT machines are available in the NHS, but not many have the necessary software installed to allow cardiac imaging, despite growing evidence over clinical and costs effectiveness. NICE guidance could add value by giving an authoritative assessment of the role of SPECT and by providing the basis for future investment decisions.

Drug eluting stents

30,000 patients a year in the UK undergo PCTA (percutaneous transluminal coronary angioplasty) a procedure to improve flow through the arteries, of which 80% involve fitting a stent (a mechanical device intended to keep the artery open). Despite the use of stents, about 10-15% of patients suffer from restenosis where tissue re-growth blocks the artery. Restenosis, when it occurs, is difficult to treat and tends to recur in 50-65% of cases. Drug eluting stents are stents coated with a pharmaceutical, which is gradually released and designed to prevent or retard restenosis. Early advice from NICE would promote consistent uptake across the NHS if the evidence shows that this technology is clinically and cost effective.

Clopidogrel and dipyridamole for prevention of atherosclerotic events

1.5 million people in England and Wales are suffering from vascular disease and should be receiving some form of anti-platelet therapy. Clopidogrel and dipyridamole are new antiplatelet agents, the former licensed for secondary prevention of myocardial infarction, stroke and vascular death, and the latter for prevention of stroke. Recent clinical trials suggest that these agents may have a clinical benefit when compared to the traditional treatment, aspirin. NICE appraisal would give guidance on whether their use can be recommended as clinically and cost effective.

Mental health

Newer hypnotic drugs

Insomnia is a very common condition in the UK and there were over 10 million GP prescriptions for hypnotic drugs in 1999 (England). All prescribed hypnotic drugs are effective in inducing and maintaining sleep, but there are major concerns over the risk of dependence. Newer hypnotic drugs are more expensive but may have less risk of dependence. Guidance from NICE would help to ensure appropriate and cost-effective use.

Diabetes

New treatments for diabetic foot ulcers

Diabetic foot ulcer is a common complication of diabetes and accounts for a large proportion of all diabetes-related hospital admissions and costs. The estimated annual incidence of diabetic foot ulcers in England and Wales is between 2% and 10% (30-150,000). Diabetic foot ulcers can be hard to heal and 70% recur within 5 years. 5-15% of people with diabetic foot ulcers eventually require a lower limb amputation. New treatments have been developed for use with diabetic foot ulcers and NICE guidance would help to promote consistent and cost-effective uptake of these treatments.

A&E**Prehospital intravenous fluid therapy in trauma**

Trauma patients suffering severe bleeding often need early initiation of fluid replacement therapy via insertion of an intravenous drip. However, the time taken to perform this procedure can result in a delay in the patient reaching hospital. NICE guidance would provide a clear view as to the most clinically and cost effective approach.

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