NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE SPECIAL HEALTH AUTHORITY NINTH WAVE WORK PROGRAMME

BREAST CANCER

On 14th October 2003 the Department of Health and the Welsh Assembly Government formally requested the National Institute for Clinical Excellence to prepare a clinical guideline as described in the box below.

Title: Clinical guideline for the diagnosis and treatment of breast cancer.

Remit: "To prepare a guideline for the NHS in England and Wales on the clinical management of breast cancer, to supplement existing service guidance. The guideline should cover:

- the key diagnostic and staging procedures
- the main treatment modalities including hormonal treatments
- the role of tumour specific bisphosphonates."

BREAST CANCER: DIAGNOSIS AND TREATMENT

Suggested by:

Cancer NSF team and the National Clinical Director for cancer.

Overview.

Breast cancer is the most common form of female cancer, accounting for nearly 30% of all cases of cancer in women. There were around 35,000 new case of breast cancer amongst women in England and Wales in 1998 and 11,340 women died from the disease in 2000.

The treatment of breast cancer depends on many factors. In the earliest stages <u>surgery</u> may be all that is needed, but surgery is often followed by <u>radiotherapy</u> to the remaining breast tissue to make sure that any remaining cancer cells are destroyed. There will also usually be <u>adjuvant therapy</u> consisting of hormonal therapy or chemotherapy drugs or both. If the cancer has spread to other parts of the body it is usually treated with <u>hormonal therapy</u>, <u>chemotherapy</u> or monoclonal antibody therapy. Radiotherapy may be used to treat secondary breast cancer cells in specific parts of the body. The proposal is for a clinical guideline covering all aspects of the diagnosis and management of breast cancer.

Evidence base.

There is an extensive evidence base relating to the diagnosis and treatment of breast cancer, including randomised trials relating to chemotherapy, hormonal therapy and surgery. Much of this evidence is referenced in *Improving outcomes in breast cancer* (see below).

Rationale for referral to NICE.

Breast cancer is a major cause of morbidity and mortality in one of the government's clinical priority areas. Although survival rates for breast cancer are reasonable and improving, they still lag behind Europe. Optimum management of certain subgroups of patients remains uncertain, as does the role of specialist drugs such as tumour specific bisphosphonates and hormonal treatments.

The proposed guideline could lead to long term cost savings as optimum initial therapy is associated with lower rates of local recurrence which is expensive and difficult to treat. It would also build on existing service guidance to help improve patient experience and outcomes, particularly for those subgroups of patients where there is uncertainty around optimum treatments.

Related NICE guidance.

The service guidance *Improving outcomes in breast cancer*, originally published by DH, was updated by NICE in August 2002. Appraisal guidance has been issued on the taxanes (updated September 2001) and trastuzumab (March 2002) and is in development for vinorelbine (expected shortly) and capecitabine (July 2003). An appraisal on the use of hormonal treatments in early breast cancer is expected to be included in the 8th wave. Guidelines on

management of familial breast cancer and referral guidelines for suspected cancer are in development.

Other available guidance.

Guidelines for surgeons in the management of symptomatic breast disease in the UK were published by the British Association of Surgical Oncologists in 1995.

Implications for funding, workforce and NHS capacity.

The likely short-term NHS costs will be met within the funding for the implementation of the Cancer Plan (as already noted, there could be longer-term savings). The potential costs of any significant new drug treatments will be already allowed for in estimates of the costs of NICE appraisals. Services for breast cancer patients have already been significantly reconfigured since the publication of Improving Outcomes Guidance in 1996 (recently updated by NICE). This would facilitate the implementation of this guidance.