

# *Effective* Health Care

**Bulletin on  
the effectiveness  
of health service  
interventions for  
decision makers**

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## The management of primary breast cancer

- Survival rates for women with breast cancer in England and Wales are worse than in most European countries. There is evidence of wide variations in the management of breast cancer within the country.
- The speed and cost-effectiveness of accurate diagnosis of breast cancer can be increased by using a combination of clinical examination, mammography and fine needle aspiration cytology (triple assessment). The use of triple assessment will reduce the number of women needing surgical biopsy.
- Women are less anxious when they are given full verbal and written information about their condition and treatment, and opportunities to discuss options with clinical staff. Doctors may overestimate the amount of information they communicate.
- Research suggests that psychosocial interventions can improve quality and length of life.
- Mastectomy and breast-conserving surgery plus radiotherapy have similar survival rates. Breast conserving surgery leads to better preservation of body image but local recurrence rates are higher.
- Adjuvant systemic therapy using tamoxifen, ovarian ablation, or chemotherapy improves survival and recurrence rates in most groups of women and is highly cost-effective.
- There is no evidence that routine intensive hospital follow-up, apart from regular mammography, improves outcomes after primary treatment compared with GP-led follow-up with ready access to specialist care when needed. Reducing intensity of follow-up can release resources.
- Research suggests that the management of breast cancer, and its outcomes, can be improved if care is provided by specialists working in multi-disciplinary teams with a sufficient throughput of new cases per year.

## A. Background

Breast cancer causes 13,000 deaths per annum in England and Wales. It is the leading cause of death in women aged 35 to 54 and the most common cause of cancer death among women.<sup>1</sup> England and Wales has one of the highest age-standardised incidence and mortality rates for breast cancer in the world.<sup>2</sup> If detected early and treated appropriately, the five-year survival rate can be over 80%.<sup>3</sup> In England, however, the 5-year age-standardised survival rate was 62.5% in 1990, whereas in Switzerland, Finland, France and Italy it was over 70%.<sup>4</sup> There are also wide variations in the management of breast cancer<sup>5,8-11</sup> and cancer-stage adjusted survival rates<sup>6,7,9</sup> between areas and providers within the UK. Standards are not uniformly high; in some places, breast cancer care is sub-optimal.

In order to help improve the overall standard of care for women with breast cancer, the Clinical Outcomes Group (COG) commissioned the production of guidance for purchasers. This guidance, put out under EL(96)66, is now available in the form of a manual and accompanying review of the research evidence, *Improving Outcomes in Breast Cancer: Guidance for Purchasers; The Manual*<sup>12</sup> and *The Research Evidence*.<sup>13</sup> These are available free of charge via the HealthLit Line (0800 555777).

This bulletin summarises the research evidence for those recommendations relevant to the management of primary breast cancer in a more succinct form. Primary (or early) breast cancer has been defined as tumours of less than 5cm diameter with no evidence of distant spread or metastases. These recommendations, if implemented, should result in significant improvements in the care of many women with breast cancer.

## B. The review process

This bulletin is based on systematic reviews of research evidence, most of which were carried out specifically to inform the guidance. These involved, at a minimum, searching MEDLINE from 1980 and the Centre for Health Economics (University of York) Economics Database, checking reference lists of papers retrieved, and consulting experts in the various fields. Further information on the review process, including the specific questions considered, is given in *Improving Outcomes in Breast Cancer: The Research Evidence*.<sup>13</sup>

## C. Diagnosis of primary breast cancer - triple assessment

There is strong evidence for the value of using the combination of clinical examination, mammography and fine needle aspiration cytology (FNAC) – known as ‘triple assessment’ – to diagnose cancer in women with breast lesions. A review of 15 follow-up studies<sup>14-28</sup> showed that triple assessment is consistently more sensitive than any single test alone, capable of picking up 95% to 100% of cancers when at least one component is positive. When all three tests give the same result, whether positive or negative, the probability that the diagnosis is correct is about 99%. In most cases, therefore, women with three positive tests can be offered therapy and those whose tests are all negative can be reassured without the need for surgical biopsy. In addition, triple assessment can be carried out in a single visit, reducing the time to achieving a definitive diagnosis.

The accuracy of triple assessment depends on the skills of those who carry out the procedures and assess the results. The quality of FNAC, in particular, is operator dependent and some clinicians may need training in this area.<sup>15,20</sup>

Triple assessment can release resources by reducing the proportion of women who need surgical biopsy<sup>16,17,30,31</sup> and the inclusion of FNAC has been shown to be cost-effective.<sup>14,29a,29b,32</sup>

## D. Management of primary breast cancer

**D.1 Surgery:** For the majority of women with early breast cancer, surgical options include breast conserving surgery (wide local excision or lumpectomy) and mastectomy. Randomised controlled trials (RCTs) have not shown any effect on life-expectancy of type of surgery.<sup>33,34</sup> Local recurrence rates tend to be lower the more tissue is removed. Against this potential advantage of more extensive surgery, however, the impact of disfigurement on the woman and her personal relationships must be balanced, and, in the case of surgical clearance of the axilla, iatrogenic arm problems.<sup>35</sup>

The option of breast conserving surgery is suitable for women with relatively small and localised tumours. This should be followed by adjuvant radiotherapy (see below), in order to reduce risk of local recurrence.<sup>33</sup> It is important that the margins of the tissue removed during surgery should be free from cancer, since local recurrence is more likely when cancer cells from tumour margins are left behind after surgery.<sup>36</sup>

Breast reconstruction after mastectomy removes dress problems associated with prostheses and it may improve

women's attitudes to their bodies.<sup>37-41</sup> Retrospective studies suggest that women who have breast conserving surgery report better body image and greater satisfaction than those who undergo mastectomy and immediate reconstruction.<sup>42-48</sup> The evidence for better general psychological and social adjustment after breast conserving surgery however is equivocal.<sup>49-51</sup> Studies of women's reactions to different types of surgery are generally of poor quality and the results may not be generalisable.

**D.2 Radiotherapy:** Adjuvant radiotherapy after surgery reduces local recurrence rates to less than one-third of the rates found in comparable women who have not had radiotherapy.<sup>34,52,53</sup> However, a systematic overview of RCTs involving a total of 17,000 women showed no difference in overall survival; in those who had radiotherapy, a slight reduction in deaths from breast cancer was counterbalanced by an increase in deaths from cardiac-related disease.<sup>34</sup> Comparison of mortality rates in more recent trials with those in earlier studies suggests that the benefits of radiotherapy in terms of lower breast cancer mortality may have increased, while adverse effects seem to have been reduced, possibly due to a reduction in the doses used.<sup>54</sup>

Although serious adverse effects appear to be uncommon, complications such as severe neuropathy, subcutaneous fibrosis, bone necrosis and arm oedema can occur, particularly in women exposed to high dose regimens.<sup>55,56</sup>

**D.3 Hormone therapy:** Most breast cancers respond to sex hormones; this depends on the hormone receptor status of the tumour. Hormone therapy can involve use of the oestrogen receptor antagonist tamoxifen, or destruction of the ovaries by surgery, radiotherapy or drugs (ovarian ablation).

### Tamoxifen

Tamoxifen can improve survival and reduce recurrence rates in most groups of breast cancer patients. A systematic review conducted by the Early Breast Cancer Trialists' Collaborative Group, which included data from almost 30,000 women in 40 randomised controlled trials, showed that tamoxifen treatment for one year or more was associated with highly significant absolute improvements in 10-year recurrence-free survival.<sup>57</sup> This benefit is greatest in women over 50 with axillary lymph node involvement because their prognosis is worse (Table 1).

**Table 1** Effects of tamoxifen treatment

Women remaining alive and free from recurrence after 10 years <sup>58</sup>		
	Treated	Untreated
Node-positive	41.9%	33.1%
Node-negative	68.1%	63.1%

Overall, the use of tamoxifen reduced the average annual odds of death by 17% (OR: 0.83; 95% CI: 0.79 to 0.87) and the average annual rate of recurrence by 25% (OR: 0.75; 95% CI: 0.75 to 0.99). There is no evidence that tamoxifen is effective for premenopausal women with oestrogen receptor negative tumours.<sup>58</sup> An update of this systematic review is in preparation and should be available in early 1997.

The effects of treatment were considerably greater in trials lasting 2 to 5 years than in shorter term trials. However, on current evidence, the use of tamoxifen for more than 5 years does not appear to be justified.<sup>59</sup> Tamoxifen treatment is associated with an increase in endometrial cancer, which may be counter-balanced by a decreased incidence of cancer in the other breast.

### Ovarian ablation

Ovarian ablation has been used for breast cancer patients for over a century, but is now less common. Data from over 3000 women who

underwent ovarian ablation, 40% of whom were over 50 years old, were considered in the Early Breast Cancer Trialists' systematic review.<sup>57</sup> The results suggest that ovarian ablation offers no benefits for women over 50. However, among women under 50, both recurrence-free and overall survival rates increased by about 25%. After 15 years, 53% of women under 50 who had ovarian ablation remained alive and free from recurrence, compared with 42% of controls. Ovarian ablation did not significantly affect non-breast cancer mortality over the period of follow-up, but it causes sudden onset of menopause, for

which women are unlikely to be offered hormone replacement therapy.

**D.4 Chemotherapy:** The effectiveness of polychemotherapy (usually CMF - cyclophosphamide, methotrexate and 5-fluorouracil), was assessed in 18,400 women enrolled in randomised controlled trials. Overall, it improved average annual survival rates by 16% (SD 3) and reduce average recurrence rates by 28% (SD 3), with greater benefits among younger women. After 10 years, 44% of treated women were alive and free from recurrence, compared with 35.6% of control women. There was no apparent effect of chemotherapy on non-cancer related deaths.<sup>57</sup>

A recent meta-analysis based on data from 3920 patients in 9 RCTs suggests that adding chemotherapy to tamoxifen in postmenopausal women does not significantly improve survival, and that the adverse effects of chemotherapy on quality of life may outweigh any potential benefit from the delay in recurrence.<sup>60</sup>

A review of 5 RCTs showed that acupuncture/acupressure is effective for reducing the nausea and vomiting associated with chemotherapy.<sup>153</sup>

**D.5 Cost-effectiveness of systemic therapy:** Analyses based on US data consistently show that systemic therapy for early breast cancer can be highly cost-effective, although a range of results have been reported.<sup>61-65</sup> Estimates of the cost per quality-adjusted life year (QALY) of treatment with tamoxifen range from \$12,000 in node negative oestrogen-receptor positive pre-menopausal women to \$4,000 in node positive pre-menopausal women (1991 \$US).<sup>63,64</sup> Since the cost of tamoxifen in the UK is considerably less than in the USA, these figures are likely to underestimate its cost-effectiveness in the UK.

The cost per QALY for adjuvant chemotherapy have been variously estimated at \$1,000–5,000 for pre-menopausal node-positive women, ranging up to \$36,000–50,000 for post-menopausal node-negative women (1991 and 1993 \$US).<sup>62-65</sup>

**D.6 Choice of systemic therapy:** Although adjuvant systemic therapy is likely to offer potential benefits for almost all women with early breast cancer, the effectiveness and cost-effectiveness of hormone therapy or chemotherapy depend on a range of factors which should be considered together by the breast care team. These include the following:

- The patient's age (younger women tend to benefit more from chemotherapy or ovarian ablation while older women benefit more from tamoxifen).
- Characteristics of the tumour (for example, oestrogen-receptor positive tumours respond better to hormone therapy).

- The prognosis (when this is relatively good, the scope for additional benefit may be limited).
- The differing adverse effects of each type of treatment.

Patients should be fully informed about the benefits and risks of systemic therapy and given the opportunity to discuss the options that are likely to be most appropriate for them.

## E. Information and communication

**E.1 Information giving:** The most common complaints made by cancer patients are about poor communication and inadequate information.<sup>66</sup> Some doctors have poor communication skills and a few behave in a way that may be perceived as insensitive, even callous.

Because issues around breast cancer may produce intense emotional reactions, information has to be given in a clear and sensitive way. Focus groups of patients reveal that they want information in both verbal and written forms, about their cancer, treatment options, the likelihood of treatment success and possible side-effects.<sup>66</sup> Patients who are given more complete information show greater satisfaction without any increase in anxiety.<sup>75</sup> In addition, giving clear information to patients allows them to contribute to decision-making about treatment.

Communication difficulties are associated with anxiety, depression, anger and confusion.<sup>85</sup> A critical and particularly difficult point in the relationship between doctor and patient is when the news of the cancer diagnosis is given for the first time, after which some patients may fail to take in information.<sup>66</sup>

Studies of consultations suggest that cancer patients and their doctors may disagree about the adequacy of information given.<sup>67,70-78</sup> Patients often feel they are not given sufficient information, while doctors tend to overestimate the amount of information they provide.<sup>67,75</sup> Some doctors are not convinced of the value of giving full information to patients<sup>76-78</sup> and some routinise the difficult task of telling bad news.<sup>78</sup> Younger, better educated patients, and those with better prognoses, tend to get more detailed information.<sup>73,75,76</sup>

Patients are likely to get more complete information when it is given in a structured way. They consistently find audiotapes of their consultation and information booklets about treatment helpful. (Table 2)<sup>68,79-84</sup>

**E.2 Participation in decision-making:** The fact that women want to be properly informed does not, however, imply that they want to be responsible for the final treatment decisions.<sup>69</sup> The degree to which women wish to take an active role in decision-making varies between individuals and is affected by age, education and other social and cultural factors.<sup>85-93</sup>

### Grading of studies in Tables and Figure

Studies are ordered by quality. The grades reflect the following features:

Grade I:	Randomised controlled trial (RCT) or review of RCTs.
IA:	Calculation of sample size, accurate and standard definition of outcome variables.
IB:	Accurate and standard definition of outcome variables.
IC:	None of the above.
Grade II:	Prospective study with comparison group (non-RCT or good cohort study).
IIA:	Calculation of sample size, accurate and standard definition of outcome variables, adjustment for the effects of important confounding variables.
IIB:	One of the above.
Grade III:	Retrospective study.
IIIA:	Comparison group, calculation of sample size, accurate and standard definition of outcome variables.
IIIB:	Two of the above.
IIIC:	None of the above.
Grade IV:	Cross sectional study.

**Table 2** Studies comparing the different ways of giving information

(Studies ordered by grade and sample size)

Author, year country	Aim of study	Patient groups	Outcomes assessed	Assessment tools	Results	Grade
Eardley, 1988 <sup>81</sup> UK	To assess the impact of a booklet about radiotherapy on patients' worry about treatment and satisfaction with information about radiotherapy.	415 new patients scheduled for a course of radiotherapy, waiting for treatment at a tertiary care centre. 200 patients sent booklet and questionnaire exploring worries about radiotherapy; 215 controls only got questionnaire.	Levels of worry about radiotherapy. Satisfaction with information about treatment.	Ad hoc mail questionnaire.	Reactions to the booklet were positive: 80% thought it was a good idea and 66% found it helpful. Patients who received the booklet significantly less concerned about side effects and more satisfied with information.	I
McHugh et al, 1995 <sup>79</sup> UK	To test whether providing cancer patients with audiotapes of their clinical interviews can improve recall and reduce psychological distress.	Consecutive series of 117 out-patients newly referred to a tertiary hospital. Most cancers were gestational trophoblastic disease, lung and testicular. 63 patients allocated to receive a tape, 54 controls. Final analysis at 6 months follow-up was based on 49 tape patients and 36 controls.	Attitudes to tape. Information retention. Measures of psychological distress.	General Health Questionnaire. Hospital Anxiety and Depression Scale. Attitude to tape questionnaire (ad hoc tool).	76% patients found the tape useful and 16% upsetting. 94% said the tape helped to remember facts they had forgotten. Patients in the tape groups recalled significantly more information. Audiotaping did not reduce general psychological distress.	I
Reynolds et al, 1981 <sup>68</sup> Australia	To assess 3 ways of providing information about illness and treatment, and effects of asking patients whether they wanted particular information.	67 patients referred to a medical oncology clinic. Most tumours were: breast, lung, lymphoma. Group 1: patients received information from a structured handout and got tape of their consultation. Group 2: the same structured information but without audiotape. Group 3: Standard information (controls).	Recall of specific information. Satisfaction with information.	Structured interview at baseline, 5 days and 6 weeks after the first consultation.	Structured approach leads to a more complete presentation of facts and provides patients with more of the information they want. Addition of audiotape did not increase recall compared to structured information alone (group 2) even though it was felt very useful. No difference between groups in satisfaction with information received.	I
Dodd, 1987 <sup>80</sup> USA	To test the efficacy of providing side effects management information proactively for chemotherapy patients.	60 cancer patients (colon, breast) an average of 10 months after diagnosis, randomly allocated to receive written information sheets (n=30) or standard oral information (n=30).	Ability to manage side effects. Anxiety. Distress and self care behaviour.	Self care behaviour log. Spielberg State Trait Anxiety Inventory. Multidimensional locus of control scale.	Patients receiving written information improved their self care activities but the information did not reduce severity and distress rating of side effects.	I
Rainey, 1985 <sup>84</sup> USA	To assess whether exposure to a patient education audiovisual programme improved knowledge and reduced anxiety compared to standard information.	60 patients at the beginning of radiotherapy treatment. Most common cancers were: head and neck, breast, brain, cervix. Experimental group (n=30) shown a 12 minute slide program on equipment, personnel, scope of radiology, etc. Control group (n=30): standard procedures.	Coping styles. Treatment related knowledge.	Avoidance Vigilance Sentence Completion Test. Modified Repression Sensitisation Scale.	Patients receiving standard information showed significantly greater treatment-related knowledge and less emotional distress at 2 months follow-up.	IIA
Deutsch, 1992 <sup>82</sup> UK	To explore the use of taping consultations in clinical oncology.	Analysis of 76 consultations in general adult clinical oncology practice. No information on patient characteristics. 76 of 97 patients (78%) returned a questionnaire exploring usefulness/acceptability of taped consultations.	Frequency of use of tape. Perceived usefulness.	Ad hoc mail questionnaire.	All patients thought the tape was worthwhile.	IIC
Hogbin et al, 1989 <sup>83</sup> UK	To assess whether it was practicable and useful to record the "bad news" consultation.	46 patients with bowel and breast cancer attending a general surgical outpatient department. 38 of 47 eligible patients (83%) returned a questionnaire exploring usefulness and acceptability of taped consultations.	Organisational problems caused by taping. Acceptability to doctors. Acceptability and perceived usefulness to patients.	Ad hoc mail questionnaire.	All patients found the tape useful although only 38% felt it helped to recall information otherwise forgotten. 21% of patients found the tape upsetting. Taping did not cause organisational inconvenience.	IIC

**Table 3** Effects of choice between breast conserving surgery (BCS) and mastectomy (MST) (Studies ordered by grade and sample size)

Author, year country	Aim of study	Patient groups	% able to choose	% choosing BCS	Outcomes assessed	Results	Grade
Street et al, 1995 <sup>100</sup> USA	To assess the effects of two methods of pre-consultation education.	Interactive video disk (n=30). Information brochure (n=30).	100 100	76 58	Active role in consultation. Type of surgery chosen.	Preconsultation education well received and felt to enhance involvement in decision making. No difference between the two techniques.	I
Fallowfield et al, 1994 <sup>54</sup> UK	To determine the impact of offering women a choice about surgery in early breast cancer.	Patients treated by: a) surgeons favouring MST (n=30) b) surgeons favouring BCS (n=121) c) surgeons offering choice (n=118).	- - 53	- - 69	Anxiety and depression at 3, 6, 12 and 36 months. Fear of recurrence, attitude to disease and treatment. Type of surgery chosen.	At 3 years between 1/4 and 1/5 of patients were anxious and depressed irrespective of their role in treatment decision. Women treated by surgeons who offered choice less depressed than those treated by surgeons favouring MST. 42% of patients were pleased they had been allowed to choose; 13% unable to decide; 37% said they had difficulties.	IIA
Cotton et al, 1991 <sup>98</sup> UK	To assess how often patients opt for BCS when they are offered the choice.	Group not eligible for BCS (n=72). Group eligible for BCS (n=91)	- 100	45	Type of surgery chosen.	Even when offered a choice, a sizeable proportion of women (50%) opt for more radical procedures. Younger women more likely to prefer BCS.	IIA
Levy et al, 1989 <sup>51</sup> USA	To assess emotional distress sequelae as a function of choice of surgical treatment.	A group of patients participating in a study examining behavioural predictors of recurrence of disease (n=98).	-	70	Emotional distress. Social support. Anxiety and depression. Functional status.	When choices played a major role, BCS patients were psychologically worse off at 3 months follow-up. The assumption that women are psychologically better off opting for BCS should be re-examined.	IIA
Pozo et al, 1992 <sup>49</sup> USA	To assess, at one year follow-up, the psychosocial impact of offering choice between BCS and MST.	A group of private patients seen at a tertiary care institution in the process of deciding between BCS and MST (n=63).	61	41	Emotional distress. Overall quality of life. Life satisfaction. Marital satisfaction. Perceived social support. Type of surgery chosen.	Choice of surgical procedure predicted higher levels of life satisfaction at 3 months. BCS patients reported higher sexual adjustment at 6-12 months post surgery.	IIA
Hughes, 1993 <sup>95</sup> USA	To assess: a) the relationship between amount and type of information regarding treatment and type of surgery; b) the relationship between a patient's choice of treatment and her ability to recall salient information.	A group of patients in the process of deciding between BCS and MST (n=71).	100	65	Amount and nature of information. Recall and specific pieces of information. Overall quality of life and functional status.	Treatment choice was unrelated to the amount of information conveyed to the patients at their clinic visit. Quality of life and functional status did not differ between those opting for BCS or MST.	IIB
Leinster et al, 1989 <sup>50</sup> UK	To assess the usefulness of an Informal Decision Analysis tool to help women make the best decision given their subjective expected utilities.	Women seen at surgical department, University of Liverpool (n=43).	42	48	Satisfaction with the choice made. Type of surgery chosen. Occurrence of depression and anxiety.	No difference in psychological adaptation between groups identified by treatment chosen. Patients felt they had been able to choose the treatment they wanted.	IIB
Morris et al, 1988 <sup>101</sup> UK	To prospectively record psychological parameters in patients (and their husbands) in order to ascertain the effects on adjustment of being offered a choice.	Group with central lesion: no choice (n=10). Group offered choice (n=20).	- 100	- 65	Anxiety and depression. Social and working activities. Marital relationships. Type of surgery chosen.	At 6 months follow-up patients offered a choice had lower (not statistically significant) levels of anxiety and depression, and reported better adjustment with respect to work and attitudes toward the future.	IIB

**Table 3** Continued

Author, year country	Aim of study	Patient groups	% able to choose	% choosing BCS	Outcomes assessed	Results	Grade
Wilson et al, 1988 <sup>96</sup> UK	To determine whether, given the choice, patients would prefer BCS or MST.	Patients seen at Newcastle General Hospital between 1979 and 1987 (n=153).	100	35	Type of surgery chosen.  Difficulties experienced in making the choice (subgroup of 28 patients).	Common reasons for choosing mastectomy included employment, hope of more rapid recovery, fear of radiotherapy. Of 28 (18%) patients interviewed 2 years after surgery, 24 said it was not difficult to choose, 4 had problems with the choice.	IIC
Wolberg et al, 1987 <sup>97</sup> USA	To quantify the proportion of patients who, given the choice, opt for BCS, and assess the psychological factors that predict preference.	A series of consecutive patients seen at the Department of Surgery, University of Wisconsin (n=206).	53	49	Psychological correlates of choice.  Type of surgery chosen.	No demographic variable was associated with choice. Women choosing BCS valued their physical appearance more highly and were less anxious and depressed.	IIIA
Ward et al, 1989 <sup>99</sup> USA	To assess: a) which factors patients consider when deciding between MST and BCS; b) to what extent patients participate in treatment decision; c) what sources of information they use.	A group who meet the surgical criteria for choice between MST and BCS (n=22).	100	50	Factors women value when deciding between MST and BCS. Perceived participation. Sources of information.	Desire for body integrity and fear of radiotherapy were the two main reasons for preferring BCS and MST, respectively. 91% said that they had participated as much as they desired. 50% said they want the decision to be fully their own. The remaining 50% said they want to share it mostly with doctors.	IIIC

Studies exploring the effects of choice between mastectomy and breast conserving surgery are summarised in Table 3. Benefits may include reduced depression and anxiety<sup>94,101</sup> and a higher level of life satisfaction.<sup>96</sup> One study however, suggested that offering a choice could cause distress,<sup>51</sup> and other studies reported that a significant proportion of women found the process of making a choice problematic.<sup>94,96</sup>

## F. Psychosocial support

Cancer patients need general emotional support and some also require practical help, for example with caring for children or other dependents or holding down a job. Doctors and nurses often fail to recognise patients' needs.<sup>102-105</sup>

**F.1 Psychosocial / psychotherapeutic interventions:** 13 studies which assessed the effects of a range of interventions

(Table 4)<sup>106-120</sup> and also 2 critical reviews of the literature were identified.<sup>121,122</sup> These studies show that psychotherapeutic counselling and educational interventions can improve quality of life and may possibly improve immune function and increase life expectancy in cancer patients. Interventions involved group or individual therapy, and usually included exploration of anxieties, expression of feelings about illness and related problems. Many also attempted to replace undesirable ways of thinking or behaving with alternatives.

Therapeutic interventions were given by a range of people, including nurses, psychologists and psychiatrists. In general, interventions that focussed on past problems, as in the psycho-analytic model, were not found to be effective, whereas those which dealt with the patient's current problems were more likely to be helpful.

A more definitive statement about the impact of psycho-social

interventions is not possible because of the poor quality of the studies, which are often small and poorly controlled. The multiplicity of types of intervention and outcomes used make comparisons between studies difficult.

However, when considered in conjunction with the evidence that informal social support from partners, friends and relatives is associated with better outcomes, this research highlights the importance of psycho-social factors for breast cancer patients.<sup>123-131</sup>

**F.2 Cognitive/behavioural interventions:** Cognitive / behavioural interventions, including psychotherapy, relaxation training, systematic desensitisation, guided imagery, pain control training, biofeedback and physical exercise, have mainly been used to reduce side-effects of cancer therapy such as nausea. They have been assessed in 21 RCTs (Table 5).<sup>132-52</sup> 16 of these studies demonstrated some degree of benefit, while the rest were

**Table 4** Effectiveness of psychosocial/psychotherapeutic counselling or support (Studies ordered by grade, length of follow-up and sample size)

Author, year	No. of patient / % breast cancer	Follow up		Content of interventions Type of provider and patient	Results	Grade
		Duration	Lost to follow -up			
Spiegel, 1989, <sup>106</sup>  1983, <sup>110</sup> 1981 <sup>111</sup>	86 100%  58 100%	10 years  12 months	0%  48%	Psychiatrist, social worker and an ex-patient led 90 minute sessions of group psychotherapy, once a week for one year. Control group received usual care.  Metastatic breast cancer patients.	10 years: the intervention increased survival by 18 months. The effect was apparent from the 8th month of treatment. 12 months: the intervention group used less psychotropic drugs and analgesics. Anxiety and depression decreased, and other psychological measures improved. Mood improvement was directly correlated with reduction of pain duration. Feeling of pain control improved.	IB
McArdle, 1996 <sup>107</sup>	272 100%	1 year	3%	Psychological and informative support was given for one year to patients by a specialised nurse (since before surgery), or voluntary organisation (after surgery) or nurse + voluntary organisation, or staff with routine approach and booklet.	The group supported by the nurse had significantly better general health, less insomnia, psychological symptoms, social dysfunction and somatic symptoms.	IB
Burton, 1995 <sup>108</sup>	215 100%	1 year	15%	Preoperative interview, preoperative interview + psychotherapeutic intervention (30 min, preoperative interview + talk (30 min). Consultant surgeon trained in client-centred counselling. Women awaiting mastectomy.	Multivariate analysis showed that the experimental intervention was a significant predictor of improvement of psychological symptoms and coping strategies, together with stressful life events, age, marital status and social support.	IB
Edgar, 1992 <sup>109</sup>	205 48%	1 year	35%	Relaxation training and problem solving techniques in two different phases of illness (just after diagnosis and some months later). Nurse, various cancer type patients at different moments of the disease.	At 8 months follow-up differences between groups were significant for depression, anxiety, and control. The group with the later intervention had more benefit. Physical health was the most significant covariate.	IB
Watson, 1988 <sup>112</sup>	20 100%	1 year	30%	Psychosocial support and information group held by a specialist nurse for one year. Specialist nurse, not further specified. Breast cancer patients just after diagnosis.	At 3 month follow-up the experimental group showed less depression, better adjustment to disease and more working activity; but at 1 year follow-up the difference disappeared. No difference for anxiety.	IB
Mock, 1994 <sup>113</sup>	14 100%	1 month	0%	Physical exercise (10-45 minutes 4-5 times/week) and psychological support group (90 minutes every two weeks). Oncology clinical specialist nurse specifically trained. Patients in chemotherapy (stage I and II). Breast cancer patients.	Adjustment to disease was worse in the control group. Emotional distress increased in the control group and decreased in treated patients.	IB
Grossarth-Maticek, 1989 <sup>114</sup>	100 100%	3 years	0%	Patients randomised to psychotherapy (behavioural, creative, depth), only chemotherapy, both chemotherapy and psychotherapy, or none. Provider not specified. Late stage patients in chemotherapy.	Number of lymphocytes and survival increased in the 3 experimental groups. Survival was 14.9 months in the psychotherapy group, 14.1 in chemotherapy, 22.4 in both therapy groups.	IC
Telch, 1986 <sup>115</sup>	41 40%	6 weeks	0%	Six 90 minute sessions once a week of behavioural strategies or psychological support group. Social worker, psychologist. Various cancer patients.	Behavioural strategy group improved psychological adjustment to illness.	IC
Gordon, 1980 <sup>117</sup>	308 32%	12 months	36%	Six month group with an educational and emotional counselling and "environmental manipulation". Psychologist, social worker and nurse, not further specified. Cancer patients, any stage.	The experimental group experienced a faster decrease of anxiety, depression, and hostility, improved general quality of life. Return to work was also slightly more frequent in treated patients.	IIB
Maguire, 1983 <sup>116</sup>	152 100%	18 months	0%	Physical rehabilitation of the arm, expression of feelings about the scar and body image, encouragement to return to work.  Specialist nurse, not further specified. Radical mastectomy patients.	Intervention delivered by the nurse not effective. 89% of women in experimental group with psychiatric problems were recognised by the specialist nurse, versus 22% among controls. 3% in intervention group had moderately severe anxiety and 4% depression, versus 21% and 20% in the control group at 12-18 months. Adjustment to illness and working activity improved. No differences in the functioning of arm, but pain lower in experimental group.	IIC



**Table 4** Continued

Author, year	No. of patient / % breast cancer	Follow up		Content of interventions Type of provider and patient	Results	Grade
		Duration	Lost to follow-up			
Houts, 1986 <sup>118</sup>	32 ?	3 months	20%	Routine supporting intervention reinforced by 3 phone calls, before and after the surgical intervention, aiming at improving the coping strategies of the patients. Social worker who had had breast cancer. Newly diagnosed cancer patients.	No effect was observed in the group receiving the enriched intervention, compared with routine care.	IIC
Youssef, 1984 <sup>119</sup>	18 100%	2 months	0%	18 sessions of group therapy lasting 1 hour every other day held for 6 weeks by a psychiatric nurse. Intervention based on crisis and self-concept theory. Psychiatric nurse, not further specified, with the investigator. Breast cancer patients admitted to hospital for treatment.	The differences between the two groups did not reach statistically significant level. Some improvement in self-esteem and depression in the intervention group.	IIC
Morgenstern, 1984 <sup>120</sup>	120 100%	6 years	45%	Psychotherapy groups were held for 90 minutes once a week. Provider not specified. Breast cancer patients.	After adjustment for interval between diagnosis and program entrance, no statistically significant effect was observed on survival at 90 months, but survival was longer in the treated group until 70 months.	IIIB

equivocal. Studies with psychological endpoints such as depression and anxiety had less consistent findings.

## G. Effectiveness of follow-up policies

Routine hospital follow-up of patients who have completed primary treatment, usually involving some combination of hospital physician visits, bone scans, sonograms, chest X-rays and laboratory tests, is currently standard practice in Britain.<sup>157</sup> However, with the exception of mammography, there is no evidence that this improves outcomes. Patients should not, therefore, routinely receive hospital-based follow-up other than mammography.

Assessment of individual patients' needs should form the basis for planning follow-up and should take the following points into account the finding that:<sup>154</sup>

- Patients value a continuing relationship with a single provider, and this is often not the case;

- Patients want to be fully informed and should have consistent information from different sources of health care;
- Patients should have easy access to care.

The effectiveness of different follow-up strategies was assessed in 2 Italian RCTs<sup>155,156</sup> and a British RCT comparing GP-based with hospital follow-up.<sup>157,158</sup> In the Italian studies, no difference was found in 5-year survival (OR: 1.03; 95% CI: 0.82 to 1.30) or health-related quality of life between patients allocated to intensive surveillance or to a control regimen in which patients were seen by doctors with the same frequency and tests performed only when patients reported problems. All women received a yearly mammogram.

Interim results of the British RCT suggest that patients followed up by their GPs experience the same quality of life as those cared for by specialist clinics, and that GP follow-up is acceptable to both patients and GPs.<sup>158</sup>

These results are not surprising, since these and other studies found that most recurrences are symptomatic and likely to be detected first by patients themselves.

Economic evaluations of different strategies in the Italian health-care system found that the cost of intensive follow-up was 3 to 5 times greater than for minimalist follow-up.<sup>159</sup> Studies in the USA also suggest that considerable savings could be achieved by less intensive follow-up.<sup>65,160,161</sup>

In England and Wales, where a smaller proportion of specialists carry out intensive testing,<sup>157</sup> the savings may be less, but the reduction in the number of specialist outpatient visits could allow the time saved to be used for activities which are more likely to benefit patients.

Women and their GPs should therefore be reassured that routine tests to detect pre-symptomatic metastatic cancer are not necessary, although they should be aware of ways of accessing the breast care team and GPs should be involved in shaping local arrangements for follow-up.

Each woman should have a contact number for her breast care nurse. This has been shown to lead to better quality of life and lower levels of psychological and physical morbidity than either routine care or support from a local voluntary agency.<sup>107</sup>

**Table 5** Effectiveness of cognitive/behavioural interventions

(Studies ordered by grade, length of follow-up and sample size)

Author, year	No of patients/ % breast cancer	Follow up		Content of interventions  Type of provider and patient	Results	Grade
		Duration	Lost to follow-up			
Bindemann, 1991 <sup>133</sup>	80 20%	3 months	11%	Relaxation training with light hypnosis. Provider not specified. Tape. Males (testicular teratoma); females (ovarian and breast cancer).	Psychological symptoms in the experimental group at the follow-up increased less. Control group women had higher scores for anxiety and depression than experimental group women. Authors cautious about a direct relationship between relaxation and psychological status.	IB
Bridge, 1988 <sup>134</sup>	154 100%	6 weeks	10%	Relaxation training and guided imagery, versus simple relaxation training. Controls were invited to express their feelings. In radiotherapy. Breast cancer patients in any stage.	Relaxation training and imagery was the most effective treatment especially in older women. Depression and tension scores decreased at a significant level.	IB
Morrow, 1992 <sup>135</sup>	72 ?	Not stated	?	'Systematic desensitisation' (relaxation training and imagery) or psychotherapy. Skilled oncology nurse, skilled oncologist (3 h. training), psychologist. Patients in chemotherapy treatment (antiemetics not withdrawn).	Both experimental groups suffered less severe nausea and less severe vomiting before and after chemotherapy; patients also became less anxious due to increased attention from their health care provider.	IB
Morrow, 1982 <sup>136</sup>	60 50%	Not stated	0%	'Systematic desensitisation' (relaxation training and imagery) or psychotherapy. Investigator not specified. Various cancer patients in chemotherapy.	Duration and intensity of vomiting and nausea decreased in the desensitisation group. The effect was independent of the type of chemotherapy and did not interact with antiemetic use.	IB
Burish, 1991 <sup>137</sup>	60 18%	Not stated	Not stated	Structured intervention of information about chemotherapy (a visit to the facilities and information on the effects of the therapy) versus individual interview and booklet, versus relaxation training and guided imagery. Relaxation therapist. In chemotherapy.	Structured information was more effective on all endpoints, reducing distress, improving knowledge, decreasing depression and hostility in daily life and decreasing nausea and vomiting.	IB
Lyles, 1982 <sup>138</sup>	50 33%	Not stated	?	Relaxation training and imagery or psychosocial counselling during chemotherapy. Various cancer patients in chemotherapy. Clinic staff member for counselling, therapist not further specified for relaxation training.	The relaxation training and imagery group improved significantly in comparison to the others. 36% in relaxation group, none in the counselling one, and 22% in the control group had very good improvement in anxiety, and 39%, 7% and 11% the best improvement in self-rated nausea. These effects were less apparent at follow-up than in the treatment session.	IB
Dalton, 1987 <sup>139</sup>	30 100%	Not stated	?	Information and pain control training (to be repeated at home if necessary). Nurse (the researcher), not further specified. Breast cancer patients in any stage.	Improved knowledge about pain was the only statistically significant measure. This mechanism did not imply better control of pain. Nevertheless, the experimental group increased consumption of analgesics less.	IB
Arathuzik, 1994 <sup>140</sup>	24 100%	Not stated	0%	Relaxation training and guided imagery, versus relaxation training and guided imagery and cognitive skills training. Nurse (the researcher), not further specified. Metastatic cancer patients experiencing physical pain in adjuvant therapy (taking analgesics).	The groups were too small; hypotheses not verified.	IB
Gruber, 1993 <sup>141</sup>	13 100%	18 months	0%	Relaxation and guided imagery. Provider not specified. Mastectomised patients, premenopausal, good health condition.	Immunological measures indicated that natural killer cells, mixed lymphocyte responsiveness, concavalin responsiveness were related at a statistically significant level with behavioural intervention.	IC
Greer, 1992 <sup>144</sup>	174 45%	4 months	15%	5 individual sessions of cognitive-behavioural psychotherapy during 4 months. Psychologist. Various cancer patients with life expectancy of at least 12 months.	Treatment reduced anxiety and depression. Severely anxious in experimental group: 46% at baseline, 20% at 4 months. Control group: 48%, 43%. Clinically depressed in experimental group: 43% at baseline, 18% at 4 months. Control group: 30%, 23%. Experimental group had poor adjustment to cancer: 31% at baseline, and 22% at 4 months had no fighting spirit, whereas in the control group these figures were 37%, and 35%. After 1 year follow-up, the overall scores of controls were unchanged but experimental group slightly deteriorated.	IC
Moorey, et al 1994 <sup>142</sup> (follow-up of Greer 1992)	11	1 year	22%	6 sessions in total		

**Table 5** Continued

Author, year	No of patients/ % breast cancer	Follow up		Content of interventions  Type of provider and patient	Results	Grade
		Duration	Lost to follow-up			
Davis, 1986 <sup>142</sup>	19 100%	8 months	?	8 weeks of biofeedback or cognitive therapy biweekly, followed by other 3 sessions, once a week.	Social worker, supervised by a psychologist. Newly diagnosed cancer patients, stage I. Anxiety and cortisol levels decreased in the experimental group.	IC
Berglund, 1994 <sup>143</sup>	199 +50%	5 months	7%	Relaxation training and physical exercise to restore arm mobility and information and coping skills training, aiming at return to work. Oncological nurse, physical trainer, oncologist, psychologist, dietitian. Breast cancer patients on adjuvant therapy (tamoxifen).	The program gave statistically significant effects after intervention at 3 months follow-up, on: physical training and strength; sleeping problems; information; fighting spirit. All these measures were related with better outcome on depression measures.	IC
Cimprich, 1993 <sup>145</sup>	32 100%	3 months	20%	Exercise aimed to direct attention, taught to patients by a nurse and practiced at home 3 times a week. Nurse, not further specified (the researcher). Breast cancer patients (stage I and II).	The experimental group showed a significant improvement in directing attention to daily activities. Attentional fatigue was more severe at the baseline among mastectomised women treated with tamoxifen.	IC
Cannici, 1983 <sup>146</sup>	26 ?	3 months	15%	3 group sessions of relaxation training, 3 times.  Relaxation therapist. Various cancer type patients.	The only improved measure in the experimental group was mean sleep onset latency (reduced from 124 to 29 minutes, compared to 116 and 104 in the control group). This difference was still present 3 months later.	IC
Burish, 1981 <sup>147</sup>	16 ?	3 months	0%	Individual relaxation training and imagery; 5 sessions (45 min) bimonthly, conducted by a nurse (to repeat at home). Therapist, not further specified. Various cancer type patients in chemotherapy with high levels of nausea, vomiting and anticipatory anxiety.	The experimental group showed less anxiety and nausea either before and after chemotherapy, but vomiting was equally distributed in the two groups.	IC
Norcross-Weintraub, 1990 <sup>148</sup>	56 39%	6 weeks	0%	Health education (nutrition, stress reduction, exercise, relaxation) versus individual session of consultation by a nurse. Investigator, not further specified. In radiotherapy.	Mean state anxiety scores were lower in consultation group but did not reach statistically significant levels.	IC
Larsson, 1992 <sup>149</sup>	62 100%	1 month	3%	4 one-hour sessions of relaxation training once a week. A tape helped individual practice at home. Nurse, not further specified. Outpatients in radiotherapy.	Treatment improved mood and general psychological state, but increased the perception of muscular tension.	IC
Burish, 1992 <sup>150</sup>	81 25%	Not stated	?	Combined EMG-biofeedback, ST-biofeedback and relaxation training in a 3x2 design. Relaxation therapist. Out-patients in chemotherapy.	Relaxation training had an anti-nausea effect in comparison with the other two interventions, but not an anti-vomiting one. Electrical biofeedback seemed not as easy to use in chemotherapy setting.	IC
Cotanch, 1987 <sup>151</sup>	60 18%	Not stated	?	Relaxation training versus music (as placebo) (22 min), twice a day. Relaxation therapist and tape. Various cancer type patients in chemotherapy.	Relaxation training group improved in anxiety, nausea and calorie intake, but not at a statistically significant level.	IC
Burish, 1987 <sup>152</sup>	24 35%	Not stated	?	1-3 sessions (30-45 min) of relaxation training and guided imagery, before chemotherapy. 5 sessions of 45 minutes during chemotherapy. Relaxation therapist. Various cancer patients.	The anti-nausea effect appeared in the fourth session. The experimental group progressively decreased anxiety, depression and hostility.	IC

## H. The breast care team

**H.1 Specialisation:** The complexity and multi-faceted nature of breast cancer management requires the involvement of a range of different types of specialist, working

together in a co-ordinated team. Specialisation of team members has been defined in terms of qualifications, experience, and time devoted to the management of breast cancer.<sup>12</sup> Studies in this area are, in general, retrospective and observational, and thus susceptible to bias. Nevertheless, considered together, they point to the likely improvement in

effectiveness associated with specialist treatment by multidisciplinary teams.<sup>7,9,162-180,196</sup> There is fairly strong evidence that specialist providers are more likely to provide good quality and up-to-date surgical care.<sup>7,9,162-171</sup> However, many of these studies used process measures of dubious validity to indicate quality of care, such as the probability of using

breast conserving surgery. Specialisation was usually defined in terms of the teaching status or size of the hospital, not the composition of the breast care team.

An observational study in Scotland found that women treated by surgeons regarded as breast cancer specialists had an 8% better chance of survival at 10 years. After adjustment for age, socio-economic status and cancer stage, the reduction in risk of death was 16% (95% CI: 6% to 25%).<sup>7</sup>

A meta-analysis of this and other observational studies shows that specialisation (however defined) is

especially when they share some responsibilities with doctors.<sup>194,195</sup>

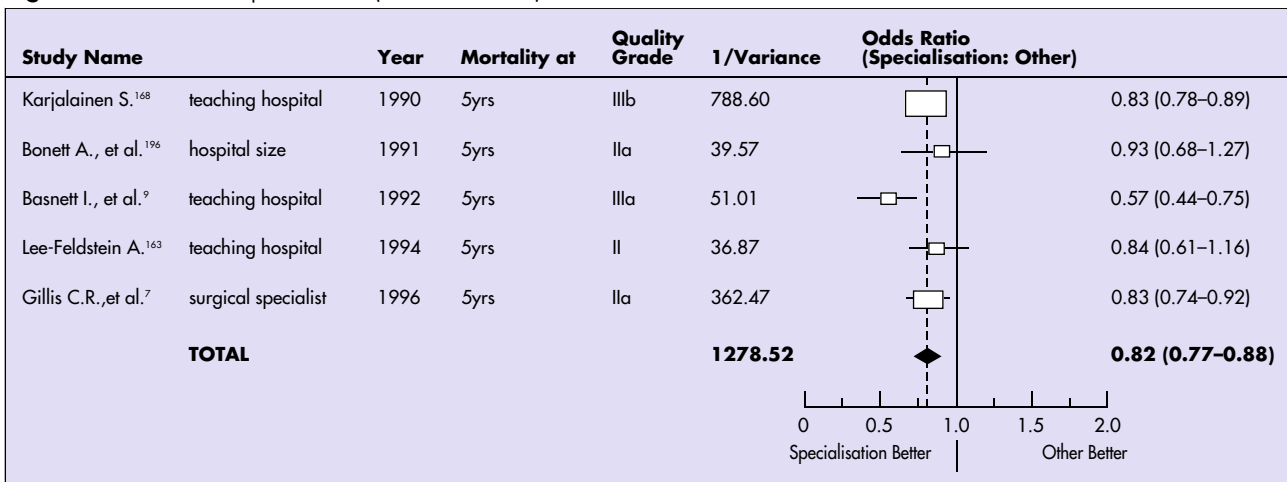
**H.2 Volume of patient throughput:** Very low patient throughput tends to be associated with poorer management and long-term outcomes, but the precise threshold below which this effect occurs is unclear. Improved outcomes with higher numbers may be a consequence of better surgical<sup>167,175,187,180</sup> and non-surgical<sup>6,11</sup> care, and may also be linked with more accurate diagnoses.<sup>177,178</sup>

In a Yorkshire study, women managed by surgeons who treated more than 30 new breast cancer

This figure is based on the following reasoning:

- Treatment by specialist providers and by those with a new patient throughput above a minimum of about 30 a year is associated with improved outcomes.
- A specialist multidisciplinary team meeting regularly is not likely to function effectively or cost-effectively if the number of new breast cancer patients falls below 2 per week.

**Fig. 1** Overall effect of specialisation (however defined) for breast cancer



consistently associated with improved survival in breast cancer patients (Fig. 1). Overall, the reduction in 5-year mortality associated with specialist care was 18% (95% CI: 12 to 23%). This estimate should, however, be treated with caution because it is derived from observational studies which are susceptible to bias, due, for example, to inadequate adjustment for differences in case-mix.

Specialist nurses can also contribute to improved outcomes for patients, in particular by reducing anxiety and depression and helping patients to participate in choices about treatment.<sup>70,74,112,116,119,148,181-193</sup> Oncology nurses can improve chemotherapy resource use,

patients per year were found to have lower 5-year mortality rates.<sup>6</sup> However, there is no evidence that the association between higher patient throughput and better quality of care holds for larger volumes. For example, a study comparing hospitals with 100 and 200 patients per year showed no difference in outcomes.<sup>175</sup>

The Clinical Outcomes Group recommended that women with breast cancer should be managed by teams which deal with at least 100 new cases of breast cancer per year (a level which may be anticipated from a catchment population of around 200,000 people).<sup>12</sup> Such teams would function in units which may cover one or more sites.

## I. Implications for health care purchasers and providers

Practical recommendations, based on this research evidence, for the sort of services which should be purchased are given in *Improving Outcomes in Breast Cancer: Guidance for Purchasers*.<sup>12</sup>

This made five key recommendations:

- Management by multi-disciplinary specialist breast care teams which are likely to be most effective and cost-effective when dealing with a throughput

of at least 100 new breast cancer patients per annum. Teams should work within written guidelines promoting the use of treatments such as adjuvant therapies, the effectiveness of which have been demonstrated by research.

- There should be a policy to ensure that good verbal and written information is given to patients, backed up by protocols to ensure that suitable information is provided. Key personnel should have training in communication skills.
- Diagnosis should normally be carried out using triple assessment for each new patient with suspected breast cancer at a single visit.
- Purchasers and providers should critically review arrangements for follow-up. Hospital follow-up (apart from regular mammography) should not be routinely offered after primary treatment, but women and their GPs should have a contact number for the breast care nurse and access to the hospital team should be readily available.
- Purchasers should monitor long-term outcomes. This requires both routine audit and the basic infrastructure for collection of data concerning patients, their disease, treatment and outcomes, and systematic reporting and recording of pathology data. This information should be sufficiently detailed to allow cancer to be staged at the individual level and for case-mix to be recorded at a population level by cancer registries.

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