

# BREAST CANCER

Report of a working group  
to the Department of Health



health  
outcomes  
indicators

## FOREWORD

The Government consultation document "A First Class Service - Quality in the new NHS", published in 1998, emphasised three essential aspects of ensuring delivery of high quality of care by the National Health Service: setting, delivering and monitoring standards. It also discussed the importance of partnership between the Government and the clinical professions and patients in achieving such quality.

This series of 10 reports concerns the third aspect - monitoring standards. It represents the culmination of work that was started several years ago under the auspices of the Clinical Outcomes Group, chaired jointly by the then Chief Medical Officer, Sir Kenneth Calman, and the Chief Nursing Officer, Dame Yvonne Moores. The work was commissioned by the former Central Health Outcomes Unit of the Department of Health. The Unit has since moved and is now called the National Centre for Health Outcomes Development (NCHOD), based jointly at the Institute of Health Sciences, University of Oxford and the London School of Hygiene and Tropical Medicine, University of London.

The background to the work was the need to ensure that the NHS is driven by considerations of quality and outcome. The Department wanted to build on an earlier set of Population Health Outcome indicators, which had been limited by the constraints of existing routine data. It therefore commissioned systematic work on ten clinical topics, to be undertaken by a Working Group on each, tasked to make recommendations on 'ideal indicators' for each condition. 'Ideal indicators' were defined as statistical measures of what should be known, and realistically could be known, about the outcomes of the condition in routine clinical practice. The Groups were asked to consider a wide spectrum of possible uses of outcome indicators, from national monitoring of NHS performance by government to the periodic assessment of local services by clinicians and users.

The work of the Working Groups was coordinated by Michael Goldacre, University of Oxford. A particular feature of the work is that the Groups have recommended definitions and technical specifications for each indicator. It is hoped that people interested in monitoring the topic covered by each indicator will use the same definitions so that comparisons can be facilitated. Moreover, the methodology adopted by the Working Groups is applicable to developing health outcome indicators for many other conditions.

The publication of these reports, however, is only one further step on a long road of quality assessment in health care. The reports present 'menus' of suggestions for ways in which outcomes might be monitored in a variety of settings, by a variety of organisations and people. It goes without saying that NCHOD will welcome feedback on the reports and on the development and use of outcome indicators.

I believe that the work described here shows the value and potential of partnerships between various parties. Each working group had members who brought together perspectives of all the relevant clinical professions plus patients, NHS managers, policy makers, researchers and others as appropriate. The recommendations of the Working groups show quite clearly how these various perspectives may contribute to a broader and more balanced monitoring of standards. I would personally like to congratulate and thank everyone who has worked so hard and well to bring this initiative to fruition.

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# OUTCOME INDICATORS FOR BREAST CANCER

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# SUMMARY OF RECOMMENDATIONS

Using a variety of check lists including a health outcome model, the Group identified outcome indicators which were specified in a standard format and included in this Report. Outcome indicators, whose numbers correspond to the specifications in Section 4, were grouped under three headings relating to the aims of the interventions.

Recommendations for implementation were made using the following categories:

- A.** To be implemented generally on a routine basis.
- B.** To be implemented generally by periodic survey.
- C.** To be implemented where local circumstances allow on a routine basis.
- D.** To be implemented where local circumstances allow by periodic survey.
- E.** To be further developed because the link with effectiveness is not clear or the indicator specification is incomplete.

Category	Page
<b><i>Indicators related to improvement of early detection and treatment of breast cancer</i></b>	
<b>A</b>	<b>14</b>
<b>B</b>	<b>16</b>
<b>E</b>	<b>18</b>
<b>E</b>	<b>21</b>
<b><i>Indicators related to reduction of death and complications from breast cancer and its treatment</i></b>	
<b>A</b>	<b>24</b>
<b>A</b>	<b>27</b>
<b>A</b>	<b>29</b>
<b>A</b>	<b>32</b>
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<b>A</b>	<b>38</b>
<b>A</b>	<b>41</b>
<b>C</b>	<b>45</b>
<b>E</b>	<b>48</b>

- 1A.** Incidence of primary breast cancer by cancer stage at diagnosis.
- 1B.** Detection rate of small primary breast cancers.
- 2.** Incidence of interval breast cancers.
- 3.** Incidence of invasive breast cancer following treatment for ductal carcinoma in situ.

***Indicators related to reduction of death and complications from breast cancer and its treatment***

- 4.** Survival rates by cancer stage at diagnosis.
- 5.** Population-based mortality rates from breast cancer in women.
- 6.** Percentage of patients, diagnosed as having breast cancer, who had received a diagnostic triple assessment.
- 7.** Percentage of patients with breast cancer under the care of a breast care specialist.
- 8.** Percentage of patients receiving treatment for breast cancer whose care was planned jointly by a multi-disciplinary group.
- 9.** Percentage of patients who, having undergone potentially curative surgery for breast cancer, were given chemotherapy as part of their primary treatment.
- 10.** Percentage of patients who, having undergone potentially curative surgery for breast cancer, were given radiotherapy as part of their primary treatment.
- 11.** Recurrence rates of breast cancer by site and type of primary surgery.
- 12.** Rates of specific complications detected, within one year of discharge from hospital, among patients having undergone in-patient treatment for breast cancer.

***Indicators related to maintenance of well-being during and following treatment for breast cancer***

- |          |           |  |
|----------|-----------|--|
| <b>C</b> | <b>50</b> | <b>13.</b> Delays from patient identification of symptoms to start of treatment for breast cancer.   |
| <b>E</b> | <b>53</b> | <b>14.</b> Patient satisfaction with specific areas of the management of their breast cancer care.   |
| <b>D</b> | <b>56</b> | <b>15.</b> Assessment of health-related quality of life within a population of patients one year after a diagnosis of breast cancer.<br><b>16.</b> Assessment of psychological distress in the patient following treatment for breast cancer:<br><br><b>A</b> - measurement of psychological distress by use of an agreed instrument.<br><b>B</b> - rate of referral to specialist psychological services. |
| <b>C</b> | <b>58</b> |  |
| <b>C</b> | <b>58</b> |  |

# 1. INTRODUCTION TO THE REPORT

## **Health outcome indicators**

- 1.1** This Report is one of a series containing the recommendations of working groups set up to develop 'ideal' indicators of the health outcomes of specific conditions. The background to the work, commissioned by the Department of Health, is summarised in Appendix A.
- 1.2** Health outcomes have been defined as changes in health, health related status or risk factors affecting health, or lack of change when change is expected. They may be the result of the natural history of the condition or may be the effect of interventions to prevent or treat it. The particular concern of the working groups has been to make recommendations about outcomes which may be attributable to interventions or the lack of them.
- 1.3** The term indicator has been defined as an aggregated statistical measure, describing a group of patients or a whole population, compiled from measures or assessments made on people in the group or the population. An indicator may not necessarily provide answers to whether care has been 'good' or 'bad'; but well chosen indicators, as the term implies, should at least provide pointers to circumstances which may be worth further investigation.
- 1.4** An 'ideal' indicator has been taken to mean what should be known, and realistically could be known, about the outcomes of the prevention and care of specific conditions. The development of the recommendations has, of course, been tempered by considerations of the likely cost and availability of information. However, the working groups have tried to be reasonably far-sighted in their views about future advances in information systems.
- 1.5** For each condition the working group has developed a menu of indicators which can be used by different groups of people for a variety of purposes. In particular, an attempt has been made to recommend, within each set, indicators which reflect a population, clinical, patient, and in relevant cases, a carer perspective.

## **Breast Cancer Working Group**

- 1.6** The terms of reference and membership of the Group are shown in Appendix B. The Group included representatives of professional, managerial and patient groups involved with the prevention and treatment of breast cancer.

**1.7** The work of the Group had three main components:

- development of check lists, including a health outcome model for breast cancer, to assist members choose candidate indicators, by which is meant potential indicators worth detailed consideration
- specification of candidate indicators
- recommendations about implementation and further development.

**1.8** In this Report:

- the health outcome model is described in Section 2
- check lists for choosing candidate indicators are outlined in Appendix C
- guidelines for specifying candidate indicators are described in Appendix D
- candidate indicators chosen for specification are listed in Section 3
- candidate indicator specifications are included in Section 4
- recommendations about implementation and development are made in Section 5
- references to all sections and appendices are in Appendix E.

### **Recommendations**

**1.9** The recommendations made by the Group were categorised as those which:

- can be implemented immediately generally throughout the NHS as there are systems available which can provide the requisite data
- could be implemented in some places now where local circumstances allow, and more generally in the near future once expected developments are in place
- require further work before a recommendation can be made.

**1.10** The recommendations have been further categorised as to whether the requisite indicators should be available:

- routinely on a universal and continuous basis
- from periodic surveys and/or sampling, either at different points in time nationally or in geographical areas when there is a particular need or interest.

## 2. HEALTH OUTCOME MODEL FOR BREAST CANCER

### **Definition and scope of the work**

- 2.1** Breast cancer is defined as a primary malignant neoplasm of the breast excluding those arising from connective tissue.
- 2.2** The Group decided not to consider male breast cancer separately as it accounts for less than 1% of new breast cancer and treatment strategies reflect those recommended for women.

### **Developing a health outcome model**

- 2.3** The greater part of the input to the development of the breast cancer model has come from already published national work including:
- *Health care needs assessment : breast cancer*, published as part of the series of epidemiologically-based needs reviews sponsored by the Department of Health (Dey et al.1996).
  - *Guidance for purchasers on improving outcomes in breast cancer*, developed by the Clinical Outcomes Group (1996)
  - *Guidelines for surgeons in the management of symptomatic breast disease in the United Kingdom*, produced by the Breast Surgeons Group of the British Association of Surgical Oncology (1995).
- 2.4** The health outcome model was developed as an aid to help Group members to identify potential indicators. The model contains four elements:
- an overview of the incidence and the natural history of the disease
  - a review of the causes and risk factors
  - a review of the course, complications and consequences
  - a review of relevant interventions.

### **Overview of the incidence and the natural history of the disease**

- 2.5** Breast cancer is the most common cause of cancer in women, with approximately one in twelve women developing it at some point in their lives. About 29,000 new cases are reported in England and Wales each year (Office for National Statistics 1997a).
- 2.6** Breast cancer caused some 12,500 deaths per year in England and Wales (Office for National Statistics 1997b) and is the most common cause of death from cancer in women. It is the leading cause of death in women aged under 50, although 90% of the deaths occur in women over 50 (Dey et al.1996).

- 2.7** The age standardised incidence and mortality in England and Wales is allegedly the highest in the world (McPherson et al. 1995). The five year survival rate appears lower than other European countries or the USA (Richards et al. 1994) and varies in different parts of the country (Dey et al. 1996).

### Cause and risk factors

- 2.8** The aetiology of breast cancer is not fully understood. Inherited genes probably account for about 5-10% of all cases of breast cancer, and two recently discovered genes are BRCA1 and BRCA2. The relative risk associated with the main risk factors are shown in Exhibit 1. These are expressed as how many more times more likely it is that someone with a risk factor will develop breast cancer compared to an individual without it.
- 2.9** Oral contraceptive use only raises the relative risk of having breast cancer diagnosed to 1.24 in current users (Collaborative Group on Hormonal Factors in Breast Cancer 1996). Hormone replacement therapy is also considered to increase the risk slightly. There is some evidence that a healthy lifestyle may reduce the risk.

### **EXHIBIT 1 : ESTABLISHED AND PROBABLE RISK FACTORS FOR BREAST CANCER WITH A RELATIVE RISK >2 (McPherson et al. 1995)**

Risk factor	Relative risk	High risk group
Age	> 10	Women aged over 50 years
Family history	4-6	Breast cancer in two first degree relatives (one < age 50)
Previous benign breast disease	4-5	Atypical hyperplasia
Cancer in other breast	4	
Age at menarche	3	Menarche < age 11
Age at first full pregnancy	3	First child > age 40
Exposure to ionising radiation	3	Abnormal exposure when young after age 10
Family history	> 2	Breast cancer in first degree relative < age 50
Age at menopause	2	Menopause > age 54
Socio-economic group	2	Groups 1 and 2
Body weight post-menopausal	2	Body mass index > 35

### **Course, complications and consequences**

**2.10** It is believed that breast cancer usually starts in the epithelium of the ductules in the breast. Initial atypical hyperplasia of the epithelium undergoes a malignant change in some women and a non-invasive cancer or carcinoma in-situ develops. This is a ductal carcinoma in-situ (DCIS) in the vast majority of cases. Untreated DCIS may progress to invasive breast cancer (Page and Dupont 1990).

**2.11** For invasion to occur a second change is needed which allows the malignant cells to break through the basement membrane and infiltrate the breast, lymphatic and venous tissue. Small clusters of cells may be disseminated throughout the body early in the disease which may give rise to metastases years later. The local lesion forms a mass in the breast (Forrest 1990).

**2.12** Around half of the women diagnosed with breast cancer will at some time develop metastases; median survival is then about two years (Clinical Outcomes Group 1996). Common sites for metastases are the bone, lungs, liver, brain and pleural and abdominal cavities (Forrest 1990).

### **Relevant interventions**

**2.13** The Group reviewed the relevant interventions for breast cancer using the following classification of interventions aimed to:

- improve early detection and treatment of breast cancer
- reduce death and complications from breast cancer and its treatment
- maintain well-being during and following treatment for breast cancer.

**2.14** Interventions with the potential to **improve early detection and treatment** are those which:

- screen all women in the appropriate age group
- limit the length of use of hormone replacement therapy
- manage pro-actively women with a strong family history of breast cancer.

**2.15** Breast screening aims to detect breast cancers when they are under 15 mm in diameter. All women aged 50-64 years are invited for screening every three years, using mammography by the NHS breast screening programme. The screening programme aims to reduce breast cancer deaths in the population invited for screening by at least 25% by the year 2000.

**2.16** Use of hormone replacement therapy for ten to fifteen years increases the risk of breast cancer. However, it is thought that the benefits of hormone replacement therapy in the first ten years in reducing ischaemic heart disease and osteoporosis and reducing menopausal symptoms outweigh the increased risk of breast cancer.

**2.17** Women with a strong family history of breast cancer may experience considerable anxiety and wish to be referred to a specialist breast cancer team or genetics clinic (Dey et al.1996). Understanding of the genetics is progressing but at present there are no primary preventive interventions.

**2.18** The main interventions **to reduce death and complications from breast cancer and its treatment** are:

- screening of all women in the appropriate age group (see paragraph 2.15)
- accurate and timely assessment of symptomatic cases
- appropriate treatment of all detected cases
- appropriate follow-up after treatment.

**2.19** All patients with known or suspected breast cancer should be referred early for assessment and treatment to specialist breast cancer teams. These should deal with at least 100 new cases of breast cancer per year as this level of workload is operationally cost effective for the deployment of a suitable group of specialists which functions as a team. There should be a multi-disciplinary team including a designated breast surgeon, breast care nurse(s), pathologist, radiologist and medical or clinical oncologist, as specialist care gives a better five year survival (Clinical Outcomes Group 1996).

**2.20** Women with symptoms suggestive of breast cancer should be assessed in a specialist breast unit providing triple assessment (clinical examination, mammography or ultrasound and fine needle aspiration cytology and/or core biopsy) (Austoker et al. 1995). Triple assessment gives a definitive diagnosis over 95% of the time. Where it does not, operative biopsy is appropriate. Results of tests should be available within five working days to reduce anxiety. There should be appropriate information, counselling and access to specialist psychological and social care to reduce levels of psychological morbidity, anxiety and symptoms (Clinical Outcomes Group 1996).

**2.21** Surgery is normally the initial treatment of choice, but the amount of tissue removed varies by procedure. For conservative surgery the margins of the excised tissue should be clear of tumour cells to reduce local recurrence. The axillary nodes should normally be either cleared or adequately sampled for staging of the tumour (Clinical Outcomes Group 1996).

**2.22** Following surgery to the primary tumour, some patients may go on to develop:

- Local recurrence:
  - within the conserved breast following treatment with breast conservation
  - within skin flaps following mastectomy.

- Regional recurrence in the draining lymph nodes, principally in the axilla.
- Distant recurrence in other organs (most commonly bone, liver, lung and central nervous system), inevitably followed by death from breast cancer
- Contralateral tumour.

To combat these, radiotherapy or prophylactic surgery may be used to avoid local and regional recurrence and adjuvant systematic therapies may delay the appearance of distant metastatic spread and prolong survival.

**2.23** Following breast conserving surgery, radiotherapy is usually given to the intact breast. This has been shown to lower the incidence of local recurrence (Veronesi et al. 1995). Following mastectomy the overall incidence of local recurrence to the skin flaps lies between 10 and 20% depending on the population selected for mastectomy. This incidence can be lowered by applying radiotherapy to the flaps. To apply radiotherapy to the flaps in all patients treated by mastectomy would mean over-treatment of some 80-90%. Radiotherapy is indicated in women at high risk of local recurrence.

**2.24** Regional recurrence may be largely prevented by surgical clearance of the lymph nodes from the axilla or by prophylactic radiotherapy. Without such measures overall regional recurrence occurs in around 30% (Berstock et al. 1985). Again axillary irradiation of all would represent over-treatment in 70%.

**2.25** The use of adjuvant systematic therapies following surgery for the primary tumour has been shown to be beneficial (in terms of years of life saved) and is indicated in women with prognostic factors indicating that they are likely to die of breast cancer. Adjuvant hormone therapy in post-menopausal women is most often given as Tamoxifen for a five year period and in pre-menopausal women by ovarian suppression. The effect of hormone therapy is highly significant in tumours strong in oestrogen receptor content but is less when tumours lack oestrogen receptors. Cytotoxic therapy is usually given as a multiple agent regime. The effect is greater in younger women. There is little direct information on the results of combining both therapies.

**2.26** Some patients are now treated with primary medical therapy such as:

- Women with large tumours (termed locally advanced primary breast cancer) may be treated with cytotoxic chemotherapy or occasionally with hormone therapy. This may either be to shrink the tumour prior to surgery or, if it is inoperable, to reduce it in size before possible radiotherapy.
- Elderly patients may receive Tamoxifen.

**2.27** Follow-up after treatment needs to be appropriate for each patient. Intensive follow-up after surgery for primary breast cancer (regular specialist follow-up, mammography, plus other diagnostic procedures such as liver and bone scans) is not associated with better survival than mammography plus examination by patient's GP when necessary (Clinical Outcomes Group 1996).

**2.28** Interventions **to maintain well-being during and following treatment are :**

- provision of clear information
- effective communication
- access to specialist psychological support
- access to specialist support for treatment of lymphoedema
- restoration of 'normal' appearance
- palliative care.

**2.29** Information which is full, clear and objective should be offered to patients in both verbal and written form at all stages of treatment. There is evidence that involving the woman in the choice of operation may be of benefit, but women vary in how much they wish to be involved in the process. Patients should be informed about sources of social and practical help.

**2.30** Effective communication between health care workers and patients is likely to reduce anxiety and anger. The breast care nurse has a key role in facilitating communication and support.

**2.31** Counselling and access to specialist psychological support should be available. These services have been shown to reduce anxiety, depression and physical symptoms and improve quality of life (Clinical Outcomes Group 1996).

**2.32** Lymphoedema of the arm may be an appreciable problem. All women with the condition require help and should have access to specialist support for its treatment.

**2.33** Reconstructive surgery or provision of a breast prosthesis is important for improving well-being. Both of these require skilled staff and the patient needs to be involved in the decision about what should be used for her.

**2.34** Palliative care should be accessible, both in the community and in specialist units, for those whose disease is progressing. A patient's care may be influenced by access to a multidisciplinary specialist team. Palliative care should include symptom control, and provide psychological, social and spiritual support for patients, their relatives and carers (Clinical Outcomes Group 1996).

### 3. CHOICE OF CANDIDATE INDICATORS

**3.1** To ensure all potentially important aspects of outcomes were considered the matrix shown in Exhibit 2 was drawn up, using the following dimensions:

- aim of intervention (see paragraph 2.13)
- perspectives of measurement (see paragraph C6).

**3.2** For each part of the matrix, consideration was given to possible indicators. The following paragraphs describe which indicators were chosen, grouped together by the aim of the health intervention. The numbers in the text relate to Exhibit 2 and to the indicator specifications in Section 4.

**3.3** Four indicators related to the **early detection and treatment** of invasive breast cancer were specified and they are:

**1A:** incidence of primary breast cancer by cancer stage at diagnosis

**1B:** detection rate of small primary breast cancers

**2:** incidence of interval breast cancers

**3:** incidence of invasive breast cancer following treatment for ductal carcinoma in situ (DCIS).

**EXHIBIT 2 : MATRIX FOR BREAST CANCER OUTCOME INDICATORS**

<b>Aim of health intervention</b>	<b>Primary measurement perspective</b>		
	<b>Population</b>	<b>Clinical</b>	<b>Patient</b>
Improve early detection and treatment of breast cancer	<b>1A,1B,2</b>		<b>3</b>
Reduce death and complications from breast cancer and its treatment	<b>4,5</b>	<b>6,7,8,9, 10,11,12</b>	
Maintain well-being during and following treatment for breast cancer		<b>13</b>	<b>14,15, 16A,16B</b>

**3.4** With respect to **reducing death and complications**, the two direct measures of mortality which were specified are :

**4:** survival rates by cancer stage at diagnosis

**5:** population-based mortality rates from breast cancer in women.

**3.5** In addition five proxy outcome measures were specified for which there is good evidence that the relevant intervention is effective in reducing morbidity or mortality. They are:

- 6:** percentage of patients diagnosed as having breast cancer, who had received a diagnostic triple assessment
- 7:** percentage of patients with breast cancer under the care of a breast care specialist
- 8:** percentage of patients receiving treatment for breast cancer whose care was planned jointly by a multi-disciplinary group
- 9:** percentage of patients who, having undergone potentially curative surgery for breast cancer, were given chemotherapy as part of their primary treatment
- 10:** percentage of patients who, having undergone potentially curative surgery for breast cancer, were given radiotherapy as part of their primary treatment.

**3.6** Two measures related to complications were specified and they are:

- 11:** recurrence rates of breast cancer by site and type of primary surgery
- 12:** rates of specific complications detected, within one year of discharge from hospital, among patients having undergone in-patient treatment for breast cancer.

**3.7** Much consideration was given to possible indicators related to **patient well-being**. Five indicators were specified and they are:

- 13:** delays from patient identification of symptoms to start of treatment for breast cancer
- 14:** patient satisfaction with specific areas of the management of their breast cancer care
- 15:** assessment of health-related quality of life within a population of patients one year after a diagnosis of breast cancer
- 16:** assessment of psychological distress in the patient following treatment for breast cancer:

**A** - measurement of psychological distress by use of an agreed instrument  
**B** - rate of referral to specialist psychological services.

## 4. CANDIDATE INDICATOR SPECIFICATIONS

- 4.1** This section contains detailed specifications of the candidate indicators chosen by the Group. They have been grouped together by their association with the types of health intervention as shown in Exhibit 2.
- 4.2** Guidance notes which explain the attributes used in these specifications are included in Appendix D.
- 4.3** The detailed work of the specifications was carried out by Moyra Amess and James Coles of CASPE Research.

## Candidate indicator 1A

### Characteristics

*Specificity:* Generic

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

<b>Title</b>	<b>Incidence of primary breast cancer by cancer stage at diagnosis</b>
<b>Intervention aim</b>	Improve early detection and treatment of breast cancer.
<b>Definition</b>	For a given female population, age-group and year: <i>the number of women newly diagnosed with breast cancer by cancer stage, divided by the size of the given population</i> . The resulting numbers expressed as a rate per 100,000 female population, should be reported with their associated numerators as overall crude, age-specific and age-standardised figures (using European or global norms).
<b>Rationale</b>	Breast care specialists are keen to encourage the collection of a standard minimum data set for all breast cancer cases. To date, data collection has tended to be more comprehensive for cancers detected through the screening programme but the goal is for the equivalent information to be available on all breast cancers. The Royal College of Pathologists are currently producing guidance documents including a minimum data set, for the reporting of common cancers. The data set is principally informed by the histopathology data set from the NHS screening programme, and it should be finalised in early 1998. The adoption of such standards for every cancer would provide a rich data source which in the future could feasibly be used to develop a currently lacking, sophisticated staging classification. For the present, to support this indicator and allow some control for cancers at different stages, the four stage classification in the National Cancer Registration System Minimum Data Set should be used. This four stage classification has the added advantage of being part of a data set collected by the cancer registries on every cancer case wherever possible.
<b>Potential uses</b>	Provider based comparisons; population based comparisons.
<b>Potential users</b>	Clinicians, commissioners, providers, policy makers.
<b>Possible confounders</b>	Local interpretation of staging definitions. Variation in quality of recording stage in clinical notes. Differences in presentation rates e.g. attendance at screening sessions.
<b>Data sources</b>	Regional cancer registries collect data on the incidence and mortality associated with all cancers. These are subsequently submitted to the Office of National Statistics for analysis and reporting. The minimum data set collected by the registries includes data elements which support this indicator. The numerator will be given by the cancer minimum data set for the given population and year where the record type = 1 (i.e. initial registration); sex = 2 (i.e. female); site of primary growth - ICD10 code = C50 (malignant neoplasm of breast) or D05 (carcinoma in situ of breast); and the anniversary date (i.e. date of diagnosis) is within the given year. The records should then be grouped by the cancer stage (where staging details are available) to obtain the various numerators. The denominator may be obtained from population estimates held by health authorities or other bodies.

**Data quality**

The method of data collection varies across regions but each region is obliged to attempt to collect the minimum data set for the national cancer registration system (NHS Executive 1996). The quality of the data will rely on the completeness and accuracy of data made available to registries. This may improve when the use of protocols is more widespread.

Although cancer registries attempt to collect staging data on all cancers, the proportion of registrations including staging data, has historically been poor. For example, in 1991 the Yorkshire Cancer Registry reported that only 12% of breast cancers were staged (Winstone-Partridge and Pheby 1996) but this performance has been improving rapidly in recent years. In some registries such as East Anglia, the proportion of breast cancer now being staged has reached as high as 80-98% (Stockton et al. 1997). The national minimum data set for cancer registration includes a baseline performance level of 30% but with a target for breast cancer of 80%. There will always be a proportion of cancers for which staging has not been possible - due to inadequate tissue sampling or no surgical attempt at sampling due to the severity of the case. In many cases, the lack of staging information is because the information has not been recorded in the patient's records.

It is also recognised that a proportion of breast cancer patients, estimated as not more than 5% for all types of breast cancers, are treated in the private sector. Agreement has been reached with the main private sector providers to register all cancers with the appropriate register.

**Comments**

No specific points.

**Further work required**

Final notification of the histopathology protocol for breast cancer.

**Conclusion & priority**

**A - To be implemented generally on a routine basis.**

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## Candidate indicator 1B

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

<b>Title</b>	<b>Detection rate of small primary breast cancers</b>
<b>Intervention aim</b>	Improve early detection and treatment of breast cancer.
<b>Definition</b>	For a given female population in a given year: <i>the number of invasive breast cancers less than 15mm (pathological size) diagnosed in women aged 50-64 as a result of a screening episode, occurring within the given year following an invitation from the NHSBSP, divided by the number of women aged 50-64 screened in the given year following an invitation from the NHSBSP.</i> This rate should be expressed as a rate per 1,000 women. Separate rates should be calculated for first time attenders (the 'prevalent round') and subsequent attenders (the 'incident round').
<b>Rationale</b>	Trials of breast cancer screening have shown that early detection can lead to a reduction in mortality from breast cancer in the population invited for screening by up to 25% (Shapiro et al. 1982, Tabar et al. 1992, Fletcher et al. 1993, Kerlikowske et al. 1995). The NHS Breast Screening Programme invites all women aged 50-64 to be screened every three years. Women aged 65 and older can elect to continue being screened although they are not currently invited.  The major impact of screening is in the detection of small invasive cancers. Evidence from the Swedish Two Counties study suggests that the prognosis is significantly better for invasive cancers smaller than 15 mm. Fifty five percent of all invasive cancers detected should be less than 15 mm if the 25% reduction in mortality is to be achieved. Target rates for detection of such small invasive cancers are thus 2.0 per 1,000 women screened in the prevalent round and 2.2 per 1,000 women screened in the incident round.
<b>Potential uses</b>	Evaluation of screening.
<b>Potential users</b>	National/regional policy makers; commissioners; cancer registries and regional breast screening quality awareness teams.
<b>Possible confounders</b>	Variability or inaccuracy in pathological measurements, particularly a tendency towards rounding to the nearest 5 or 10 mm.
<b>Data sources</b>	KC62 national statistical return for breast screening.
<b>Data quality</b>	The KC62 returns are routinely validated by the breast screening quality assurance reference centres and the data are generally reliable.

**Comments**

The minimum standards which have been set by the National Breast Screening Programme are 1.5 small cancers per 1,000 women screened in the prevalent round and 1.65 per 1,000 women screened in the incident round. All breast screening programmes are expected to achieve at least the minimum standard and any shortfall will be investigated by the quality assurance team. One third of units within the breast screening programme are expected to achieve the targets.

The indicator should be interpreted together with all standards for the NHS Breast Screening Programme for the population of interest. Data on all standards will be available locally for each screening unit and summary data from the KC62 are reported in the annual statistical bulletin on the breast screening programme (Department of Health 1997).

**Further work required** None recommended.

**Conclusion & priority** **A - To be implemented generally on a routine basis.**

**References**

Department of Health (1997). *Statistical bulletin: breast screening programme, England 1995-6*. Department of Health, London.

Fletcher, S.W., Black, W., Harris, R., Rimmer, B.K., and Shapiro, S. (1993). Report on the international workshop on screening for breast cancer. *Journal of the National Cancer Institute*, **85**, 1644-1656.

Moss, S., and Blanks, R. (1997). Calculating approximate target cancer detection rates and expected interval cancer rates for the UK NHS Breast Screening Programme. *Journal of Epidemiology and Community Health*, **52**, 111-115.

Shapiro, S., Veret, W., Strax, P., Veret, L., and Roeser, R. (1982). Ten to fourteen year effect of screening on breast cancer mortality. *Journal of the National Cancer Institute*, **69**, 349-355.

Tabar, L., Duffy, S.W., and Gad, A. (1992). Update of the Swedish two-county program of mammographic screening for breast cancer. *Radiologic Clinics of North America*, **30**, 187-210.

## Candidate indicator 2

### Characteristics

*Specificity:* Generic

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

<b>Title</b>	<b>Occurrence of interval breast cancers</b>
<b>Intervention aim</b>	Improve early detection and treatment of breast cancer.
<b>Definition</b>	For a given female population in a given year: <i>the number of women who had a negative breast cancer screening result in the given year and who were subsequently diagnosed with breast cancer within the following three years, divided by the number of women aged 50-64 screened in the given year following an invitation from the NHSBSP</i> . This rate should be expressed as a rate per 10,000 women screened in the given year. The yearly incidence of interval cancers over the three years could also be reported. Three years is included in the definition because this is the current screening interval. As the number of cancers detected for a single programme will be very small, in order to obtain meaningful data, it is suggested that figures are only analysed for larger populations of over a million. The rate for the given year can only be reported three years subsequently.
<b>Rationale</b>	Trials of breast cancer screening have shown that early detection can lead to a reduction in mortality from breast cancer in women by up to 25% (Shapiro et al. 1982, Tabar et al. 1992, Fletcher et al 1993, Kerlikowske 1995). The NHS Breast Screening Programme invites all women aged 50-64 to be screened every three years. Women aged 65 and older can elect to continue to participate in screening although there is currently no national policy to invite them for screening. An <i>interval cancer</i> is any breast cancer occurring within three years of a negative screening assessment. Although interval cancers are an inevitable feature of breast screening, poor sensitivity indicated in low cancer detection rates will result in higher than expected interval cancer rates in due course. Size, grade and lymph node stage of interval cancers should be ascertained since higher numbers of good prognosis interval cancers can result from a successful programme of breast awareness. Expected numbers of interval cancers have been calculated as 1.2 per 1,000 women screened in the first twenty four months after screening, and 1.3 per 1,000 women screened between twenty four and thirty six months after (Moss and Blanks 1998).
<b>Potential uses</b>	Evaluation of screening.
<b>Potential users</b>	National/regional policy makers, cancer registries and regional breast screening quality assurance teams.

**Possible confounders**

Variations in ascertainment practices and coding between cancer registries will affect comparisons. In addition, large populations are needed for statistical significance. Large populations will generally be served by several screening units. Units are not of uniform quality and problems in one unit may be disguised in the indicators covering the larger population. More sensitive indicators than interval breast cancer rates should be used to judge the performance of individual units. The interval cancer rate will also be higher where there is a significant level of private sector mammographic screening in the interval between NHS screens. It may also be higher where there are very effective symptomatic services. Finally, a small number of screening units operate a routine screening interval of less than three years.

**Data sources**

The cases of interval cancers can be identified by linking records held by the screening centres and cancer registries (Woodman et al. 1995). To obtain the relevant cases for this indicator any cases of cancer diagnosed within three years of the given screening year (excluding screen-detected cancers) should be matched with screening records with a negative result from the screening year in question. Name, date of birth and first line of the address may be used as patient identifiers. Universal use of the new NHS number will also assist this record linkage. The numerator will be given by the number of cases of cancer linked with a negative screen result within the three year period. The denominator is the total number of women screened in the given year. These figures should be available locally from the screening centres who then report their rates to the Department of Health as part of the Korner statistics.

**Data quality**

The quality of the data will depend on the completeness and quality of both screening and registry records, which are unlikely to be uniformly high. Incomplete ascertainment of interval cancers may lead to spurious comparisons of screening quality and incorrect conclusions.

**Comments**

If screening parameters change nationally, in the areas of frequency or age group, the expected rates for this indicator will need to be adjusted accordingly.

The indicator should be interpreted alongside the cancer detection rates for the population of interest and other screening programme performance indicators. Populations of at least a million women are needed to obtain statistically valid rates (Patrick and Gray 1993).

Since interval cancers manifest at some time interval from the previous screening episode this indicator can never reflect the current performance of a screening programme.

<b>Further work required</b>	Protocols are needed for communication between screening service, breast screening quality assurance and cancer registries. More definitional analysis is needed.
<b>Conclusion &amp; priority</b>	<b>E - To be further developed because further work is needed on the methods of measurement.</b>
<b>References</b>	<p>Fletcher, S.W., Black, W., Harris, R., Rimmer, B.K., and Shapiro, S. (1993). Report on the international workshop on screening for breast cancer. <i>Journal of the National Cancer Institute</i>, <b>85</b>, 1644-1656.</p> <p>Kerlikowske, K.M., Grady, D., Rubin, S.M., Sandrook, C.I. and Ernster, V.L. (1995). Efficacy of screening mammography. A meta-analysis. <i>Journal of the American Medical Association</i>, <b>273</b>, 149-154.</p> <p>Moss, S., and Blanks, R. (1997). Calculating approximate target cancer detection rates and expected interval cancer rates for the UK NHS Breast Screening Programme. <i>Journal of Epidemiology and Community Health</i>, <b>52</b>, 111-115.</p> <p>Patrick, J., and Gray, J.A.M. (1993). <i>Guidelines on the collection and use of breast cancer data</i>. NHS Breast Screening Programme, Sheffield.</p> <p>Shapiro, S., Veret, W., Strax, P., Veret, L., and Roeser, R. (1982). Ten to fourteen year effect of screening on breast cancer mortality. <i>Journal of the National Cancer Institute</i>, <b>69</b>, 349-355.</p> <p>Tabar, L., Duffy, S.W., and Gad, A. (1992). Update of the Swedish two-county programme of mammographic screening for breast cancer. <i>Radiologic Clinics of North America</i>, <b>30</b>, 187-210.</p> <p>Woodman, C.B.J., Threlfall, A.G., Boggis, C.R.M., and Prior, P. (1995). Is the three year breast screening interval too long? Occurrence of interval cancers in NHS breast screening programme's North Western Region. <i>British Medical Journal</i>, <b>310</b>, 224-226.</p>

## Candidate indicator 3

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

<b>Title</b>	<b>Incidence of invasive breast cancer following treatment for ductal carcinoma in situ (DCIS)</b>
<b>Intervention aim</b>	Improve early detection and treatment of breast cancer.
<b>Definition</b>	For a given provider unit population and year: <i>the number of women with invasive breast cancer who received treatment for DCIS in the previous 0 to 36 months (or 0 to 60 months), divided by the number of women treated for DCIS in the year and unit concerned.</i> The resulting fraction should be expressed as a percentage and reported with its associated numerator as overall crude and age-standardised figures for truncated age-groups. As well as the overall figures, the rate should be reported by the stage of DCIS at diagnosis (localised or widespread), whether it was screen detected or symptomatic and by the type of treatment received (see below).
	<i>Treatment type:</i>
	<ul style="list-style-type: none"> <li>- Conservative surgery only</li> <li>- Radiotherapy only</li> <li>- Surgery and radiotherapy</li> <li>- Other</li> <li>- Unknown.</li> </ul>
<b>Rationale</b>	The treatment for DCIS will depend on the stage of the disease at diagnosis. Limited surgery may be appropriate for low-grade (non-comedo) localised DCIS, with reported recurrence rates of 5% at eight years. Mastectomy with or without adjuvant therapy may be considered for high grade (comedo) or widespread DCIS. Survival rates following mastectomy for DCIS are high with 98% survival at five years. The rate of invasive carcinoma following DCIS may reflect both the appropriate assessment of disease in these women and the success of the various treatments given as part of their care (McPherson et al. 1995). However as DCIS is now commonly detected through the breast screening programme the figures for survival and recurrence in this group are likely to be different from those cited as they are related to a population diagnosed through symptomatic presentation, prior to the advent of the screening programme. Until rates of survival from screen detected cancers are available, trends over time may be difficult to interpret.
<b>Potential uses</b>	Provider based comparisons; clinical audit.
<b>Potential users</b>	Commissioners, clinicians.
<b>Possible confounders</b>	Patient choice of treatment.

**Data sources**

The denominator for this indicator should include all patients who have a diagnosis of DCIS (ICD10 - D05.1) within their records (in-patient, out-patient or day case records) and evidence of receiving treatment for the DCIS (such as surgery, or radiotherapy) in the relevant year. The latter information should be retrievable from patient notes, or accompanying operation and prescription charts. Relevant contract minimum data will be those episodes with an ICD10 diagnosis code of DCIS (D05.1) on admission and an OPCS4 code for surgical or radiotherapeutic procedures (e.g. B27- Total excision of breast, B28 - Other excision of breast, B32 - Biopsy of breast, B33 - Incision of breast, Y90.2 - Radiotherapy). As well as the CMDS, other non-in-patient records will also need to be searched to capture any patients who attend as day cases or out-patients to receive treatment for DCIS. Clinical information systems dedicated to breast care such as the BASO database (see indicator 6) or Thames Cancer Registry database will provide the best data for this indicator but may exist in only a few provider units. Where such systems are not available, periodic surveys of notes (in-patients, out-patients and day case) may prove the most reliable method by which to ascertain all cases.

The numerator will be the subset of patients from the denominator group who 0 to 36 months (or 0 to 60 months) later have a diagnosis of invasive breast cancer, (ICD-10 C50). Linkage of records using the new NHS number is required to ensure all cases are identified. However, although record linkage of CMDS records will identify relevant in-patient cases at any hospital, currently day or out-patient cases are not recorded as part of a mandatory data set or collected centrally and so could not be identified nationally. A more reliable source in the future may be if the cancer registries choose to record recurrences. One or two registries have begun reviewing cases a year after diagnosis with a view to capturing complete data on treatment. This method would also allow identification of any recurrences at one year.

**Data quality**

In those units where specialised information systems are in place, the index case data may be quite reliable as it is those entering data into the system who both use it and benefit from it. Where a survey of the notes is the only source, the quality of the data will depend on the quality of the notes which may not be uniformly high. The problem remains as to the follow-up of patients and identifying those with a subsequent diagnosis of invasive cancer. Reliance on the new NHS number to link CMDS records will provide a proportion of the cases but is likely to miss day attenders as stated above. While information on day attenders and out-patients is not part of a mandatory data set and collected centrally it is unlikely that this information will be complete or available for record linkage nationally.

<b>Comments</b>	The validity of this indicator is undermined by data sources which are unlikely to yield complete data.
<b>Further work required</b>	Further research as to the issues underlying the differences between symptomatic and non-symptomatic DCIS and whether they should be reported together or separately. Consideration should also be given as to whether a more appropriate denominator might include all DCIS not solely treated DCIS.
<b>Conclusion &amp; priority</b>	<b>E - To be further developed because further work is needed on the methods of measurement.</b>
<b>References</b>	McPherson, K., Steel, C.M., and Dixon, J.M. (1995). Breast cancer: epidemiology, risk factors, and genetics. In <i>ABC of Breast Diseases</i> (ed. J Dixon). BMJ Publishing Group, London.

## Candidate indicator 4

### Characteristics

*Specificity:* Generic

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

<b>Title</b>	<b>Survival rates by cancer stage at diagnosis</b>
<b>Intervention aim</b>	Reduce death and complications from breast cancer and its treatment.
<b>Definition</b>	For a female resident population and year: <i>the number of women who are alive now who were diagnosed with breast cancer five (or ten) years earlier, divided by the number of women diagnosed with breast cancer in the given year</i> . The resulting fractions should be expressed as percentages for five and ten years and reported with associated numerators and denominators, as both crude and age-specific, age-standardised figures. Rates should also be reported by stage of cancer at diagnosis (see staging classification discussion in Indicator 1).
<b>Rationale</b>	Accounting for variation in survival at five and ten years after treatment for cancer could lead to improvements in care, and subsequent survival. If breast cancer is detected early and treated appropriately, the five year survival rate can be over 80% (Miller et al. 1995). Variation in five year survival rates is apparent within Europe. In 1990, England reported a rate of 62.5%, whereas in Switzerland, Finland, France and Italy it was over 70% (Effective Health Care 1996). Variations continue to exist between areas and providers when survival rates are adjusted by cancer stage (Effective Health Care 1996). There is also some evidence of variations resulting from different care management. One study found the five-year survival rate was 9% higher for patients cared for by specialist surgeons compared to those cared for by surgeons with no specialist interest when controlling for tumour stage, age and socio-economic status (Gillis and Hole 1996). Monitoring survival rates across different countries will allow comparisons of the effectiveness of health care at a national level.
<b>Potential uses</b>	National and local population based comparisons of the effectiveness of health care.
<b>Potential users</b>	Policy makers, commissioners, clinicians, public.
<b>Possible confounders</b>	Comparisons should be made in the context of case-mix information covering the severity and co-morbidity of the patient populations (see data sources).

**Data sources**

If available, denominator data should be obtained from the cancer registry for the given resident population and given as the number of breast cancers registered in the given year. Where linkage is feasible, survival of all patients up to the end of both five and ten years should be ascertained from death certificates linked by an identifier. All death certificates which mention a cancer are forwarded to a cancer registry.

With general linkage of hospital activity and death certificate data, previous admissions for relevant morbidities in the two years before and one month after the date treatment commenced for cancer could be derived from the CMDS records, and used as a basis for standardisation. However, this would require universal use of the new NHS number. This method was used by the Scottish Clinical Outcomes Groups in their report on Clinical Outcome Indicators (Clinical Outcomes Working Group 1995).

**Data quality**

The validity of this indicator will depend on the quality of information on death certificates. In a study of the accuracy of death certificate information, breast cancer was one of the diseases which was correctly reported in a high proportion of cases (Goldacre 1993). Variation in the availability of information on the staging of tumours may affect the interpretation of the indicator.

Variations between regions may reflect differences in the processing of death certificates and the diligence with which registries seek evidence to confirm the diagnosis of such cancers. The NHSE core contract (1996/7) for cancer registries recommends that the proportion of Death Certificate Only (DCO) registrations for which no further information is available should be no more than 5% (target 2%) of all registrations (NHS Executive 1996). Where no other information can be found registration is limited to information contained on the death certificate. DCOs are therefore normally excluded from survival analysis and variation in the extent of follow-up on receipt of death certificates has implications for comparing survival between geographical regions (Winstone-Partridge and Pheby 1996). The problem of DCOs is likely to be less of an issue with breast cancer than some other cancers.

**Comments**

Small numbers may mean aggregation at the regional level and above is required. Other time frames of say 15 years may also be useful.

**Further work required**

None recommended.

**Conclusion & priority**

**A - To be implemented generally on a routine basis.**

**References**

- Clinical Outcomes Working Group of the Clinical Resource and Audit Group (1995). *Clinical outcome indicators*. NHS in Scotland, The Scottish Office.
- Effective Health Care (1996). *The management of breast cancer*. University of Leeds and University of York.
- Gillis, C.G., and Hole, D.J. (1996). Survival outcome of care by specialist surgeons in breast cancer: a study of 3786 patients in the West of Scotland. *British Medical Journal*, **312**, 145-148.
- Goldacre, M.J. (1993). Cause-specific mortality: understanding uncertain tips of the disease iceberg. *Journal of Epidemiology and Community Health*, **47**, 491-496.
- Miller, W.R., Ellis, I.O., and Sainsbury, J.R.C. (1995). Prognostic factors. In *ABC of breast diseases* (ed. J Dixon). BMJ Publishing Group, London.
- NHS Executive (1996). *Cancer registries: core contract specification*. EL(96)7. Department of Health, Leeds.
- Winstone-Partridge, C.J., and Pheby, D.F.H. (1996). *Final report of the nationwide audit of the quality and comparability of data held by regional cancer registries*. University of the West of England, Bristol.

## Candidate indicator 5

### Characteristics

*Specificity:* Generic

*Perspective:* Population

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

<b>Title</b>	<b>Population-based mortality rates from breast cancer in women</b>
<b>Intervention aim</b>	Reduce death and complications from breast cancer and its treatment.
<b>Definition</b>	From the Public Health Common Data Set indicator CDS-C4 (Department of Health 1993b). For a given female population, year and age-group: <i>deaths from malignant neoplasm of female breast (ICD 10 - C50) per 100,000 female population</i> . The resulting figures should be given as age-standardised rates and reported in five yearly age-groups with the associated numerator reported separately.
<b>Rationale</b>	The Health of the Nation initiative identified breast cancer as one of the key areas, and a target was set to reduce the death rate for breast cancer in the population invited for screening by at least 25% by the year 2000 (from a baseline in 1990) (Secretary of State for Health 1992).
<b>Potential uses</b>	National population based comparisons of the effectiveness of health advice and care.
<b>Potential users</b>	Policy makers, commissioners.
<b>Possible confounders</b>	Comparisons should be made in the context of case mix information covering the severity and co-morbidity of the patient populations (see data sources).
<b>Data sources</b>	The data should be obtained from the cancer registry for deaths from breast cancer within the given resident population.  With general linkage of hospital activity and death certificate data, previous admissions for relevant morbidities in the two years before and one month after the date treatment commenced for cancer could be derived from the CMDS records, and used as a basis for standardisation. This would however require universal use of the new NHS number. This method was used by the Scottish Clinical Outcomes Groups in their report on clinical outcome indicators (Clinical Outcomes Working Group 1995).
<b>Data quality</b>	The validity of this indicator will depend on the quality of information on death certificates. However, in a study of the accuracy of death certificate information, breast cancer was correctly reported in a high percentage of cases (Goldacre 1993).
<b>Comments</b>	For comparison with PHCDS data, rates may be reported for the following age-groups: 35-64, 65-74 and 75+ years.

**Further work required** None recommended.

**Conclusion & priority** **A - To be implemented generally on a routine basis.**

**References** Clinical Outcomes Working Group of the Clinical Resource and Audit Group (1995). *Clinical outcome indicators*. NHS in Scotland, The Scottish Office.

Department of Health (1993b). *Public health common data set 1993. Part 1: indicator definitions*. Institute of Public Health, University of Surrey.

Goldacre, M.J. (1993). Cause-specific mortality: understanding uncertain tips of the disease iceberg. *Journal of Epidemiology and Community Health*, **47**, 491-496.

Secretary of State for Health (1992). *The Health of the Nation: a strategy for health in England*. HMSO, London.

## Candidate indicator 6

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Patient/clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Indirect

<b>Title</b>	<b>Percentage of patients diagnosed as having breast cancer who had received a diagnostic triple assessment</b>
<b>Intervention aim</b>	Reduce death and complications from invasive breast cancer and its treatment.
<b>Definition</b>	For a given female provider unit population, and year: <i>the number of women diagnosed with breast cancer within three months following symptomatic presentation who had previously received a 'triple assessment', divided by the number of women diagnosed with breast cancer following symptomatic presentation for a given provider unit and year.</i> The resulting fraction should be expressed as a percentage, and its associated numerator and denominator reported separately.
<b>Rationale</b>	Diagnosis of a breast lesion is determined from three complementary investigations - clinical examination, imaging, and fine needle aspiration cytology (FNAC) or other acceptable means of obtaining a tissue sample often referred to as a 'triple assessment'. A review of the evidence supports this type of assessment as a sensitive diagnostic process, detecting 95-100% of cancers (Effective Health Care 1996).
	The indicator is specified to identify cases of breast cancer as the denominator rather than those women presenting with breast symptoms to recognise that for many women presenting with a breast complaint the triple assessment will not have been required. Significant changes in the indicator rate may highlight deficiencies in the service and promote action to rectify any problems. Comparisons across breast units/clinics may also detect variations worthy of investigation.
<b>Potential uses</b>	Commissioning of services; planning and management of services; clinical audit.
<b>Potential users</b>	Commissioners and providers, clinicians.
<b>Possible confounders</b>	No specific ones identified.
<b>Data sources</b>	The Breast Surgeons Group of the British Association of Surgical Oncology commissioned the development of a database (the BASO database) (Clatterbridge Centre for Oncology 1997) with funding from Zeneca Pharmaceuticals, to assist and promote the collection of a comprehensive data set within breast cancer units for every women receiving health care for breast disease. The database is currently being used by an estimated 100-150 of the 300 breast units in the country to collect routine data on each patient. In the future it is anticipated that there will be central aggregation of the locally collected data for analysis on a larger scale (Forbes, personal communication). Thames Cancer Registry also have an ongoing project which collects a similar data set from all NHS trusts in their region (Bell and Ma 1997).

The indicator would most easily be derived from this database or similar locally developed databases where an equivalent level of detail is collected on each cancer. Denominator data will be the number of patients diagnosed with breast cancer following symptomatic presentation in the given year. The data set variable 'source of referral' allows the selection of patients referred from their GP or self referred with symptoms of breast cancer, and the exclusion of those referred following diagnosis through the NHS Breast Screening Programme. The numerator will be the subset of those who present symptomatically who are subsequently diagnosed with breast cancer, for whom the following three procedures have all been recorded as undertaken within two weeks: clinical examination, mammogram, and fine needle aspiration cytology (FNAC) or similar procedure such as core biopsy. Triple assessment should normally take place on the same day.

The Breast Surgeons Group are encouraging all breast care units to use the BASO database so it is anticipated that all units may be collecting data in this structured way in the future. In the meantime however, other local systems may yield these data. Alternatively, the out-patient contract minimum data set can provide much of the data by identifying the number of out-patient episodes with a diagnosis code of breast cancer (ICD-C50). The numerator would be given by the subset of this group for whom the following procedures are recorded as having been undertaken: FNAC (Read - 71382; OPCS4 - 37.1); Mammogram (Read - 537..); and Breast examination (Read - XB002) (NHS Centre for Coding and Classification 1997). Unfortunately the data set does not discriminate between referrals from the NHS breast screening programme and self- or GP-referrals.

The final method, practical on a periodic basis, would be through surveys of a sample of notes.

The data collection difficulties will ease as breast services become properly organised and over the next two years it should be possible to obtain these data universally and routinely.

#### **Data quality**

As the database and its use is in the early stages, there is no information on the quality of the information. Although validation checks are being built into the latest version to improve data entry, the quality of the data collected will only be truly tested through use of the data.

The collection of the out-patient minimum data set is not mandatory, therefore it is likely that data will be incomplete within trusts and may not be available for comparisons across trusts. Validation of the completeness of this data set through a survey of notes may be worthwhile.

<b>Comments</b>	No specific points.
<b>Further work required</b>	Testing and comparisons of validity of indicator using different data sets currently available.
<b>Conclusion &amp; priority</b>	<b>A - To be implemented generally on a routine basis.</b>
<b>References</b>	<p>Clatterbridge Centre for Oncology (1997). <i>BASO Breast Unit Database Version 1.0</i>. Clatterbridge Centre for Oncology, Wirral.</p> <p>Effective Health Care (1996). <i>The management of breast cancer</i>. University of Leeds and University of York.</p> <p>NHS Centre for Coding and Classification (1997). <i>The Read Codes, March 1997 demonstrator</i>. NHS Executive, Leeds.</p> <p>Bell, J., and Ma, M. (1997). <i>Prospective audit of breast cancer</i>. North Thames Cancer Registry, London.</p>

## Candidate indicator 7

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Indirect

<b>Title</b>	<b>Percentage of patients with breast cancer under the care of a breast care specialist</b>
<b>Intervention aim</b>	Reduce death and complications from breast cancer and its treatment.
<b>Definition</b>	For a given female population in a given year: <i>the number of women diagnosed with breast cancer, who were seen by a designated or trained breast surgeon, divided by the number of women diagnosed with breast cancer in the given year and population.</i> The resulting fraction should be expressed as a percentage, and its associated numerator and denominator reported separately. The indicator should also state the type of population for which it is reporting e.g. hospital provider unit population or resident population.
<b>Rationale</b>	Guidelines for surgeons in the management of symptomatic breast disease in the United Kingdom recommend that specialist breast clinics have a surgeon with a specific interest and training in breast disease, and work within a properly staffed and equipped multi-disciplinary breast clinic (Breast Surgeons Group of the British Association of Surgical Oncology 1995). This indicator identifies the proportion of women seen by an appropriately trained breast surgeon. Within breast care units, consultants are identified by the unit itself as 'trained breast surgeons' and these are made known to the regional cancer co-ordinator. The indicator may be helpful in identifying those units where women are not typically seen by a trained breast surgeon and allow closer examination of the reasons for this practice.
	This indicator may be collected and aggregated for different populations: a provider unit hospital population, or resident population (see data sources).
<b>Potential uses</b>	Commissioning, planning and management of services.
<b>Potential users</b>	Commissioners, provider management, clinicians and the public.
<b>Possible confounders</b>	Definition of trained breast surgeon across trusts.
<b>Data sources</b>	<i>For a provider unit population:</i> Unless dedicated clinical information systems are available which support the collection of breast care data (e.g. BASO database or Thames Cancer Registry clinical database) this information would need to be gathered through a periodic survey of the notes. For those units collecting data via the BASO database, the 'initial visits' section collects data on whether the women were seen by a consultant, the name of the consultant, whether they were a 'trained breast surgeon', the name of the trained breast surgeon or whether they were 'seen by other'. The numerator will be those patients seen by a 'trained breast surgeon who is a consultant' (Clatterbridge Centre for Oncology 1997). Denominator data should be taken as the number of patients with a diagnosis of breast cancer dated in the given year.

*For a resident population:*

On each cancer registry return reporting a diagnosis of cancer, information on the consultant is included. Each cancer registry is also provided with information from the regional cancer co-ordinator as to who are 'trained breast surgeons' within breast care units and centres. Some registries, e.g. North Western region, already collect this indicator annually (Dey, personal communication).

Currently there is a duplication of data collection. Ideally, the rates for the different populations should be used alongside one another and examined as to which is yielding the more accurate and complete data.

**Data quality**

There is currently no specific information on the quality of data yielded using the BASO database, although the second version does include validation checks for data entry.

There has been little research into the quality of data collected within the regional cancer registries. One recent study investigating the quality and comparability of data held by the registries found that there were discrepancies in incidence dates which effect survival rate calculations and there was room for improvement in the coding of treatments. Principally, it reported the need for convergence in the methods and types of data collection across registries to allow meaningful comparisons across populations (Winstone-Partridge and Pheby 1997). Many aspects of the quality of cancer registry data, particularly completeness, is however limited by the quality of the information documented in the clinical records which registries often use as their key source.

**Comments**

It should be recognised that in the near future all hospitals which offer a breast care service will have specialist consultants, and so over time the required standard for this indicator should approach 100%.

Currently, there are no specified training requirements to become identified as a 'trained breast surgeon', and units themselves are responsible for their identification. Without consistency, the difficulty in interpreting this indicator may reduce its value.

**Further work required**

None recommended.

**Conclusion & priority**

**A - To be implemented generally on a routine basis.**

**References**

- Breast Surgeons Group of the British Association of Surgical Oncology (1995). Guidelines for surgeons in the management of symptomatic breast disease in the United Kingdom. *European Journal of Surgical Oncology*, **21** (suppl. A), 1-13.
- Clatterbridge Centre for Oncology (1997). *BASO Breast Unit Database Version 1.0*. Clatterbridge Centre for Oncology, Wirral.
- Winstone-Partridge, C.J., and Pheby, D.F.H. (1996). *Final report of the nationwide audit of the quality and comparability of data held by regional cancer registries*. University of the West of England, Bristol.

## Candidate indicator 8

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Indirect

<b>Title</b>	<b>Percentage of patients receiving treatment for breast cancer whose care was planned jointly by a multi-disciplinary group</b>
<b>Intervention aim</b>	Reduce death and complications from breast cancer and its treatment.
<b>Definition</b>	<p>For a given female population in a given year: <i>the number of women diagnosed with breast cancer in the given year, whose primary management was based on assessment by a functioning specialist breast care team (COG definition) within two weeks of diagnosis, divided by the number of women diagnosed with breast cancer in the given year and population.</i> The resulting fraction should be expressed as a percentage, and its associated numerator and denominator reported separately.</p> <p><i>In the COG definition</i> (Clinical Outcomes Group 1996) <i>core members of the breast care team</i> are designated breast surgeons, breast care nurses, pathologist, radiologist and oncologists.</p> <p>The indicator should also state the type of population for which it is reporting e.g. hospital provider unit population or resident population.</p>
<b>Rationale</b>	<p>It is recognised that breast cancer care should be provided by breast specialists in each discipline, working as a team and providing services from early detection through to care of the advanced disease (Breast Surgeons Group of the British Association of Surgical Oncology 1995). Close liaison should be maintained between surgeons and radiotherapists/oncologists to plan primary treatment and facilitate subsequent adjuvant therapy. Core members of the breast team should meet formally to discuss the diagnosis and management of women with breast cancer under their care.</p> <p>This indicator by identifying the proportion of women assessed by core members of the breast cancer team will identify the proportion of women who are receiving a multi-disciplinary team approach to their care. Comparison across units will allow closer attention to be given to areas where the proportion is low.</p> <p>This indicator may be collected and aggregated for different populations: either for the provider unit hospital population, or the resident population (see data sources).</p>
<b>Potential uses</b>	Commissioning, planning, and management of services.
<b>Potential users</b>	Commissioners, purchasers and clinicians.
<b>Possible confounders</b>	No specific ones identified.

## Data sources

### *For a provider unit population:*

Unless dedicated clinical information systems are available which support the collection of breast care data (e.g. BASO database or Thames Cancer Registry clinical database) this information would need to be gathered through a periodic survey of the notes. For those units collecting data using the BASO database, information is recorded on whether the patient was seen by a specialist breast surgeon, and whether the patient was given the opportunity to see the breast care nurse (in both the initial and follow-up visit form sections), however there is no specific recording for assessments by radiologists or cytologists. This information would need to be collected directly from the notes. The numerator will be those patients seen by all members of this core team. Denominator data should be taken as the number of patients with a diagnosis of breast cancer dated in the given year. In hospitals without dedicated breast care information systems audit of the notes on a periodic survey basis will be needed to collect this information.

### *For a resident population:*

Some cancer registries are working with their health authorities and collecting indicators in these areas e.g. the North Western Regional Cancer Registry has collected data on the proportion of women with invasive breast cancer seen by a breast care nurse prior to definitive treatment and the proportion of women seen by core members of the breast team. This was done by periodic surveys of medical and breast cancer nurse specialists' notes (Dey, personal communication).

Currently there is a duplication of data collection. Ideally, the rates for the different populations should be used alongside one another and examined as to which is yielding the more accurate and complete data.

## Data quality

There has been no assessment of the quality of BASO data, and this is likely to vary from unit to unit.

There has been little research into the quality of data collected within the regional cancer registries. One recent study investigating the quality and comparability of data held by the registries found that there were discrepancies in incidence dates which effect survival rate calculation and there was room for improvement in the coding of treatments. Principally, it reported the need for convergence in the methods and types of data collection across registries to allow meaningful comparisons across populations (Winstone-Partridge and Pheby 1997). Many aspects of the quality of cancer registry data, particularly completeness, is however limited by the quality of the information documented in the clinical records which registries often use as their key source.

<b>Comments</b>	No specific points.
<b>Further work required</b>	None recommended.
<b>Conclusion &amp; priority</b>	<b>B - To be implemented generally by periodic survey.</b>
<b>References</b>	<p>Breast Surgeons Group of the British Association of Surgical Oncology (1995). Guidelines for surgeons in the management of symptomatic breast disease in the United Kingdom. <i>European Journal of Surgical Oncology</i>, <b>21</b> (suppl. A), 1-13.</p> <p>Clinical Outcomes Group (1996). <i>Guidance for purchasers: improving outcomes in breast cancer</i>. NHS Executive, Leeds.</p> <p>Winstone-Partridge, C.J., and Pheby, D.F.H. (1996). <i>Final report of the nationwide audit of the quality and comparability of data held by regional cancer registries</i>. University of the West of England, Bristol.</p>

## Candidate indicator 9

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Indirect

<b>Title</b>	<b>Percentage of patients who, having undergone potentially curative surgery for breast cancer, were given chemotherapy as part of their primary treatment</b>
<b>Intervention aim</b>	Reduce death and complications from breast cancer and its treatment.
<b>Definition</b>	For a given female population having undergone potentially curative surgery for non-metastatic breast cancer in a given year: <i>the proportion of women receiving polychemotherapy as part of their primary treatment for breast cancer within six months of their surgery</i> . The resulting fraction should be expressed as a percentage and reported with its associated numerator in the following age-groups: < 50; 50 to 69; and 70+. Ideally, the indicator should also be reported by type of surgery i.e. none, mastectomy, and breast conserving surgery, and whether the treatment was polychemotherapy or single-agent chemotherapy. The indicator should also state the type of population for which it is reporting e.g. hospital provider unit population or resident population.
<b>Rationale</b>	Adjuvant therapy is given in an attempt to control micrometastatic disease. Early trials evaluating the benefits of chemotherapy in women with node-positive disease have demonstrated better outcomes in terms of a reduction in local recurrence and overall survival (Sledge 1996). A systematic review of all trials since 1985 have shown highly significant reductions in the annual rates of recurrence and of death as a result of tamoxifen and polychemotherapy (Early Breast Cancer Trialists' Collaborative Group 1992). It is suggested that the indicator is reported by the type of chemotherapy as it has been shown that polychemotherapy is significantly better than a single-agent (Early Breast Cancer Trialists' Collaborative Group 1992). Risk reductions have been demonstrated in patients who are both node-positive and node-negative, although the absolute improvement in ten year survival is about twice as great for the former (at least twelve deaths avoided per 100 women treated) as for the latter (Early Breast Cancer Trialists' Collaborative Group 1992).
	The indicator is specified to report the results in various age-groups since it is recognised that its effectiveness varies with age. In particular it is recognised that patients over 70 tend to benefit less from chemotherapy.
<b>Potential uses</b>	Clinical audit and provider based comparisons; commissioning.
<b>Potential users</b>	Clinicians, provider management, commissioners.
<b>Possible confounders</b>	For some patients, there may be contraindications for chemotherapy and these patients should be reported on separately as should women who decline chemotherapy. Migration of patients may confound this indicator if linkage of all relevant records nationwide is not possible. There may be rare occasions when a woman has two primaries and chemotherapy is given for the other cancer.

**Data sources***For a provider unit population:*

Records relevant to the numerator will be included among hospital records (in-patient and out-patient) within an 18 month period from the start of the given year, which record a primary diagnosis of breast cancer (ICD10-C50) without reference to metastases (e.g. C79.5, C79.7, C80), and relevant procedures for chemotherapy (e.g. intramuscular - X37.3, intravenous - X35.2, and sub-cutaneous - X38.4) with a start date within six months of their surgery date. To obtain the relevant sub-set of cases relating to surgery in the given year and unit, these records must be linked by means of a patient identifier (ideally the NHS number) to CMDS data for the given year and unit with a primary diagnosis of breast cancer on admission (ICD10-C50) without reference to metastases (e.g. C79.5, C79.7, C80), and a relevant surgical procedure for breast cancer (OPCS4 - B27, or B28).

The denominator data will be obtained from CMDS data for the given year and unit with a primary diagnosis of breast cancer on admission (ICD10-C50) without reference to metastases (e.g. C79.5, C79.7, C80), and a relevant surgical procedure for breast cancer (OPCS4 - B27, or B28).

Alternatively, for those units which use the BASO database or similar dedicated breast cancer information systems (e.g. the Thames Cancer Registry clinical database) this information may be more readily available. The BASO data set has a dedicated non-surgical treatment section where the treatment type and date when treatment started is recorded. Whether chemotherapy was given pre- or post-operatively can be recorded plus the specific regime (including whether this is single agent or otherwise). Specific operation details are also collected to facilitate reporting the indicator by type of surgery.

*For a resident population:*

For population level data, cancer registries record treatment details for each cancer registered, including the date, hospital, type of treatment and the consultant leading the care. Some regions are already using this information to compile similar indicators e.g. the North Western Regional Cancer Registry records the proportion of women with invasive breast cancer aged 49 years or less with positive axilla lymph nodes who receive adjuvant chemotherapy, expressed as a proportion of all women resident in a health authority aged 49 years or less in a similar time period (Dey, personal communication).

**Data quality**

The validity of the data relies on the quality of both diagnosis and procedure coding as well as identifying those patients who migrate away from where they receive their original surgery. The level at which drug therapy such as chemotherapy is routinely coded as part of the CMDS is unknown but likely to be variable across trusts. Although use of the new NHS number would allow linkage of CMDS records across hospitals, care provided on an out-patient basis would require universal collection of the out-patient minimum data set which is not currently mandatory. Manual systems of surveying notes may enhance accuracy but would be costly in staff time. There has been no assessment of the quality of BASO data, and this is also likely to vary from unit to unit.

There has been little research into the quality of data collected within the regional cancer registries. One recent study investigating the quality and comparability of data held by the registries found that there were discrepancies in incidence dates which effect survival rate calculation and there was room for improvement in the coding of treatments. Principally, it reported the need for convergence in the methods and types of data collection across registries to allow meaningful comparisons across populations (Winstone-Partridge and Pheby 1997). Many aspects of the quality of cancer registry data, particularly completeness, is however limited by the quality of the information documented in the clinical records which registries often use as their key source.

**Comments**

No specific points.

**Further work required**

Pilot study to evaluate quality of data on CMDS records with particular respect to chemotherapy interventions.

**Conclusion & priority**

**A - To be implemented generally on a routine basis.**

**References**

- Early Breast Cancer Trialists' Collaborative Group (1992). Systemic treatment of early breast cancer by hormonal, cytotoxic, or immune therapy. *Lancet*, **339**, 1-15, 71-85.
- Sledge, G.W. (1996). Adjuvant therapy for early stage breast cancer. *Seminars in Oncology*, **23**(1 Suppl 2), 51-54.
- Winstone-Partridge, C.J., and Pheby, D.F.H. (1996). *Final report of the nationwide audit of the quality and comparability of data held by regional cancer registries*. University of the West of England, Bristol.

## Candidate indicator 10

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Indirect

<b>Title</b>	Percentage of patients who, having undergone potentially curative surgery for breast cancer, were given radiotherapy as part of their primary treatment
<b>Intervention aim</b>	Reduce death and complications from breast cancer and its treatment.
<b>Definition</b>	For a given female population having undergone potentially curative surgery for non-metastatic breast cancer in a given year: <i>the proportion of women receiving radiotherapy, as part of their primary treatment for breast cancer within six months of their surgery</i> . The resulting fraction should be expressed as a percentage and reported with its associated numerator by the following age-groups: < 50; 50 to 69; and 70+. Ideally, the indicator should also be reported by type of surgery i.e. none, mastectomy, and breast conserving surgery. The indicator should also state the type of population for which it is reporting e.g. hospital provider unit population or resident population.
<b>Rationale</b>	Following surgery for breast cancer, adjuvant therapy will be considered. An overview of randomised trials looking at the effects of radiotherapy and surgery in early breast cancer compared to surgery alone, demonstrated a recurrence rate three times lower in those receiving radiotherapy (Early Breast Cancer Trialists' Collaborative Group 1995). A delay of six months or more in the administration of radiotherapy has been associated with worse local control and overall survival rates (Buchholz et al. 1993). It has been recommended that radiotherapy, whenever feasible, should not be delayed beyond 16 weeks (Harris and Recht 1993).
	This indicator identifies the proportion of women who are given radiotherapy as part of their primary treatment within a given provider unit and/or resident population, both of which are of potential value to local commissioners. Some health authorities are setting standards for the treatment of this group of women. For example Wigan and Bolton HA have set a standard that the proportion of women with invasive breast cancer undergoing breast conserving surgery who receive radiotherapy should be 90%. Even where absolute standards are not specified the indicator will allow the identification of those units whose rates vary greatly and so provide a focus for closer inspection.
<b>Potential uses</b>	Clinical audit and provider based comparisons; commissioning.
<b>Potential users</b>	Clinicians, provide management, commissioners.
<b>Possible confounders</b>	For some patients, there may be contra-indications for radiotherapy and these should be excluded from analysis and reported separately as should women who decline chemotherapy. Migration of patients may confound this indicator if linkage of all relevant records nationwide is not possible.

## Data sources

### *For a provider unit population:*

Records relevant to the numerator will be included among hospital records (in-patient and out-patient) within an 18 month period from the start of the given year, which record a primary diagnosis of breast cancer (ICD10-C50) without reference to metastases (e.g. C79.5, C79.7, C80), and relevant procedures for radiotherapy (OPCS-4 - Y90.2/Read code: Xa851) with a start date within six months of their surgery date. To obtain the relevant sub-set of cases relating to surgery in the given year and unit, these records must be linked by means of a patient identifier (ideally the NHS number) to CMDS data for the given year and unit with a primary diagnosis of breast cancer on admission (ICD10-C50) without reference to metastases (e.g. C79.5, C79.7, C80), and a relevant surgical procedure for breast cancer (OPCS4 - B27, or B28).

The denominator data will be obtained from CMDS data for the given year and unit with a primary diagnosis of breast cancer on admission (ICD10-C50) without reference to metastases (e.g. C79.5, C79.7, C80), and a relevant surgical procedure for breast cancer (OPCS4 - B27, or B28).

Alternatively, for those units which use the BASO database or similar dedicated breast cancer information systems (e.g. the Thames Cancer Registry clinical database), this information may be more readily available. The BASO data set has a dedicated non-surgical treatment section where the treatment type and date when treatment started is recorded. Whether radiotherapy was given as treatment and to which site(s) e.g. breast, chest wall, or axilla should be identifiable. Specific operation details are also collected to facilitate reporting the indicator by type of surgery.

### *For a resident population:*

For population level data, cancer registries record treatment details for each cancer registered, including the date, hospital, type of treatment and the consultant leading the care. Some regions are already using this information to compile similar indicators e.g. the North Western Regional Cancer Registry records the proportion of women with invasive breast cancer undergoing breast conserving surgery who receive radiotherapy (Dey, personal communication).

## Data quality

The validity of the data relies on the quality of both diagnosis and procedure coding as well as identifying those patients who migrate away from where they receive their original surgery. The extent to which radiotherapy treatment is routinely coded as part of the CMDS is unknown but likely to be variable across trusts. Although use of the new NHS number would allow linkage of CMDS in-patient records across hospitals, care provided on an out-patient basis would require universal collection of the out-patient minimum data set which is not currently mandatory. Manual systems of surveying notes may enhance accuracy but would be costly in staff time. There has been no assessment of the quality of BASO data, and this is also likely to vary from unit to unit.

There has been little research into the quality of data collected within the regional cancer registries. One recent study investigating the quality and comparability of data held by the registries found that there were discrepancies in incidence dates which effect survival rate calculation and there was room for improvement in the coding of treatments. Principally, it reported the need for convergence in the methods and types of data collection across registries to allow meaningful comparisons across populations (Winstone-Partridge and Pheby 1997). Many aspects of the quality of cancer registry data, particularly completeness, is however limited by the quality of the information documented in the clinical records which registries often use as their key source.

#### **Comments**

Following recent results from two prospective 15 year studies (Overgaard et al. 1997; Ragaz et al. 1997) suggesting that radiotherapy as well as chemotherapy in pre-menopausal node-positive women greatly improves survival, it has been proposed that all breast cancer patients with positive nodes treated by mastectomy should have radiation therapy to the chest wall and internal mammary nodes. It has also been suggested that such treatment be extended to patients who undergo breast conserving surgery (Wise 1997). Such developments may have implications for Indicators 9 and 10 which may need adjustment in the future if such therapy becomes part of common practice.

#### **Further work required**

None recommended.

#### **Conclusion & priority**

**A - To be implemented generally on a routine basis.**

#### **References**

Buchholz, T.A., Austin-Seymour, M.M, Moe, R.E., Ellis, G.K., Livingston, R.B., Pelton, J.G., and Griffin, T.W. (1993). Effect of delay in radiation in the combined modality treatment of breast cancer. *International Journal of Radiology, Oncology, Biology and Physiology*, **26**, 23-35.

Early Breast Cancer Trialists' Collaborative Group (1995). Effects of radiotherapy and surgery in early breast cancer. *New England Journal of Medicine*, **333**, 1444-1455.

Harris, J.R., and Recht, A. (1993). Sequencing adjuvant chemotherapy and radiotherapy in breast cancer patients. *International Journal of Radiology, Oncology, Biology and Physiology*, **26**, 183-185.

Overgaard, M., Hansen, P.S., Overgaard, J., Rose, C., Andersson, M., Bach, F., Kjer, M., Gadeberg, C.C., Mouridsen, H.T., Jensen, M., and Zedeler, K. for the Danish Breast Cancer Co-operative Group 82b Trial (1997). Post-operative radiotherapy in high-risk pre-menopausal women with breast cancer who receive adjuvant chemotherapy. *New England Journal of Medicine*, **337**, 949-955.

Ragaz, J., Jackson, S.T., Le, N., Plenderleith, I.H., Spinelli, J.J., Basco, V.E., Wilson, K.S., Knowling, M.A., Coppin, C.M.L., Paradis, M., Coldman, A.J., and Olivotto, I.A. (1997). Adjuvant radiotherapy and chemotherapy in node-positive pre-menopausal women with breast cancer. *New England Journal of Medicine*, **337**, 956-962.

Winstone-Partridge, C.J., and Pheby, D.F.H. (1996). *Final report of the nationwide audit of the quality and comparability of data held by regional cancer registries*. University of the West of England, Bristol.

Wise, J. (1997). Radiotherapy plus chemotherapy is best for breast cancer. *British Medical Journal*, **315**, 902.

## Candidate indicator 11

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

### Title

**Recurrence rates of breast cancer by site and type of primary surgery**

### Intervention aim

Reduce death and complications from breast cancer and its treatment.

### Definition

In a given year and unit, for that female population who had undergone surgery for breast cancer x years previously: *the number of patients who have experienced a recurrence of their disease in each recurrence classification category (see below), divided by the total number of women who underwent surgery for breast cancer in the given unit x years previously.*

x = 1,2,3 ...etc. years.

Recurrence rates should be reported separately for each period of interest e.g. 1, 5, 10, 20 year recurrences. Each fraction should be expressed as a percentage for each recurrence category and reported with the associated numerators by age-group. Each figure may also be reported by type of surgery (see below). If staging data are available, the indicator could be reported by stage at diagnosis rather than type of surgery undertaken or both.

*Recurrence classification:*

- Breast or chest wall
- Axilla/ or supraclavicular fossa (SCF)
- Contralateral tumour
- Other.

*Type of surgery:*

- Breast conserving surgery
- Breast conserving surgery and radiotherapy
- Mastectomy
- Mastectomy and radiotherapy.

### Rationale

Recurrence of disease will reflect both the severity of the disease and also the extent to which the original treatment was appropriately selected and successful at controlling the disease. This classification is selected due to its simplicity and recognisable relationship to treatment (personal communication, John Yarnold).

Intermediate outcomes such as recurrence are highly desirable as survival rates. Although important sources of information, they are less likely to influence individual clinical practice.

<b>Potential uses</b>	Clinical audit, provider based comparisons.
<b>Potential users</b>	Clinicians, commissioners, provider managers.
<b>Possible confounders</b>	Ideally, cases where the initial surgery included axillary sampling should be identified and reported separately. Migration of patients may confound this indicator if linkage of all relevant records nationwide is not possible.
<b>Data sources</b>	The denominator is given by the number of CMDS episodes for the given year and unit with both a primary diagnosis of breast cancer on admission (ICD10-C50) and a relevant surgical procedure for breast cancer (OPCS4 - B27- Total excision of breast, B28 - Other excision of breast, B32 - Biopsy of breast) in the year concerned. To obtain the numerator, any recurrences in this group of patients should be identified by linkage of records using a unique patient identifier to any subsequent admissions or out-patient attendances (to any provider unit) with a primary or secondary diagnosis of metastases (e.g. ICD10 - C80 (metastases), C79.8 (secondary malignant neoplasm of other specified sites), C77.3 (secondary unspecified malignant neoplasm of axillary-upper limb lymph node), and a previous primary or secondary diagnosis of breast cancer (ICD10-C50). To identify cases from out-patient data ICD or Read codes may be used to code primary or secondary diagnoses (i.e. Read codes: Xa982 (metastases), B58y0 (metastases to breast), Xa980 (metastases to lymph node) (NHS Centre for Coding and Classification 1997).
	Migration of patients over the time period will effect the reported rate unless patients are tracked between hospitals using, for example, the new NHS number as the patient identifier.
	Alternative sources of data may be available such as dedicated clinical information systems e.g. the BASO data set which records local and regional recurrences and distant metastases.
<b>Data quality</b>	The validity of the indicator will depend on the accuracy and completeness of clinical coding which may not be uniformly high. Linkage of hospital records by the NHS number is required to identify admissions for recurrence to other hospitals, which may not be available everywhere. The validity of the indicator also relies on identifying all in-patient and out-patient episodes for cancer recurrences at any unit. As the out-patient minimum data set is not mandatory, there may be problems in identifying all relevant episodes of care by record linkage. To date, there has been no assessment of the quality of data collected in BASO databases, and this is likely to vary from unit to unit.

**Comments**

Reliability of the recurrence classification is untested. Problems may arise if skin nodules appear just outside the breast.

Other recurrences which are not separately identified in the indicator include haematogenous metastases, contralateral lymphatic spread, skin nodules by permeation (cancer en cuivasse).

As numbers in each recurrence category are likely to be small at a provider unit level, aggregation for a larger population may be necessary to obtain meaningful data.

**Further work required**

Testing of recurrence classification for reliability and comparability across units.

**Conclusion & priority**

**C - To be implemented on a routine basis where local circumstances allow.**

**References**

NHS Centre for Coding and Classification (1997). *The Read Codes, March 1997 demonstrator*. NHS Executive, Leeds.

## Candidate indicator 12

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

<b>Title</b>	<b>Rates of specific complications, detected within one year of discharge from hospital, among women having undergone in-patient treatment for breast cancer</b>
<b>Intervention aim</b>	Reduce death and complications from breast cancer and its treatment.
<b>Definition</b>	For a given provider unit, year and complication (listed below): <i>the number of women discharged from an episode of in-patient treatment for breast cancer within the given year who have suffered the specified complication within the 12 months following that discharge, divided by the number of women discharged from an episode of in-patient treatment for breast cancer within the given year.</i> This fraction, expressed as a percentage, should be reported with its numerator both as an overall figure and by patient age-group.
	<i>Complications:</i>
	<ul style="list-style-type: none"><li>- Lymphoedema</li><li>- Breast pain/tenderness</li><li>- Radiation-induced brachial plexopathy (RIBP).</li></ul>
<b>Rationale</b>	Post-operative complications may cause discomfort and/or lead to hospitalisation or other increased use of resources. They may also lead to an overall outcome that is poor. With appropriate consideration of patient risk factors, increased complication rates may draw attention to pre-, intra- and post- operative or therapeutic procedures which require improvement.
	There are major problems in the recording of complications unless one relies on patient self-assessment. There are currently no formal questionnaires which have been tested and accepted as valid for routine assessment of complications following treatment of breast cancer. Several trials are currently underway assessing quality of life in patients receiving adjuvant chemotherapy, radiotherapy and/or ovarian ablation. In the future these tools may be valuable for routine assessment, but to date they have not been validated for use outside of a research trial setting.
<b>Potential uses</b>	Clinical audit and provider based comparisons.
<b>Potential users</b>	Clinicians, provider management, commissioners.
<b>Possible confounders</b>	Complication rates for breast cancer treatment should be considered in the context of information on severity of disease and other co-morbidity.

**Data sources**

There are currently no tools used to collect routinely information about complications among women following treatment for breast cancer. Although various instruments have been developed for research trials, these are very long and unsuitable for routine data collection. Such instruments may be valuable as a basis for the development of an instrument for routine use following adaptation and thorough testing in the relevant setting. Such examples of research instruments for possible adaptation are the EORTC (European Organisation for Research on Treatment of Cancer) QLQ (Quality of Life questionnaire core 30) and the EORTC BR-23 breast cancer module questionnaires. These are currently in use in the Adjuvant Breast Cancer (ABC) Trial Quality of Life study (personal communication: John Yarnold). The specific aspects which refer to complications of treatment may be drawn from these and provide a valuable starting point for the development of a practical tool for routine use.

In the meantime, such information may be collectable through an audit of the notes or by using clinical information systems which include data on complications. However, the consistency with which complications would be identified by such methods may be limited, and may prevent useful comparisons of complication levels across hospitals.

**Data quality**

Any new tool for assessing the rate of complications would need to be tested for reliability and validity as well as its suitability in a clinical setting.

**Comments**

The one year period may be too short.

**Further work required**

Development of a suitable practical tool for the routine assessment of complications following breast cancer treatment. Ascertainment of the appropriate time period for measuring the presence of complications.

**Conclusion & priority**

**E - To be further developed because further work is needed on the methods of measurement.**

**References**

Aaronson, N.K., Ahmedzai, S., Bergman, B., Bullinger, M., Cull, A., Duez, N.J., Filiberti, A., Fechtner, H., Fleishman, S. B., and de Haes, J. C. (1993). The European Organisation for Research and Treatment in Cancer QLQ-C30: a quality of life instrument for use in international clinical trials in oncology. *Journal of the National Cancer Institute*, **85**, 365-376.

## Candidate indicator 13

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Clinical

*Timeframe:* Cross-sectional

*Outcome relationship:* Indirect

<b>Title</b>	<b>Delays from patient identification of symptoms to start of treatment for breast cancer</b>
<b>Intervention aim</b>	Maintain well-being during and following treatment for breast cancer.
<b>Definition</b>	<p>For a given female population diagnosed with breast cancer having presented symptomatically in a given year: <i>the median value in days, between:</i></p> <ul style="list-style-type: none"><li><i>i) the identification of symptoms by the patient to presentation to the GP;</i></li><li><i>ii) presentation to the GP and GP onward referral date;</i></li><li><i>iii) GP referral date and initial hospital appointment date and;</i></li><li><i>iv) hospital appointment date and start of treatment for breast cancer.</i></li></ul>
	A median score should be reported for each delay and where possible these delays reported by the stage of cancer at histological diagnosis.
<b>Rationale</b>	The purpose of minimising delays between identification and presentation of symptoms, assessment by specialist, and delivery of treatment, is to alleviate anxiety by enabling early provision of reassurance as to the nature of the problem and the timely delivery of appropriate treatment for breast cancer.
	<p>There are two aspects of delay: patient delay and system delay. Patient delay is the time between the patient detecting breast symptoms and visiting a health care provider to seek evaluation of the symptom (measured in i) while system delay is the time from that contact to the start of treatment (measured in ii to iv) (Nosarti et al. 1997). A recent study at King's College Hospital showed that both patient and system delays had highly skewed distributions with a mean patient delay of 123 days (median 13) and a mean system delay of 45 days (median 18). Patient delay also seemed to contribute to the bulk of total delay (Nosarti et al. 1997). This may not be representative of the country as a whole.</p>
	Knowledge of variation in delays across populations may highlight specific deficiencies in some services and indicate areas where improvements could be made.
<b>Potential uses</b>	Provider based comparisons of service provision across populations.
<b>Potential users</b>	Commissioners, provider units, policy makers.
<b>Possible confounders</b>	Availability of specialist breast units with direct access facilities and greater access to resources.

**Data sources**

The population of interest may be obtainable from the provider unit's CMDS for the given year and should be taken as all cases with a primary diagnosis of breast cancer (C50) which were not identified through the NHS breast screening programme. Reliance on the CMDS assumes that diagnosis and treatment of the population in question involved an in-patient admission.

Several sources may be required to obtain data on the time delays. Clinical assessment during both GP and specialist consultations will address the history of the complaint and therefore the information needed for (i) should be obtainable, if documented, through a retrospective audit of patient notes. These should also provide the referral date and details. GP records may be valuable as a source for these data but would require significant resources to pursue information from each of the relevant general practices for the hospital population. In general practices which have computerised patient records, data may be identified through use of Read coding for example, breast lump (K3171), referral to breast surgeon (XaAgn), and operative breast procedure (713...) (NHS Centre for Coding and Classification 1997). Although the BASO data set does not include data on delays, it would allow the identification of cancers which present following symptoms as opposed to screen-detected cancers.

To obtain this indicator for a residential population regional cancer registries may be able to provide the relevant data. Some cancer registries already collect this information routinely. e.g. Yorkshire Registry collect the date the patient identified the symptoms, the date of the referral letter, the date of first appointment and the date the treatment started (Haward, personal communication).

Where data are not available, new data collection practices may need to be introduced or notes audited on a periodic basis.

**Data quality**

The reliability of patient information on time of hospital referral may be variable and validation against information given to the GP may be worthwhile. Relying on the CMDS to identify the population of interest assumes that the relevant population will all be admitted as in-patients, although this will not always be the case. Equally, the in-patient CMDS data do not discriminate between symptomatically presenting cases and screening programme detected cases and so supplementary information will be required.

Some cancer registries may provide more comprehensive information on the timing of events if such information is not routinely documented in the clinical setting.

<b>Comments</b>	No specific points.
<b>Further work required</b>	None recommended.
<b>Conclusion &amp; priority</b>	<b>C - To be implemented on a routine basis where local circumstances allow.</b>
<b>References</b>	<p>Breast Surgeons Group of the British Association of Surgical Oncology (1995). Guidelines for surgeons in the management of symptomatic breast disease in the United Kingdom. <i>European Journal of Surgical Oncology</i>, <b>21</b> (suppl.),1-13.</p> <p>NHS Centre for Coding and Classification (1997). <i>The Read Codes, March 1997 demonstrator</i>. NHS Executive, Leeds.</p> <p>Nosarti, C., David, A., Crayford, T., Elias, E., and Roberts, J. (1997). Delayed diagnosis for breast disease is mostly due to patients. <i>British Medical Journal</i>, <b>315</b>, 1021.</p> <p>Warden, J. (1997). Labour acts to cut NHS costs. <i>British Medical Journal</i>, <b>314</b>, 1574.</p>

## Candidate indicator 14

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Patient

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

<b>Title</b>	<b>Patient satisfaction with specific areas (including the provision of information) of the management of their breast cancer care</b>
<b>Intervention aim</b>	Maintain well-being during and following treatment for breast cancer.
<b>Definition</b>	For a provider unit population of women with breast cancer diagnosed in a given year: <i>a summary of patients' responses to a questionnaire (to be specified), measuring satisfaction with specific areas of the management of their breast care, administered six months after the initial diagnosis.</i> The summary statistics will describe the distribution of scores from the instrument, broken down by patient age-group.
<b>Rationale</b>	While satisfaction is itself a desirable outcome, there is also evidence that care which is less satisfactory to the patient is also less effective (Kaplan et al. 1989). It has been shown that patients' reported levels of satisfaction can reflect doctors' technical competence as judged by independent, professional assessors (Dimatteo and Hays 1980).
	Although there is evidence of specific problems regarding satisfaction with breast cancer care among patients, a suitable questionnaire to evaluate such satisfaction has not been developed for use in a routine setting. Alternative methods of seeking patients' opinions have however been successful, for example the use of focus groups to gather patient's experiences and views (College of Health 1994). Work specific to cancer has been undertaken using focus group methodology to evaluate satisfaction with the various aspects of follow-up within cancer care (Bradburn et al. 1992). Focus groups may be considered a more valuable approach, but one which may have greater resource implications.
<b>Potential uses</b>	Clinical audit, trends over time.
<b>Potential users</b>	Clinicians, provider management, commissioners, public.
<b>Possible confounders</b>	A range of social and demographic variables have been shown to influence patient satisfaction (Fitzpatrick 1990). As a minimum, comparative analyses of satisfaction should be informed by knowledge of the age/sex of patients at different units.

<b>Data sources</b>	A major component of breast cancer treatment is surgery. One approach may be to evaluate this particular aspect using a tool specifically designed for surgical patients. The Royal College of Surgeons (RCS) comparative audit service provides an extensive and standard survey of satisfaction among surgical patients (Meredith and Wood 1994).  The comprehensive nature of this measure, with respect to surgical interventions may make it an appropriate benchmark against which alternative generic measures (e.g. Thompson 1988; Wilkin et al. 1992; Smith 1992) may be judged and a basis for developing a breast cancer surgery specific version.
<b>Data quality</b>	Alternative methods, such as focus groups, to ascertain levels of satisfaction with the services for women with breast care may be preferable and should certainly be encouraged while no appropriate survey tool is available.
<b>Comments</b>	Pilot testing of the RCS instrument has reported acceptable response rates across surgical patients.
<b>Further work required</b>	No specific points.  Selection of a generic measure, or development of a condition-specific questionnaire, on the basis of pilot data collection experience with breast cancer patients.
<b>Conclusion &amp; priority</b>	<b>E - To be further developed because further work is needed on the methods of measurement.</b>
<b>References</b>	<p>Bradburn, J., Maher, E.J., Young, J., and Young, T. (1992). Community based cancer support groups: an undervalued resource? <i>Clinical Oncology</i>, <b>4</b>, 377-380.</p> <p>College of Health (1994). <i>Consumer audit guidelines</i>. College of Health, London.</p> <p>Dimatteo, M.R., and Hays, R. (1980). The significance of patients' perceptions of physician conduct: a study of patient satisfaction in a family practice centre. <i>Journal of Community Health</i>, <b>6</b>, 18-34.</p> <p>Fitzpatrick, R. (1990). Measurement of patient satisfaction, In <i>Measuring the outcomes of medical care</i>, (ed. A. Hopkins, D.Costain). Royal College of Physicians, London.</p> <p>Kaplan, S., Greenfield, S., and Ware, J. (1989). Assessing the effects of physician-patient interactions on the outcomes of chronic disease. <i>Medical Care</i>, <b>27</b>, S110-S127.</p>

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## Candidate indicator 15

### Characteristics

*Specificity:* Condition-specific

*Perspective:* Patient

*Timeframe:* Cross-sectional

*Outcome relationship:* Direct

<b>Title</b>	<b>Assessment of health-related quality of life within a population of patients one year after a diagnosis of breast cancer</b>
<b>Intervention aim</b>	Maintain well-being during and following treatment for breast cancer.
<b>Definition</b>	For a given provider unit population of women diagnosed within a given year as having breast cancer: <i>an aggregate summary of patients' responses to a cancer-specific quality of life measure (to be specified), as administered one year after diagnosis.</i> The summary statistics will describe the distribution of scores for each dimension of the instrument, broken down by age-group.
<b>Rationale</b>	Quality of life (QoL) is beginning to play an increasingly important role in the evaluation of treatment in medicine generally and in oncology in particular (Bowling 1995, 1997; Lancet 1995; Fallowfield 1990; Gill and Feinstein 1994). While the exact relationships between QoL and other clinical outcomes and their importance in routine clinical decision-making is yet to be fully understood, the inclusion of such a dimension should now be considered.
	A great deal of developmental work has gone in to producing well-validated and psychometrically sound cancer-specific QoL measures. The two measures that should be considered first are the European Organisation for Research and Treatment in Cancer (EORTC) Quality of Life Questionnaire (QLQ-C30) (Aaronson et al. 1993; Fayers et al. 1995; Sprangers et al. 1993) and the Functional Assessment of Cancer Therapy Scale (FACT) (Cella et al. 1993; Cella 1994). Both these have general and site-specific modules, are psychometrically sound and are available in a number of languages. They are relatively easy to complete and are 'user-friendly'.
<b>Potential uses</b>	Clinical audit, provider based comparisons.
<b>Potential users</b>	Clinicians, commissioners, provider management, consumers/public.
<b>Possible confounders</b>	Co-morbidity and other major life events affecting health.
<b>Data quality</b>	Data arising from the measures noted above are generally held to be reliable and valid.
<b>Comments</b>	Currently, routine assessment of women's quality of life is not being carried out in all centres.
<b>Further work required</b>	The routine use of QoL measurement has yet to occur and there is a need for the evaluation of such tools in clinical practice. Cancer centres and cancer units need to have access to appropriate professional expertise.

**Conclusion & priority**

**D - To be implemented by periodic survey where local circumstances allow.**

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## Candidate indicator 16

### Characteristics

*Specificity:* Generic

*Perspective:* Patient

*Timeframe:* Cross-sectional/  
longitudinal

*Outcome relationship:* Direct

<b>Title</b>	<b>Assessment of psychological distress in the patient following treatment for breast cancer:</b> <b>A) Measurement of psychological distress by use of an agreed instrument</b> <b>B) Rate of referral to specialist psychological services</b>
<b>Intervention aim</b>	Maintain well-being during and following treatment for breast cancer.
<b>Definition</b>	A) For a given population of women following treatment for breast cancer: <i>the percentage of women who score above an agreed level on a standardised measure of psychological distress at one year after diagnosis.</i>  B) For a given population of women following treatment for breast cancer: <i>the percentage of women referred to relevant services (e.g. specialist counselling services, clinical psychology services, liaison psychiatry teams etc.) within a one year period from diagnosis.</i>
	These fractions, expressed as percentages should be reported with their numerators both as overall figures and by age-group.
<b>Rationale</b>	The experience of breast cancer can be emotionally traumatising as it requires women to deal with the emotional impact of a potentially life-threatening disease; mutilating or disfiguring surgery; and treatments that have both short- and long-term effects on their bodies. Data from a variety of studies (e.g. Cull et al. 1995; Fallowfield et al. 1994; Ford et al. 1995; Ibbotson et al. 1994; Kelsen et al. 1995; McDaniel et al. 1995; Maguire et al. 1980; Minagawa et al. 1996; Parle et al. 1996; Ramirez et al. 1995) suggest that in groups of people with cancer, between 20% and 30% may have psychological distress serious enough to warrant intervention by a mental health professional at some stage in their illness. The effects of this distress are varied and, while certainly leading to a reduced quality of life, may also indirectly effect other treatment outcomes. Recent reviews and meta-analyses (Fallowfield et al. 1995; Fawzy et al. 1995; Meyer and Mark 1995; Moyer 1997) have shown a variety of different interventions to be effective in reducing psychological distress.
<b>Potential uses</b>	Management of individual patients; local management of practice; local audit.
<b>Potential users</b>	Commissioners; clinicians; consumers/public.
<b>Possible confounders</b>	Other major life events, including recurrence.
<b>Data sources</b>	Regular use of appropriately standardised psychometric measures. Examples of suitable measures are the Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983) and the General Health Questionnaire (Goldberg and Williams 1988). There are a variety of other measures and advice about these should be obtained from those experienced in the field of psycho-oncology.

<b>Data quality</b>	Data arising from psychometric measures are generally held to be reliable and valid. Clinically-derived data are much less reliable and valid but provide an important additional source of data if limitations are respected. Referral patterns, though 'hard data' in themselves, may reflect individual preferences, and knowledge about and availability of services.
<b>Comments</b>	Currently routine assessment of women's emotional needs is not being carried out in all centres. This may be due both to the relative dearth of appropriately trained professionals and to deficiencies in the training of medical and nursing staff.
<b>Further work required</b>	Confirmation of need in this area since existing epidemiological data are rather sparse. Evaluation of the skill base in medical and nursing staff with a view to developing appropriate training at both pre- and post-qualification levels. Ensuring that cancer centres and cancer units have access to appropriate professional expertise.
<b>Conclusion &amp; priority</b>	<b>C - To be implemented on a routine basis where local circumstances allow.</b>
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## 5. RECOMMENDATIONS

### To be implemented generally on a routine basis

- 5.1** It is **recommended** that the following indicators be implemented generally on a routine basis (the numbers refer to those in Section 4):
- 1A: incidence of primary breast cancer by cancer stage at diagnosis**
  - 1B: detection rate of small primary breast cancers**
  - 4: survival rates by cancer stage at diagnosis**
  - 5: population-based mortality rates from breast cancer in women**
  - 6: percentage of patients diagnosed as having breast cancer, who had received a diagnostic triple assessment**
  - 7: percentage of patients with breast cancer under the care of a breast care specialist**
  - 9: percentage of patients who, having undergone potentially curative surgery for breast cancer, were given chemotherapy as part of their primary treatment**
  - 10: percentage of patients who, having undergone potentially curative surgery for breast cancer, were given radiotherapy as part of their primary treatment.**
- 5.2** The production of information about the **incidence of primary breast cancer** will be facilitated by improvements in the regional cancer registers as they are obliged to collect a minimum data set for each cancer registered. Simple staging systems are available but work being carried out by the Royal College of Pathologists will lead to more sophisticated classifications which should be implemented in due course.
- 5.3** The major impact of screening is in the **detection of small breast cancers**, those smaller than 15 mm. These data are collected currently and validated by the breast screening quality assurance reference centres.
- 5.4** **Survival rates** have been key outcome indicators for many years. To improve understanding of this information they should be reported as age-specific and (when summarised) as age-standardised figures and by the stage of the cancer at diagnosis. Ten year survival rates should be produced as well as those for five years. The validity of this indicator depends on the completeness of staging data.
- 5.5** **Population based mortality rates** are part of the Public Health Common Data Set and their reduction was a Health of the Nation target. The validity of the indicator depends on the quality of death certificate information.

- 5.6 Triple assessment** comprises clinical examination, imaging and fine needle aspiration cytology and it is effective in diagnosing 95-100% of breast cancers. The indicator has been specified with a denominator of diagnosed breast cancer rather than women presenting with symptoms because many of the latter will not require a triple assessment. Although comprehensive data collection systems are not yet available, it is feasible to collect and aggregate the data for analysis. Low rates of triple assessment may highlight important deficiencies in the care provided by a breast service.
- 5.7** Breast surgery should be carried out by **breast care specialists** with a specific interest and training in the disease. Although there are some difficulties in obtaining a standard definition of 'trained breast surgeon' and in obtaining data to derive the indicator, these can be resolved. The importance of ensuring that breast surgery is only done by experts has led the Group to recommend the general and routine implementation of this indicator despite the data production problems.
- 5.8 Chemotherapy** is given in an attempt to control micrometastatic disease and adjuvant therapy has led to significant reductions in recurrences and mortality rates. The indicator should be reported by age group as the effectiveness of adjuvant therapy varies with age, with patients over 70 deriving less benefit. Assembling the data to produce the indicator requires record linking and the validity will rely on the quality of diagnosis and procedure recording as well as tracing patients who move from where they had the original surgery.
- 5.9 Radiotherapy** has been shown to lead to lower recurrence rates. This indicator shares with the chemotherapy indicator similar problems of data collection and validity. The importance of having quick information about the use of effective procedures to supplement the long term data about survival has led the Group to recommend the general and routine implementation of the chemotherapy and radiotherapy indicators despite the current lack of a comprehensive data collection system.

**To be implemented generally by periodic survey**

- 5.10** It is **recommended** that the following indicator be implemented generally by periodic survey:
- 8: percentage of patients receiving treatment for breast cancer whose care was planned jointly by a multi-disciplinary group.**

**5.11** The importance of involving a **multi-disciplinary group** in the planning and provision of breast care is now recognised. Core members of the group comprise surgeon, radiologist, pathologist, oncologist and breast care nurse. It is likely that the data to derive the requisite information for the indicator will need to be obtained from medical notes and thus it should be implemented by periodic survey.

**To be implemented when local circumstances allow on a routine basis**

**5.12** It is **recommended** that the following indicators be implemented when local circumstances allow on a routine basis:

- 11: recurrence rates of breast cancer by site and type of primary surgery**
- 13: delays from patient identification of symptoms to start of treatment for breast cancer**
- 16: assessment of psychological distress in the patient following treatment for breast cancer:**
  - A - measurement of psychological distress by use of an agreed instrument**
  - B - rate of referral to specialist psychological services.**

**5.13** The **recurrence** of breast cancer reflects both the severity of the disease and the extent to which the original treatment was appropriately selected and successful at controlling the disease. The indicator uses a classification which is simple and has a recognisable relationship to the disease. The validity of the indicator depends on the accuracy and completeness of clinical coding and the ability to link data between hospitals. Information about intermediate outcomes such as recurrence is highly desirable because it is likely to influence individual clinical practice.

**5.14** The minimisation of **delays from the onset of symptoms to the start of treatment** alleviates anxiety and ensures the timely delivery of treatment. The indicator, which has four components, distinguishes between patient delay in seeking help and delays caused by the NHS referral and scheduling processes. To produce the information on a routine basis, local data collection and aggregation procedures may need to be changed.

**5.15** Two indicators have been recommended for the **assessment of psychological distress following treatment for breast cancer**. The experience of breast cancer can be emotionally traumatising as it involves a life threatening disease and potentially mutilating or disfiguring treatments. A variety of well validated measures of psychological distress are available. The process measure recommended relates to the referral to specialist psychological services.

**To be implemented when local circumstances allow by periodic survey**

**5.16** It is **recommended** that the following indicators be implemented when local circumstances allow by periodic survey:

**15: assessment of health-related quality of life within a population of patients one year after a diagnosis of breast cancer.**

**5.17 Quality of life** is becoming recognised as an important outcome to measure for cancer care. Two measurement tools have been identified as suitable for breast cancer and they are well validated and easy to complete. If agreement could be reached about the preferred methodology it would be possible to compare outcomes between units.

**To be further developed**

**5.18** It is **recommended** that the following indicators be further developed before an implementation decision be made:

- 2: incidence of interval breast cancers**
- 3: incidence of invasive breast cancer following treatment for ductal carcinoma in situ (DCIS)**
- 12: rates of specific complications detected, within one year of discharge from hospital, among patients having undergone in-patient treatment for breast cancer**
- 14: patient satisfaction with specific areas of the management of their breast cancer care.**

**5.19** An **interval cancer** is a breast cancer occurring between a negative screening assessment and the next due assessment. The indicator can be derived by linking records held in the screening centres and cancer registries. Populations of at least one million are needed to obtain statistically valid rates and interpretation is further complicated by confounders such as variations in coding and ascertainment and the presence of private sector screening.

**5.20** The **rate of invasive cancer following DCIS** may reflect both the appropriate assessment of the disease and the success of treatments given as part of the women's care. Cases of DCIS may be detected through the breast screening programme or in women presenting with symptoms, the majority being picked up by screening. Before the indicator can be recommended for implementation further work is required to identify:

- any difference between symptomatic and non-symptomatic DCIS
- methods which would allow complete data collection and aggregation.

**5.21 Complications following treatment** may cause discomfort and lead to an overall poor outcome. There are major problems in the recording of complications unless data are obtained by patient self-assessment. There are as yet no validated questionnaires for collecting these data. Appropriate measurement tools are being developed and when this work has been completed they should be considered as the means for deriving this important outcome indicator.

**5.22** Although there is evidence of patient unhappiness with breast cancer care there are no suitable questionnaires to measure **patient satisfaction** in a routine situation. For the purely surgical aspects of management the Royal College of Surgeons has a generic measurement tool. Before an indicator can be recommended for implementation, further work must be done to identify the appropriateness of a generic measure for breast cancer or to develop a specific questionnaire covering all aspects of breast care.

### **Conclusions**

**5.23** The Group's work on breast cancer outcome indicators has implications for other cancers in that:

- each cancer needs a menu of short term and long term indicators
- data from different sources must be linked to provide the requisite information for some indicators
- indicators should be used to highlight differences which require action.

**5.24** The traditional outcome measures for cancer relate to survival and mortality. There is a need to balance these long term measures with:

- short term measures relating to quality of life and satisfaction with the care provided.
- process indicators related to interventions with proven benefits which will give an early indication of likely improved outcomes.

**5.25** The information used to assemble cancer outcome indicators requires the linking of data from different sources such as:

- clinical and histopathological data
- data from hospitals with death certificate information
- data from different hospitals
- screening unit data with that from symptomatic patients.

**5.26** The importance of cancer registers as the major agents for assembling these data into outcome information cannot be underestimated. A national approach must be taken to ensure that:

- regional registers collect requisite data sets to prescribed standards
- data providers submit complete and accurate data to regional registers.

**5.27** Indicators can be used to highlight differences:

- over time
- between providers
- between groups of patients.

**5.28** The main use of indicators is to make broad comparisons to identify significant differences or anomalies that require further detailed examination. Small differences in routine indicators may be attributable to a wide range of factors, many of which will not reflect differences in health outcome which can be attributed to the process of care.

**5.29** Some indicators may be best used in combination to gain additional information. For example:

- population based mortality (Indicator 5) with incidence (Indicator 1A) and survival rates (Indicator 4)
- survival rates (Indicator 4) with organisation of care (Indicators 7 & 8) and specific treatments (Indicators 9 & 10)
- recurrence rates (Indicator 11) with survival and mortality rates (Indicators 4 & 5), organisation of care (Indicators 7 & 8) and specific treatments (Indicators 9 & 10).

# APPENDIX A: BACKGROUND TO THE WORK

## **Summary**

**A.1** Over the last few years a major component of the Department of Health's and NHS Executive's strategy has been to promote the development and use of measures of health outcome. In July 1993 the Central Health Outcome Unit (CHOU) was set up within the Department of Health (DoH). Commissioned by the DoH, in 1993 a feasibility study of potential outcome indicators was published by the Faculty of Public Health Medicine and a package of indicators was published by the University of Surrey for consultation. Following these two phases of development, a third phase of work was initiated by the CHOU. Its remit is to report on 'ideal' health outcome indicators.

## **Central Health Outcome Unit**

**A.2** The CHOU is an internal DoH unit whose goal is 'to help secure continuing improvement in the health of the people of England through cost-effective and efficient use of resources' (Lakhani 1994). The objectives of the Unit are to:

- encourage and co-ordinate the development of health outcome assessment, particularly in respect of the development of appropriate methods, appropriate data collection systems, expertise, analytical skills, and interpretation
- encourage and support the use of health outcome assessment and information in making policy about health interventions and in the planning, delivery and monitoring of services.

**A.3** Several national committees have a special interest in outcomes and have been kept informed of progress:

- Clinical Outcomes Group
- Public Health Network
- CMO Working Group on Information Management and Technology.

## **Phases 1 and 2**

**A.4** The Faculty of Public Health Medicine was commissioned to undertake a feasibility study of potential indicators which reflect health end-points for health services and which cover topics in which health care has an important contribution to make. This work (McColl and Gulliford 1993) was constrained in that the set of indicators were to:

- be based on reliable routinely collected data
- reflect health service interventions rather than the wider influence on health.

**A.5** The University of Surrey was commissioned to produce a package of comparative statistics based on the outcome measures recommended in the feasibility study. Forty indicators were chosen, 18 for maternal and child health, three for mental health and the rest for other topics in adult health. The publication (Department of Health 1993a) contained indicator definitions, maps and scatter plots showing geographical variations, and tables presenting the rates, with corresponding observed numbers and confidence intervals when appropriate.

#### **The Phase 3 work: ideal indicators of health outcome**

**A.6** In the third and current phase of the work on health outcomes a number of research institutions were commissioned to assist in developing a structured approach to identify indicators to cover a number of clinical topics. The prime contractor is the Unit of Health-Care Epidemiology, Department of Public Health and Primary Care, University of Oxford.

**A.7** The respective roles of the supporting organisations are as follows:

- Unit of Health-Care Epidemiology, University of Oxford, to provide epidemiological and managerial support to the Group and co-ordinate the input of the other agencies.
- CASPE Research, in London, to provide technical advice with regard to the indicators and their data sources and to prepare the detailed specifications.
- Royal College of Physicians' Research Unit, in London, to co-ordinate the clinical input.

**A.8** In the previous work a key criterion for selection of indicators was the requirement for the work to be based on routinely available data. This practical constraint has meant that the recommended indicators were selected and opportunistic rather than an ideal set. This inevitably led, as the DoH acknowledged, to a bias towards outcomes which may be measurable now but which may not necessarily be those which are most appropriate and most needed. The aim of the third phase is to advise on and develop 'ideal' outcome indicators without confining recommendations to data which have been routinely available in the past.

**A.9** The initial task of the third phase of the work was to select clinical topics for detailed study. In order to ensure that the work would be manageable, and that the NHS would have the capacity to absorb the output, the CHOU decided to limit the activity to five clinical topics a year.

**A.10** A workshop to initiate the work which was attended by over 70 individuals representing a wide range of interests was held in January 1995. A report of the proceedings has been published (Goldacre and Ferguson 1995). The main aims of the workshop were:

- to identify the criteria which should be used to choose clinical topics for the Phase 3 work
- to suggest a list of potential clinical topics which workshop participants would like to be included in the Phase 3 work.

**A.11** Following further consultation within and outside the DoH, the CHOU decided in June 1995 to include the following topics in the first two years of Phase 3 work:

- Asthma
- Breast cancer
- Cataract
- Diabetes mellitus
- Fracture of neck of femur
- Incontinence
- Myocardial infarction
- Pregnancy and childbirth
- Severe mental illness
- Stroke.

### **Health outcome information**

**A.12** In this work the potential uses of outcome information have been identified as follows:

- for clinical decision-making and audit of clinical work, including:
  - management of individual patients
  - audit and management of health professionals' practice
  - research
- for informing decisions about the strategic and operational development of services
- for comparisons of organisations in the delivery of services which may be:
  - provider based
  - population based

- for assessing progress towards agreed standards or targets for health outcomes, agreed nationally or locally, which may be:
  - identified from the research literature
  - set by clinical and managerial decisions.

**A.13** Current managerial interests which are relevant to the use of health outcome information include:

- NHS goal ‘to secure, through the resources available, the greatest improvement in the physical and mental health of people in England’
- clinical audit
- evidence-based purchasing.

**A.14** An important purpose of the work has been to recommend indicators which, if possible, would allow ‘health gain’ to be assessed alongside information used to measure health service input. The particular focus has been to make recommendations about aggregated statistical information about people with particular conditions which can be used to:

- enable providers of care to review outcomes of the care of their patients
- make comparisons, where appropriate, of health outcomes against locally agreed targets and/or between different places and/or over time.

**A.15** The information may be obtained from continuous data collection systems but, when having continuously collected information is unnecessary, or when the cost or complexity of this is high, use should be made of sample survey techniques or periodic surveys.

**A.16** Health indicators are more likely to be successful if they fit naturally into the everyday work of health care professionals than when they have to be collected as a separate activity. The aim is to have indicators that are:

- *Relevant* because professionals use them everyday in treating their patients and will record them accurately.
- *Reliable* because they can be validated or cross checked from other sources.
- *Responsive* because they readily identify changes in the patient’s state of health.
- *Research-based* because there is a plausible link between processes of care and outcome.

- A.17** In common with the approach taken to other types of indicators by the NHS, it is recognised that useful outcome indicators should be capable of identifying circumstances worthy of investigation but that, in themselves, they may not necessarily provide answers to whether care has been 'good' or 'bad'. In particular it is acknowledged that there may be difficulties in drawing causal conclusions - say, that a particular aspect of care caused a particular outcome - from indicators derived from non-experimental clinical settings. Nonetheless, the vast majority of clinical care is delivered in routine rather than experimental practice. The assessment of its outcomes entails, by definition, the use of observational rather than experimental data.
- A.18** To be useful, work on 'ideal' outcome aspects needs to incorporate considerations of practicability. It is a time of rapid change in information technology. What may be feasible now in some places may not be feasible everywhere. What may not be practical today may become so in a year or two.

## APPENDIX B: THE BREAST CANCER WORKING GROUP

**B.1** The Breast Cancer Working Group was formally constituted in February 1997 and met three times, completing its work in July 1997. The Report was completed in September 1997. The terms of reference were:

- To advise on indicators of health outcomes of the prevention and management of invasive breast cancer.
- To make recommendations about the practicalities of the data collection and compilation and interpretation of the indicators, and to advise if further work is needed to refine the indicators and/or make them more useful.

**B.2** The membership of the Working Group and the staff of the supporting organisations are shown below. The composition of the Group included the major professional and managerial groups and representatives of patients involved with the prevention and management of breast cancer.

### MEMBERSHIP OF THE GROUP

#### Chairman and members

Consultants	Mary Armitage Roger Blamey Amanda Ramirez Mike Richards Richard Sainsbury Robin Wilson John Yarnold	Bournemouth (Oncologist) Nottingham (Breast surgeon) London (Psychiatrist) London (Palliative care) Huddersfield (Breast surgeon) Nottingham (Breast radiologist) Royal Marsden (Oncologist)
GP	Sarah Kelly	Chichester
Psychologist	Peter Harvey	Birmingham
Nurse	Lesley Thomson	Manchester
Public health & information	Bob Haward  Paola Dey Helen Forbes Paul Watson	Northern & Yorkshire Cancer Registry and Information ( <b>Chair</b> )  Manchester Clatterbridge Cambridge
CEOs	Brian Cottier Richard Priestley	Clatterbridge Stoke-on-Trent
DoH	Elizabeth Wilson	London
Voluntary body	Becky Miles	Oxford

#### Academic support and secretariat

Michael Goldacre, Alastair Mason & Ewan Wilkinson, University of Oxford  
James Coles, Robert Cleary & Moyra Amess, CASPE Research, London  
Vincent O'Brien, Central Health Outcome Unit, DoH

## APPENDIX C: METHODS FOR CHOOSING INDICATORS

**C.1** Candidate outcome indicators were identified by the Group with the help of the following:

- the health outcome model for breast cancer (see Section 2)
- various classifications of the characteristics of outcome indicators.

**C.2** The Group noted that indicators may be related to:

- i. environmental factors in the general population or relating to the individual
- ii. knowledge, attitudes, behaviour in the general population
- iii. knowledge, attitudes including satisfaction with service delivery, behaviour of individual patients with breast cancer
- iv. patients' symptoms, function, health status, well-being
- v. patients' clinical state
- vi. patients' pathological/physiological state
- vii. events occurring to patients as the endpoints of earlier occurrence of disease and/or interventions such as contacts with general practitioners, issuing of prescriptions, out-patient visits, in-patient admissions and death .

**C.3** The data sources for the indicator entities noted in paragraph C.2 will differ. It is likely that:

- indicators for (i) and (ii) would come from population surveys
- indicators for (iii) and (iv) would come from patients either opportunistically or when specifically called
- indicators for (v) and (vi) would come from doctors and other health professionals
- indicators for (vii) would come from administrative information systems.

**C.4** The Group recognised the high cost and complexity of obtaining information from continuous data collection systems. Particular consideration was given to obtaining outcome indicator data from sample survey techniques such as a periodic survey when it is not essential to have continuously collected data.

**C.5** Four characteristics of an outcome indicator have been identified and each has been classified. They are:

- measurement perspective, relating to whose perspective the indicator is most relevant (see paragraph C.6)
- specificity (see paragraph C.7)
- measurement timeframe (see paragraph C.8)
- outcome relationship, in that the indicator is either a direct or an indirect, proxy measurement of outcome (see paragraph C.9).

- C.6** For the Group's purposes, measurement perspective was classified as that from the patient's, the clinical, or the population's viewpoint. In the treatment of breast cancer, for example, a measure of quality of life may be most relevant to the patient's perspective while clinical concerns may properly focus on the presence of complications. The population perspective has a broader view, best addressed by measures able to assess the burden of the disease as a whole. Of course, these perspectives are not necessarily in opposition and will often be associated with shared goals. Where possible, a set of indicators should be developed which satisfies all three measurement perspectives.
- C.7** The specificity of an indicator relates to whether it is specific or generic in application. For example, recurrence of breast cancer is specific while the measurement of mobility is much less so and would be influenced by a number of conditions. Condition-specific indicators have the advantage that their relative insensitivity to other conditions is likely to increase their sensitivity to changes in the condition of interest. Generic measures provide outcomes relevant to a wide range of conditions. A comprehensive indicator set might contain examples of both generic and specific indicators.
- C.8** The measurement timeframe relates to whether the indicator is:
- cross-sectional and thus an indicator at a single point in time for any one individual
  - a longitudinal measure of progression over time for any one individual.
- C.9** The Group's main task has been to develop direct indicators of health outcome although in many areas it may be difficult to identify or obtain such information. However, it is recognised that some care processes are so closely related to the production of benefits that the successful completion of the intervention might be used as a proxy measure of the actual outcome. In the absence of direct outcomes, proxy indicators have therefore been developed.
- C.10** There is increasing recognition of the importance of outcome measures derived from data generated by patients. For the purposes of the Group's work, three main areas of interest have been identified:
- impact of the condition on the patient
  - satisfaction of the patient with the care provided and/or outcome achieved
  - awareness of the patient of the management of the condition, and services available.

**C.11** With the assistance of the check-lists and a knowledge of the disease, the Group addressed the following key questions:

- What are health professionals trying to achieve for each patient?
- What can each patient realistically expect will be achieved for him/herself?
- What should be achieved for the population as a whole in respect of the prevention and treatment of the condition.

## APPENDIX D: GUIDANCE NOTES FOR CANDIDATE INDICATOR SPECIFICATIONS

<b>Indicator title</b>	A short title to identify the indicator.
<b>Intervention aim</b>	Distinguishes the level of intervention for which the indicator is primarily developed. It is assumed that, for a given condition, an ideal set of indicators would be reasonably balanced across the spectrum of health intervention stages. For breast cancer these stages are: <ul style="list-style-type: none"><li>- improve early detection and treatment</li><li>- reduce death and complications from the condition and its treatment</li><li>- maintain well-being during and following treatment.</li></ul>
<b>Characteristics</b>	Classifies the indicator on four dimensions (see Appendix C) : <ul style="list-style-type: none"><li>- Specificity: <i>condition specific or generic</i>.</li><li>- Perspective: <i>population, clinical or patient</i>.</li><li>- Timeframe: <i>cross-sectional measure or longitudinal</i> assessment of change.</li><li>- Outcome relationship: whether it is a <i>direct</i> measure of outcome or an <i>indirect</i> measure of structure or process, used as a proxy for outcome.</li></ul>
<b>Indicator definition</b>	In addition to a definition of the variable of interest, the description specifies: <ul style="list-style-type: none"><li>- how the variable is to be aggregated across cases, e.g. definitions of both a numerator and a denominator</li><li>- if a variable is to be reported with respect to a set of denominators, e.g. mortality broken down by age and sex</li><li>- if appropriate, how longitudinal change in the variable is to be represented, e.g. over what time interval and whether absolute difference or proportional change.</li></ul>
<b>Rationale</b>	A brief statement of the reasons and objectives behind the indicator, both in terms of the issues it addresses and its selection from a range of potential alternatives.
<b>Breast cancer definition</b>	Breast cancer has been defined as a primary malignant neoplasm of the breast excluding those arising from connective tissue.
<b>Potential uses</b>	The following classification has been used: <ul style="list-style-type: none"><li>- local management of practice</li><li>- local audit</li><li>- provider based comparisons</li><li>- population based comparisons</li><li>- assessment of regional/national trends or progress towards targets.</li></ul>

It is recognised that a given indicator may serve several purposes. Indicators that are valuable for the management of individual patients are likely to have practical advantages with respect to data collection in a clinical setting. However, in order for such indicators to be useful for other purposes, a method of aggregation across cases must be specified for the variable of interest.

**Potential users**

The following classification has been used:

- clinicians
- provider management
- commissioners
- national/regional policy makers
- consumers/public.

**Possible confounders**

This section has attempted to identify the population risk factors likely to influence the outcome indicator, and therefore useful in its interpretation. Where such factors are well defined and have a clear or potential association with the outcome of interest, they may be used to specify denominators to be included in the indicator definition itself.

**Data sources**

Where possible, existing sources of data have been identified for deriving the indicator and the degree to which complete coverage of the population of interest would be obtained has been noted. Where data are not widely available from existing systems, suggestions for new methods of data collection, capable of wide implementation have been made.

**Data quality**

While the theoretical capabilities of existing and proposed information systems are outlined above, the actual or expected limitations of those systems - in terms of their completeness and accuracy etc. - are noted in this section.

**Comments**

General comments regarding the indicator's definition, validity, practicality etc.

**Further work required**

Suggestions about the additional research and development work required to complete the indicator's specification to a level appropriate for large scale piloting.

**Conclusions & priority**

A statement indicating the Working Group's assessment of the priority for implementation.

**References**

Appropriate references used in the construction of the indicators.

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