Institutional validation of breast cancer treatment guidelines

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of the clinical practice guidelines developed in 1996 by the National Comprehensive Cancer Network (NCCN) for the primary and adjuvant treatment of invasive breast cancer. These 1996 NCCN guidelines established procedures for the primary treatment of invasive breast cancer patients. Full details of the guidelines are available in the paper.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with stage I to III invasive breast cancer. Patients with carcinoma in situ, inflammatory cancer, stage IV disease and co-morbid conditions that affected treatment were not included in the study.

Setting
The setting was a hospital. The study was carried out at the University of Florida, USA.

Dates to which data relate
The effectiveness and cost data related to the period 1 January 1991 to 1 January 1993. The price year was 1998.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing appears to have been conducted retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
The authors reported that 504 patients would have been required in both groups to reach statistical significance at the 0.05 level. Among 206 consecutive breast cancer patients, 129 were identified for the effectiveness analysis. Of these, 93 (72%) were treated according to the NCCN guidelines and 36 (28%) received NCCN-Dev treatment. The authors did not report evidence that the study sample was representative of the study population.

Study design
This was a retrospective cohort study that was carried out in a single centre. The duration of follow-up was 5 years. There was loss to follow-up, with the authors reporting that 5-year survival data were available for 93% of the patients (90% of the NCCN patients and 100% of the NCCN-Dev patients). QoL/functional status was ascertained by a confidential mail survey, which was sent to all surviving patients.

Analysis of effectiveness
The basis for the effectiveness analysis was not reported, but it may have been treatment completers only. The health outcomes assessed in the effectiveness analysis were the 5-year survival rates and QoL/functional status. The authors stated that 5-year survival was assessed using Kaplan-Meier analysis. Five-year survival data were available for 93% of the patients (90% of the NCCN patients and 100% of the NCCN-Dev patients). QoL/functional status was assessed using a mailed confidential survey, which measured 12 parameters using a Likert-type scale. The parameters assessed were degree of fatigue, breast and arm pain, swelling, numbness, tingling, and several parameters relating to body self-image and interest in sexual activity since the breast cancer treatment. The authors reported that 33% of the surviving NCCN patients, and 31% of the surviving NCCN-Dev patients, responded to the survey. The authors stated that the NCCN and NCCN-Dev groups were similar both demographically and in terms of the stage of disease distribution, with a greater proportion of African-American patients in the NCCN group, (p=0.258), although this did not reach statistical significance.

Effectiveness results
The 5-year survival rates were 87.6% for the NCCN group and 83.3% for the NCCN-Dev group, (p=0.319, non significant).

There were no statistically significant differences in the QoL/functional assessment between the groups in terms of the mean scores for breast and arm pain, numbness, tingling, swelling, generalised fatigue and body self-image, (p>0.50 for all the comparisons).

Clinical conclusions
Deviation from the clinical practice guidelines did not affect the survival rates or QoL.

Measure of benefits used in the economic analysis
No summary measure of health benefit was used in the economic analysis. Therefore, the study was classified as a cost-consequences analysis.

Direct costs
The direct costs considered in the economic analysis were those of the hospital. These included laboratory costs, pharmacy costs, operating room costs, diagnostic radiology costs and other radiology costs. The resource quantities were not reported separately from the costs. Hospital charges were used as a proxy for costs. The hospital charges came from the inpatient, outpatient and emergency room billings that resulted from treatment episodes related to breast cancer. Therefore, the charges were estimated from actual data. The hospital charges appear to have been reported for the whole study period, but this was not stated clearly. Also, the authors did not state clearly whether the hospital charges referred to the average charges per patient or to the whole group.

The price year was 1998. All charges were adjusted for inflation using a 4% rate per year for any cost data prior to 1998. No discounting appears to have been performed, and it is unclear whether it would have been necessary. If hospital charges referred to the whole study period, discounting would have been required since the study period was longer than 2 years.

Statistical analysis of costs
Hospital costs were compared by means of t-tests. The authors reported the mean and the standard error of the mean.
(SEM) for each of the categories of direct costs included in the economic analysis.

**Indirect Costs**
No indirect costs were reported.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total mean charges were $20,300 (SEM=1,800) for the NCCN group and $59,700 (SEM=25,200) for the NCCN-Dev group. This difference was significantly lower for the NCCN group than for the NCCN-Dev group, (p=0.016).

It was not stated whether the costs of adverse effects were dealt with in the costing.

**Synthesis of costs and benefits**
The cost and benefits were not combined due to the cost-consequences approach adopted.

**Authors’ conclusions**
The adherence to National Comprehensive Cancer Network (NCCN) guidelines can significantly reduce the cost of breast cancer care without adversely affecting either survival or quality of life (QoL).

**CRD COMMENTARY - Selection of comparators**
The comparator was justified on the grounds that some patients were treated according to deviations from the NCCN guidelines. However, the authors did not state what kind of deviations they referred to. You should decide whether the clinical practice guideline considered in this study is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis used a retrospective cohort study, which may have been adequate for the purpose of the study. As the authors stated, the retrospective nature of the study may have led to selection bias. The authors provided evidence to show that the study sample was representative of the study population. The questionnaire used to assess the QoL of the patients was not validated, which introduces uncertainty into the reliability of the conclusions. Moreover, although the authors reported the percentages of surviving patients answering the questionnaire, the numbers may have been very small and not representative of the patients participating in the study, particularly for the NCCN-Dev group, whose sample size was rather small. Although no statistically significant differences were found, both in terms of the comparability of the groups or in terms of the health outcomes, the authors stated that this might have been due to the fact that the study lacked the necessary statistical power to detect small difference. In terms of the comparability of the groups, unidentified variables may have influenced treatment decisions and hence variations in clinical practice.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The study was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
The perspective adopted was limited since only the hospital-related costs were included in the analysis. All the categories of hospital costs seem to have been included in the economic analysis. Hospital charges were used as proxies for costs, which may not reflect the opportunity costs. The fact that the charges were collected retrospectively may have led to some loss of information. The deviations of NCCN-Dev resource utilisation, compared with the NCCN guidelines, were not reported. In addition, the resource quantities and the costs were not reported separately. A further limitation is that the authors did not clearly state whether the charges related to the whole study period or to a specific period (e.g. cost per year). They also did not state clearly whether average charges were reported per patient or for the whole group. These facts introduce uncertainty into the reliability of the conclusions. The price year was stated, thus aiding refiation exercises. Discounting was not performed, and it is unclear whether it was relevant since the authors did not state the period considered for the reported costs.

**Other issues**
The authors did not compare their findings with those from other studies. The issue of generalisability of the results to other settings was not addressed. The authors’ conclusions reflected the scope of the analysis, that is, the study enrolled invasive breast cancer patients and this was reflected in the authors' conclusions.

**Implications of the study**
The authors recommend that prospective studies should be carried out to demonstrate the ability of NCCN treatment guidelines to change physician behaviour and subsequently influence patient outcome. They warn that practice guidelines need to be constantly updated and may fail to take account of individual differences among patients.

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