Cluster randomised controlled trial comparing the effectiveness and cost-effectiveness of two primary care interventions aimed at improving attendance for breast screening

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 two interventions aimed at increasing the uptake of breast screening. The first was a letter, including a translation sheet and information leaflet, sent one month before women received their routine invitation for breast screening. The second was a green card (flag), plus an encounter form integral to the flag and an information leaflet, to be inserted into the patient’s notes 6 months before the woman’s call for breast screening.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women aged 50 to 64 years whose practice was called for breast screening. Women inappropriate for screening, such as those who had undergone bilateral mastectomy or who were terminally ill, were excluded. General practices were included when the second-round uptake for breast screening was below 60%, and there were at least 100 women eligible for screening in the second round.

Setting
The setting was primary care. The economic study was carried out in north-west London and the West Midlands in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered between July 1997 and August 1998. The costs were reported in 1998 to 1999 prices.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on a sub-sample of the patients used in the effectiveness analysis.

Study sample
Sample size calculations indicated that, with 24 practices involving approximately 6,048 women in total and with 1,512 women in each intervention group, a difference of 8.5 to 10% in the breast screening uptake rate could be detected with
80 to 90% power at a 5% two-sided significance level. There were 99 eligible practices that fell into the two geographical areas of north-west London and the West Midlands, which had a low uptake in the second round of screening and were scheduled to be screened between July 1997 and August 1998. Of these, 24 practices were included in the analysis. Of the 75 practices not participating in the study, most did not respond to the invitation or declined to participate (the reason was given). Of the 6,362 eligible women, 229 were immediately excluded, mainly due to inaccuracies in the notification list or the inability to locate the patient's records. The remainder were allocated to four groups. There were 1,721 women assigned to the control group, 1,818 to the letter group, 1,232 to the flag group, and 1,362 to the combined letter and flag group. The mean age of the women was 56.3 (+/- 4.3) years in the control group, 55.9 (+/- 4.3) years in the letter group, 56.1 (+/- 4.4) years in the flag group, and 55.5 (+/- 4.3) years in the combined letter and flag group. The baseline characteristics of the participating practices and women attending were provided.

**Study design**
This was a pragmatic, factorial, cluster randomised controlled trial, which was carried out in 24 practices in north-west London and the West Midlands. The practices were stratified by area (12 practices in each area) and within each area, by practice size. Randomisation was carried out using random number tables. The practices were randomised within strata by study staff blinded to the identities of the individual general practice. One practice was found to be ineligible immediately after randomisation and was replaced by a comparable practice from a reserve list. The length of follow-up was 6 months after each practice had been screened, when the outcome was assessed. The loss to follow-up was 401 women. This comprised 100 women in the control group, 115 in the letter group, 81 in the flag group, and 105 in the combined letter and flag group. The main reasons for loss to follow-up were that letters were returned unopened, or the women had moved away or had been screened recently.

**Analysis of effectiveness**
The basis for the analysis of the clinical study was intention to treat. The primary health outcome assessed in the analysis was attendance for third-round breast screening. The effectiveness of each intervention, adjusted for the presence or absence of the other intervention, was assessed using a random-effects logistic regression analysis. The effects of cluster randomisation, and the stratification variables of practice size and area, were also adjusted for. The interaction between the two interventions was also estimated, but with limited power. The study groups were generally comparable at baseline, although there was a high variation in the second-round uptake of breast screening among practices (mean: 47%; standard deviation: 8%). In addition, the practices in the combined letter and flag group had a lower mean uptake rate, compared with the practices in the other groups. The participating practices and those who did not enter the study were similar.

**Effectiveness results**
The mean uptake rates were 55.3% (95% confidence interval, CI: 52.9 - 57.8) in the control group, 64.4% (95% CI: 62.1 - 66.7) in the letter group, 65.3% (95% CI: 62.5 - 68.1) in the flag group, and 67.9% (95% CI: 65.3 - 70.5) in the combined letter and flag group.

The random-effects logistic regression analysis indicated that the odds ratio of attendance was 1.31 (95% CI: 1.05 - 1.64; p=0.015) for the letter and 1.43 (95% CI: 1.14 - 1.79; p=0.0019) for the flag.

The interaction between letter and flag did not achieve statistical significance.

**Clinical conclusions**
The effectiveness analysis showed that flag and letters, independently, were both effective in increasing the uptake rates. The flag was marginally more effective than the letter. There was no statistically significant interaction between flag and letter.

**Measure of benefits used in the economic analysis**
The benefit measure used in the economic analysis was the attendance rate, as assessed in the effectiveness analysis.
Direct costs
Discounting was irrelevant as the costs were incurred over a short period of time. The unit costs were given. The health service costs were included in the economic analysis. These were for additional attendances due to the interventions, the identification of eligible women from an early prior notification list, any additional consultation, lengthier consultations, and the production and administrative processes associated with both interventions. The total costs of each intervention were calculated in an hypothetical practice with 256 eligible women. The cost/resource boundary adopted was that of the NHS. The costs were estimated from official published data, while the resources used were estimated from the trial. The costs referred to 1998 to 1999 prices.

Statistical analysis of costs
To estimate additional consultations, the economic analysis was carried out on a sub-sample of patients included in the effectiveness analysis. Power calculations were carried out to detect a statistically significant difference between 11 and 14% in the proportion of women consulting, with 80% power at a two-sided 5% significance level.

Indirect Costs
The indirect costs were not included.

Currency
UK pounds sterling ({}).

Sensitivity analysis
Sensitivity analyses were mainly carried out to assess the impact of some missing data on the estimated benefits and costs. In particular, it was assumed that among the 401 women lost to follow-up, those in the three categories of under breast care, being screened and recently screened, did attend. It was also assumed that those in the four categories of dead, ended screening, moved away and letters returned unopened, did not attend for screening. Moreover, the primary analysis was repeated assuming either that all 401 women attended or that none of them did. Further sub-group sensitivity analyses were carried out to investigate the effect of flag activation for women in the two flag groups. Also, to determine the effects of the interventions on women according to consultation status (infrequent consulters and others) and screening history (first time invitee, called previously but never attended, called previously and had attended, screening history missing).

On the cost side, sensitivity analyses were performed to assess the impact of variations in the cost of production and administrative processes associated with the interventions. Also, to assess variations in the costs of retrieving flags, who activated the flags, and the costs and number of additional attendances.

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

Cost results
The total costs were 395 (42% borne by the practice) for the letter, 806 (67% borne by the practice) for the flag, and 1,201 (59% borne by the practice) for the combination of letter and flag.

Synthesis of costs and benefits
An incremental cost-effectiveness analysis was performed to combine the costs and benefits of the interventions. The extra cost per additional attendance was 26 for the letter in comparison with no intervention, 41 for the flag in comparison with no intervention, and 41 for the combination of letter and flag over the letter alone. The estimated costs per additional attendance were generally not affected by the variations examined in the sensitivity analyses. The
exception was two extreme cases favouring the flag intervention. First, if the administrative costs of the letters were more than double those estimated, or second, if the additional attendances were recalculated using the odds ratios by the lower confidence limit for the letter and the upper confidence limit for the flag.

Authors’ conclusions
Both the flag and the letter independently improved attendance for breast screening. The letter proved to be the most cost-effective intervention. However, as the practice usually incurs a proportion of costs higher than the NHS, the choice of the intervention may differ from the perspective of the NHS or the practice.

CRD COMMENTARY - Selection of comparators
The comparator selected in the analysis was no intervention, which was justified as the aim of the study was to assess the active value of the letter and the flag independently. The combination of both methods was then considered as a possible alternative.

Validity of estimate of measure of effectiveness
The effectiveness analysis used a pragmatic factorial cluster randomised controlled trial, which was appropriate for the study question. The internal validity of the analysis was further enhanced by the performance of power calculations. The method of randomisation was reported, and the study sample was representative of the study population. Appropriate statistical analyses were carried out to estimate the effect of interactions between the interventions. The study took place in several centres, and clustering and stratification processes were performed. Comparability between the practices participating in the study and those who refused was demonstrated. Although the study groups were not perfectly comparable at baseline, due to the clusterRCT, the authors have dealt with this problem using the appropriate statistical methods.

Validity of estimate of measure of benefit
The benefit measure was derived directly from the effectiveness analysis.

Validity of estimate of costs
The analysis of the costs was carried out from the perspective of the NHS. It would seem that all the relevant categories of costs have been included in the analysis. Power calculations were performed on the cost side, as the cost data were derived using a sub-sample of patients included in the effectiveness analysis. Statistical analyses were performed on some quantities of resources. The price year and prices were appropriately given, thus making reflation exercises to other settings easy. However, the quantities of resources were not reported. The cost estimates were also somewhat specific to the NHS setting.

Other issues
The authors compared their findings with published studies. In terms of the issue of the generalisability of the study results to other settings, the authors noted that the study findings may be generalised to other areas with similar uptake rates for breast screening. However, the external validity of the analysis was weakened on the cost side, as the unit costs were not reported. The authors noted some limitations of the analysis (see previous fields).

Implications of the study
The authors suggest that both interventions (flag and letter) were effective in increasing breast screening, but the letter was more cost-effective. The decision to implement one or both of the interventions depends on the willingness of the NHS to pay for the extra benefits gained. The authors also suggest that future research should focus on the duration of the flags in the physician's records, the value of translation sheets, and the role of interventions for older women. Emphasis should be placed on more recent genetic aspects of breast cancer.
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