Who can best recruit to randomized trials: randomized trial comparing surgeons and nurses recruiting patients to a trial of treatments for localized prostate cancer (the ProtecT study)

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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 surgeons, compared with nurses, for recruiting patients to randomised trials of treatments for localised prostate cancer.

Type of intervention
Other: experimental trials.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised men aged 50 to 69 years who agreed to undertake prostate-specific antigen (PSA) testing and who were subsequently found to have localised prostate cancer.

Setting
The setting was primary care. The location of the trial was not explicitly stated, but the patients were recruited from three general practices in the UK.

Dates to which data relate
The effectiveness data were gathered between 1999 and 2001. The dates relating to the resource use data and prices were not given.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
An a priori power calculation established that a sample size of 150 patients would detect a 20-percentage point difference in the proportion agreeing to randomisation, with a power of 80%. Men identified by the PSA test as having localised prostate cancer attended an appointment with an urologist. The urologist explained the diagnosis and sought consent to enter the patient into the recruitment trial. Of 167 eligible patients, 17 (10%) did not accept randomisation while 150 agreed to enter the recruitment trial. Those participating were randomly allocated into two groups of 75 patients.
Study design
The randomised controlled trial was undertaken at three centres. This recruitment trial was nested within the ProtecT (Prostate Testing for Cancer and Treatment) study. Randomisation was achieved using computer-generated blocks of size six. Stratification by the study centre and decade of age was included. The patients were not followed-up beyond recruitment to the trial.

Analysis of effectiveness
The effectiveness study was analysed on an intention to treat basis. The effectiveness outcome was agreement to be randomised to the treatment trial for radical surgery, radical radiotherapy, or monitoring of localised cancer of the prostate. The baseline comparability of the two groups of patients was not shown.

Effectiveness results
Fifty patients (67%) randomised to see a nurse agreed to participate in the treatment trial compared with 53 patients (71%) who saw a urologist. The 4% (95% confidence interval, CI: -10.8 - 18.8) difference in recruitment rates was not statistically significant, (p=0.6). Significant differences in the recruitment rates were noted between study areas, although differences within centres between nurses and urologists were considered smaller.

Clinical conclusions
The researchers concluded that nurses were as effective as doctors at recruiting patients to enter the trial.

Measure of benefits used in the economic analysis
The results showed no difference in the effectiveness of doctors and nurses in recruiting patients to enter the treatment trial. Thus, the economic analysis was based on cost-differences only and was a cost-minimisation analysis.

Direct costs
The resource quantities and the costs were reported separately as the average duration of the appointment and the average cost of staff time for the doctor or nurse. Staff time was calculated using annual salaries, including employer on-costs of contributions to pensions and National Insurance. These were taken from one centre and were adjusted by the number of hours worked per week, the number of weeks worked per year, and the proportion of time spent with the patients. The dates to which the price data referred were not specified and no price year was provided. No other direct costs were included in the analysis. Discounting was not relevant as the costs were incurred in less than 2 years.

Statistical analysis of costs
The authors provided mean values and standard deviations of the costs. Differences between the mean costs of the nurses and urologists were investigated using t-tests and 95% CIs.

Indirect Costs
The indirect costs were not included, which was consistent with the stated perspective.

Currency
UK pounds sterling (€).

Sensitivity analysis
Sensitivity analyses were carried out to increase the generalisability of the results. They explored the impact of the number of information appointments the patient attended and the staff present. More specifically, by varying the
number of appointments dependent on whether a nurse or urologist conducted the appointments, and adding in the presence of a nurse as a second member of staff at the appointments.

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

**Cost results**
The cost per patient averaged 36.40 for a nurse-led appointment and 43.29 for an urologist-led appointment. The difference between these two means was statistically significant, \((p=0.039)\). From the sensitivity analysis, the only sensitive parameter was the presence of a second nurse at the appointment. In the scenario where a second nurse attended 50% of the nurse-led appointments, nurses became the more expensive option. The authors noted that it was rare for a second nurse to be present at a nurse-led appointment. Also, that the cost rose considerably if 50% of doctor-led appointments were also attended by a nurse.

**Synthesis of costs and benefits**
Not relevant since the economic analysis was based on cost-differences only.

**Authors' conclusions**
Nurses were as effective, and were more cost-effective, than urologic surgeons at recruiting patients to a trial of treatments for localised prostate cancer. While noting the need to further investigate the generalisability of the evidence, the study suggested an enhanced role for nurses in recruiting patients to trials.

**CRD COMMENTARY - Selection of comparators**
It was not explicitly justified why nurses, rather than any other professionals allied to medicine, were chosen as the comparator to doctors. Implicit justification was provided in the referencing of two articles, which examined the expansion of the role of the nurse and substitution for doctors. You should decide whether nurses represent a valid alternative to urologists in the recruitment of patients to trials.

**Validity of estimate of measure of effectiveness**
The estimates of the effectiveness are likely to be valid because of the study design, basically a prospective randomised trial. The methods of sample selection and randomisation were reported. The basis of the analysis of the clinical study was intention to treat. Further, power calculations were performed in the preliminary phase of the study. The sample of patients is likely to have been representative of the study population. No loss to follow-up appears to have occurred. Approximately 10% (17) of the patients declined to participate in the recruitment trial but of these, 11 agreed to be randomised to the treatment trial. These issues tend to enhance the internal validity of the analysis. However, the patients' characteristics were not reported and the baseline comparability of the study groups was not discussed. The possible effect of the gender of the recruiter was not considered.

**Validity of estimate of measure of benefit**
The analysis of benefit was based upon the equivalence of the effectiveness outcomes. Therefore, the economic analysis included only the costs.

**Validity of estimate of costs**
All the categories of cost relevant to the perspective adopted were included in the analysis. The average cost per patient appointment and average duration of appointment were reported separately. Set-up costs, specifically the training of nurses, were not included, biasing costs in their favour. Descriptive statistics of the duration of the nurse-led or doctor-led appointment from the study were reported and compared using a t-test. The staff costs were taken from one of the
trial centres and were reported only as the cost per appointment.

The greater cost-effectiveness of nurses compared with doctors was dependent on the pay differential between the two groups. If recruitment to trials is viewed as an expansion of the nursing role, it may be accompanied by an expectation of pay increases. A sensitivity analysis could explore this. The authors noted that the results would be different if doctors were paid on a fee-for-service rather than salary basis, thus affecting the generalisability of the results to countries with other systems of payment. A statistical comparison of the cost per appointment was performed. Discounting was not necessary. The price year was not reported, thus making reflation exercises in other settings difficult.

Other issues
The authors did not compare their findings with those from other studies. They reported that little published research on the topic was available. The authors highlighted two more factors that limited the generalisability of the results. First, the difference between the two groups was much less than between centres, suggesting an “individual” style, which may mask group differences. Second, older men were reported to be more likely than other groups to accept randomisation.

Implications of the study
The training of nurses twice per year is recommended. The authors also acknowledged the need to investigate the topic in other contexts.

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