Gender patterns in cost effectiveness of quality improvement for depression: results of a randomized, controlled trial

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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
Two practice-based quality improvement (QI) programmes for patients suffering from depression were examined. One involved medication management (QI-Meds) and the other psychotherapy (QI-Therapy). In QI-Meds, nurse specialists were trained to provide follow-up assessment and to support medical adherence to the programme for 6 months. In QI-Therapy, local psychotherapists were trained in 8- to 12-session courses to provide individual and group cognitive-behavioural therapy. In both QI programmes, patients and clinician retained the choice of treatment and their use of intervention resources. In addition, local practice teams were trained in a 2-day workshop, and were provided with patient education materials, patient tracking forms, and clinical manuals and pocket reminder cards.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients suffering depression. Patient were eligible for the study if they intended to use the clinic participating in the study for the year following the beginning of the study, were aged over 17 years, did not have an acute medical emergency, spoke English or Spanish, and had either insurance or a public-pay arrangement that covered the intervention care. Eligible patients were screened for depression using the "stem" items for major depressive and dysthymic disorder from the 12-month Composite International Diagnostic Interview (CIDI, edition 2.1), and items assessing depressed symptoms in the month before enrolment.

Setting
The setting was primary care. The economic study was conducted in primary care clinics in the USA.

Dates to which data relate
The effectiveness and resource use data referred to patients enrolled in the study between June 1996 and March 1997. The data were collected over 24 months of follow-up. 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 was carried out prospectively on the same patient sample as that used for the effectiveness analysis.
Study sample
The study sample was selected from 27,332 consecutive patients who presented to the participating centres between June 1996 and March 1997. Of the patients screened, 3,918 were potentially eligible for the study. Of these, 241 were found to be ineligible. Of those who read the informed consent, 1,356 (79%) were enrolled. There were 443 patients in UC, 424 in QI-Meds and 489 in QI-Therapy. The final enrolled sample comprised 375 male and 981 female patients. No power calculations were performed to determine whether the study sample size was sufficient to detect any differences in outcome.

Study design
The study was a group-level, randomised controlled trial (RCT) that was conducted in six managed care organisations in the USA. The study sites included a staff model health maintenance organisation (HMO), several group model HMOs, an independent physician network, and a public delivery system. All primary care practices with at least two clinicians were eligible to participate, and 46 of the 48 did so. Within organisations, the practices were matched into blocks of three clusters, based on factors expected to affect outcomes. Within blocks, the practices were randomised to usual care or one of the two interventions (QI-Meds or QI-Therapy). The method of randomisation was not described. The primary care clinicians were recruited before learning their clinic’s randomised assignment. The patients and carers retained the choice of type of treatment (QI-Meds or QI-Therapy) or none.

Self-administered mail surveys were obtained at baseline every 6 months for 2 years. The survey response rates were 88% for the baseline survey, and 83% for the 6- and 12-month surveys. The response weights were not used to adjust for different enrolment. No blinded assessment was reported.

Analysis of effectiveness
The basis for the analysis of the clinical study was intention to treat. The primary health outcomes used were quality of life scores, days of depression burden and employment status. Quality of life scores were estimated for each 6-months’ follow-up period. These were based on either the health utility index from the Short-Form 12-Item Health Survey (SF-12) or positive scores of three measures, specifically, probable major depressive disorder, significant depressive symptoms (based on a Modified Center for Epidemiology Studies Depression Scale) and poor mental health-related quality of life (HRQOL). The employment was measured by averaging employment status at the start and end of each 6-month period and multiplying by the number of work days in 6 months.

The study groups were comparable at baseline for most characteristics such as age, educational attainment, or severity of depression. However, some statistical difference was observed. Female patients in the intervention groups were better educated than the controls. They were also more likely to have current major depression or dysthymia (versus sub-threshold symptoms; p<0.01 for QI-Meds relative to UC). Adjustments were made for potential confounding factors. The initial treatment rates were around one third higher for women than for men.

Effectiveness results
The authors did not report quality of life scores, depression-burden day and employment status for UC.

For male patients, QI-Therapy reduced the number of depression-burden days by 54 over 24 months, (p=0.11) while QI-Meds increased them (this result was not shown, although the authors reported that the difference was not statistically significant). For female patients, QI-Therapy reduced depression-burden days by 51, (p=0.014) and QI-Meds reduced them by 50, (p=0.038).

Among men, QI-Meds increased employment by 6 days over 2 years (the difference was not statistically significant) and QI-Therapy increased it by 37 days, (p=0.022). Among women, QI-Meds increased employment by 26 days, (p=0.0245) and QI-Therapy increased it by 14 days (the difference was not statistically significant).

Clinical conclusions
For both male and female patients, the interventions led to clinical improvement and positively affected the availability
for work. The exception was QI-Meds for men, which was not clinically effective.

**Measure of benefits used in the economic analysis**
The benefit measure used was the quality-adjusted life-years (QALYs) gained. Two measures of QALYs were used. QALY-SF was estimated for each 6-month follow-up period based on the health utility index from the SF-12. QALY-DB was assessed using depression-burden days on the basis of positive scores of three measures (probable major depressive disorder, significant depressive symptoms, and poor mental HRQOL). To derive QALY-DB, the study adopted the finding of published literature that a year of depression was associated with losses of 0.2 to 0.4 QALYs.

**Direct costs**
It appears that the cost/resource boundary was that of society. The direct costs consisted of intervention-specific costs and other health care costs. The former were for screening, intervention materials, initial nurse specialist assessments, and 20 minutes of supervision by nurses and therapists per enrolled patient. Research-specific costs were excluded from the analysis. Follow-up visits to intervention staff were included in patient reports of outpatient visits. The latter (other health care costs) involved emergency department visits, medical and mental health visits, and psychotropic medications used. The estimated costs included facility charges, professional fees and ancillary services associated with the visits. The costs and the quantities were not analysed separately. The costs were estimated on the basis of provider reimbursement rates, which were used as proxies for health care costs, and were derived from a national database. The price year was 1998. Discounting was not carried out as the costs were incurred over 24 months.

**Statistical analysis of costs**
Due to the skewed distribution of the costs in the trial, two-part models were used to examine intervention effects on care costs. The first model was the probability of positive costs, using logistic regression. The second model was the log of costs, using ordinary least-squares regression.

**Indirect Costs**
The indirect costs included patient time costs for obtaining health care. These consisted of time for outpatient medical and mental health visits, emergency department visits, travel and waiting times, and time to fill prescriptions. The patients' time was priced using the reported hourly wage at baseline and a gender-specific mean wage for those not working. The costs and the quantities were not analysed separately.

**Currency**
US dollars ($).

**Sensitivity analysis**
The authors did not report whether a sensitivity analysis was conducted.

**Estimated benefits used in the economic analysis**
For male patients, the incremental QALY-SF was 0.023 due to QI-Therapy, (p not significant) and -0.011 due to QI-Meds, (p=not significant). For female patients, it was 0.022 due to QI-Therapy, (p=0.019) and 0.018 due to QI-Meds, (p=0.06).

For male patients, QI-Therapy produced incremental QALYs-DB ranging from 0.03 to 0.059. For female patients, QI-Therapy produced incremental QALYs-DB ranging from 0.028 to 0.056 and QI-Meds produced incremental QALYs-DB ranging from 0.027 to 0.055.

**Cost results**
For men, the average costs per patient under UC were estimated to be $3,148. These increased by $429 for QI-Meds patients, (p not significant) and by $983 for QI-Therapy patients, (p<0.10). For women, the average costs per patient under UC were estimated to be $4,139. These increased by $425 for QI-Meds participants and by $275 for QI-Therapy participants, (both not significant).

Synthesis of costs and benefits
For male patients, compared with UC, the incremental costs per QALY-SF for QI-therapy were $42,554 and QI-Meds was not cost-effective. For female patients, compared with UC, the incremental costs per QALY-SF were $12,500 for QI-therapy and $23,611 for QI-Meds.

For male patients, compared with UC, the incremental cost per QALY-DB for QI-therapy ranged from $16,611 to $33,222 and QI-Meds was not cost-effective. For female patients, compared with UC, the incremental cost per QALY-DB ranged from $4,920 to $9,841 for QI-Therapy and from $7,756 to $15,512 for QI-Meds.

Authors’ conclusions
Among men, the quality improvement programme involving psychotherapy (QI-Therapy) yielded cost-effectiveness towards the upper range of accepted medical interventions, while the programme involving medication management (QI-Meds) was not cost-effective. Among women, the relative cost-effectiveness for both interventions was well within the range of other accepted medical interventions, particularly for QI-Therapy because of its relatively small effect on costs.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. UC was selected because it represented the routine intervention for patients with depression. However, more details on the UC addressed in the study would have been appreciated for comparisons with practices in other settings. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The authors’ conclusion was ensured by using an RCT and a large sample size in the effectiveness analysis. In addition, appropriate statistical analyses were conducted on the outcome measures. However, power calculations were not performed and, therefore, the study may have lacked sufficient power to detect statistical significance in all health outcomes. In addition, the study groups were not completely comparable at baseline, although appropriate multivariate techniques, conducted on all intention to treat analyses, were used to deal with the issue of confounding variables. The authors indicated that this at least partially dealt with the differences between patient groups, although the possibility of confounding variables could not be ruled out. These issues tend to limit the internal validity of the analysis.

Validity of estimate of measure of benefit
QALYS derived from a health utility index and from days of depression burden were used as the measure of benefit. This was appropriate since they captured the impact of the interventions on he patients’ quality of life.

Validity of estimate of costs
Although the perspective from which the costing was carried out was not specified, it appears to have been that of society since both the direct and indirect costs were assessed. All the relevant categories of costs seem to have been included in the analysis. Some cost items were not included, but these omissions were unlikely to have affected the study's conclusions. However, the authors stated that some cost estimations were not precise, despite the large sample size. The costs and the quantities were not reported separately, and this would not enable the analysis to be easily extrapolated to other settings. In addition, reimbursement rates were used as proxies for costs. This has the limitation of not reflecting true opportunity costs, thus restricting the external validity of the results. The price year was reported, which aids reflation exercises in other settings. An appropriate statistical analysis of costs was performed. Discounting
was appropriately not carried out as the costs were incurred over 24 months.

**Other issues**
The authors compared their results with those from other published studies. The issue of generalisability of the results to other settings was not addressed. The authors reported a number of limitations to their study. For instance, the lack of precision in the cost estimates, and the potential of recall or other bias resulting from self-reported outcomes and the lack of sufficient practice networks. Other limitations were that only patients who sought health care from a primary care were included, and that the study design did not allow the authors to identify the effects of individual components of each intervention on the outcomes assessed. The results of the study were adequately reported. The study considered patients suffering from depression and this was reflected in the authors' conclusions. The authors' conclusions reflected the scope of the analysis.

**Implications of the study**
The authors inferred that further research is needed to understand the positive outcomes of the QI-Therapy for men; why QI-Meds was effective for women but not for men; and why QI-Meds yielded larger improvement in women’s labour supply than did QI-Therapy.

**Source of funding**
Funded by the National Institutes of Mental health (R01MH64658, P50MH54623), the Agency for Healthcare Research and Quality (R01-HS08349), and the John D and Catherine T MacArthur Foundation (grant number 96-42901A-HE).

**Bibliographic details**

**PubMedID**
16005520

**DOI**
10.1016/j.jad.2005.03.018

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM
MeSH
Adult; Cost-Benefit Analysis; Depressive Disorder, Major /economics /therapy; Female; Health Care Costs; Humans; Male; Quality of Life /psychology; Surveys and Questionnaires; Treatment Outcome

AccessionNumber
22005001308

Date bibliographic record published
31/05/2006

Date abstract record published
31/05/2006