Use of standardised outcome measures in adult mental health services: randomised controlled trial


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 authors considered the use of standardised outcome measures comprising two elements: the completion of outcome measures by patients and staff and the receipt of identical feedback on these outcome measures. Outcome measures were completed on a monthly basis by postal questionnaire. Feedback was provided by research staff at 3-monthly intervals and comprised colour-coded graphics and text showing change over time and highlighting areas of disagreement.

Type of intervention
The authors aimed to analyse the process of care by considering the outcomes measure that were used and the sharing of the results from these outcome measures.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult mental health patients. Patients were included if they had been on the case load in any of the study settings during the dates of the trial for at least 3 months and were aged between 18 and 64 years.

Setting
The setting was tertiary care (community mental health teams). The economic study was carried out in the UK.

Dates to which data relate
The patients were recruited between May 2001 and December 2002 and follow-up was completed by July 2003. Resource use was measured over the same period of time. The costs were reported in 2001 - 2002 prices.

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 using the same patient sample as that used in the effectiveness study.

Study sample
The authors carried out power calculations in advance of carrying out their study in order to estimate the potential impact of chance and inform the optimal sample size of the trial. The sample was then selected by including all mental health patients within the study setting who conformed to the inclusion criteria. Patients were excluded if they could not
be contacted or if they refused consent. One hundred and sixty of the 433 patients assessed for eligibility were allocated, 101 to receive standardised outcomes (the intervention group) and 59 to receive treatment as usual (the control group). The authors noted that 117 patients refused consent having had no explanation of the study, and that a further 15 refused consent after an explanation of the study. A single further individual withdrew consent after randomisation. Each patient was paired with an appropriate member of staff.

**Study design**
The authors designed a stratified randomised controlled trial, with stratification taking account of age, gender, ethnicity, diagnosis and community mental health team. The Stata program was used to ensure random allocation of the patients and balanced stratifying factors. Allocation to the stratified group was concealed until the intervention was assigned. The staff and patients were aware of their allocation. The patients were followed for 7 months. Five patients allocated to the intervention group and 10 to the control group were lost to follow-up because they were too unwell to interview (4), not contactable (6), or refused further contact (5). The study was based within eight community health teams in Croydon, South London, UK.

**Analysis of effectiveness**
The analysis was based on intention to treat principles. The primary outcome measures were the Camberwell Assessment of Need Short Appraisal Schedule patient version (CANSAS-P) and the Manchester Short Assessment (MANSA). The authors defined a reduction of 1.0 in unmet needs (from the CANSAS-P questionnaire) or an increase of 0.25 on the MANSA questionnaire as criteria to identify improved effectiveness. The groups were compared extensively at baseline in terms of their demographic variables and clinical variables, but the authors did not report statistically significant differences between patients in the intervention and comparison groups. The authors did not find any differences in demographic or clinical variables for patients with and without full follow-up data.

**Effectiveness results**
The baseline scores for the primary outcome measures were as follows:

- the mean CANSAS-P unmet needs score was 4.36 (standard deviation, SD=3.36) for the intervention group and 4.98 (SD=4.05) for the control group;
- the mean CANSAS-P met needs score was 4.23 (SD=2.81) for the intervention group and 4.17 (SD=3.04) for the control group;
- the mean MANSA score was 4.25 (SD=0.99) for the intervention group and 4.25 (SD=1.05) for the control group.

The scores at follow-up were as follows:

- the mean CANSAS-P unmet needs score was 3.96 (SD=3.58) for the intervention group and 4.10 (SD=4.31) for the control group, a difference of 0.15 (95% confidence interval, CI: -1.2 to 1.5);
- the mean CANSAS-P met needs score was 4.39 (SD=3.32) for the intervention group and 4.63 (SD=4.71) for the control group, a difference of 0.25 (95% CI: -1.1 to 1.6);
- the mean MANSA score was 4.27 (SD=1.04) for the intervention group and 4.20 (SD=1.14) for the control group, a difference of -0.07 (95% CI: -0.4 to 0.3).

**Clinical conclusions**
The authors reported that there was no evidence of differences between the groups in mean follow-up of patient rated unmet need and in mean follow-up of quality of life (according to the MANSA scores). These conclusions were supported by a series of sensitivity analyses that adjusted for baseline levels, random effects for staff member and community mental health teams, and missing data.
Measure of benefits used in the economic analysis
The authors used quality of life as their summary measure of health benefit. Although not explicitly stated in their net benefit analysis, this estimate seems to have been taken from the MANSA scores. The net-benefit analysis was used to enable the evaluation of cost-effectiveness over a range of plausible thresholds.

Direct costs
The authors did not state a specific perspective for their economic analysis, except to say that the perspective was broad. They reported that production costs were not included in the analysis, but it was unclear which production costs they referred to. For instance, they might have been referring to the production of patient and staff questionnaires, or the production of feedback. CSRI (not defined) data were combined with the unit costs to estimate the costs of providing the service. The unit costs were also obtained from published sources. The average cost of providing the intervention was based on an assessment of processing time and the use of researchers' time. Patient level data on service contacts (bed-days for inpatient care) and the costs of follow-up were noted. Discounting was not required because of the relatively short-run horizon for this study. The costs were reported in 2001 - 2002 prices. The quantities were reported separately from the unit costs.

Statistical analysis of costs
Owing to the skewed nature of the costs, the authors used bootstrapping with 1,000 repetitions to produce cost-differences. For cost-effectiveness estimates, a hypothetical amount (lambda) was used to assign a value to health outcomes, with the authors using regression analysis with lambda between 0 and 90 as a dependent variable. Bootstrapping re-samples were then used to estimate the likelihood that the intervention was more cost-effective that the control. Cost-effectiveness acceptability curves were stated to have been constructed but were not presented in the paper.

Indirect Costs
The indirect costs were not estimated. Since the perspective was not specific, it was unclear whether indirect costs might have been relevant.

Currency
UK pounds sterling (£).

Sensitivity analysis
A sensitivity analysis was carried out by assessing the significance of the difference in total costs after excluding inpatient care.

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

Cost results
The total mean cost for all services at baseline was 5,097 (SD=7,863) for the control group and 5,548 (SD=7,431) for the intervention group.

The total mean cost for all services at follow-up was 6,206 (SD=9,994) for the control group and 3,620 (SD=4,095) for the intervention group.

The 95% CI of the difference at follow-up was -5,391 to -102.

The majority of the cost-difference was due to reduced inpatient costs.
Synthesis of costs and benefits
If no value were placed on lambda, the probability that the intervention was cost-effective would be 0.98. Positive values of lambda would improve this probability.

Authors' conclusions
The study demonstrated the "feasibility to implement a carefully developed approach to routine outcome assessment in mental health services" and that the "cost could be more than offset by savings in service use".

CRD COMMENTARY - Selection of comparators
The authors assessed standardised outcome measures comprising two elements: the completion of outcome measures by patients and staff and the receipt of identical feedback on these outcome measures. The comparator was usual care. The reader must define usual care within their own setting in order to assess whether these are appropriate comparators in their own setting.

Validity of estimate of measure of effectiveness
The authors designed a stratified randomised controlled trial, the aim being to reduce systematic differences between patients in the two groups and thereby reducing the possibility of confounding factors. The clustering further helped distribute patients with specific characteristics evenly between the two groups. The study sample was representative of the population as it included adult mental health patients who then met the inclusion and exclusion criteria. The authors reported detailed statistics on why different potential patients did not enter the final study and also baseline demographical and clinical data (although they failed to report statistical differences). The analysis was handled credibly using intention to treat principles, random effects to account for missing data, and statistical information to indicate uncertainty in the effectiveness estimates.

Validity of estimate of measure of benefit
The authors used the outcome measures from the clinical study to estimate a summary measure of health benefit. This measure provides data that are comparable only with other health technologies that have been assessed with this measure, and hence provides a narrow base for comparison. Nevertheless, the measure provides a valuable assessment of quality of life.

Validity of estimate of costs
The authors did not report a specific perspective from which the costs were estimated and this is a weakness of the costing analysis. It is not possible to assess whether all the relevant cost estimates have been included, and it was not clear to which group (society, decision-makers, health care providers) the results apply. Despite this, the authors used detailed costing sources, unit costs from published sources and applied resource use as indicated in the effectiveness trial to estimate the costs. The unit costs and resource use were reported in detail, which will enable the reader to gain a good understanding of the cost-drivers and to assess whether the analysis is generalisable to other settings. Statistical and sensitivity analyses were used to explore the impact of uncertainty.

Other issues
The authors noted that this was the first study to assess the use of standardised outcome measures. Nevertheless, they were able to draw a comparison with previous work suggesting that "as with previous studies subjective outcomes did not improve". The issue of generalisability to other setting was not explicitly addressed or discussed, but the use of sensitivity analyses, both in the effectiveness and costing elements, improved generalisability. Readers must assess the comparability with their own setting. The results were presented thoroughly and the conclusions were a true representation of these results. Several limitations were discussed. These included the possibility of recall bias in patient reported service use data, the fact that neither the patients nor staff were blinded, and that clustering might have been used to control for member of staff.
Implications of the study
The authors noted the relatively short follow-up period, stating that this should be extended in future work. They also noted that, despite the lack of difference in subjective outcome measure between the groups, the intervention could be cost-saving because of savings in service usage (fewer admissions).

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