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 study compared two ways of providing care for tuberculosis (TB) patients in Kenya. One was conventional hospital-based care, while the other was the new more decentralised option providing increased community and primary care.

The conventional approach to care for new smear-positive patients involved hospital admission for the 2-month intensive phase of treatment. This was followed by 6 months of outpatient care during which the patients were expected to visit a health facility once a month to collect their drugs. Sputum smears were monitored after 2, 5 and 8 months of treatment. In the new pilot approach, patients were only admitted to hospital if their clinical condition necessitated it. Otherwise, they received directly observed treatment (DOT) on an outpatient basis during the intensive phase, with a choice of observation at a health facility or by a community volunteer. After the first 2 months, treatment was exactly as in the conventional approach.

For new smear-negative and extra-pulmonary TB patients, the conventional approach involved a 12-month regimen. The first month of treatment was provided in hospital. The remaining 11 months were provided on an unsupervised outpatient basis, with patients required to collect their own medicines once a month from a health facility. The new approach involved a short-course 8-month oral regimen. The first 2 months of treatment were directly observed at a health facility of their choice, or by a community volunteer. The remaining 6 months of treatment were unsupervised, and patients were required to collect a 1-month supply of drugs on a monthly basis from their nearest health clinic.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised new smear-positive, new smear-negative and extra-pulmonary adult patients living in Machakos District, a rural area 50 km east of Nairobi, Kenya.

Setting
The study setting was community, primary and secondary care. The economic study was carried out in Kenya.

Dates to which data relate
The effectiveness and resource use data were collected from patients registering in the TB programme before decentralisation (1996), and from patients who registered in the TB programme after decentralisation (1998 and 1999). The price year was 1998.
Source of effectiveness data
The effectiveness data were derived from a single study (Kangani et al. 2003, see ‘Other Publications of Related Interest’ below for bibliographic details).

Link between effectiveness and cost data
For the evaluation of the old centralised TB programme, the costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study. For the evaluation of the new decentralised programme, the costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
No sample size was determined in the planning phase of the study. In addition, power calculations were not performed retrospectively.

A total of 1,141 patients registered with the centralised TB programme during the control period. Of these patients, 600 (52.6%) were new smear-positive cases, 479 (42.0%) were new smear-negative cases, 5 (2.2%) were new extra-pulmonary TB cases and 34 (3%) were retreatment smear-positive cases.

During the first year of the intervention period, a total of 1,522 patients registered with the decentralised TB programme. Of these patients, 863 (56.7%) were new smear-positive cases, 553 (36.3%) were new smear-negative cases, 76 (5%) were new extra-pulmonary TB cases and 30 (2%) were retreatment smear-positive cases. During the second year of the intervention period, a total of 1,722 patients registered with the decentralised TB programme. Of these patients, 821 (47.7%) were new smear-positive cases, 662 (38.4%) were new smear-negative cases, 183 (10.6%) were new extra-pulmonary TB cases and 56 (3.3%) were retreatment smear-positive cases.

The authors did not give the age or gender characteristics of the two groups of patients (i.e. those registered during the control period, and those registered during the intervention period).

Study design
This was a cohort study with historical controls that was undertaken in the Machakos District, Kenya. The patients appear to have been followed up for one year. The authors reported no loss to follow-up.

Analysis of effectiveness
It would appear that all the patients included in the study were accounted for in the analysis. The measure of effectiveness used for new smear-positive patients was the percentage of patients successfully treated (i.e. the percentage of patients for whom cure was confirmed by sputum smear microscopy, plus the percentage of patients who completed treatment but for whom cure was not confirmed by sputum smear microscopy). For smear-negative and extra-pulmonary TB patients, the measure of effectiveness used was the percentage of patients who completed treatment. Other outcome measures included the proportion of deaths, transfers and default. The authors provided no baseline characteristics of the patients treated in the control and the intervention periods. Consequently, it was unclear if the groups were comparable at analysis in terms of age, gender and prognostic features.

Effectiveness results
Outcomes for new smear-positive pulmonary TB patients: the successful treatment rate was 84.9% with the conventional approach to care, and 87.6% with the new pilot strategy, \( p=0.523 \).

Outcomes for new smear-negative pulmonary TB and extra-pulmonary TB patients: the treatment completion rate was 48.5% with the conventional approach to care, and 78.9% with the new pilot strategy, \( p<0.0001 \).

Clinical conclusions
The authors concluded that the decentralisation of the intensive phase of TB treatment resulted in the maintenance of good TB programme performance.

**Measure of benefits used in the economic analysis**

The measure of effectiveness used for new smear-positive patients was the percentage of patients successfully treated (i.e. the percentage of patients for whom cure was confirmed by sputum smear microscopy, plus the percentage of patients who completed treatment but for whom cure was not confirmed by sputum smear microscopy). For smear-negative and extra-pulmonary TB patients, the measure of effectiveness used was the percentage of patients who completed treatment.

**Direct costs**

The authors included the direct costs of the health service, patients and family members in their analysis. The costs to the provider included the costs of hospitalisation, drugs, a sputum smear and DOT visit. The hospital costs were derived from data supplied by a government and non-governmental organisation hospital. Other sources of data included budget and expenditure files for the hospital, published drug prices, published pay scales, vehicle logbooks, laboratory workload records, interviews with directors, and quantity surveys of employees, engineers, architects and clinical staff. The costs to the patients were estimated from a survey in which a random sample of patients on TB treatment was asked about travel and time costs associated with visits to clinics and treatment. The time costs were then converted into a monetary value based on the average reported hourly wage among the patients interviewed. Family costs included the costs associated with accompanying patients on outpatient DOT visits, and the costs associated with hospital stay. These costs were derived from interviews. The costs incurred by community volunteers were estimated to be zero. Discounting was unnecessary, as the costs were incurred during 1 year, and was therefore not performed. The study reported the average costs. The price year was 1998.

**Statistical analysis of costs**

The costs were treated as point estimates (i.e. the data were deterministic).

**Indirect Costs**

The indirect costs were not included.

**Currency**

US dollars ($). The exchange rate to convert from Kenya’s national currency to US$ was not reported.

**Sensitivity analysis**

No sensitivity analyses were undertaken.

**Estimated benefits used in the economic analysis**

See the 'Effectiveness Results' section.

**Cost results**

The average cost per patient treated for new-smear positive pulmonary TB was $591 during the control period ($294 incurred by the health system, $117 by the patients and $180 by the family) and $209 during the intervention period ($120 incurred by the health system, $51 by the patients and $38 by the family).

The average cost per patient treated for new-smear negative and extra-pulmonary TB was $311 during the control period ($160 incurred by the health system, $61 by the patients and $90 by the family), and $197 during the intervention period ($106 incurred by the health system, $53 by the patients and $38 by the family).
Synthesis of costs and benefits
Cost-effectiveness was calculated as the cost per patient successfully treated (for new smear-positive pulmonary TB patients) and the cost per patient completing treatment (for new smear-negative pulmonary and extra-pulmonary patients).

The authors reported that the cost per new smear-positive patient successfully treated fell by 66%. The cost per patient completing treatment fell by 61% for new smear-negative and extra-pulmonary patients.

Authors' conclusions
There was a strong economic case for the expansion of decentralisation and strengthened community-based care in Kenya.

CRD COMMENTARY - Selection of comparators
A justification was given for using the centralised, hospital-based approach to TB case management as the comparator. It represented current practice in the authors' own settings. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a cohort study with historical controls, which was appropriate for the study question. However, this study design has the potential of introducing biases into the study, as both interventions are compared over different time periods. Hence, external influences might have affected the authors' results. Although the study sample was representative of the study population, the authors failed to report sufficient details on the study population. For example, they did not explain what smear-negative or smear-positive cases entailed. The patient groups were not shown to be comparable at analysis, and no baseline characteristics were reported. Appropriate statistical analyses were undertaken to test if differences in clinical outcomes between patients treated in the control and intervention periods were statistically significant.

Validity of estimate of measure of benefit
The measure of effectiveness used for new smear-positive patients was the percentage of patients successfully treated. The authors reported that this measure was the standard indicator of programme success used by the World Health Organization. For smear-negative and extra-pulmonary TB patients, the measure of effectiveness used was the percentage of patients who completed treatment. The authors reported that this was the desired outcome of treatment in the treatment outcome monitoring system for these patients.

Validity of estimate of costs
All the categories of cost relevant to the perspective adopted were included in the analysis. The authors' cost analysis included the perspectives of the health care service, family and patients. All the major direct costs for these perspectives were included in the analysis. Although the costs and quantities were not reported separately for all categories of cost, the authors did report unit costs and for some categories they also reported resource use. This will increase the generalisability of the authors' results to other settings. The resources used and costs were derived from numerous sources, including interviews, published data and information from the authors' settings. No statistical or sensitivity analyses of the costs were performed. Discounting was not relevant, as all the costs were incurred during 1 year, and was therefore not performed. The authors did not report the currency exchange rate used to convert the costs into US dollars. The price year was reported, which will aid any possible inflation exercises.

Other issues
The authors reported that, to date, there have been no studies of the cost and cost-effectiveness of alternative ways of treating TB patients in Kenya. However, they reported that their findings were consistent with findings from other
studies in other low-income countries, including those also undertaken as part of the "Community TB Care in Africa" project. The issue of generalisability to other settings was not addressed, although the authors reported that their cost results were probably broadly generalisable. They reported that the costs per day in hospital and outpatient visit, the main components of cost, were likely to be similar in other parts of Kenya. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis.

The authors reported a number of further limitations to their study. For example, the cost analysis for hospital care was based on data from only one district hospital. This hospital, which reported lower costs than other hospitals, was where the majority of patients were admitted. Hence, the large fall in costs reported in this study may not be realised in practice.

**Implications of the study**
The authors reported that the new TB programme will require new funds for start-up training and community mobilisation costs in order to strengthen community-based care in Kenya.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
12971650

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adult; Community Health Services /economics /utilization; Cost-Benefit Analysis; Costs and Cost Analysis; Health Care Costs /statistics & numerical data; Humans; Kenya; Primary Health Care /economics /utilization; Rural Health Services /economics; Rural Population; Tuberculosis, Pulmonary /drug therapy /economics

**AccessionNumber**
22003001274

**Date bibliographic record published**
30/04/2006

**Date abstract record published**