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 examined two programmes for the treatment of tuberculosis (TB): directly observed treatment, short course (DOTS) versus self-administered therapy (SAT). TB patients under SAT visited the health centre every month to receive a one-month supply of medication. TB patients under DOTS visited the health centre three times weekly during the first 2 months of intensive treatment and twice weekly thereafter for supervised medication intake.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis, cost-utility analysis

Study population
The study population comprised a hypothetical cohort of patients with TB.

Setting
The setting was an outpatient clinic. The economic study was carried out in Brazil.

Dates to which data relate
Some clinical data were derived from studies published between 1995 and 2004. The costs and resource use data were obtained in 2004. The price year was 2004.

Modelling
The published TB transmission model included a separate HIV-infected sub-population to reflect the higher risk of developing TB in this patient group. The model took susceptibility, the proportion of patients latently infected, infectious and non-infectious TB, and recovery into account. A time horizon of 10 years was chosen. A graphical representation of the model was provided.

Study designs and other criteria for inclusion in the review
The clinical data used in the analysis were cure rates (with DOTS or SAT), case fatality rates, relapse rates, prevalence of disease, the proportion of susceptible individuals and all-cause mortality rates.

Sources searched to identify primary studies
Data on the effectiveness of treatments came from epidemiological estimates derived from the Health Department in Rio de Janeiro. Other epidemiological data on disease prevalence were derived from published studies, details of which were not given. Some assumptions were also made.

Methods used to derive estimates of effectiveness
Primary sources were selected in order to reflect the epidemiological characteristics and the clinical practice of the authors' context. No systematic search of the literature was carried out.

Measure of benefits used in the economic analysis
The summary benefit measures used were TB cases averted, TB deaths averted and disability-adjusted life-years (DALYs). These were all estimated using the decision model. An annual discount rate of 3% was applied.
Direct costs
The analysis of the costs was carried out from a societal perspective. It included the following medical costs for a health clinic operating at full capacity: supplies, medications, clinical tests, staff, incentives (bus tokens and vouchers for food purchase), transportation and waiting area. The unit costs and the quantities of resources used were not presented separately but were given as macro-categories. All costs and quantities were derived from administrative data based on the Rio de Janeiro Municipal Health Secretariat, and supplemented by real estate and equipment valuations from the private sector. Discounting was relevant, as 10-year costs were determined, and an annual rate of 3% was applied. The price year was 2004.

Statistical analysis of costs
The costs and quantities were treated deterministically, but minimum and maximum values were reported.

Indirect Costs
Productivity costs were appropriately included in the analysis because a societal perspective was adopted. Data on productivity losses due to lost time to patients were based on a time-motion study on the flow of over 100 patients through a sample of DOTS clinics conducted by the Rio de Janeiro Municipal Health Secretariat. As in the analysis of the direct costs, the price year was 2004 and an annual discount rate of 3% was applied.

Currency
US dollars ($). The conversion rate to Brazilian reales (BRL) was BRL 2.64 = $1.00.

Sensitivity analysis
A deterministic sensitivity analysis was performed to address the issue of uncertainty surrounding model inputs. The sources of ranges of values were not reported clearly for all inputs, but might have been based both on published studies and observational data from the Rio de Janeiro Municipal Health Secretariat. A first-order Monte Carlo simulation was also performed 10,000 times.

Estimated benefits used in the economic analysis
Over 10 years (in a population of 262,000 individuals), 5,485 (range: 5,043 to 5,937) TB cases, 264 (range: 228 to 301) TB deaths and 10,246 (range: 8,947 to 11,584) DALYs were expected with SAT.

Over 10 years (in a population of 262,000 individuals), 3,927 (range: 3,625 to 4,233) TB cases, 121 (range: 97 to 146) TB deaths and 4,820 (range: 3,950 to 5,709) DALYs were expected with DOTS.

Cost results
The 10-year costs (in a population of 262,000 individuals) were $580,271 (range: 526,594 to 637,395) with SAT and $1,047,886 (range: 964,381 to 1,139,588) with DOTS.

In relation to cost categories, staff costs accounted for 28% of the total costs for DOTS and 21% for SAT, medication costs 7% (DOTS) and 34% (SAT), clinical test costs 5% (DOTS) and 21% (SAT), and productivity costs 28% (DOTS) and 24% (SAT).

Synthesis of costs and benefits
An incremental analysis was performed in order to combine the costs and benefits of the alternative strategies.

The incremental cost of DOTS over SAT was $300 (range: 289 to 312) per TB case averted, $3,270 (range: 3,123 to 3,435) per TB death averted and $86 (range: 74 to 100) per DALY averted.

The incremental cost per DALY averted was below the gross domestic product (GDP) per capita in Brazil ($2,710 in 2003), thus DOTS would appear to be a cost-effective strategy.

The sensitivity analysis showed that the incremental costs were sensitive to changes in costs for health care staff and transportation, variations in the proportion of new infections not captured by the intervention, TB case-fatality rate and
TB cure rates (results not reported).

Authors’ conclusions
The authors concluded that directly observed treatment, short course (DOTS) was a highly cost-effective alternative to self-administered therapy (SAT) for the treatment of tuberculosis (TB) in the setting of the Rio de Janeiro health care system.

CRD COMMENTARY - Selection of comparators
The selection of comparators under examination appears to have been appropriate. The two programmes reflected standard care and a potential effective alternative in the authors’ context. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The clinical data were derived from sources that reflected the authors’ context. An administrative database was used for most epidemiological data. Other clinical estimates were derived from published studies, details of which (in terms of design and patient population) were not reported. Key clinical estimates were varied in the sensitivity analysis in view of the uncertainty in most of them. The authors also made some assumptions that were justified.

Validity of estimate of measure of benefit
Benefits were derived using the decision model. TB cases and TB deaths are widely used, but these are disease-specific measures which are comparable only with similar programmes. The use of DALYs ensures the possibility of wider comparisons with the benefits of other interventions. The approach used to calculate DALYs was not reported. The use of alternative discount rates was investigated.

Validity of estimate of costs
The choice of a societal perspective was appropriate and all the relevant costs were included in the analysis. Specifically, productivity costs are particularly relevant given that the majority of patients are still in the workforce. The costs were presented as macro-categories and a detailed breakdown of the cost items was not given. This might limit the possibility of replicating the analysis in other settings. Minimum and maximum values for costs were reported, although the source of these ranges was not clear. Other statistical analyses of the costs appear not to have been performed. The costs reflected the Brazilian accounting system but the sensitivity analysis considered variations in most economic data. The price year was reported, which will aid reflation exercises in other time periods.

Other issues
The authors did not report the findings from other studies. They stated that their analysis was more comprehensive in the evaluation of costs than other published economic evaluations. In terms of the issue of the generalisability of the study results, the authors pointed out that caution will be required if extrapolating the current findings to settings outside Rio de Janeiro, especially with respect to staff costs which may vary substantially. The results of the sensitivity analysis were not presented satisfactorily. Overall, much of the information was presented in a technical appendix that can be obtained from the authors on request.

Implications of the study
The study results strongly support the implementation of DOTS for the treatment of TB.

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Other publications of related interest
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