Methods: Sample 2

Tupasi TE, Gupta R, Quelapio MID, Orillaza RB, Mira NR, et al. (2006) Feasibility and Cost-Effectiveness of Treating Multidrug-Resistant Tuberculosis: A Cohort Study in the Philippines. PLoS Med 3(9): e352

Problem: multidrug-resistant TB.

Purpose: In April 1999, a DOTS-Plus pilot project was initiated at the Makati Medical Center (MMC) in Manila, Philippines [25]. This article assesses the project's feasibility, effectiveness, cost, and cost-effectiveness.

Methods

Setting

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Comment: Headings for the various subsections

Philippines is a lower middle–income country with a per capita gross national income of US$1,080 in 2003 [26]. Globally, it ranks eighth in terms of the estimated number of new TB cases that occur each year, with about 240,000 cases in 2004 [4]. It is estimated that there are 25,803 MDR-TB cases: 7,238 new cases and 18,565 previously treated cases [3,27].

DOTS is implemented nationally, with a case detection rate of 73% and a successful treatment rate of 89% for new smear-positive cases [4], both in excess of WHO targets. DOTS treatment involves a four-drug first-line regimen for new cases, and a five-drug retreatment regimen for patients who fail treatment with this first regimen or who have had TB before and have suffered a relapse. Patients who fail the retreatment regimen are defined as chronic cases [28], and as of March 2006, no treatment was available for them in the public sector. Treatment in the private sector is generally of unknown quality and limited by patients willingness and ability to pay.

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Comment: Descriptions include numerical data.

MMC is a private tertiary hospital in the main commercial district of Manila. It established DOTS services in 1999, in partnership with the Department of Health and the local government [29]. A DOTS-Plus pilot project was started in April 1999. In March 2006, MMC remained the only facility in the country offering such treatment.

Description of the DOTS-Plus Pilot Project

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Comment: Treatment.

Two major categories of TB cases were eligible for treatment in the DOTS-Plus project: (a) chronic cases of MDR-TB referred from public or private facilities; and (b) cases with a diagnosis of MDR-TB during treatment with the first-line retreatment regimen. A few patients with MDR-TB identified among new cases during contact tracing or treatment with first-line drugs were also enrolled. Diagnosis was based on smear and culture examination. After informed written consent, patients were treated with an individualised regimen based on drug susceptibility testing results for all first-line drugs, three second-line drugs (kanamycin, ciprofloxacin, and ofloxacin), and

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Comment: Passive voice

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Comment: Protocol using human subjects must conform to IRB recommendations.

previous use of other drugs as reported by patients. In the intensive phase of treatment, a daily five-drug regimen was used. This typically consisted of an injectable drug, a fluoroquinolone, other oral second-line drugs, and first-line drugs to which the patient was not resistant. In the continuation phase, started after six consecutive months of negative culture results, the injectable or (occasionally) a noninjectable to which the patient was intolerant was dropped from the regimen. Treatment was continued until cultures were negative for 18 consecutive months. During the intensive phase, direct observation of treatment (DOT) was provided by MMC staff. In the continuation phase, alternating clinic and home-based DOT was used. Patients who defaulted were followed up by telephone, telegram, and/or home visits.

Patient Cohort Studied

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Comment: Subjects/experimental groups.

We considered the patient cohort enrolled between 1 April 1999 and 31 March 2002.

Treatment Outcomes

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Comment: A little confusing: sounds like a result. In fact it should say: "Assessment of treatment outcomes"

Treatment outcomes for the DOTS-Plus project were assessed using internationally agreed consensus definitions [30]. …

Cost and Cost-Effectiveness Analysis

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Comment: Methodology for data analysis

Any cost-effectiveness analysis requires comparison of relevant alternative strategies [31]. We compared the DOTS-Plus project with the situation that would apply in the absence of the project, i.e., what would have happened to the cohort of DOTS-Plus patients had they not been enrolled in the project…

Statistical Analysis

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Comment: Statistical analysis goes in Methods (statistical significance is mentioned in figures and/or results)

In addition to the uncertainty analysis described above, we compared the clinical and demographic characteristics of the cohort enrolled in treatment with patients who were eligible but not enrolled in treatment, using chi-square tests for categorical outcome variables and *t*-tests for continuous outcome variables. We also used the chi-square test to compare the treatment outcomes of chronic cases with those of new and retreatment cases. Given the small number of new cases ($n = 5$), we combined new and retreatment cases in one category when making comparisons with chronic cases.