The cost effectiveness of testing for onychomycosis versus empiric treatment of onychodystrophies with oral antifungal agents

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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
The study compared the diagnosis of onychomycosis before initiating treatment, with the empiric treatment of thickened nails using oral antifungal agents.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The characteristics of the study population were not described in detail. The study evaluated thickened (dystrophic) nail samplings.

Setting
The setting was secondary care. The economic analysis was conducted in the USA.

Dates to which data relate
The effectiveness evidence and resource use data were collected over a one-year period in 1997. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively on a different sample from that used in the effectiveness study.

Study sample
No power calculations were used to determine the sample size. The method used to select the study sample was not described, and there was no evidence to suggest that the initial sample was appropriate for the clinical study question. A total of 688 thickened nails from patients were examined in the laboratory. All 688 nails were submitted for histologic examination. Correspondence with the authors indicates that the nail samples were taken from 688 patients.

Study design
This was a single-centre, cohort study. The duration of follow-up and loss to follow-up were not reported. There was no blinding method for the assessment of outcomes.

**Analysis of effectiveness**
It was not reported whether the analysis was based on intention to treat or treatment completers only. The primary health outcome used was the percentage of onychomycoses found in the population of dystrophic nails, by histologic examination. No other measures of effectiveness were reported.

**Effectiveness results**
Of the 688 dystrophic nail samples, 65% were found to be positive for onychomycosis by histologic examination.

**Clinical conclusions**
By establishing a diagnosis for onychomycosis prior to treatment, the needless exposure to oral antifungal medications, and their side-effects, is avoided in those patients who do not require treatment.

**Measure of benefits used in the economic analysis**
No summary measure of benefits was reported. The study was therefore categorised as a cost-consequences analysis.

**Direct costs**
The quantities and costs were not analysed separately.

The cost of empiric treatment for the total patient sample (n=688) comprised medication costs and the cost of blood tests associated with the oral antifungal agents. The unit cost of medication was taken as the average unit cost of 84 capsules of itraconazole and terbinafine. This was estimated using the data from five pharmacies. The unit cost of blood tests was derived from the average unit cost of blood tests associated with itraconazole and terbinafine. This was estimated using the data from three laboratories. The cost of diagnosing before treatment was determined by multiplying the most expensive diagnostic test by the total number of patients in the sample (n=688). The most expensive method of testing was estimated from a survey of dermatopathology laboratories in the USA, but was not defined explicitly. The cost of the diagnosis was then added to the cost of treating all patients found to be positive for onychomycosis (n=444) to give the total cost.

The time horizon for the study was not reported. Discounting was not carried out. The price year was not reported. The resources, in terms of the number of patients and the number of positive tests for onychomycosis, were measured in 1997.

**Statistical analysis of costs**
There was no statistical analysis of the costs.

**Indirect Costs**
No indirect costs were reported.

**Currency**
US dollars ($). No currency conversion was reported.

**Sensitivity analysis**
No sensitivity analysis was reported.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total cost of testing all the patient sample (n=688) and then treating only those with positive results for onychomycosis was $296,360.

The total cost of empirically treating all the patient sample (n=688) was $405,920.

The incremental saving associated with prior testing was $109,560 for the total sample of nails, or $159 per patient.

Synthesis of costs and benefits
The benefits and costs were not combined.

Authors' conclusions
Compared with empiric treatment, the diagnosis of onychomycosis prior to treatment resulted in cost-savings of $109,560 for the total patient sample, or $159 per patient.

CRD COMMENTARY - Selection of comparators
This study compared diagnosis of onychomycosis prior to antifungal drug therapy, with the empiric treatment of onychomycosis using oral antifungal agents. The three diagnostic approaches compared were the direct microscopic examination of a potassium hydroxide preparation, fungal culture, and histologic analysis of the nail plate. Of the three types of oral antifungals available (itraconazole, fluconazole and terbinafine), only two (itraconazole and terbinafine) were assessed in the study. Further, the study did not clearly report the diagnostic tests used in practice. You should consider whether the methods evaluated by the authors are widely used health technologies in your own setting.

Validity of estimate of measure of effectiveness
There were insufficient details of the study design, and it was not reported whether power calculations were used to determine the sample size. Thus, robust conclusions of the effectiveness of diagnosis or the empiric treatment cannot be drawn. A sample of 688 nails, collected from 688 patients, was evaluated. The authors did not estimate the number or severity of side-effects due to antifungal treatment.

Validity of estimate of measure of benefit
The authors concluded that by establishing a diagnosis of onychomycosis prior to treatment, the needless exposure to oral antifungal medications, and their side-effects, is avoided in those patients who do not require treatment. However, this study did not evaluate the impact of drug-related side-effects on the patient population.

Validity of estimate of costs
No details about the perspective, time horizon or methods of collecting resource data were reported. It was unclear whether all the relevant costs were included in the analysis. The authors reported the costs of laboratory tests but did not report details about whether there were other costs associated with the three types of diagnosis, such as the cost of collecting samples or interpretation of laboratory data.

Other issues
The authors did not compare the results of their evaluation with those from other studies. Correspondence with the authors indicates that they did not find any other studies of the cost-effectiveness of treatment at the time the paper
was prepared for publication. The authors did not discuss the extent to which their results were transferable to alternative settings or patient populations. The authors referred to this study as a cost-effectiveness analysis, but they did not synthesise the measures of effectiveness or benefit with the costs. The study is actually a cost-consequences analysis. A sensitivity analysis was not reported. There was also a lack of detail about the measure of effectiveness and the costs. These factors limited the internal validity and the generalisability of the study to other clinical settings.

Implications of the study
The authors suggested that there were significant cost-savings associated with confirming the diagnosis of onychomycosis prior to treatment. They recommended that all patients should have the diagnosis of onychomycosis confirmed prior to therapy. They did not recommend which diagnostic method should be used.

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None stated.

Bibliographic details

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Other publications of related interest

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Subject indexing assigned by NLM

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