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Cost-effectiveness of implementing national guidelines in the treatment of acute otitis media in children

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Objectives: Acute otitis media (AOM) is one of the most common diseases of childhood, representing a major disease burden on the society. New evidence-based guidelines for AOM, focusing on children under 7 years of age, were introduced in Finland in 1999. The aim of this study was to evaluate the cost-effectiveness of implementing those guidelines in Finland.
Methods: A 5-year prospective trial was conducted in thirty community primary healthcare centers in Finland. All AOM patients between 0 and 6 years of age visiting the study health centers for the first time, for this episode of illness, during 1 week in November 1998 ($n = 579$) and November 2002 ($n = 369$) were included in this study. The outcome measure was the percentage of symptom-free patients.
Results: The mean direct cost of an AOM episode per patient stayed almost the same after implementing the guidelines, €152 in 1998 and €150 in 2002. After implementing the guidelines, the percentage of symptom-free patients was 10 percentage points higher than before the guidelines. The treatment after the implementation of the guidelines, thus, was a dominant strategy.
Conclusions: Implementing the guidelines to the treatment of AOM in children was associated with extra health benefits at slightly lower direct costs and, thus, is a dominant strategy. The focus of this study was on the short-term effects of the treatment; including long-term effects in the analysis might affect the results.

Keywords: Cost-effectiveness, Acute otitis media, Practice guidelines, Implementation

Clinical practice guidelines are "systematically developed statements designed to assist practitioners and patients make decisions about appropriate health care for specific clinical circumstances" (4). Their origin is in the rising healthcare costs and variation in the quality of care. Although guidelines traditionally have tended to focus on issues of effectiveness, introducing economic data to them has become increasingly popular over the past years (8). In Great Britain, each guideline-development group has to include a health economist, whose role is to promote the societal viewpoint (16). In an optimum case, cost-effectiveness data should be incorporated into the guideline-development process. In practice, there has been no widely accepted and successful way to incorporate economic data into guidelines (4).

Acute otitis media (AOM) is one of the most common diseases of childhood, representing a major disease burden on the society. In Finland, which has a population of 5.2 million, it has been estimated that children suffer from approximately 500,000 attacks of AOM yearly, giving rise to total annual costs of US$138 million (€129 million with the 1999 average exchange rate (1)) (11). New evidence-based guidelines for AOM, focusing on children under 7 years of age, were introduced in Finland in 1999 (12). Key messages of the new guidelines are presented in Table 1. In this study, we evaluate the cost-effectiveness of implementing the new guidelines in the treatment of AOM in children.

MATERIALS AND METHODS

The MIKSTRA program was a nationwide research and development initiative designed to optimize diagnostic and treatment practices for common infections in primary care. As a part of the program, a 5-year prospective trial of

Table 1. Key Messages of the Finnish Guidelines for AOM in Children

Diagnostic tools
• Pneumatic otoscopy
• Use of tympanometry
Medication
• Drug of choice: amoxicillin or penicillin V
• Duration of treatment: 5 (to 7) days
• Symptomatic medication of pain
Follow-up visit after 1 month

AOM, acute otitis media

implementing guidelines for six common infections (including AOM) was conducted in thirty health centers (13). The trial included yearly surveys of treatment practices during a 1-week period in November from 1998 to 2002. The health centers studied represented the whole country with respect to type (rural/urban), size, and geographical location. Also, the number of antibiotic prescriptions per 1,000 inhabitants in 1996 was similar to the national average. The population covered by the study health centers was 819,777 people (16 percent of the Finnish population).

The questionnaires filled in both by the patients or their caregivers and the health personnel are available in English on the MIKSTRA Web site (9). The patients filled out the questionnaire before the consultation and the health personnel filled it out during or immediately after the consultation. Furthermore, a random sample of patients with one of the six major infections was interviewed by telephone 2 weeks after the consultation.

All AOM patients between 0 and 6 years of age visiting the study health centers for the first time for this episode of illness, either in 1998 or 2002, were included in this study. Table 2 summarizes the characteristics of the patients. All analyses and comparisons were performed on the basis of intention to treat.

New guidelines for AOM were published in October 1999. An educational intervention was conducted at the study health centers during 2000 and 2001. The aim of the intervention was to familiarize all health personnel at the study health centers with the AOM guidelines. The educational methods used were academic detailing or problem-based learning and feedback. The educational sessions lasted for 2 hours and were facilitated by trained local general practitioners.

Table 2. Characteristics of the Patients

	1998	2002
No. of participants (no. of all AOM patients)	579 (915)	369 (583)
Mean age in years (SD)	2.56 (1.88)	2.63 (1.84)
No. of female participants (%)	266 (46%)	171 (47%)
No. of interviewed patients at 2 weeks (%)	94 (16%)	94 (25%)

AOM, acute otitis media.

We performed a cost-effectiveness analysis in which we estimated the costs and effectiveness of treatment after the implementation of the guidelines compared with treatment before the guidelines. The economic evaluation was carried out from the societal perspective. This means that the total direct costs of an AOM infection episode, including direct healthcare costs and costs of the educational intervention, were considered. The costs of producing and updating the guidelines were not included in this study. Also, we took a conservative approach by excluding productivity costs from our base case analysis. However, we have considered productivity costs in a sensitivity analysis.

We obtained unit costs for all resources and services used either from national statistics or from the trial data. For example, the unit cost for antibiotic courses was an Anatomical Therapeutic Chemical (ATC) classification-specific average calculated from the data, using retail prices (value added tax deducted) (7). The total cost of the educational intervention was estimated at the 2002 price level and then divided by the number of 0- to 6-year-old AOM patients treated during the study week. Table 3 summarizes unit costs used and their sources. All costs are reported in euros at the 2002 price level. If necessary, the unit costs were inflated to the 2002 price level with the price index of public health service. These unit costs were combined with the resource volumes to obtain an average cost per patient. Resources and services used were monitored for a period of 2 weeks. However, we have included the cost of a follow-up visit (basic visit to a general practitioner) to the cost of healthcare visits, if it was reported as planned at the time of the telephone call in either year.

We measured effectiveness in terms of percentage of symptom-free patients 14 days after the initial consultation (according to the telephone interview). Given the time horizon, we did not discount costs or health effects. The average cost-effectiveness was calculated as total costs divided by the number of symptom-free patients (per 100 patients) and incremental cost-effectiveness ratio (ICER) as the extra cost needed to generate an additional symptom-free patient after implementing the guidelines.

Economic evaluation is subject to uncertainty because of methodological, data requirement, and generalization issues (2). One of the most debated methodological issues in recent years has been whether and how to incorporate productivity costs into a cost-effectiveness analysis (3;17). We, therefore, conducted a sensitivity analysis to test the robustness of the results to changes in the assumptions by adding productivity costs to the analysis. Furthermore, in year 2002, there was one patient, who at the time of the telephone interview reported having been hospitalized for 3 days. During our 5 follow-up years, there were only two occasions (one in 1999 and the other one in 2002) when a patient had been hospitalized for AOM. This rate suggests that such an incident is more or less

Table 3. Unit Costs

Cost component	Euros	Source
Healthcare visits		
General practitioner		
• Basic visit (no diagnostic tests included)	56	(6)
• Extended visit (diagnostic tests included)	100	(6)
Private practice (incl. office expenses)	54	(6)
Nursing staff	23	(6)
Phone consultation	16	(6)
Specialist by appointment	102	(6)
Hospital outpatient visit to pediatric emergency room	202	(6)
Hospital treatment per day in children's ward	672	(6)
Medicines		
Antimicrobials	Various	Trial data & (7)
Symptomatic	Various	(14)
Over the counter	Various	Trial data & (7)
Other costs		
Travel costs		
• Primary healthcare visit	6	(6)
• Special healthcare visit	31	(6)
Time costs		
• Primary healthcare visit	7	(6)
• Special healthcare visit	19	(6)
Educational intervention (total costs/52 weeks/no. of AOM patients (0–6 years old) treated during the study week	1	(10)
Productivity costs (sensitivity analysis)		
A day of parental leave (average earnings per month/average working days × employer's contributions)	158	(15)

incidental. Therefore, we conducted a sensitivity analysis in which we excluded the cost of a hospital treatment. Also, we examined uncertainty in effectiveness by performing a sensitivity analysis in which the percentage of symptom-free patients was varied by using the 95 percent confidence intervals (95 percent CI). All data were analyzed with SPSS version 11.5 for Windows.

RESULTS

Table 4 shows the costs per 100 patients before and after the implementation of the guidelines. The percentage of symptom-free patients 2 weeks after the initial consultation increased from 68 percent (95 percent CI, 58–77) in 1998 to 78 percent (95 percent CI, 68–85) in 2002.

The mean direct cost per patient of an AOM episode decreased from €152 to €150 after implementing the guidelines. The average cost-effectiveness ratio was €224 and €192, respectively. Treatment after the implementation of the guidelines seems thus to be a dominant strategy, because it produces extra health benefits at a lower cost (Table 5).

Table 4. Costs of Treating AOM in Children before and after the Implementation of the Guidelines (per 100 Patients in Each Year)

Cost component	Before guidelines in 1998 (euros)	After guidelines in 2002 (euros)
Healthcare visits		
• Primary health care		
• Basic visit	8,823	7,418
• Extended visit	449	270
• Nursing staff	8	38
• Private practice	113	59
• Phone consultation	9	71
• Referral to specialist	0	113
• Hospital outpatient visit	425	439
Total	9,827	8,408
Hospital treatment	0	2,184
Medicines (excluding VAT)		
• Antimicrobials	974	1,128
• Symptomatic	1,227	441
• Over the counter	439	193
Total	2,641	1,763
Travel (excluding VAT) and time costs	2,748	2,523
Educational intervention	0	135
Total direct cost	15,216	15,013
Sensitivity analysis:		
Productivity costs	4,174	6,423

AOM, acute otitis media; VAT, value added tax.

When the productivity costs were included in the analysis, the mean total cost per patient of an AOM episode increased from €194 to €214 after implementing the guidelines. The average cost-effectiveness ratio was €285 and €275, respectively, and the ICER of treatment after the implementation of the guidelines was €205. Excluding the costs of hospital treatment from year 2002 caused the mean direct cost per person to decrease to €128 with an average cost-effectiveness ratio of €164. This exclusion would clearly enhance the dominant position of the treatment after implementing the guidelines. Varying the percentage of symptom-free patients by using the 95 percent CIs around the baseline did not change the result of the treatment after the implementation of the guidelines being the dominant strategy. An exception was the alternative, where the percentage of symptom-free patients before guidelines was at the upper limit of the 95 percent CI and that after guidelines at the lower limit of the 95 percent CI, when the ICER of treatment before guidelines was €23.

DISCUSSION

Implementing new guidelines to the treatment of AOM in children seems to be associated with extra health benefits at

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Table 5. Cost-Effectiveness of Treating 100 Children with AOM before and after Implementing the Guidelines

Strategy	Cost (C) euros	Incremental cost (IC)	Effectiveness (E)	Incremental effectiveness (IE)	C/E	Incremental cost-effectiveness ratio (IC/IE)
Before guidelines in 1998	15,216		68		224	
After guidelines in 2002	15,013	−203	78	10	192	Dominant

AOM, acute otitis media.

slightly lower direct costs, thus being a dominant strategy. Inclusion of productivity costs changed the results so that the ICER of the treatment after the implementation of the guidelines was €205.

Productivity costs grew 54 percent from 1998 to 2002. The reason for this increase is unclear, because the actual guidelines do not include any directions on the issue. However, Finnish economy was in a deep recession in the 1990s, whereas the beginning of the new millennium has been a time of rapid economic growth. Thus, one hypothesis is that the labor market climate in 2002 was more understanding toward taking child-care leaves.

The use of symptomatic medication for pain was one the key messages of the new guidelines for AOM. However, contrary to the guidelines, the total cost of symptomatic medication decreased 64 percent from 1998 to 2002. The most commonly used ear drop medicine for earache was a prescription drug in 1998, whereas in 2002, the same medication could be purchased over the counter. Therefore, it is possible that healthcare personnel reported the use of symptomatic medication differently in 1998 and 2002.

We have used the percentage of symptom-free patients 2 weeks after the initial consultation as our measure of effectiveness. This kind of measure does not necessarily show the full effectiveness of a treatment for two reasons. First, the assessment of effectiveness was given by the caregiver of the actual patient. This strategy might lead to some incorrect estimation. We have tried to control for this possible source of error by performing a sensitivity analysis in which we varied the percentage of symptom-free patients. Second, the follow-up time was quite short, only 2 weeks. Because one of the main purposes of the guidelines for the treatment of AOM in children is to constrain adverse long-term effects, including development of resistant strains and complications, further work is required to measure the cost-effectiveness against long-term endpoints.

Changing professional behavior has proven to be difficult. Grimshaw et al. (5) reported that, of 235 studies on the strategies of guideline dissemination and implementation they had investigated, only in a minority of the interventions modest to moderate improvements in care were observed. Also, in this trial, not all of the professionals followed the recommendations of the guidelines in all aspects of the treatment. However, marked changes can be observed especially in the focus messages of the educational intervention, that is, the choice and length of the antimicrobial courses.

POLICY IMPLICATIONS

The findings from this study showed that changing acute otitis media treatment practices in children toward the national guidelines does not produce additional costs. In fact, the results suggest that more frequent use of tympanometry as a diagnostic tool might even lead to cost savings through avoiding unnecessary antibiotic treatments.

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