Pharmacoeconomic aspects of antibacterial therapy with azithromycin of community-acquired pneumonia in servicemen

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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 use of oral azithromycin (Sumamed PLIVA, Croatia) in the treatment of community-acquired pneumonia (CAP) was examined. The drug regimen was 500 mg given orally once daily for 3 days.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised male military servicemen between the ages of 18 and 21 years, with clinical symptoms and radiological evidence of pneumonia. The patients were classified as low risk in terms of short-term mortality and had not been given antibiotic treatment for 48 hours before treatment was started, unless it had resulted in no clinical improvement. Patients were excluded if they had a history of allergy to beta-lactams or macrolides, severe pneumonia, marked renal or hepatic impairment, or gastrointestinal disorders which could affect absorption. They were also excluded if they had received more than one daily dose of any antimicrobial drug prior to study enrolment.

Setting
The setting was secondary care. The economic study was carried out in Kiev, Ukraine.

Dates to which data relate
The dates to which the effectiveness evidence and resource use data referred were not reported. The price year of the drugs used was 2001.

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

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
No power calculations were reported. All patients who met the inclusion criteria appear to have been included in the study. There were 26 patients in the oral azithromycin group and 29 in the benzylpenicillin group.
Study design
This was a randomised controlled trial (RCT) in which the patients were randomised to receive one of the antibiotic treatments. The patients were followed up for 15 days after the initiation of treatment. No details of how randomisation was achieved were reported. In addition, it would appear that blinding did not take place.

Analysis of effectiveness
The basis of the analysis was intention to treat. The patients’ outcomes were assessed for presence of clinical cure and presence of improvement. Clinical cure was defined as the complete disappearance of signs and symptoms of infection. Improvement was defined as the partial disappearance of signs and symptoms of infection, without the need for additional antibiotic treatment. The patient groups appear to have been comparable in some, but not all, respects. For example, the proportion with concomitant illness was 15.4% (+/- 7.1) in the azithromycin group versus 10.3% (+/- 5.6) in the benzylpenicillin group.

Effectiveness results
The proportion cured was 88.5% (+/- 6.3) in the azithromycin group and 86.2% (+/- 6.4) in the benzylpenicillin group.

The proportion improved was 7.7% (+/- 5.2) in the azithromycin group and 10.3% (+/- 5.6) in the benzylpenicillin group.

The difference was not statistically significant, (p>0.05).

The speed of improvement was reported as being equally fast in the two groups. Two patients in the azithromycin group and three in the benzylpenicillin group suffered from adverse events.

Clinical conclusions
The authors concluded that both forms of antibiotic treatment were equally effective for treating CAP in young male servicemen who do not have severe pneumonia.

Measure of benefits used in the economic analysis
No summary measure of benefit was produced, as the authors considered the two treatments to be equally effective. As such, only the costs were considered in the economic analysis.

Direct costs
The direct costs included were those of the antibiotics, the materials necessary for injections, and the labour cost of the injections. The costs of the antibiotics were broken down into prices and quantities, whereas the other costs (additional materials and labour for injections) were not. The costs were estimated using actual data. The data source was the hospital. No discounting was carried out as the costs were incurred during less than 2 years. The price year for the antibiotics was 2001.

Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
No indirect costs were estimated.

Currency
US dollars ($).
Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The cost of antibiotic therapy was $10.1 (+/- 0.1) for the azithromycin patients and $24.6 (+/- 1.8) for the benzylpenicillin patients.

Synthesis of costs and benefits
Not relevant as no summary measure of benefit was derived.

Authors’ conclusions
Both forms of antibiotic were equally effective for young servicemen with community-acquired pneumonia (CAP). However, azithromycin was cheaper and so should be chosen.

CRD COMMENTARY - Selection of comparators
The choice of the comparator (intramuscular benzylpenicillin) was justified by it having represented standard practice in the authors' setting. You should decide if it represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a single-centre RCT. The study design was appropriate for the hypothesis, but it was unclear whether the numbers were large enough to establish reliable results. In addition, it was not reported how randomisation was achieved. All patients meeting the inclusion criteria were included, thus the study sample was representative of the study population. However, the patient population considered was very specific and the generalisability of the results obtained is likely to be limited. The patients were not shown to be comparable at analysis. It was not apparent that any blinding or concealment of allocation took place. The authors reported that the speed of recovery was the same in both patient groups, but they did not provide any data to support this view. In other ways the analysis of effectiveness was handled credibly.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit as they considered the effectiveness outcomes equal. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The costs of the antibiotics and their administration were included. However, no other hospital costs or the costs of adverse events were considered. It is unclear how these omissions would have affected the results. Some of the costs were given separately from the quantities, but the administration costs of the drugs were not. The resource use quantities were taken from a single study, while the prices were taken from the authors' setting. No other sources were used for the resource quantities or prices. No statistical, sensitivity, or any other kind of analysis of the quantities or prices was conducted. The price year for the drugs was given, but it was unclear whether the other costs were adjusted to the same price year.

Other issues
The authors did not compare their results with the findings from other studies. The issue of generalisability to other settings was not addressed. The authors failed to present their results in full, in that they did not report the data on speed of improvement. The authors’ conclusions reflected the scope of the analysis. However, the authors did not discuss or acknowledge the limitations of their study. Such limitations included, for example, the small sample size, no blinding, no randomisation details, and the lack of information on the total hospital costs.

**Implications of the study**
The authors concluded that azithromycin should be given to young patients with CAP as described in the study, as it results in clinical outcomes as good as those with intramuscular benzylpenicillin but costs less. However, the drawbacks described mean that insufficient information was given to reach that conclusion.

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