treatment failure was defined on day 4 or 5 as lack of substantial improvement in symptoms, worsening of otoscopic signs, or both and on days 10 to 12 as failure to achieve complete or nearly complete resolution of symptoms and otoscopic signs. In the Turku trial, treatment failure was defined on day 3 as lack of improvement in the child’s overall condition, on day 8 as lack of improvement in otoscopic signs, and at any time as worsening of the overall condition, the occurrence of tympanic membrane perforation, or inability to continue assigned medication. For the present analysis, we combined results from children younger than 2 years in the 2 trials. In keeping with the recent AAP guideline, we defined illness as severe if otalgia was described by parents as moderate or severe or if the child’s temperature had been recorded as, or was estimated to have been, 39°C or more within 24 hours. Overall efficacy of amoxicillin-clavulanate was measured by pooling results from the 2 trials in a random-effects model using inverse-variance weighting. These findings make a case for a uniform approach to antimicrobial treatment in children younger than 2 years with stringently diagnosed AOM, irrespective of laterality or apparent severity of their illness, and suggest that the AAP guideline’s recommendation of prompt antimicrobial treatment for children younger than 2 years with AOM that is bilateral and/or apparently severe should be extended to include also those children whose disease is unilateral and apparently nonsevere.

### Results

Results are summarized in the Table. Among children whose infection was unilateral and/or whose illness was nonsevere, those treated with placebo had relatively high rates of treatment failure, whereas those treated with amoxicillin-clavulanate had substantially lower rates. Overall, the effects of antimicrobial treatment were similar across the various laterality and severity subgroups.

### Discussion

These findings make a case for a uniform approach to antimicrobial treatment in children younger than 2 years with stringently diagnosed AOM, irrespective of laterality or apparent severity of their illness, and suggest that the AAP guideline’s recommendation of prompt antimicrobial treatment for children younger than 2 years with AOM that is bilateral and/or apparently severe should be extended to include also those children whose disease is unilateral and apparently nonsevere.

### Table. Treatment Failure Rates in Children at or Before the End-of-Treatment Visit, According to Laterality and Severity of Illness at Entry

<table>
<thead>
<tr>
<th>Laterality and Severity of AOM at Entry</th>
<th>No. of Children With Treatment Failure/Total No. (%)</th>
<th>RR, AMOX/CLAV vs Placebo (95% CI)</th>
<th>ARR (95% CI)</th>
<th>No. Needed to Treat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral nonsevere</td>
<td>AMOX/CLAV Placebo AMOX/CLAV Placebo AMOX/CLAV Placebo</td>
<td>4/39 (10) 15/42 (36) 6/33 (18) 11/23 (48) 10/72 (14) 26/65 (40)</td>
<td>0.34 (0.18-0.65) 0.27 (0.13-0.41)</td>
<td>4</td>
</tr>
<tr>
<td>Unilateral severe</td>
<td>AMOX/CLAV Placebo AMOX/CLAV Placebo AMOX/CLAV Placebo</td>
<td>2/29 (7) 14/28 (51) 9/48 (19) 19/42 (45) 11/77 (14) 31/70 (47)</td>
<td>0.28 (0.10-0.79) 0.34 (0.18-0.50)</td>
<td>3</td>
</tr>
<tr>
<td>Bilateral nonsevere</td>
<td>AMOX/CLAV Placebo AMOX/CLAV Placebo AMOX/CLAV Placebo</td>
<td>7/40 (18) 18/35 (51) 6/20 (30) 11/20 (55) 13/60 (22) 29/55 (53)</td>
<td>0.43 (0.25-0.73) 0.31 (0.14-0.48)</td>
<td>4</td>
</tr>
<tr>
<td>Bilateral severe</td>
<td>AMOX/CLAV Placebo AMOX/CLAV Placebo AMOX/CLAV Placebo</td>
<td>10/34 (29) 26/38 (68) 7/34 (21) 18/37 (49) 17/68 (25) 44/75 (59)</td>
<td>0.43 (0.27-0.67) 0.34 (0.18-0.48)</td>
<td>3</td>
</tr>
</tbody>
</table>

Abbreviations: AMOX/CLAV, amoxicillin-clavulanate potassium; AOM, acute otitis media; ARR, absolute risk reduction; RR, relative risk.

### Author Contributions

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### Notes


### CORRECTION

Alphabet Designators Omitted From Table I: In the Original Investigation titled “Extreme Binge Drinking Among 12th-Grade Students in the United States: Prevalence and Predictors” published online September 16, 2013, and published in the November 1, 2013, print issue of JAMA Pediatrics (2013;167[11]:1019-1025), the alphabet designators were omitted from the body of Table I.