**Abstract**

**Objectives:**
To assess the impact of Statements 6 and 7 in the 2013 Clinical Practice Guidelines for Tympanostomy Tubes in Children (CPG) on the identification of preoperative and intraoperative middle ear fluid (AOM/OME) in children undergoing tympanostomy tube placement (BMT).

**Methods:**
The records of patients who underwent BMT for recurrent acute otitis media (RAOM) at a tertiary care children’s medical center were retrospectively reviewed. We enrolled 240 patients before (BG) and 240 patients after (AG) the introduction of the CPG.

**Results:**
The baseline characteristics of the two groups were comparable. The total number of BMT performed at our institution decreased from 3,957 (BG) to 3,083 (AG). There was a non-significant increase in the rate of pre-operative AOM/OME identification following CPG introduction (BG 78.3% vs AG 83.3%, P=0.164). The rate of identification of AOM/OME in both clinic and the OR increased from 54.2% (BG) to 71.3% (AG, P<0.001). Cases with concordant clinic and OR AOM/OME occurred in younger children (P=0.045), with fewer episodes of AOM (P=0.043) and shorter time between the clinic and OR dates (P=0.008).

**Conclusions:**
Following the introduction of the CPG, there was not a significant increase in the appropriate recommendation of BMT in children with RAOM and AOM/OME present at the preoperative appointment. The non-significant increase in compliance with Statements 6 and 7 following introduction of the CPG may be related to multiple clinician and patient derived factors.

**Introduction**

- The cumulative incidence of AOM by age 3 exceeds 80% in the US.
- RAOM is defined by 3 episodes of AOM in 6 months or 4 episodes of AOM in 12 months.
- RAOM has negative consequences on development, missed work and school time, antibiotic resistance and healthcare expenditures.
- BMT is accordingly the most commonly performed surgical procedure in the United States.
- The AAO-HNS published a CPG on Tympanostomy Tube in Children in 2013.
- Statements 6 and 7 in this CPG recommend offering BMT in children who meet criteria for RAOM and have evidence of unilateral or bilateral OME or AOM at the time of evaluation.
- Evidence that these Statements influence clinical practice is currently lacking.

**Methods and Materials**

- IRB approved study protocol from University of Pittsburgh
- Retrospective chart review of children undergoing BMT for RAOM at a single tertiary care children’s hospital
- 240 cases were reviewed from 2012 (before guidelines, BG) and 240 from 2014 (after guidelines, AG)
- Exclusion criteria included prior BMT or other otologic surgery; indications for BMT other than RAOM including cleft palate, syrinx, hearing or speech delay only, history of OME only
- Statistical analysis performed using SPSS 23 (IBM, Armonk, NY). Independent samples t-test and Pearson’s Chi-square test were used.

**Results**

- 20 children were included from each month to account for seasonal variation, totaling 240 for 2012 (BG) and 240 for 2014 (AG)
- There were no differences in the demographic characteristics between groups (Table 1)
- The total number of BMT performed at CHP of UPMC decreased from 3,957 to 3,083 from 2012 to 2014
- Overall, there was a 5% increase in the identification of AOM/OME in clinic prior to BMT following introduction of the CPG. This difference was not significant (P=0.164).
- There was a significant increase in the rate of identification of AOM/OME in the OR (P<0.001)
- There was also a significant increase in the finding of AOM/OME at both the clinic appointment and the OR (Table 2)
- Secondary study measures identified that clinic-OR AOM/OME concordance was more common in younger children, those with fewer episodes of AOM and those with a shorter interval time between clinic and the OR (Table 3)

**Discussion**

- The main outcome measure of appropriately identifying middle ear fluid in the clinic prior to proceeding with BMT did not significantly improve following introduction of the CPG (78.3% vs 83.3%, P=0.164)
- The overall decrease in BMT volume and significant increase in identifying middle ear fluid in the OR suggest that the surgeons became more selective in ways not captured by this study.
- Potential barriers to compliance with Statements 6 & 7 include:
  - Parental preference:
    - Distance traveled for pediatric and specialist care
    - Excessive missed work and school time
    - Concerns about antibiotic exposure
    - Subjective concerns for speech delay and hearing loss
    - Summertime clinic appointments
  - Clinician lack of awareness of CPG
  - Clinician resistance to change in practice
- The decrease in total BMT performed from 2012 to 2014 may reflect the continued decline in the overall incidence of AOM following the introduction of the PCV-13 vaccine
- Younger age and fewer episodes of AOM as predictors of AOM/OME concordance between clinic and OR are counterintuitive. Perhaps clinical exam becomes increasingly limited as children age beyond 1 year.
- The shorter time between clinic and OR in cases with concordant AOM/OME in clinic and the OR suggests that children begin to clear their middle ear fluid beyond 3 weeks and the preoperative exam is less predictive when BMT is scheduled far in advance.

**References**

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**Conclusions**

- Statements 6 and 7 of the Tympanostomy Tube CPG did not result in a statistically significant increase in the rate of proceeding with BMT when AOM/OME was identified at the preoperative clinic appointment.
- Institutions should periodically monitor their compliance with Academy published guidelines and seek areas of quality improvement.

**Table 1. Comparison of demographics between groups.**

<table>
<thead>
<tr>
<th>P-value</th>
<th>BG (2012)</th>
<th>AG (2014)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.920</td>
<td>1.88</td>
<td>1.86</td>
</tr>
<tr>
<td>0.399</td>
<td>36.7%</td>
<td>40.4%</td>
</tr>
<tr>
<td>0.877</td>
<td>4.11</td>
<td>3.93</td>
</tr>
<tr>
<td>0.588</td>
<td>7.5%</td>
<td>6.3%</td>
</tr>
<tr>
<td>0.455</td>
<td>62.1%</td>
<td>58.8%</td>
</tr>
<tr>
<td>0.229</td>
<td>22.2</td>
<td>24.4</td>
</tr>
</tbody>
</table>

**Table 2. Comparison of middle ear fluid identification in clinic and the OR.**

<table>
<thead>
<tr>
<th>BG (2012)</th>
<th>AG (2014)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>78.3%</td>
<td>83.3%</td>
<td>0.164</td>
</tr>
<tr>
<td>54.2%</td>
<td>71.3%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>55.1%</td>
<td>71.3%</td>
<td>&lt;0.001</td>
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</tbody>
</table>

**Table 3. Comparison of characteristics of cases with middle ear fluid in both clinic and OR (Concordant fluid) versus cases with discrepant fluid status (Discordant).**

<table>
<thead>
<tr>
<th>Discordant AOM/OME</th>
<th>Concordant AOM/OME</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to tubes (days)</td>
<td>26.2</td>
<td>20.6</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>2.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Mean # of AOM episodes</td>
<td>4.58</td>
<td>4.25</td>
</tr>
</tbody>
</table>