Appendix A. The 20 Suggested Questions on Diagnosis and Treatment of Otitis Media with Effusion (OME)

Suggested Question 1:

What is the relative risk of developing otitis media with effusion (OME) in the child with food or inhalant allergies compared to the child without food or inhalant allergies?

Suggested Question 2:

What is the natural history (spontaneous resolution rate over time without treatment) for:

- OME persisting after a discrete episode of acute otitis media
- newly diagnosed OME of unknown duration (unilateral or bilateral)
- established OME persisting for weeks or months (unilateral or bilateral)
- bilateral OME lasting 3 months or longer (also called "surgical" OME)

Suggested Question 3:

What is the long-term level of speech and language development (receptive and expressive) in infants and preschool children with untreated OME?[1]

Do children with untreated OME with certain risk factor(s)[2] have worse long-term speech and language development (receptive and expressive) than those without those risk factor(s) or with other risk factor(s)?

Suggested Question 4:

What are the sensitivity, specificity, and predictive values for alternative methods of diagnosing OME compared to the gold standard?[3] These methods include, but are not limited to:

- patient or parent reported symptoms
- non-pneumatic otoscopy
- pneumatic otoscopy
- handheld (portable) tympanometers
- tabletop (professional) tympanometers
- acoustic reflectometry with spectral gradient
- otoacoustic emissions
- pure-tone audiometry

[1] The project staff has assumed that Dr. Rosenfeld was referring to untreated OME.
[2] The risk factors for investigation and their stratification need to be delineated by the TEP.
[3] The TEP will need to delineate the gold standard or comparators for these questions. A possible gold standard would be tympanocentesis and assessment of signs and symptoms.

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Suggested Question 5:

In the presence of selected indicator(s) of failure[4] in the child treated conservatively (nonsurgically) for OME, what are the comparative relative risks of the child who remains on conservative treatment compared to the child who undergoes surgical intervention(s)[5] in terms of poor outcome:[6]

- short term: partial OME resolution; complete OME resolution
- long term: percent or absolute time with OME; incidence or absolute number of episodes of acute otitis media (AOM); hearing levels; speech; language; behavior; cognition; academic achievement

Suggested Question 6:

What is the effectiveness of alternative methods

- pneumatic otoscopy
- tympanometry
- acoustic reflectometry with spectral gradient
- otoacoustic emissions

compared to the gold standard, to each other, or to other comparator(s)[7] as indicators in deciding on intervention(s)[9] for OME in terms of the following outcomes:[10]

- short term: partial OME resolution; complete OME resolution
- long term: percent or absolute time with OME; incidence or absolute number of episodes of acute otitis media (AOM); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects

Suggested Question 7:

What is the effectiveness of unilateral hearing decrease compared to bilateral hearing decrease as indicators in deciding on intervention(s)[9] for OME in terms of long-term level of hearing decrease.

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[4] The TEP will need to delineate failure indicators and stratification levels for investigation.

[5] The TEP will need to delineate the interventions. During the Conference Call 1, 11/16/99, the TEP indicated that adenoidectomy might be one of the interventions to investigate in the context of AHCPR#3.

[6] During Conference Call 1, 11/16/99, the TEP discussed the issue of outcomes. First, the TEP decided that short-term outcomes occurred within the first 8 weeks after diagnosis of OME and that long-term outcomes occurred 1 year or longer after diagnosis of OME. Short-term outcomes were partial (at least one affected ear) OME resolution or complete (both ears) OME resolution. The TEP decided that the analysis should note how each study diagnosed OME resolution since different methods have different sensitivities and specificities. Long-term outcomes were percent or absolute time with OME, incidence or absolute number of episodes of acute otitis media (AOM), hearing levels, speech, language, behavior, cognition, and academic achievement The TEP was asked if there was a more "scientific" manner to select these outcomes, and the TEP decided that there was not and that expert opinion was the "state of the art" at this time. If expert opinion is "state of the art" in selecting outcomes for OME, then questions AHCPR#4 and AHCPR#5 are not amenable to evidence-based analysis.

Appendix A (Continued)

Suggested Question 8:

What is the effectiveness of certain hearing level(s) [7] compared to other hearing level(s) as indicators in deciding on intervention(s) [9] for OME in terms of the following outcomes:[10]

- short term: partial OME resolution; complete OME resolution
- long term: percent or absolute time with OME; incidence or absolute number of episodes of acute otitis media (AOM); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects

Suggested Question 9:

Are **antibiotics**[8] more effective than placebo[9] in treating OME[10] in terms of the following outcomes:[10]

- short term: partial OME resolution; complete OME resolution
- long term: percent or absolute time with OME; incidence or absolute number of episodes of acute otitis media (AOM); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: diarrhea, rash, anaphylaxis, hematologic, cardiovascular, central nervous system, endocrine, renal, hepatic, and respiratory effects, bacterial resistance[11]

When antibiotics are used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[12] in terms of the above outcomes?

When antibiotics are used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?

Suggested Question 10:

Are **steroids** more effective than placebo[13] in treating OME[14] in terms of the following outcomes:[10]

- short term: partial OME resolution; complete OME resolution

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[7] During Conference Call 1, 11/16/99, the TEP indicated that one of the hearing levels of interest was 20 decibels. The TEP will need to delineate other hearing levels of interest.
[8] The TEP will need to delineate how antibiotics are to be categorized, if at all, e.g. standard spectrum versus broad spectrum.
[9] The project staff has assumed that the effectiveness of antibiotics and steroids is being compared against placebo.
[10] The project staff has assumed that antibiotics, steroids, antibiotics and steroids, interventions for allergies, and antihistamines and/or decongestants are considered possible interventions in the treatment of all types of OME regardless of duration as noted in the Overview of OME (p.7).
[11] The project staff assumed that the adverse effects of antibiotics, steroids, and antihistamines and decongestants were those noted in the Overview of OME (p.11).
[12] During Conference Call 1, 11/16/99, the TEP mentioned the potential influence of age and previous history of OME on outcomes related to OME treated with adenoidectomy. The project staff has expanded the original AHCPR and RR questions related to interventions to include questions on these two influencing factors. The TEP will need to delineate if these two or other influencing factors will be investigated for each intervention.

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- long term: percent or absolute time with OME; incidence or absolute number of episodes of acute otitis media (AOM); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: agitation, behavioral changes, sleeplessness, increase in appetite, weight gain, gastrointestinal disorders, angina, Cushing's disease, disseminated varicella[15]

When steroids are used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[16] in terms of the above outcomes?

When steroids are used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?

Suggested Question 11:

Do **antibiotics[12] add an incremental benefit to steroids** in treating OME[14] in terms of the following outcomes:[10]

- short term: partial OME resolution; complete OME resolution
- long term: percent or absolute time with OME; incidence or absolute number of episodes of acute otitis media (AOM); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: (antibiotics) diarrhea, rash, anaphylaxis, hematologic, cardiovascular, central nervous system, endocrine, renal, hepatic, and respiratory effects, and bacterial resistance; (steroids) agitation, behavioral changes, sleeplessness, increase in appetite, weight gain, gastrointestinal disorders, angina, Cushing's disease, disseminated varicella[15]

Do antibiotics add a greater incremental benefit to steroids in treating OME in terms of the above outcomes in children younger than 3 years old than children 3 years or older? [16]

Do antibiotics add a greater incremental benefit to steroids in treating OME in terms of the above outcomes in children without previous history of OME than children with previous history of OME? [16]

Suggested Question 12:

Are **interventions for allergies** (food or inhalant) more effective than placebo[13] in treating OME[14] in terms of the following outcomes:[10]

- short term: partial OME resolution; complete OME resolution
- long term: percent or absolute time with OME; incidence or absolute number of episodes of acute otitis media (AOM); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects

Appendix A (Continued)

When interventions for allergies (food or inhalant) are used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[16] in terms of the above outcomes?

When interventions for allergies (food or inhalant) are used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?

Suggested Question 13:

Are **antihistamines and/or decongestants** more effective than placebo[13] in treating OME[14] in terms of the following outcomes:[10]

- short term: partial OME resolution; complete OME resolution
- long term: percent or absolute time with OME; incidence or absolute number of episodes of acute otitis media (AOM); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: insomnia, drowsiness, behavior changes, changes in blood pressure, seizures[15]

When antihistamines and/or decongestants are used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[16] in terms of the above outcomes?

When antihistamines and/or decongestants are used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?

Suggested Question 14:

Are **tympanostomy tubes** more effective than other intervention(s) [13] in treating OME of greater-than 3 months duration[14] in terms of the following outcomes:[10]

- long term: percent or absolute time with OME (e.g. days of middle-ear effusion per year); incidence or absolute number of episodes of acute otitis media (AOM) (e.g. AOM episodes per child-year); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: tympanosclerosis, atrophic scars, atelectasis, retraction pockets, obstruction of tube lumen, persistent TM perforation, otorrhea, secondary infection with otorrhea through tube, premature extrusion, dislocation of tube into middle ear cavity, hearing loss, hyperacusis, nuisance factors such as inability to swim or shampoo,[15] risk of anesthesia

When tympanostomy tubes are used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[16] in terms of the above outcomes?

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[13] The TEP will need to delineate the comparator interventions. The comparator intervention may be placebo.

[14] The project staff has assumed that tympanostomy tubes, adenoidectomy, tonsillectomy, myringotomy, alternative or complementary therapies, and prophylactic antibiotics are interventions for OME of greater-than 3 months duration as noted in the Overview of OME (p. 8).

[15] The project staff has assumed that the complications and sequelae of tubes referred to in RR#5 were those noted in the Overview of OME (p. 11).

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When tympanostomy tubes are used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?
(AHCPR#8 and RR#5 modified)

Suggested Question 15:

Is **adenoidectomy** more effective than other intervention(s) [17] in treating OME of greater-than 3 months duration[18] in terms of the following outcomes:[10]

- long term: percent or absolute time with OME (e.g. days of middle-ear effusion per year); incidence or absolute number of episodes of acute otitis media (AOM) (e.g. AOM episodes per child-year); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: risk of general anesthesia, postoperative bleeding[16]

When adenoidectomy is used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[16] in terms of the above outcomes?

When adenoidectomy is used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?
(TEP)

Suggested Question 16:

Is **tonsillectomy** more effective than other intervention(s) [17] in treating OME of greater-than 3 months duration[18] in terms of the following outcomes:[10]

- long term: percent or absolute time with OME (e.g. days of middle-ear effusion per year); incidence or absolute number of episodes of acute otitis media (AOM) (e.g. AOM episodes per child-year); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: risk of general anesthesia, postoperative bleeding

When tonsillectomy is used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[16] in terms of the above outcomes?

When tonsillectomy is used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?
(TEP)

Suggested Question 17:

Is **myringotomy** more effective than other intervention(s) [17] in treating OME of greater-than 3 months duration[18] in terms of the following outcomes:[10]

[16] The risks of adenoidectomy are taken from the OME Guidelines (Stool, Berg, Berman et al., 1994).

- long term: percent or absolute time with OME (e.g. days of middle-ear effusion per year); incidence or absolute number of episodes of acute otitis media (AOM) (e.g. AOM episodes per child-year); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: risk of general anesthesia

When myringotomy is used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[16] in terms of the above outcomes?

When myringotomy is used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?
(TEP)

Suggested Question 18:

Are **alternative or complementary therapies** more effective than other intervention(s) [17] in treating OME of greater-than 3 months duration[18] in terms of the following outcomes:[10]

- long term: percent or absolute time with OME (e.g. days of middle-ear effusion per year); incidence or absolute number of episodes of acute otitis media (AOM) (e.g. AOM episodes per child-year); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: risk of general anesthesia

When alternative or complementary therapies are used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[16] in terms of the above outcomes?

When alternative or complementary therapies are used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?
(TEP)

Suggested Question 19:

Are **prophylactic antibiotics** more effective than intervention(s) [17] in treating OME of greater-than 3 months duration[18] in terms of the following outcomes:[10]

- long term: percent or absolute time with OME (e.g. days of middle-ear effusion per year); incidence or absolute number of episodes of acute otitis media (AOM) (e.g. AOM episodes per child-year); hearing levels; speech; language; behavior; cognition; academic achievement
- adverse effects: diarrhea, rash, anaphylaxis, hematologic, cardiovascular, central nervous system, endocrine, renal, hepatic, and respiratory effects, bacterial resistance[15]

When prophylactic antibiotics are used in treating OME, do children younger than 3 years old have better outcome than children 3 years or older[16] in terms of the above outcomes?

Appendix A (Continued)

When prophylactic antibiotics are used in treating OME, do children without previous history of OME have better outcome than children with previous history of OME[16] in terms of the above outcomes?

Suggested Question 20:

What is the effectiveness of alternative methods

- pneumatic otoscopy
- tympanometry
- acoustic reflectometry with spectral gradient
- otoacoustic emissions

of monitoring as indicators of need for intervention(s) [9] for OME in terms of the following outcomes:[10]

- short term: partial OME resolution; complete OME resolution
- long term: percent or absolute time with OME; incidence or absolute number of episodes of acute otitis media (AOM); hearing levels; speech; language; behavior; cognition; academic achievement.