Appendix C. Technical Expert Panel Comments on Scope

Key Question 1: Natural History

Domain	a/	b/	c/	d/	e/	f/	g/	h/	i/	j/	k/	l/	Total Accept	Total Revise	Total Abstain
1/Disease Entity	1	1	1	1	1	1	1	0[1,h]	0[1,i]	1	1	1	10	2	0
2/Patient Population	1	0[2,b]	1	1	0[2,e]	1	1	0[2,h]	1	1	0[2,k]	0[2,l]	7	5	0
3/Setting	1	0[3,b]	1	1	1	1	1	0[3,h]	1	0[3,j]	1	1	9	3	0
4/Exclusion Factors	1	0[4,b]	1	1	1	1	1	1	0[4,i]	9	1	0[4,l]	8	3	1
5/Intervention	1	1	1	1	1	1	1	1	0[5,i]	1	1	1	11	1	0
6/Diagnostic Methods															
7/Gold Standard															
8/Non-treatment Factors Influencing Outcomes	0[8,a]	0[8,b]	1	0[8,d]	9	1	1	1	0[8,i]	0[8,j]	1	0[8,l]	5	6	1
9/Outcome Measures	0[9,a]	0[9,b]	1	0[9,d]	1	1	1	1	0[9,i]	1	1	1[9,l]	8	4	0
10/Literature Source	1	1	1	1	9	1	1	1	1	1	0[10,k]	1	10	1	1
11/Language	1	1	1	1	9	1	1	1	1	0[10,j]	1	0[11,l]	9	2	1
12/Study Design	0[12,a]	0[12,b]	1	1	9	1	0[12,g]	1	1	1	0[12,k]	1	7	4	1
13/Wording of Key Question	1	1	1	1	1	1	1	1	0[13,i]	1	9	0[13,l]	9	2	1
14/Key Words for Literature Search	[14,a]	9	9	9	9	9	9	9	9	9	9	[14,l]			
15/Other/References/ Studies	9	9	9	9	9	9	9	9	9	9	9	9			
9-abstain, 1-accept, 0-revise															

1/
[h] delete bullet 3;
[I] replace with "unilateral and bilateral OME, duration >= 3 months"

2/
[b] Do we need to specify: community-based, primary care, specialty care
[e] change to 6 month to 3 year old
[h] lower upper age of follow-up (probably 8 years)
[k] change age at diagnosis to 0-12 years
[l] through 8 years

3/
[b] Need to look at evidence that primary and secondary care groups are homogeneous
[h] more recent is better (unknown year)

[j] Why only beyond 1996?

4/
[b] exclude structural defects (cleft palate, etc)
[i] exclude children with cleft palate, Down syndrome, other craniofacial anomalies
[l] exclude craniofacial syndrome patients (e.g. cleft palate, ear atresia), primary mucosal disorders (e.g. immotile cilia, cystic fibrosis)

5/
[I] add with antimicrobial treatment

6/

7/

Appendix C. Technical Expert Panel Comments on Scope (Continued)

8/ [a] add number of hours per week to attendance at day care center, add not breast-fed, add conductive vs. sensorineural loss to hearing level, consider age of onset of prevous OME, add allergies, add MRI to type of monitoring [b] add number of sibs, breastfed, prior tube, prior adenoidectomy [d] inclusion of acoustic reflectometry assumes that it has been validated, and I don't believe it has been adequately validated for monitoring [i] add gender, number of children in household, duration of OME prior to intervention >=3 months only, delete otitis prone, previous OME, early onset of previous OME, craniofacial anomaly, immunodeficiency, genetic syndrome, parent/caretaker factors, type of examiner, setting, and parent from monitoring section [j] replace "Eskimo or Native American" with race, add "family history", change "day care center" to "child care center", add "developmental delay [l] change “previous OME” to “previous OMEs”, add age first OM and delete otitis prone, early onset of previous OME, craniofacial anomaly, immunodeficiency, genetic syndrome, “'Otitis prone' has so many different definitions that the term is near-useless."
9/ [a] not sure about difference between relapse and recurrence [b] Include AOM [d] define difference between relapse and recurrence [i] delete partial OME resolution; [l] comment: "Definitions here are difficult and critical."
10/ [k] include proceedings of the International OM Symposia
11/ [j] I would search initially all languages. However, if you have to know the search words in all language that could be a problem. Also if interpreters are not available that would also present a problem. [l] add non-English sources identified in Medline, Embase, and Cochrane Library
12/ [a] add case-control studies [b] add natural history studies [g] observational studies included [k] exclude retrospective studies
13/ [i] change as per footnote 1,i [l] add "Barotrauma Challenge(s)" to non-treatment factors influencing outcome
14/ [a] resolution and OM, duration of effusion; [l] otitis media with effusion, mastoid
15/

Key Questions 2 and 3: Speech/Language/Hearing As of 01/06/00

Domain	a/	b/	c/	d/	e/	f/	g/	h/	i/	j/	k/	l/	Total Accept	Total Revise	Total Abstain
1/Disease Entity	0[1,a]	1	1	1	0[1,e]	1	1	1	0[1,i]	0[1,,j]	1	1	8	4	0
2/Patient Population	1	0[2,b]	1	1	0[2,e]	1	1	1	0[2,i]	1	1	1	9	3	0
3/Setting	1	0[3,b]	1	1	1	1	1	0[3,h]	1	0[3,j]	1	1	9	3	0
4/Exclusion Factors	1	0[4,b]	1	1	1	1	1	1	0[4,i]	9	1	1	9	2	1
5/Intervention	0[5,a]	1	1	0[5,d]	1	1	1	0[5,h]	0[5,i]	1	1	0[5,l]	7	5	0
6/Diagnostic Methods															
7/Gold Standard															
8/Non-treatment Factors Influencing Outcomes	0[8,a]	1	1	0[8,d]	9	1	1	1	0[8,i]	0[8,j]	1	0[8,l]	6	5	1
9/Outcome Measures	0[9,a]	1	1	0[9,d]	1	1	0[9,g]	1	1	1	1	1	9	3	0
10/Literature Source	1	1	1	1	9	1	1	1	1	1	0[10,k]	1	9	1	1
11/Language	1	1	1	1	9	1	1	1	1	0[10,j]	1	0[11,l]	9	2	1
12/Study Design	1	1	1	1	9	1	1	1	0[12,i]	1	0[12,k]	1	9	2	1
13/Wording of Key Question	0[13,a]	1	1	1	0[13,e]	1	1	1	0[13,i]	0[13,j]	0[13,k]	1	7	5	0
14/Key Words for Literature Search	9	9	9	9	9	9	9	9	9	9	9	[14,l]			
15/Other/References/ Studies	9	9	9	9	9	9	9	9	[15,l]	9	9	9			

9-abstain, 1-accept, 0-revise

1/
[a] Add to treatment factors with or without steroids; add to non-treatment factors: allergies; monitoring methods should include type of equipment and times of recheck" (These comments will be entered in appropriate domains)
[e] address duration of MEE
[i] change to "all types of OM that involve the presence of MEE"
[j] delete "as long as MEE is present", may not know MEE is present, but assume if AOM or OME are present

2/
[b] Do we need to specify: community-based, primary care, specialty care
[e] change to 6 month to 3 year old
[i] follow-up through 9 years

3/
[b] Need to look at evidence that primary and secondary care groups are homogeneous
[h] more recent is better (unknown year)
[j] Why only beyond 1996?

4/
[b] Exclude structural defects (cleft palate, etc)
[i] exclude children with known risk factors--e.g. prematurity, congenital anomalies, birth injury, syndromes, etc."

5/
[a] add with or without steroids
[d] allow combination therapies, I.e. tubes and adenoidectomy, or simplify into three categories: no intervention, medical intervention, surgical intervention. I rec. the simplified approach, because there are very few speech/language studies with any kind of intervention. Most are purely descriptive."
[h] don't think tonsillectomy needs to be there"
[i] keep "with or without tympanostomy tubes", delete others, add "tubes with or without antibiotics" and "no tubes with or without antibiotics"
[l] add with or without systemic steroids, decongestant, antihistamine

Appendix C. Technical Expert Panel Comments on Scope (Continued)

6/
7/
8/ [a] add number of hours per week to attendance at day care center, add not breast-fed, change to early onset of OME, add allergies, add MRI to type of monitoring, add equipment type and recheck times to monitoring methods [d] add audiometry and auditory brainstem responses/brainstem auditory evoked responses [i] add gender and number of children in household and delete age, ethnicity, tobacco smoke exposure, season, otitis prone, previous OME, early onset of previous OME, craniofacial anomaly, immunodeficiency, genetic syndomre, parent/caretaker availability, parent/caretaker preference, type of examiner, and parent from monitoring section [j] replace "Eskimo or Native American" with race, add "family history", change "day care center" to "child care center", add "developmental delay" [l] change "previous OME" to "previous OMEs, add age first OM and delete early onset of previous OME, craniofacial anomaly, immunodeficiency, genetic syndrome
9/ [a] add expressive and receptive to speech, add expressive and receptive to language [d] add speech perception and production, and expressive/receptive language [g] add cognition, measures of intelligence
10/ [k] include proceedings of the International OM Symposia
11/ [j] I would search initially all languages. However, if you have to know the search words in all language that could be a problem. Also if interpreters are not available that would also present a problem. [l] add non-English sources identified in Medline, Embase, and Cochrane Library
12/ [i] delete case-control studies since "inherently susceptible to selection bias" [k] exclude retrospective studies
13/ [a] change to "What is the level of speech/language development.....in children with OME by the age of 6 years (or older-whatever the panel determines) [e] Q2--should the duration of MEE as a parameter be stated" and "Q3--At what point is hearing tested and how long does MEE need to be present before testing? [i] Too diffuse. 2. What are relationships, if any, between persistent early life OME and later speech and language development? 3. Is OME-associated conductive hearing loss in the first 3 years of life a risk factor for fixed hearing loss later in life? [j] Reword Key Question 2 to read: "Do infant and preschool children with OME have delays in the speech and language development (receptive and expressive)? Do children with OME with certain risk factor(s) have greater delays in their long-term speech and language development (receptive and expressive) than those without those risk factor(s) or with other risk factor(s)? For Key Question 3 change the term "hearing decrease" to "heearing loss or increase in hearing level." [k] As worded the question refers to outcomes in children with OM; the real issue is outcomes in OM "positive" and OM "negative" controls
14/ [l] otitis media with effusion, mastoid
15/ [i] All of my publications on the subject--see my CV

Key Question 4: Diagnostic Methods As of 01/06/00

Domain	a/	b/	c/	d/	e/	f/	g/	h/	i/	j/	k/	l/	Total Accept	Total Revise	Total Abstain
1/Disease Entity	1	0[1,b]	1	1	1	1	1	1	0[1,i]	1	1	1	10	2	0
2/Patient Population	0[2,a]	0[2,b]	1	1	0[2,e]	1[2,f]	0[2,g]	1	0[2,i]	0[2,j]	0[2,k]	1	5	7	0
3/Setting	0[3,a]	0[3,b]	1	1	1	1	1	0[3,h]	1	0[3,j]	1	1	8	4	0
4/Exclusion Factors	1	0[4,b]	1	1	1	1	1	1	0[4,i]	9	0[4,k]	1	8	3	1
5/Intervention															
6/Diagnostic Methods	1[6,a]	1	9	1	0[6,e]	1	1	1	0[6,i]	1	1	0[6,l]	8	3	1
7/Gold Standard	1	1	9	0[7,d]	9	9[7,f]	0[7,g]	9[7,h]	0[7,i]	1	1	0[7,l]	4	4	4
8/Non-condition Factors Influencing Diagnostic Performance	0[8,a]	1	1	9	9	1	1	1	0[8,i]	0[8,j]	1	0[8,l]	6	4	2
9/Outcome Measures	1	0[9,b]	1	1	1	1	1	1	1	1	1	1	11	1	0
10/Literature Source	1	1	1	1	9	1	1	1	1	1	0[10,k]	1	10	1	1
11/Language	1	1	1	1	9	1	1	1	1	0[10,j]	1	0[11,l]	9	2	1
12/Study Design	0[12,a]	1	1	1	9	1	1	1	1	1	1	1	10	1	1
13/Wording of Key Question	1	1	1	1	9	1	0[13,g]	1	0[13,i]	1	1	0[13,l]	9	2	1
14/Key Words for Literature Search	[14,a]	9	9	9	9	9	9	9	9	9	9	[14,l]			
15/Other/References/ Studies	[15,a]	9	9	9	9	9	9	9	9	9	9	9			

9-abstain, 1-accept, 0-revise

1/
[b] narrow to OME;
[i] change to MEE

2/
[a] could be extended throughout childhood. Much of the available data is on children over the age of 3 years. Also, the tympanometer that most primary care practitioners have in their offices is not reliable in children under 6 months;
[b] Do we need to specify: community-based, primary care, specialty care Note: may need to accept varying age ranges for different methods. Would consider 0-6, 6-36, and >36
[e] change to 6 month to 3 year old
[f] Actually this could be for most any age
[g] would extend to 5 years of age
[i] change to 0-6 years

[j] could you go higher to 8 years or 5 years
[k] change to 0-12 years

3/
[a] You may want to search back farther--there is not a lot of data on diagnosis
[b] Need to look at evidence that primary and secondary care groups are homogeneous
[h] more recent is better (unknown year)
[j] Why only beyond 1996?

4/
[b] exclude structural defects (cleft palate, etc)
[i] exclude children with cleft palate, Down syndrome, other craniofacial anomalies

Appendix C. Technical Expert Panel Comments on Scope (Continued)

[k] exclude studies of AOM

5/

6/
[a] Acoustic reflectometry…was redesigned in 97 or 98…data from the redesigned instrument should be used
[e] Subdivide Pneumatic otoscopy into validated and un-validated examiners
[i] delete signs/symptoms, non-pneumatic otoscopy, and audiometry
[l] add air and bone conduction thresholds

7/
[d] change to tympanocentesis and MRI, "I rec. allowing myringotomy and tubes, because it has been the accepted gold standard for so long, that almost no studies will be available otherwise. Could establish hierarchy of gold standards: 1. tympanocentesis (non-sedated), 2. MRI, 3. myringotomy (sedated),4. validated pneumatic otoscopy
[f] Neither are practical for the practicing physician
[g] may have studies with CT Scan
[h] will eliminate many patients and studies since these are not routinely done
[i] add validated otoscopist, tympanocentesis or MRI, not practicable in normative population
[l] delete tympanocentesis only and MRI only

8/
[a] add number of hours per week to attendance at daycare center, "Diagnosis should not be affected by environmental factors or by clinical factors. Diagnosis is seeing or determining what is there and describing it."
[i] delete all demographic factors except age, all symptoms/signs, all other clinical factors, and all examiner factors except type of examiner, "Diagnostic skill is what is being tested."
[j] replace "Eskimo or Native American" with race, add "family history", change "day care center" to "child care center", add "developmental delay
[l] change “previous OME” to “previous OMEs, add age first OM and delete hearing level, early onset of previous OME, craniofacial anomaly, immunodeficiency, genetic syndrome, adenoid hyperplasia

9/
[b] positive and negative predictive values are prevalence specific. So, should include prevalence rate when studying positive and negative predictive values

10/
[k] include proceedings of the International OM Symposia

11/
[j] I would search initially all languages. However, if you have to know the search words in all language that could be a problem. Also if interpreters are not available that would also present a problem.
[l] add non-English sources identified in Medline, Embase, and Cochrane Library

12/
[a] Add list of other studies, info may be found here as well

13/
[g] would consider eliminating MRI; may need to eliminate direct comparison to “gold” standard as many studies will not have direct comparison
[i] change as per footnote 6,i
[l] simplify non-condition factors influencing diagnostic performance to OME laterality and anesthetic

14/
[a] otoscopy, pneumatic otoscopy, tympanometry, otoacoustic emissions
[l] otitis media with effusion, mastoid

15/
[a] Book chapter on Diagnosis in Rosenfeld & Bluestone: Evidence-based Otitis Media. I also have sensitivity & specificity results from a training tape used during our workshop (Diagnostic Accuracy) presented at SENTAC 12/99.