

(1997; 1998; 2004; 2006; 2010; & 2012; 2012; & 2015; 2015).

(1995; 2000).

1999; A 2011; 2013; 2020).

75% A 2010; 2011; 2011).

A (A 2019).

(A 2011; & 2012; 2013; 2015; 2020). A (2020)

(A), 0.5, 1, 2, 4, 6, 8, 12, 16, 20, 25, 40, 60, 80, 100% (2016). A (<3 2011).

25 40% (2020).

(A), 12 N, A (2022).

MATERIALS AND METHODS

Study Design

N

A 2019).

(2017 2019) 15

N A 14

12 A

18

(A),

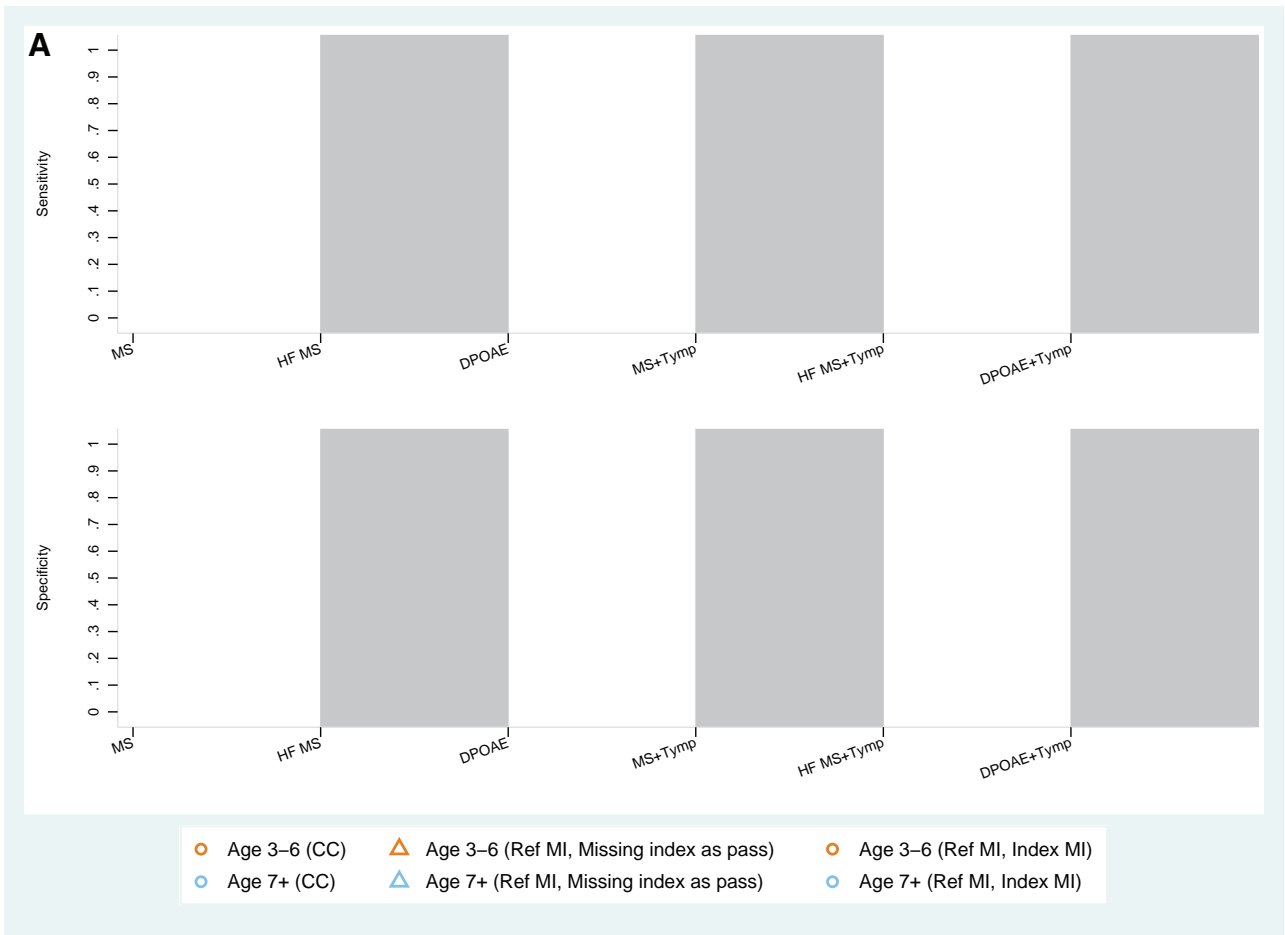
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1997), ... (1).
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mHealth Plus Tympanometry Screening Protocol

**Tool 1: mHealth Pure-Tone Screening (1, 2, 4kHz)
Alone**

()
94.9% (93.9 95.9), (3).
40.3% (36.2 44.5)



Age 3-6 (CC) = 72.0%, 62.0-82.1;
 Age 3-6 (Ref MI, Missing index as pass) = 12.5%, 3.7-22.8;
 Age 3-6 (Ref MI, Index MI) = 59.9%, 55.3-64.3;
 Age 7+ (CC) = 3.4%, 1.1-7.6;
 Age 7+ (Ref MI, Missing index as pass) = 88.2%, 84.8-91.5;
 Age 7+ (Ref MI, Index MI) = 88.2%, 84.8-91.5.

Diagnostic Accuracy by Grade

Grade 5-6: 88%, 88-91.5
 Grade 7-8: 88%, 88-91.5
 Grade 9-10: 88%, 88-91.5
 Grade 11-14: 88%, 88-91.5
 Grade 15-18: 88%, 88-91.5
 Grade 19-25: 88%, 88-91.5

Diagnostic Accuracy by Threshold Definition

Threshold > 25: 0.2%, 3.9-4.4
 Threshold 20: 0.2%, 3.9-4.4
 Threshold 15: 0.2%, 3.9-4.4
 Threshold 10: 0.2%, 3.9-4.4
 Threshold 5: 0.2%, 3.9-4.4
 Threshold 0: 0.2%, 3.9-4.4

(...)
 (22.4 28.6%),
 16.8%
 3 6
 3 6
 A, A
 10- 18-
 (2004),
 1003
 5 6 13.2%,
 (= 1449,
 12)
 17.1%. A
 65%
 >25 2% 0.5, 1, 2, 4
 1)
 A >25
 20 2%
 10 2% 35 (2) 85 (65% 95 () 25 (125.1 1 8 5 (3 10 40

TABLE 3. Diagnostic accuracy (with 95% confidence intervals) of index screening protocols by reference standard using complete case data for all ages

Tool	N	Sensitivity	Speci city	PPV	NPV	LR+	LR-	Youden Index	Concordance
Full audiometric evaluation with high frequency (>25 dB)*									
MS	2541	40.3 (36.2, 44.5)	94.9 (93.9, 95.9)	68.0 (62.9, 73.1)	85.6 (84.1, 87.0)	7.92 (6.22, 9.63)	0.63 (0.58, 0.67)	35.2 (31.0, 39.5)	83.4 (81.9, 84.8)
HF MS	2541	49.1 (44.8, 53.3)	93.7 (92.6, 94.8)	67.7 (63.1, 72.3)	87.3 (85.9, 88.7)	7.80 (6.32, 9.28)	0.54 (0.50, 0.59)	42.8 (38.4, 47.1)	84.3 (82.8, 85.7)
DPOAE	2560	57.7 (53.5, 61.8)	91.3 (90.1, 92.6)	64.1 (59.8, 68.3)	89.0 (87.6, 90.3)	6.65 (5.60, 7.71)	0.46 (0.42, 0.51)	49.0 (44.7, 53.3)	84.2 (82.8, 85.6)
MS + Tympanometry	2525	60.2 (56.0, 64.4)	94.0 (92.9, 95.0)	72.7 (68.5, 76.8)	89.9 (88.6, 91.2)	10.01 (8.14, 11.88)	0.42 (0.38, 0.47)	54.2 (49.9, 58.5)	86.9 (85.6, 88.2)
HF MS + Tympanometry	2525	67.0 (63.0, 71.0)	92.8 (91.6, 93.9)	71.1 (67.2, 75.1)	91.4 (90.1, 92.6)	9.28 (7.72, 10.84)	0.36 (0.31, 0.40)	59.8 (55.6, 63.9)	87.4 (86.1, 88.7)
DPOAE + Tympanometry	2542	68.1 (64.1, 72.1)	90.5 (89.3, 91.8)	65.6 (61.7, 69.6)	91.5 (90.2, 92.7)	7.20 (6.14, 8.26)	0.35 (0.31, 0.40)	58.6 (54.5, 62.8)	85.8 (84.5, 87.2)
Middle ear disease†									
MS	2733	45.7 (40.4, 51.0)	91.6 (90.5, 92.7)	43.5 (38.4, 48.7)	92.3 (91.2, 93.3)	5.45 (4.49, 6.40)	0.59 (0.53, 0.65)	37.3 (31.9, 42.7)	85.9 (84.6, 87.2)
HF MS	2733	50.1 (44.8, 55.5)	88.9 (87.7, 90.2)	39.1 (34.5, 43.7)	92.6 (91.6, 93.7)	4.53 (3.83, 5.23)	0.56 (0.50, 0.62)	39.1 (33.6, 44.5)	84.1 (82.7, 85.5)
DPOAE	2840	67.6 (62.8, 72.4)	87.5 (86.2, 88.8)	44.6 (40.5, 48.7)	94.8 (93.9, 95.7)	5.43 (4.74, 6.11)	0.37 (0.32, 0.43)	55.1 (50.2, 60.1)	85.0 (83.7, 86.3)
MS + Tympanometry	2711	82.6 (78.5, 86.7)	90.4 (89.3, 91.6)	54.2 (49.8, 58.6)	97.4 (96.8, 98.1)	8.63 (7.48, 9.78)	0.19 (0.15, 0.24)	73.0 (68.7, 77.3)	89.5 (88.3, 90.6)
HF MS + Tympanometry	2711	84.4 (80.5, 88.3)	87.9 (86.6, 89.2)	48.8 (44.7, 53.0)	97.6 (97.0, 98.3)	6.96 (6.14, 7.78)	0.18 (0.13, 0.22)	72.3 (68.1, 76.4)	87.5 (86.2, 88.7)
DPOAE + Tympanometry	2817	88.2 (84.8, 91.5)	86.6 (85.3, 87.9)	48.7 (44.8, 52.5)	98.1 (97.5, 98.6)	6.58 (5.87, 7.28)	0.14 (0.10, 0.18)	74.8 (71.1, 78.4)	86.8 (85.5, 88.0)

*Reference standard includes referral for: pure-tone average (0.5, 1, 2, 4kHz) >25 dB OR any tone (0.5, 1, 2, 4, 6, 8kHz) 30 db OR type B/C tympanometry OR digital otoscopy with pathological findings (occluding cerumen, retraction, effusion, acute otitis media, otorrhea, perforation, patent or plugged tube, external otitis, foreign body) requiring healthcare follow-up.
†Reference standard includes type B or C tympanometry OR otoscopy findings of retraction, effusion, acute otitis media, otorrhea, perforation, presence of tympanostomy tube, or external otitis requiring healthcare follow-up.
DPOAE, distortion product otoacoustic emissions; HF, high frequency (add 6 kHz); LR+, positive likelihood ratio; LR-, negative likelihood ratio; NPV, negative predictive value; PPV, positive predictive value; Tympanometry, tympanometry.

TABLE 4. Diagnostic accuracy statistics (with 95% confidence intervals) for children aged 3 to 6* by index tool and missing data approach, by reference standard

Reference Standard and Index Tool	N	Sensitivity	Speci city	PPV	NPV	LR+	LR-	Youden Index
High-frequency gold standard (>25dB)†								
MS	2541	22.4 (12.4, 32.4)	94.9 (92.6, 97.2)	45.5 (28.5, 62.4)	86.5 (83.1, 89.9)	4.4 (1.60, 7.13)	0.82 (0.71, 0.93)	17.3 (7.0, 27.5)
Complete case	2898	16.8 (11.3, 22.3)	94.6 (92.6, 96.6)	45.5 (28.5, 62.4)	86.5 (83.1, 89.9)	4.4 (1.60, 7.13)	0.82 (0.71, 0.93)	17.3 (7.0, 27.5)
Ref MI, missing index as pass								

*Reference standard includes referral for: pure-tone average (0.5, 1, 2, 4kHz) >25 dB OR any tone (0.5, 1, 2, 4, 6, 8kHz) 30 db OR type B/C tympanometry OR digital otoscopy with pathological findings (occluding cerumen, retraction, effusion, acute otitis media, otorrhea, perforation, patent or plugged tube, external otitis, foreign body) requiring healthcare follow-up.
†Reference standard includes type B or C tympanometry OR otoscopy findings of retraction, effusion, acute otitis media, otorrhea, perforation, presence of tympanostomy tube, or external otitis requiring healthcare follow-up.
DPOAE, distortion product otoacoustic emissions; HF, high frequency (add 6 kHz); LR+, positive likelihood ratio; LR-, negative likelihood ratio; NPV, negative predictive value; PPV, positive predictive value; Tympanometry, tympanometry.

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