

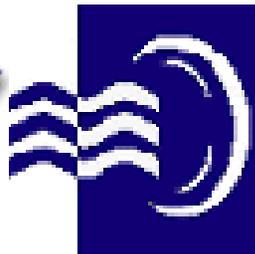
NCRAR Workshop

Ototoxicity Early Identification & Monitoring

VA Rehabilitation Research & Development
National Center for Rehabilitative Auditory Research



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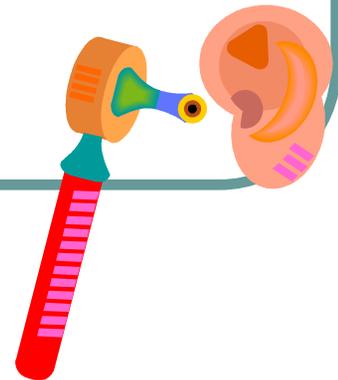


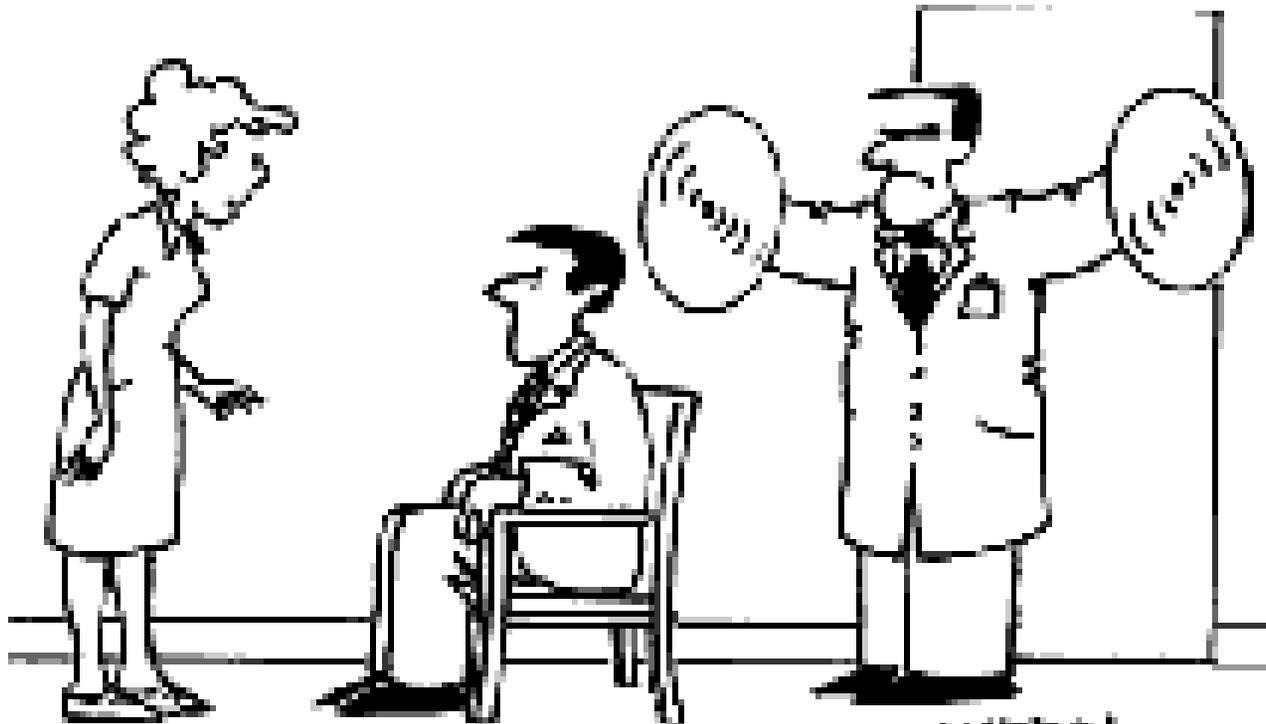
Outline

- I. Learner Outcomes
- II. Overview: Basic Principles
- III. Tinnitus Monitoring
- IV. Ototoxicity Monitoring in Adults
- V. Objective Monitoring
- VI. Ototoxicity Monitoring in Children
- VII. Establishing Program

IV. Monitoring Hearing in Adults

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HARDIN

"Now just relax and we'll begin
your hearing test."

Test Characteristics

- **Sensitivity & Specificity**
 - (high hit rate & low false positive rate)
- **Reliability (test-retest)**
- **Time efficiency**

Sensitivity & Specificity

- **Sensitivity (hit rate)**

- Percentage of times ears with hearing change identified as having hearing change by the experimental measure
- 100% - sensitivity = false negative or miss rate

- **Specificity (correct rejection rate)**

- Percentage of times ears with no hearing change are correctly labeled as no change by the experimental measure
- 100% - specificity = false positive or false alarm rate

Sensitivity & Specificity

EXPERIMENTAL MEASURE

GOLD STANDARD

CHANGE

NO CHANGE

CHANGE

Hits
(Sensitivity)

False Alarms

NO CHANGE

Misses

**Correct
Rejection**
(Specificity)

100%

100%

Reliability & Time Efficiency

- **Reliability (test-retest)**
 - Determine size change (e.g., in pure-tone threshold or OAE amplitude) likely to be real and not random variability
 - Significantly different change with 0.05 level of confidence provides 95% probability that change is real
- **Time Efficiency (clinically practical)**

Monitoring Principles

- High- to low- frequency progression
- High-frequency testing is reliable (Fausti et al., 1998; Frank, 1990; Frank & Driesbach, 1991; Gordon et al., under review)
- Studies have shown the efficacy of high-frequency monitoring (Dreschler et al., 1989; Fausti et al. 1984; Jacobson et al., 1969; Ress et al., 1999; Tange et al., 1985; Van der Hulst et al., 1988; Fausti et al., 1993; Fausti et al., 1994)
- Studies have shown testing in 1/6-octave intervals provides earlier detection (Fausti et al., 2003; Vaughan et al., 2003)
- Individualized protocols targeting the *highest frequencies* a person can hear

Keep in Mind

- There are no normative high-frequency sensitivity (i.e., threshold) standards due to lack of standardization in
 - calibration,
 - instrumentation,
 - and methodological procedures

Fausti SA, Frey RH, Rappaport BZ, Schechter MA. High-frequency audiometry with an earphone transducer. *Sem Hear* 1985;6:347-357

Keep in Mind

- There is also a high degree of inter-subject threshold variability in high frequency sensitivity
 - Threshold variability increases with age (in elderly) and with higher test frequencies

Schechter MA, Fausti SA, Rappaport BZ, Frey RH. Age categorization of high-frequency auditory threshold data. *J Acoust Soc Am* 1986;79:767-771.

Matthews LJ, Lee FS, Mills JH, Dubno JR. Extended high-frequency thresholds in older adults. *J Speech Lang Hear Res* 1997;40:208-214.

Does it Matter for Monitoring?

- However, the key to serial monitoring is intrasubject **reliability**
- High-frequency test-retest threshold variability is within a clinically acceptable range (± 10 dB)
- As a result, monitoring near individual's high-frequency hearing limit is effective

ASHA Change Criteria

≥ 20 dB change at 1 test frequency

≥ 10 dB change at 2 adjacent test frequencies

Loss of response at 3 consecutive test frequencies where responses were previously obtained

*Change confirmed by retest

ASHA Change Criteria

- Normal variability in pure-tone thresholds occurs at random frequencies
- Threshold shifts at adjacent test frequencies indicate more systematic change (Atherly, 1963; Dobie, 1983)
 - Notion of examining threshold shift across frequencies
- Threshold shifts on repeated tests are also a stronger indication of a true threshold change (Royster & Royster, 1982)

*1/6th Octave Testing
Provides Earlier
Detection*

1/2 Octave vs. 1/6 Octave

1/2 Octave Protocol	
Test Frequency (kHz)	Change From Baseline
≤ 8	0
11.2	+10
16	5

1/6 Octave Protocol	
Test Frequency (kHz)	Change From Baseline
≤ 8	0
9	5
10	5
11.2	+10
12.5	+10
14	+10
16	5

1/2 Octave vs. 1/6 Octave

1/2 Octave Protocol	
Test Frequency (kHz)	Change From Baseline
1	0
1.5	0
2	0
3	0
4	0
6	5
8	+10

1/6 Octave Protocol	
Test Frequency (kHz)	Change From Baseline
1	0
1	0
2	0
3	0
4	5
6	5
6.35	+10
7.13	+15
8.00	+10

1/6th-Octave vs Conventional

	AMG (N=25 ears)	Cisplatin or Carboplatin (N=185 ears)
Percentage of Ears Missed or Detected Later	28%	37%

Compared to testing in 1/6th-octave steps above and below 8 kHz, testing conventional frequencies alone resulted in initial ototoxic hearing change missed or detected later in 76/210 ears

Number of Frequencies between 2 –
20 kHz in 1/6 Octave steps?

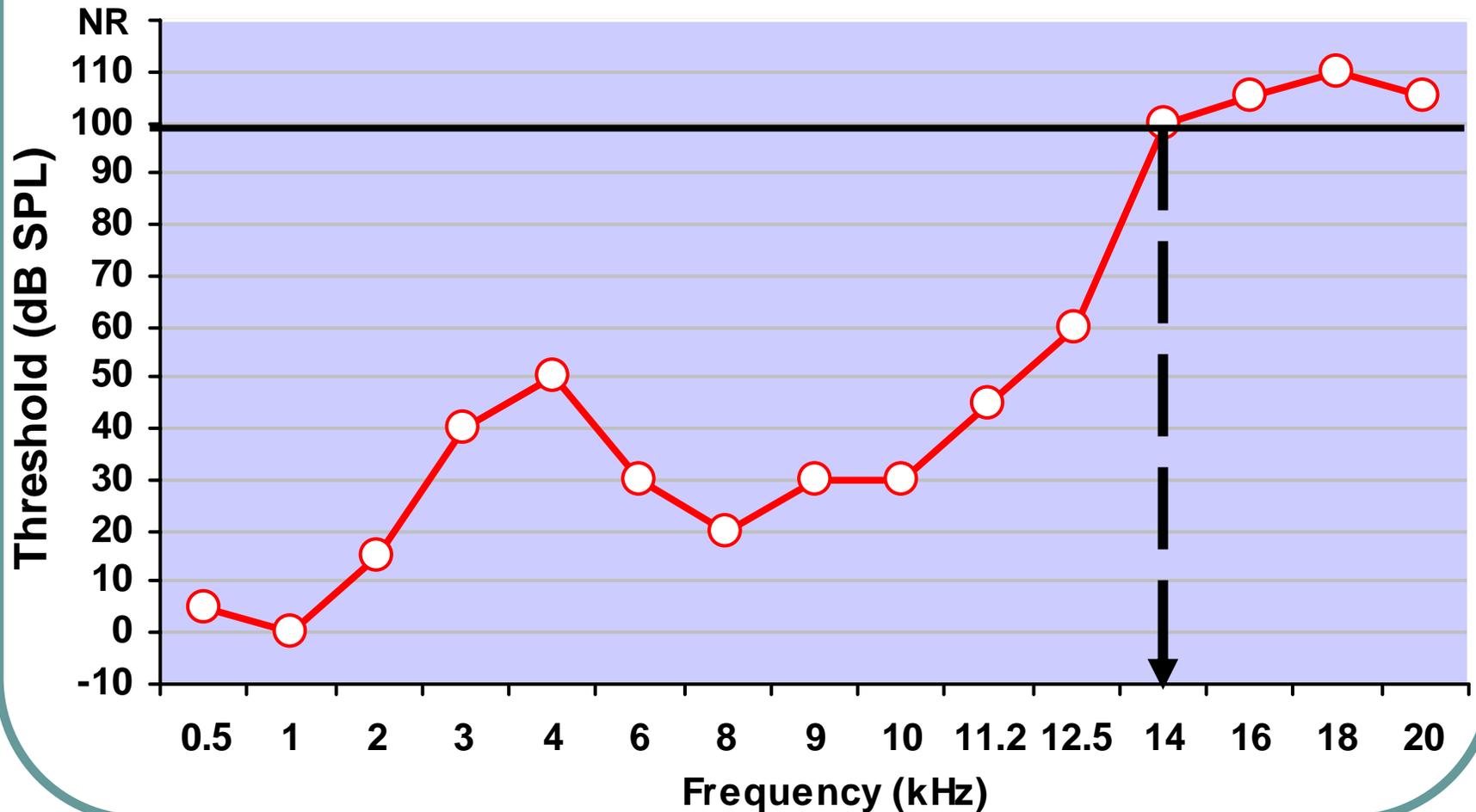
.....25 Test Frequencies x 2 ears =

50 Test Frequencies

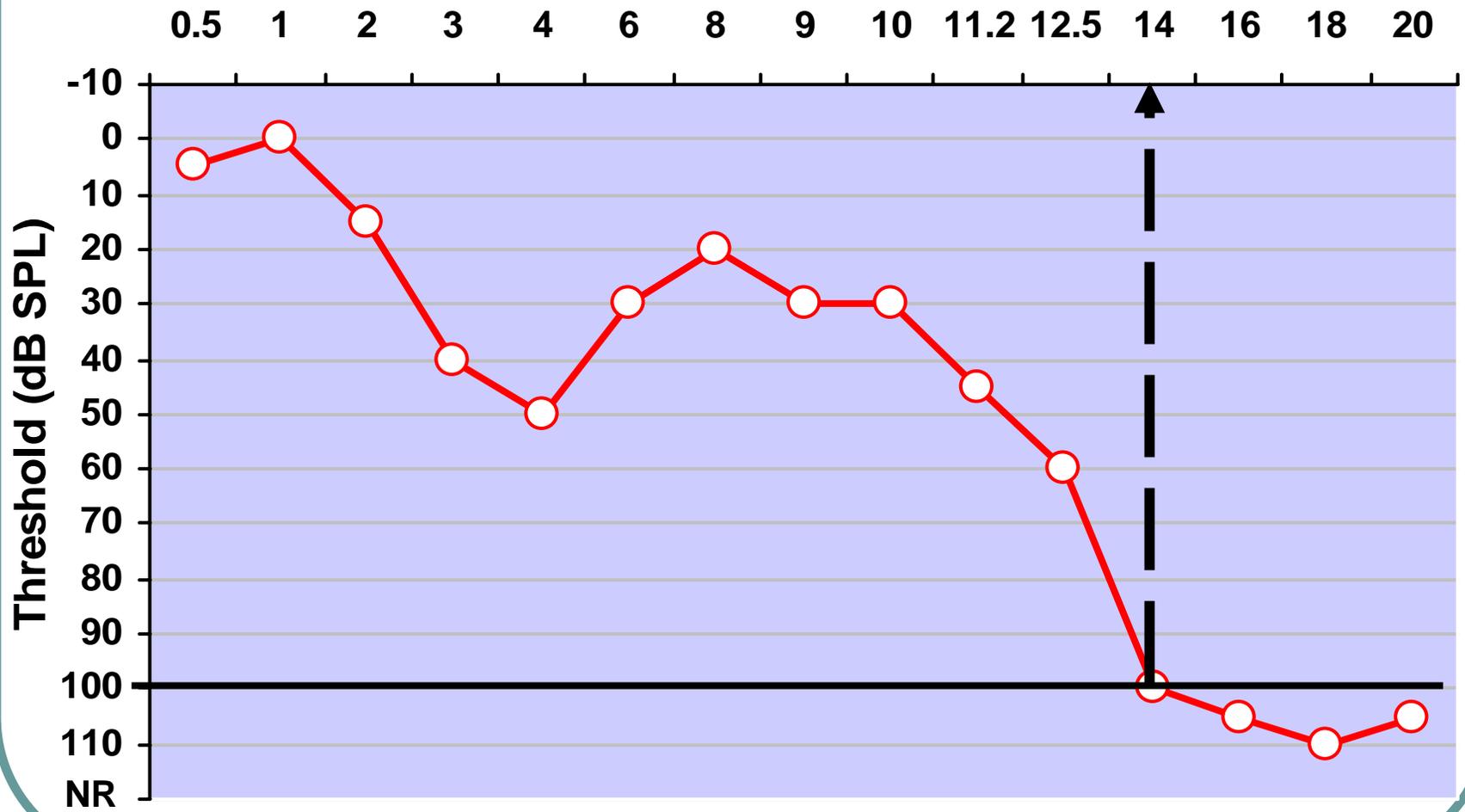
OUCH!

*Individualized Sensitive
Range for Ototoxicity
(SRO)*

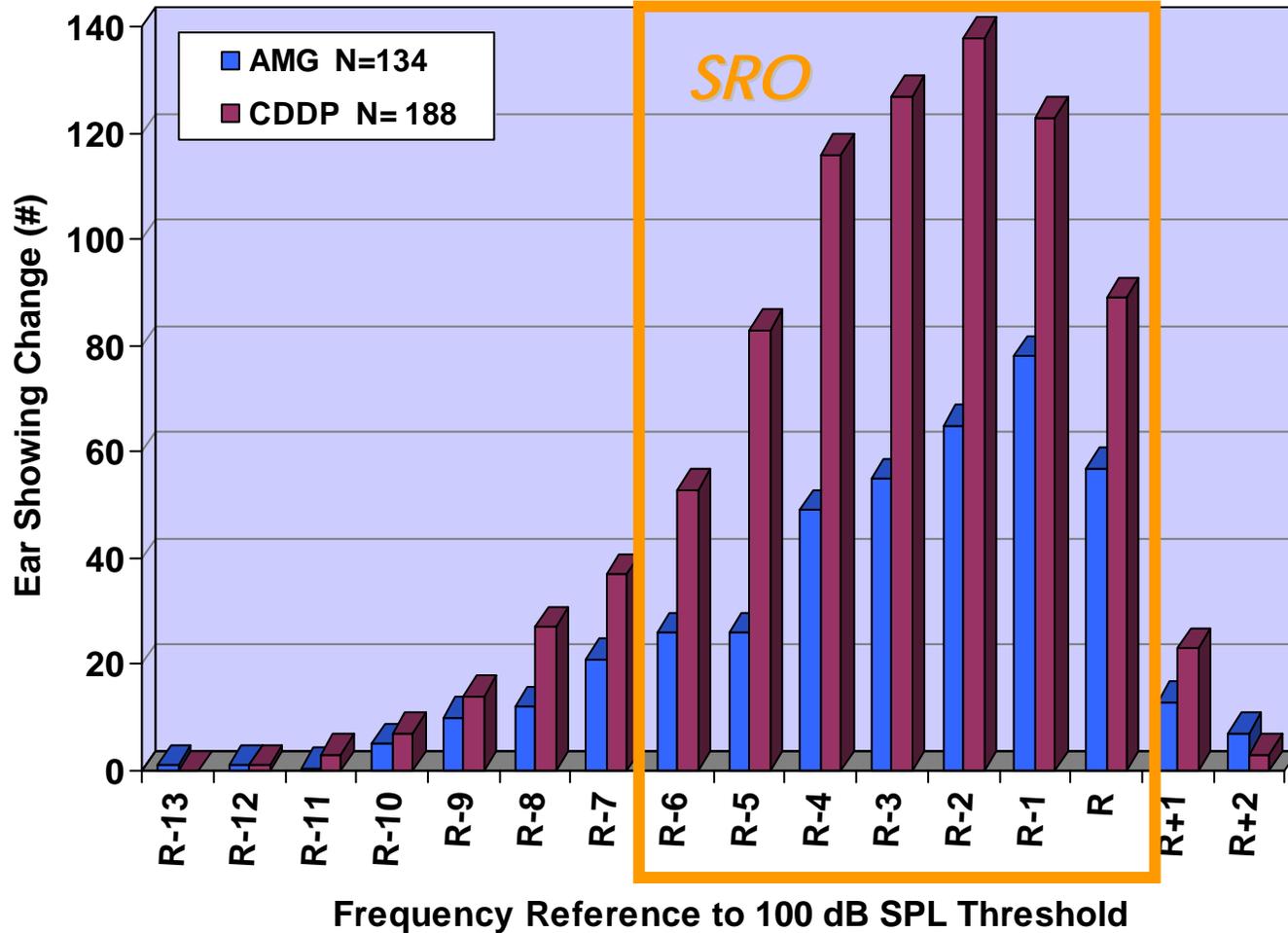
Highest Audible Frequency



Highest Audible Frequency



Initial Ototoxicity Detection

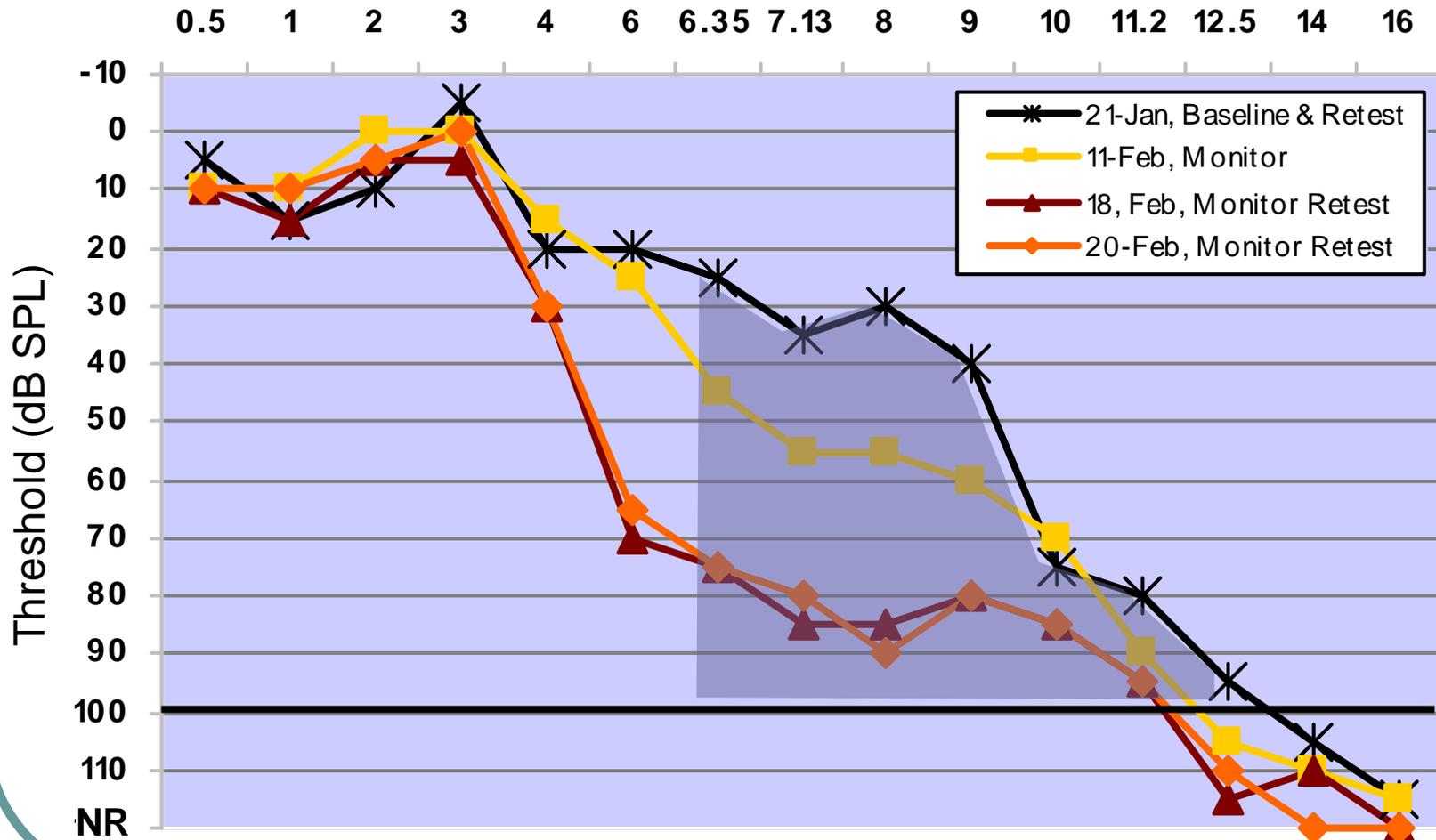


SRO Principle

- Thresholds > 100 dB SPL remain unchanged
- Most initial changes seen within **one octave** below the highest audible frequency
- Range for each **individual is unique** and specific to their hearing configuration

A sensitive range for ototoxicity (SRO) is the uppermost frequency with a threshold ≤ 100 dB SPL and 6 lower consecutive frequencies in $1/6^{\text{th}}$ octave steps

Case Example using SRO

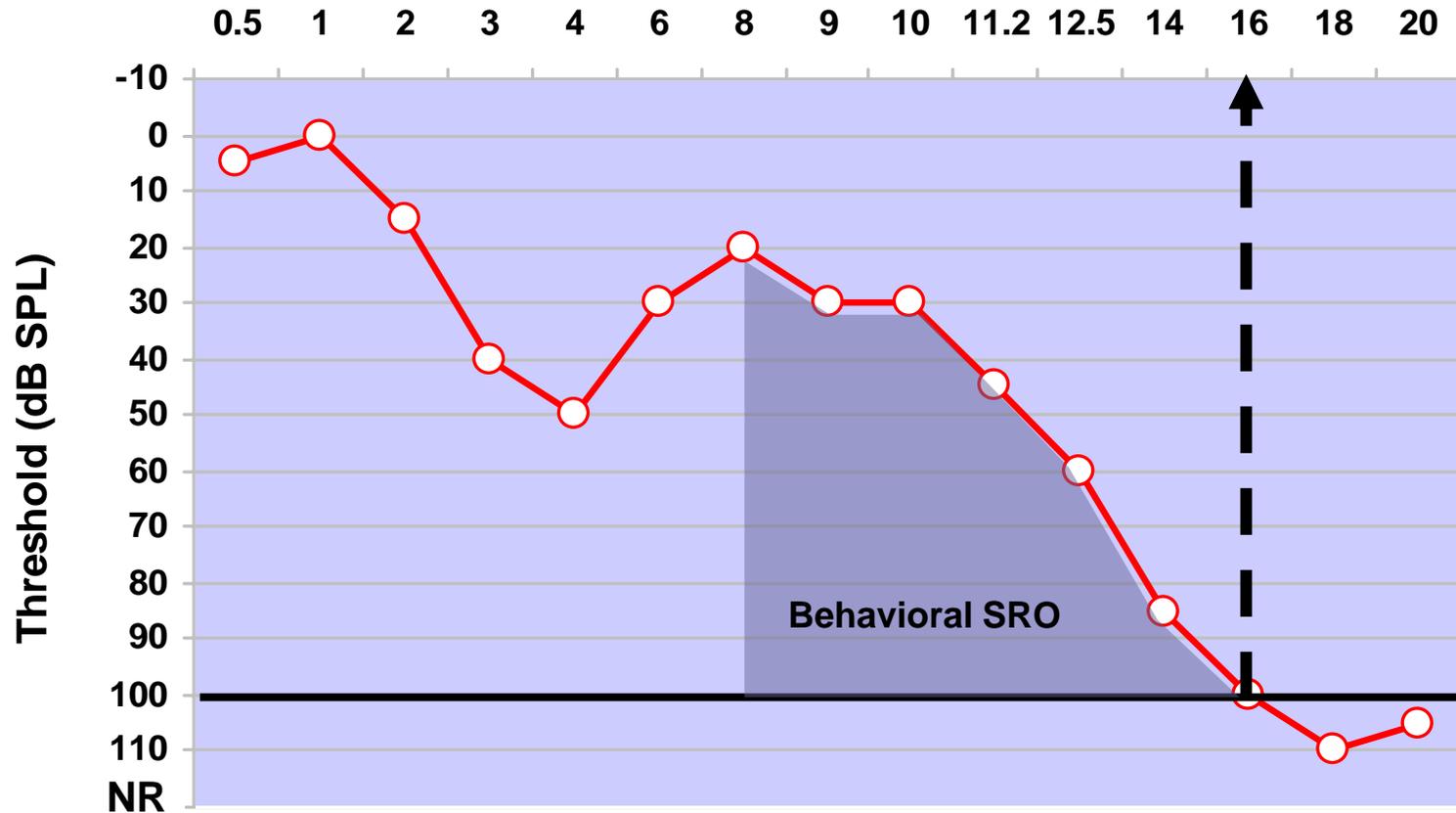


Sensitivity: SRO 1/6th Octave

	Total (Ears)	Hit	Miss	Initial Change on SRO
AMG	54	46	8	85%
Cisplatin	226	207	19	92%
Carboplatin	59	50	9	85%
Total	339	303	36	89%

Fausti SA, Helt WJ, Phillips DS, Gordon JS, Bratt GW, Sugiura KM, Noffsinger D:
Early detection of ototoxicity using 1/6th-octave steps. *J Am Acad Audiol* 14(8):444-50,
2003.

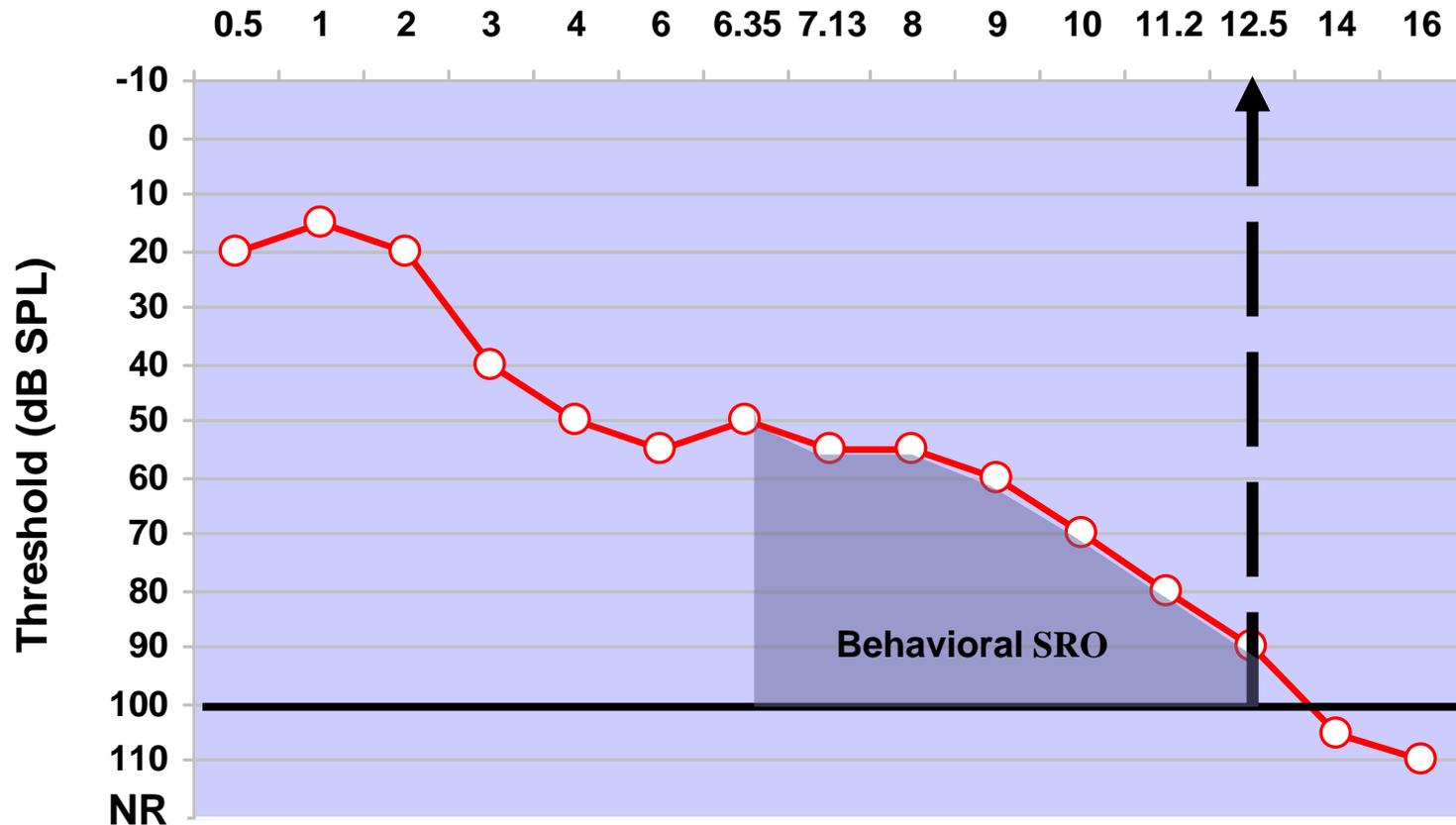
Example SRO Above 8 kHz



SRO Test Frequencies:

8, 9, 10, 11.2, 12.5, 14, 16 kHz

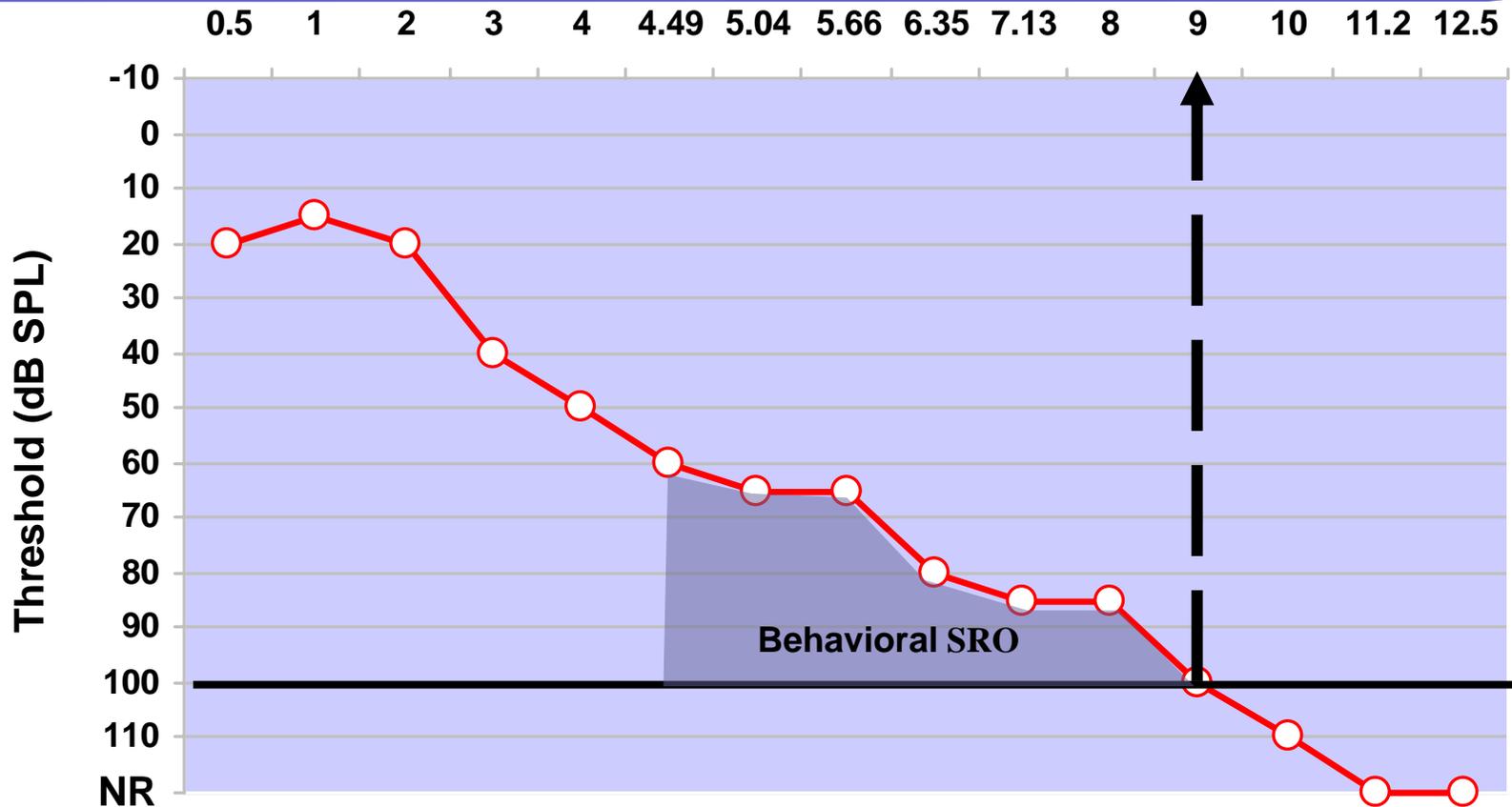
Example SRO Below 8 kHz



SRO Test Frequencies:

6.35, 7.13, 8, 9, 10, 11.2 12.5 kHz

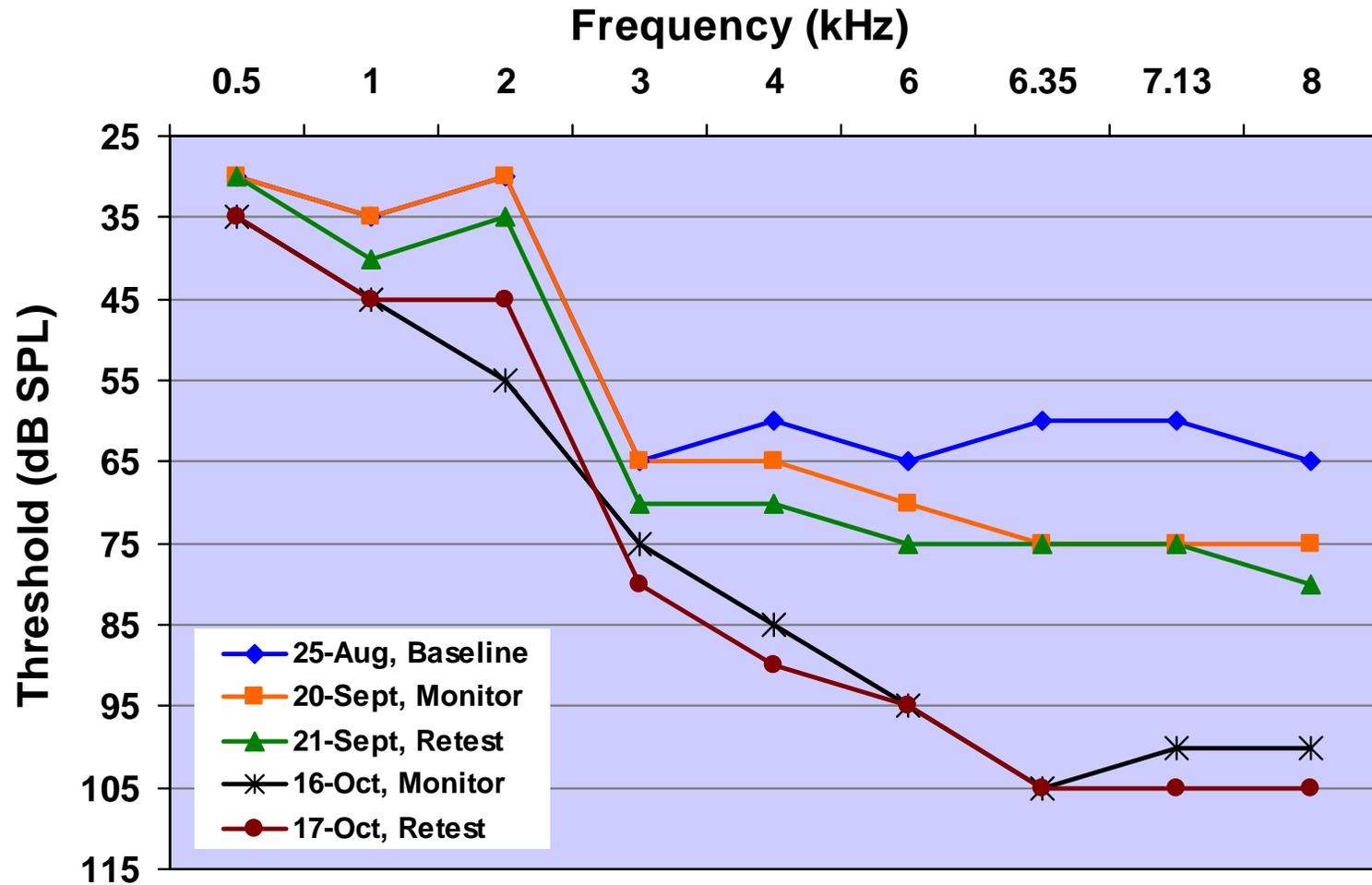
Example SRO Below 8 kHz



SRO Test Frequencies:

4.49, 5.04, 5.66, 6.35, 7.13, 8, 9 kHz

Case Example of Ototoxic Threshold Shifts: SRO < 8 kHz



SRO Principle

S = ***Sensitive***, detects ototoxicity 90% of the time

R = ***Range***, 1 octave in 1/6 octave steps (7 frequencies) at the upper limits of hearing

O = ***Ototoxicity***, early detection is key

Ototoxicity Identification Device

A portable, handheld audiometer-like device that will enable time-efficient, reliable and sensitive early detection of ototoxicity.



Specificity: Booth vs. Ward

False Positive rate, using ASHA Criteria

Earphone Type	Booth		Ward		Frequency Range
	≥ 20 dB at 1 Frequency	≥ 10 dB at 2 Consecutive Frequencies	≥ 20 dB at 1 Frequency	≥ 10 dB at 2 Consecutive Frequencies	
Koss Pro/4X*	0%	0%	0%	7%	2, 5-16
ER-4B*	0%	0%	0%	0%	2, 5-16
Sennheiser HDA 200**	0%	2%	n/a	n/a	8-16

*Gordon JS, Konrad-Martin D, Phillips DS, Helt WJ, Fausti SA: The evaluation of insert earphones for high-frequency bedside ototoxicity monitoring. *JRR&D*, under review.

**Frank T: High-Frequency (8 to 16 kHz) reference thresholds and intrasubject threshold variability relative to ototoxicity criteria using Sennheiser HAD 200 earphone. *Ear & Hearing* 22 (2): 161-168, 2001.

Technical Considerations

- **Audiometer**

- High frequencies and 1/6th octave capability
- Capable of high output with low noise floor
- Portable

- **Earphone Selection**

- High frequency capability
- High output capability
- Insert ER-3A and Circumaural TDH-39/49 WILL NOT work for high frequency measurement

- **Calibration**

Technical Considerations

- Earphone placement
- Stimulus Tone:
 - Pulsed
 - Increase duration of tone presentation
- Ambient Noise:
 - Single-walled vs. Double-walled sound booth
 - Hospital ward testing
 - Make noise measurements
 - “Do Not Enter - Test in Progress” sign
- Listening check:
 - High frequencies, High Output

***CONSISTENT
EARPHONE
PLACEMENT IS KEY***

Conclusions

Evidence-based protocol

Time-efficient protocol

Portability

- High frequencies are reliable
- Sensitive Range for Ototoxicity (SRO) exists
- ~90% initial detection rate using SRO
- Only 7 frequencies in SRO
- OtoID
- Earphones can be used on ward