



Adult Ear-Related Red Flags: Medical Referral Criteria

PURPOSE

This protocol:

- assures adult client safety and health during the process of any hearing health care service
- provides the CSHHPBC registrants, i.e., hearing instrument practitioners (RHIPs) and registered audiologists (RAUDs), a list of those conditions deemed “red flags” that require medical clearance prior to providing hearing health care services, including providing hearing instruments

SCOPE

All registered audiologists and/or registered hearing instrument practitioners

BACKGROUND

The red flags originated with the U.S. Food and Drug Administration (FDA; 2013) regulations 21 C.F.R. § 801.420(c)(2); they each mandated a referral to a physician, preferably an ear, nose and throat (ENT) physician, regarding those ear conditions that may possibly be treated medically and/or which might require prompt medical intervention. Red flags listed in this protocol (may be observed while taking the client’s case history, through more than cursory otoscopic examination, or subsequently through detailed audiometric testing. In many cases, the client may present with pathologies of the external or middle ear (e.g., cerumen impaction, infection, allergy, trauma, deformity). In other cases, possible signs of cochlear, retrocochlear or central pathologies may be evident to practitioners skilled in taking case history, otoscopy, and in recognizing those conditions that would be deemed red flags.

DEFINITIONS

Client waiver: a written waiver signed by the client declining physician referral or consultation based on informed consent

Medical clearance: verbal or written clearance from a medical physician, according to agency policy

Red flag: any condition that requires medical consultation and/or intervention

APPLICATION PARAMETERS

All adult clients must be assessed for red flags prior to a hearing assessment, taking ear mold impressions or dispensing amplification. For those whose hearing difficulties can be improved with prompt medical attention, taking of ear mold impressions or dispensing amplification is prohibited.



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ADULT EAR-RELATED RED FLAGS

Red flags which must be assessed for include:

- history of sudden or rapidly progressive or fluctuating hearing loss
- history of active drainage activity or bleeding from the ear(s), in the preceding 90 days or visible drainage on examination
- ongoing pain or discomfort in the ear
- unilateral or pulsatile tinnitus
- acute, recurring episodes, or chronic dizziness or increasing imbalance.
- visible evidence of foreign object in the external auditory meatus (ear canal) or significant cerumen accumulation

NOTE: Management of the cerumen is permissible (a) if the registrant has been granted advanced certification in cerumen management by CSHHPBC and (b) if not otherwise contraindicated (e.g., irrigation in the presence of a perforated tympanic membrane, warfarin, diabetic, etc.)

- visible traumatic or unexplained abnormality of the external ear canal or previously uninvestigated congenital abnormality
- unilateral or asymmetrical hearing loss greater than 30 dB HL at any one frequency
- air/bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz and 2000 Hz
- difference in inter-aural word recognition scores of greater than 40% using a 25-word list (recorded presentation) and given a symmetrical hearing loss
- facial nerve paralysis (requires urgent attention)

NOTE: Red flags for pediatrics are not included in this protocol.

INTERVENTION

In the event of one or more red flags being present, portions or all of the assessment may be precluded until the presenting condition is appropriately treated and/or medical clearance is received. Medical referral for all conditions on the red flag list is mandatory.

Prior to proceeding with the hearing health care service, registrants must advise clients to consult a medical professional; if clients choose not to do so, they must sign a waiver indicating their informed consent.

It should be emphasized that there will be clients who do not fit the red flag categories but nevertheless should receive medical attention. Registrants are expected to use their discretion in such cases.



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CLIENT EDUCATION AND DISCHARGE INFORMATION

Registrants who identify red flags through inquiry, direct observation, or review of any other applicable available information should advise clients to consult promptly with their physicians or, preferably, with ENT physician.

DOCUMENTATION

All registrants must take comprehensive notes on prospective clients' medical and health status, including medications, and work more closely with their family and ear physicians, as necessary. Documentation should be consistent with the CSHHPBC standard of practice (SOP-PRAC-01) Documentation and Record Management and clinical practice guideline CPG-04 Documentation and Record Management.

CLINICAL OUTCOMES

The clinical outcomes are to prevent adverse client events from occurring and to ensure treatable conditions are addressed in a timely manner.

REFERENCES

- American Academy of Otolaryngology – Head and Neck Surgery. (2014). *Red flags – warning of ear disease*. Retrieved from <https://www.entnet.org/content/red-flags-warning-ear-disease>
- Chartrand, M.S. (n.d.). *The FDA red flags video otoscopy observation and referral*. Retrieved from http://ihsinfo.org/ihsv2/hearing_professional/2003/010_January-February/030_fda_red_flags.cfm
- Hicks, G.W. (n.d.). *Management of ear, hearing and balance disorders: fact, fiction, and future*. Midwest Ear Institute. Retrieved from <http://www.islha.org/Resources/Documents/Hicks%20-%20FINAL.pdf>
- Canadian Interorganizational Steering Group (CISG). (2010). *Infection prevention and control guidelines for audiology*. Retrieved from <http://www.canadianaudiology.ca/assets/docs/Infection%20Prevention%20and%20Control%20Guidelines%20for%20Audiology.pdf>
- United States Food and Drug Administration. (2013). *Code of federal regulations title 21*. Retrieved from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.420>
- Valente, M. (2006). Guidelines for the audiologic management of adult hearing impairment, Valente M. Task Force, *Audiology Today*, 18:5, 1-44 (see also ACPG-06 on [CSHHPBC website](#))
- WorkSafe BC. (2014). *Hearing aid program reference manual clinical*. Retrieved from http://www.worksafebc.com/health_care_providers/Assets/PDF/HearingAidClinicalReferenceManual.pdf



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RELATED CSHHPBC DOCUMENTS

Audiological Management of Adult Hearing Impairment (Valente, 2006) (CPG(A)-06)



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Clinical Masking for Audiometric Testing in Adults (PROT-QA-03)

Documentation and Record Management (CPG-04)

Documentation and Record Management (SOP-PRAC-01)

Hearing Assessment and Hearing Instrument Fitting and Dispensing for Adults (POL-
QA-05)

Real Ear Probe Microphone Measurement Verification of Hearing Aids in Adults (PROT-
QA-02)