

Cerumen Impaction CLIFF Peer Review

1. *Strength of evidence presented in CLIFF in modeling the characteristics and mission impact of this medical condition within the spaceflight environment?*

Score: 3

Grading Scale:

4 - *Confident*

3 - *Somewhat confident*

2 – *Neutral*

1 – *Somewhat unconfident*

0 – *Not confident*

2. How confident are you that these data accurately represent the spaceflight environment?	Tables 1, 2 Composite Incidence and Level of Confidence	Table 3, 4 BC/WC Loss of Crew and probability	Table 4 - Clinical Phase 1, 2 durations Table 5 – CP 2 Loss of Crew	Table 4 – RTDC % Table 6 – RTDC Loss of Crew	Table 4 – Loss of Crew Life % Table 7 – Loss of Crew Life, Loss of Crew	Table 8 – TI
Score	3	3	3	4	4	3

Comments and limitations:

1. **General comments.** Cerumen, or earwax, impaction is a very common medical condition that is usually self-limited. Cerumen is typically expelled spontaneously from the ear; however, it can obstruct the external auditory canal and cause conductive hearing loss. Hearing loss is considered in a different CLIFF. While there is no spaceflight data, it would appear that terrestrial data is a good approximation of the incidence in space as there should not be any major differences in the way that cerumen is produced and naturally expelled during spaceflight. It should be noted that irrigation, which is a typical treatment for cerumen impaction on earth, would be a more difficult procedure to perform in space because of fluid containment issues. Manual dis-impaction may be required; however; it is associated with elevated risks of canal laceration or eardrum perforation.

2. **Incidence.** A terrestrial study with a large sample size was used to compute the incidence of cerumen impaction. Unfortunately, there is no spaceflight data on this condition, most likely because impaction is self-limited and astronauts are accustomed to dealing with this condition on earth. There is no data to indicate that the incidence would be different in space than on earth. Because of its large sample size, the study used to compute the composite incidence most likely

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overestimates the confidence we have in the assigned value. The literature on cerumen impaction is very limited in distinguishing between complicated and uncomplicated impactions, especially in ways that meet the definitions of BC and WC. The best case/worst case probabilities, clinical phase durations, RTDC and Loss of crew life probabilities are supported by terrestrial evidence, and I am in agreement with their calculation. The probability density curve that was derived appears to be a reasonable representation of the data presented, but the small variance due to large sample size may not reflect the uncertainty we have in the incidence value.

3. Clinical phase data. I am in agreement with the clinical phase 1 duration entered in this CLIFF. This data was compiled by a team of expert clinicians, and I was involved in the discussions leading to the calculation of the clinical phase duration. CP2 duration was supported by terrestrial evidence.

4. Task impairment. The analysis was performed and reviewed by a separate team of expert clinicians. I am aware of the methods that were used but did not directly participate in the discussions.

5. Dependence on mission phase or duration of mission. This medical condition should not be dependent on mission phase.

6. Limitations

- There is no spaceflight data available to inform this condition. However, the terrestrial studies provide robust data which should approximate the occurrence of the condition in the spaceflight environment.
- Because of the large sample size, the study used to compute the composite incidence most likely overestimates the confidence we have in the assigned value.
- Under-reporting for this condition was probably significant during past space missions.
- The literature on cerumen impaction is very limited in distinguishing between complicated and uncomplicated impactions, especially in ways that meet the definitions of BC and WC.

Reviewed by:

David C. Hilmers