

Otitis Externa 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	2	3	2	3	3

Comments and limitations:

1. General comments. This CLIFF characterizes otitis externa (OE), a condition that involves infection or inflammation of the ear canal. OE often presents with rapid onset of otalgia, itching, otorrhea, ear canal edema and erythema. It is often associated with water exposure and high humidity, conditions that are unlikely to be encountered during space flight. OE can be acute, often associated with bacterial infections, or it can be chronic, associated with diabetes or immunodeficient states. Given the baseline good health of astronauts, chronic OE is much less likely than in the general population. The best case is considered to be otitis externa resolving with one course of antibiotics and associated pain is controlled with non-opioid analgesics. The worst case is otitis externa that is accompanied by pain that cannot be controlled with non-opioid analgesics or requires more than one course of antibiotics.

2. Incidence. Spaceflight data is available, but some studies only categorize “ear problems” and do not further classify it. The most specific evidence comes from Antonsen, 2017 and LSAH data sets in which a total 3 cases of OE have been reported over 45.49 person-years. The best case/worst case probabilities used data from several terrestrial studies that show about 98% of non-complicated OE

Otitis Externa CLIFF Peer Review

cases resolve with one course of appropriate treatment within 2 weeks. Another study reported around 1.5% of cases have persistent disease despite treatment. Thus, a best case/worst case split of 98%/2% was chosen. The 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.

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 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 is not dependent on mission phase as otitis externa may occur any time during the mission.

6. Limitations

- Most available studies examining OM reflect terrestrial and pediatric populations, which are not generalizable to the spaceflight population.
- There was no available data regarding the number of cases that were uncontrolled with non-opioid analgesics. This is a subjective point of quantification, and likely the necessity of opioid analgesia for OM would be provider and patient dependent. Therefore, it was difficult to calculate the likelihood of the BC and WC in spaceflight.
- The worst case definition as it applies to the administration of antibiotics is a bit nebulous since it doesn't specify what length of antibiotics represents "a course" and therefore what represents treatment failure.

Reviewed by:

David C. Hilmers