

Otitis Media 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	2	3	3	3	2	3

Comments and limitations:

1. General comments. This CLIFF characterizes otitis media (OM) which is inflammation or infection of the middle ear. Most OM in adults is due to an upper respiratory tract infection or seasonal allergies and resolves spontaneously without treatment. Since many of these cases cause only mild symptoms, they may go unreported. However, bacterial superinfection may result (acute otitis media or AOM) in which resolution of symptoms is more rapid with antibiotics. AOM often presents with low grade fever, ear pain and muffled or decreased hearing. Although rare, complications of AOM include extracranial infections (e.g. mastoiditis, mastoid abscess, fistulas) and intracranial infections (eg. meningitis, brain abscess). The best case is considered to be acute otitis media that resolves with a single course of antibiotics and responds to non-opioid analgesics while the worst case is severe acute otitis media that is accompanied by pain that cannot be controlled with non-opioid analgesics, causes hearing loss, or requires more than one course of antibiotics.

2. Incidence. The incidence calculation was based on two LSAH data drops that showed a total of 4 episodes of OM during shuttle, MIR, and ISS missions. There was also one documented case

Otitis Media CLIFF Peer Review

during Apollo spaceflights. These were combined to calculate the incidence distribution. Terrestrial and analog data were not considered to be representative of the spaceflight environment. It is likely that mild cases of OM have not been reported in the past which could lead to a small underestimate of the true value. The best case/worst case probabilities used data from terrestrial studies that showed a progression to hearing loss or other complications (worst case) of 2% or less. The clinical phase durations, RTDC and LOCL 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 OM may occur during any time during the mission.

6. Limitations

- Under-reporting for this condition could have occurred during past space missions due to mild cases of OM associated with upper respiratory infections that were not of clinical consequence. This may result in underestimation of the incidence.
- 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