Clinical Finding Form (CliFF)

Branch Baseline

ICL24_Cerumen Impaction

Cerumen (earwax) impaction is a common and often benign medical complication but can be accompanied by more serious symptoms including aural fullness, hearing loss, ear pain, tinnitus (ringing in the ears), and increase risk of otitis externa (ear infection). It occurs when the natural clearing process is impaired and often is iatrogenic in that cotton swabs or digital manipulation can pack cerumen deep into the ear canal. Irrigation of the ear canal and cerumenolytics are common therapies which are also performed with ease terrestrially, however, may be more complicated in a microgravity setting. Manual removal may be required, however is associated with elevated risks of canal laceration or eardrum perforation (Horton et. al., 2020).

INCIDENCE DATA INCLUDED IN THE MODEL

The model imports the following incidence information from the MEDPRAT Evidence Library Database: incidence data category, space adaption status, EVA status, incidence data type, incidence and occurrence distribution data and incidence data characteristics. Data category defines the type of data available for incidence calculations (i.e. raw data vs. adjusted data). Space adaptation identifies medical events that where onset occurs in the first 5-7 days of flight and does not reoccur. EVA-related incidence values identify medical events that occur only during an EVA. Incidence values types vary by data category and define the number of medical events per person-year (rates) or medical events per person at-risk (proportion) for each medical condition. Incidence values can be modified by crew characteristics such as gender sex and certain crew medical history characteristics. Modifying characteristics are noted below and incidence values are listed individually for each characteristic. Distributions are assigned to medical events incidence values and occurrences in the model. For each crewmember in a given trial, the incidence and number of occurrences of each medical condition are randomly selected from these probability distributions. Detailed descriptions of the distributions are included in the MEDPRAT Technical Description Document.

INCIDENCE DATA

SPACEFLIGHT LITERATURE

There are no data regarding spaceflight incidence of cerumen impaction.

ANALOG LITERATURE

There are no data regarding analog incidence of cerumen impaction.

TERRESTRIAL LITERATURE

Eekhof et al 2001 discusses a 1994 Dutch study (Lamberts, 1994) which reported an incidence of cerumen impaction in 3.9% of patients, however we cannot analyze that data further. Guest et al 2004 compiles the data from a number of smaller studies revealing an incidence of hearing loss from cerumen impaction to be 2.1%. Lastly, Yang et al 2016 reports an incidence rate of 2.68% after evaluating over 1 million cerumen disimpaction claims to Medicare over a year.

OVERALL INCIDENCE SUMMARY

INCIDENCE

mean 0.0268 SD 2.358E-5

INCIDENCE SUMMARY

The Bayesian posterior distribution for the incidence rate given the reference data (1,323,845 events in 49.4 million people during 1 year) under an uninformative prior is Gamma(shape=1291760, rate=48200017) with mean 0.0268 and SD 2.358E-5. While unfortunately there are not spaceflight or analog data to guide incidence estimation, numerous terrestrial studies have been performed attempting to provide epidemiologic data on cerumen impaction. As explained in Table 2, we had the highest confidence in Yang et. al., 2016 which evaluated 1,323,845 cerumen disimpactions over 49.4 million patients over a year via Medicare clams. From this an incidence rate was calculated to be: 0.0268 (95%CI: 0.02678, 0.02684).

TABLE 1. INCIDENCE MODEL

Incidence Details

Incidence Type
General

Segment
All

Env. Exposure
NA

Sex
Any

Crowns
Any

Contacts
Any

Pregnancy
Any

Incidence Distribution

Occurrence Dist
Poisson

Incidence Dist.
Gamma

Mean
0.0268

SD
2.358E-05

Gamma
(Shape): 1.29176E+06
(Rate): 4.82E+07

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Schwartz, 2017	Terrestrial	2
Eekhof, 2001	Terrestrial	2
Roeser, 1997	Terrestrial	2
Guest, 2004	Terrestrial	2
Yang, 2016	Terrestrial	3

With exception of Yang et al 2016, all of these studies report incidence numbers based on estimations or provide strictly prevalence numbers. Yang includes the data in terms of events and patients from records directly as opposed to citing secondary sources and thus garnered the highest level of confidence and was used exclusively for chosen incidence above. With that said, with limited terrestrial data and no analog or spaceflight data, confidence in this incidence is limited.

CREWMEMBER SELECTION/PREVENTION

DISQUALIFYING CONDITIONS

Refer to Medical Evaluation Documents (MED) Volume A, Medical Standards for ISS Crewmembers, International Space Station Program, Rev 3.4 (2016).

PREFLIGHT PREVENTATIVE MEASURES

Hearing assessments, consisting of audiometric tests at specified frequencies within the range of 250 Hz - 10,000 Hz, tympanometry, and additional audiological tests as determined by an audiologist are performed pre-flight, on orbit, and post-flight.

BEST CASE SCENARIO DEFINITION

Cerumen impaction that is easily identified and removed on first attempt.

WORSE CASE SCENARIO DEFINITION

Cerumen impaction that results in pain, tinnitus, interferes with mission objectives, or requires multiple attempts at removal. (Note "hearing loss" is a separate condition).

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

None

BEST CASE/WORST CASE PROBABILITY COMMENTS

A worst-case probability is difficult to determine for a number of reasons. First, at least 50% of patients have a symptom such as pain or tinnitus that brings them to the doctor in the first place, however, these symptoms may not be significantly interfering with ADLs. Second, there is not good data on failure to disimpact or immediate recurrent risk, however, one study found a 2.1% failure rate combined with 3.8% of patients continuing to have pain and 3.8% of patients suffering from ear bruising or laceration. These three combined for a 9.7% complication rate (Gabriel 2015). Lastly, children under 20 and adults over 61, in addition to those with intellectual disability or medical comorbidities, are more likely to suffer from excessive symptoms or complications, and thus the astronaut population may be at less risk than the terrestrial literature may present. Unfortunately, it is not known whether microgravity or other factors unique to spaceflight might increase the risk of cerumen impaction. In light of all of these considerations and uncertainties, a 10% worst case probability is reasonable.

TABLE 3.BEST/WORST CASE PROBABILITY LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Gabriel, 2015	Terrestrial	3
Adegbiji, 2014	Terrestrial	2
Guest, 2004	Terrestrial	2
Yang, 2016	Terrestrial	2

All evidence is terrestrial and is limited by numbers, population, and environment. We have some confidence in the complication rates presented in Gabriel et. Al. 2015 as discussed above.

TABLE 4. CLIFF TREATMENT & OUTCOME TABLE BY CLINICAL PHASE

Case Scenario	Composite Incidence	Condition Probability %	CP1: Diagnosis		CP2: Treatment			CP3: Condition End State				
			TI%	Duration	TI%	Duration		TI%	RTDC		LOCL	
			Preset	Preset	Preset	Min	Max	Preset	Min%	Max%	Min%	Max%
Treated Best Case (TBC)	mean 0.0268 SD 2.358E-5	90 - 90	100	0.533	100	0.25	0.36	0	0	0	0	0
Treated Worst Case (TWC)		10 - 10	100	1.416	100	0.25	0.36	0	0	0	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	0.533	0	120	336	1.17	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	1.416	27.9298	120	336	27.93	0	0	0	0

TABLE 4 KEY

Composite Incidence: The same composite incidence will be used for both TBC and TWC. For EVA conditions: events per EVA (events/EVA). For space adaptation conditions: events per person (events/person). For non-spaceflight conditions: events per person year (events/py).

Condition Probability: The probability that CLiFF condition progresses to a worst case scenario. Best case scenario: 100%-Worst Case.

Clinical Phase General Comments:

- TI% = Task Impairment %. Task Impairment is the % of tasks that the crewmember is incapable of performing without impairment secondary to the medical condition.
- Durations are defined in hours.
- Removal to Definitive Care (RTDC): The probability the entire crew aborts the mission and returns to earth. This is considered as a condition end state result if any of the following criteria are met: 1) the potential for LOCL, 2) potential for significant permanent task impairment, or 3) potential for intractable pain.
- Loss of Crew Life (LOCL): The probability of death of affected crewmember due to medical condition.

Clinical Phase 1: Initial Assessment and Diagnosis:

- Covers only the initial assessment and diagnosis of the affected crewmember to define his or her medical condition. While the affected crewmember is being assessed, he or she is not able to perform any assigned tasks, thus Task Impairment (TI) during this phase is considered 100%. In the untreated case, there is no diagnosis performed, therefore Task Impairment and Duration will always be " not applicable."

Clinical Phase 2: Stabilization, Treatment, and Convalescence:

- The affected crewmember is receiving any appropriate initial or follow-on treatment for his or her medical condition to allow the crewmember to recover as much as he or she is able to recover in the spaceflight environment. Clinical phase 2 also encompasses relapses or recurrences of the same original medical condition in Clinical Phase 1. The duration of Clinical Phase 2 is expressed as minimum and maximum hours.

Clinical Phase 3: Condition End State:

- Reached once the affected crewmember has recovered from the medical condition as much as he or she is able to recover in the spaceflight environment amongst treated and untreated best and worst case scenarios. This may or may not be recovery from the given medical condition to the full extent possible. If this “recovered” state results in Removal to Definitive Care (RTDC) or Loss of Crew Life (LOCL) this will be noted in the condition end state results.

SCENARIO OVERVIEW COMMENTS

Cerumen impaction is a very common every-day occurrence for humans on Earth. It rarely leads to complication or significantly complicates activities of daily living. Further, there is a paucity of evidence evaluating durations, RTDC, or LOCL in the setting of these terrestrial symptoms. However, though these measures are estimated by expert clinical opinion, given the relatively benign nature of cerumen impaction, it is logical to all medical professionals that RTDC or LOCL would be 0%. 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 disimpaction may be an alternative consideration, however, it is associated with elevated risks of canal laceration or eardrum perforation.

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Pavlidis, 2005 has revealed previous durations of treatment using water irrigation and syringes ranging from 0.25-0.36 hours to disimpact the ear. RTDC or LOCL would not be expected for this condition.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

This review revealed no studies that specifically differentiate between the provided best and worst-case definitions. This is likely due to the benign nature of the condition and the clinical practice guideline (Schwartz, 2017) that asymptomatic cerumen impaction should not be routinely treated as long as the tympanic membrane can be adequately examined. With that said, Pavlidis, 2005 has revealed previous durations of treatment using water and syringes ranging from 0.25-0.36 hours to disimpact the ear. RTDC or LOCL would not be expected for this condition.

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

Especially in light of the fact that most patients with cerumen impaction that meets the BC definition do not present for care, it is difficult to estimate the number of cerumen impactions that resolve spontaneously. Keane, 1995 revealed that after 5 days of observation 5% of those studied had complete clearing of ear spontaneously and 26% had moderate clearing of the ear. Thus, while 31% of participants likely had spontaneous improvement of the disimpaction, there is a paucity of evidence evaluating the upper limit of UTBC scenarios. Michaudet, 2018 reviews numerous treatments for cerumen impaction and reveals that some non-irrigation home remedies may take up to 14 days. As these are the max ranges for non-first-line therapy they are the closest reasonable estimation for a max untreated scenario. As with treated scenarios, an exhaustive literature review does not find evidence concerning for RTDC or LOCL.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

Untreated worst-case scenarios are best felt to operate under the same considerations as UTBC scenarios. No additional literature affected duration, RTDC, or LOCL.

TABLE 5. CLINICAL PHASE II DURATION LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Pavlidis, 2005	Terrestrial	2
Keane, 1995	Terrestrial	
Michaudet, 2018	Terrestrial	
Schwartz, 2017	Terrestrial	

These studies are limited by being terrestrial only, reporting bias, and incomplete reporting of timing of symptoms with or without treatment, thus the level of confidence in this data remains neutral.

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Pavlidis, 2005	Terrestrial	2
Keane, 1995	Terrestrial	
Michaudet, 2018	Terrestrial	
Schwartz, 2017	Terrestrial	

The LOC remains neutral in that there is only terrestrial data without evacuation data from any spaceflight or analog source. With that said, while the LOC is neutral based off of the data, the LOC that RTDC would likely remain 0% remains high given the relatively benign nature of this condition.

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Pavlidis, 2005	Terrestrial	2
Keane, 1995	Terrestrial	
Michaudet, 2018	Terrestrial	
Schwartz, 2017	Terrestrial	

The LOC remains neutral in that there is only terrestrial data without evacuation data from any spaceflight or analog source. With that said, while the LOC is neutral based off of the data, the LOC that LOCL would likely remain 0% remains high given the relatively benign nature of this condition.

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Capabilities and Resourcing Scope

Overview
Cerumen, or earwax, is substance comprised of glandular secretions and exfoliated squamous epithelium that can accumulate in ear canals. Although this substance is typically expelled from the ear canal in a self-cleaning manner via propulsion stemming from jaw improvement, in a limited number of people, the substance can become stuck or obstructed (Michaudet et al. 2018). When cerumen impaction occurs, this can lead to aural fullness, pruritis, otalgia, discharge, odor, hearing loss and tinnitus (McCarter et al. 2007).

The best-case scenario requires minimal intervention. In terrestrial conditions, most subjects who experience the best-case scenario would not seek medical care. In the worst-case, an intervention is required given the high communication-related task-impairment associated with this condition. In the worst case, although not explicitly stated, a conductive hearing loss would be expected secondary to the occlusion of the ear canal. However, related conditions including hearing loss, barotrauma, otitis externa, otitis media are all covered in separated CRT conditions.

CNES: None

Diagnostic Scope and Resourcing
In the best case, the diagnosis will be made via history and physical exam. Given the benign nature of this condition, ground communications are not resourced for the best case. Diagnostics in the worst case do not change except for the addition of inflight audiometry to help provide a simple differential diagnosis. Although we expect the diagnosis to be readily apparent on exam with an otoscope, inflight audiometry can serve as a reserve diagnostic in cases when an otoscope cannot be immediately provided. For this effort, we made inflight audiometry a necessity of ‘zero’ as this condition can still be treated without this technology; still, for most missions, we expect crewmembers to have access to inflight audiometry as it is necessary to treat other CRT conditions. Inflight audiometry not only serves to help quantify the severity of and expected hearing loss but can also differentiate between the type of hearing loss by quantifying air- and bone conduction thresholds. With this technology, there is no need to possess a tuning fork to conduct Weber and Rinne tests. Further, if a conductive loss is identified, the latest iteration of the inflight audiometric test (KUDUwaveTM) can perform tympanograms. In the worst case, we would expect a Type B tympanogram, or a flat curve, given the lack of compliance of the cerumen impaction. Of note, tympanometry and pneumatic otoscopy have equivalent sensitivity (approximately 90%) and specificity (70%-80%); there is concern that pneumatic otoscopy may be difficult to perform in microgravity. Given the “interference with mission objectives” explicitly stated in this condition, CRT group consensus was to resource ground communications for the worst-case scenario.

Clinical Phase 1 Duration and Rationale
This version of IMPACT presumes physician level knowledge, skill, and ability will be present on the mission. The CRT working group SME consensus duration is as follows:

CP1 BC (Treated or Untreated): 0.53 hours
This is the longest reasonable time to complete the task for a crewmember (adjusted for being in the spaceflight environment) 1) to remove a crewmember from duties 2) obtain a history and 3) examine the patient
CP1 WC (Treated or Untreated): 1.42 hours
This is the longest reasonable time to complete the task for a crewmember (adjusted for being in the spaceflight environment) 1) to remove a crewmember from duties 2) obtain a history 3) examine the patient 4) conduct and interpret an inflight audiometry test 5) set up for ground

communications.
The highest scope of practice code used in this CRT which includes interpretation of diagnosis, performing diagnostic tests and performing treatment would be a two: this is at Paramedic/Military medic

Treatment Scope and Resourcing
In the best-case scenario, treatment is limited to irrigation. In general, there are only three recommended cerumen removal techniques in terrestrial conditions: irrigation, topical cerumenolytics and manual removal (Schwartz et al. 2017). Cerumenolytics require multiple doses to be effective, negating their usefulness in the best-case scenario. During microgravity conditions, manual removal is a less favorable option given the risk of tympanic membrane perforation. In the worst-case scenario, cerumenolytics are preferred given the lack of risk of canal or membrane trauma—albeit, these may take longer to be effective. A recent Cochrane review revealed that water or saline are non-inferior to other solutions as cerumenolytics (Aaron et al. 2018; Burton et al. 2009). Consequently, to save resources and space, this CRT prioritizes water and saline over commercial preparations. For severe impactions, terrestrial patients are sometimes referred to otolaryngologists for manual removal with a binocular microscope (Schwartz et al. 2017); in spaceflight, a binocular microscope would not be available. Therefore, manual removal will need to be completed with a handheld otoscope or headlamp. Given the limited visibility with these instruments, CRT consensus was to allocate for only blunt tools inside the canal to decrease the risk of tympanic membrane trauma.

Communications and Support Needs
In the best-case scenario, diagnosis and course of treatment is uncomplicated and likely within the scope of care of onboard crew members. In the worst-case condition, ground communications are necessary given the sudden impairment of the affected crewmember and the need to ensure an accurate diagnosis.

IMM CLIFF RECONCILATION COMMENTS

There was no previous IMM CLiFF for this condition.

LIMITATIONS SUMMARY

There are numerous limitations of the data regarding the diagnosis and management of cerumen impaction in spaceflight. Likely the largest of these limitations is that our robust review revealed no spaceflight or analog manuscripts that were able to inform these measures. Another large limitation of this work is that cerumen impaction is a relatively benign medical complication for which most people can expectantly manage at home or attempt home remedies or over the counter medications for, such as dripping olive oil into the ears or using water. Lastly, the literature on cerumen impaction is very limited in separating out complicated and uncomplicated impactions, especially in ways that meet our definitions of BC and WC.

TABLE 8. TASK IMPAIRMENT CALCULATION BASED ON AFFECTED HUMAN SYSTEMS TASK CATEGORIES (HSTC)

Clinical Phase 2: Treatment												
	Affected HSTCs											
	Cognitive - Simple	Cognitive - Complex	Communications	Inter-personal Skills	Vision	Hearing	Cardio-pulmonary	Dentition	GI	GU		
Treated Best Case (TBC)	223	664	113	89	854	44	145	5	13	6		
Untreated Best Case (UTBC)												
Treated Worst Case (TWC)	223	664	113	89	854	44	145	5	13	6		
Untreated Worst Case (UTWC)		664				44						
	Affected HSTCs (Continued)								TI Calculation			TI Score
	Hand (Dom)	Hand (Any)	Upper Extremity	Lower Extremity	Ambul & Standing (g)	Translation & Stabilization (microgravity)	Don/Doff Equipment	Pressure Ops	Total Tasks Impaired By Condition	Total Human System Category Tasks Full Mission	TI Decimal	TI %
Treated Best Case (TBC)	132	564	414	22	196	34	34	211	3763	3763	1	100
Untreated Best Case (UTBC)									0	3763	0	0
Treated Worst Case (TWC)	132	564	414	22	196	34	34	211	3763	3763	1	100
Untreated Worst Case (UTWC)	132							211	1051	3763	0.279298	27.93

Clinical Phase 3: Condition End State												
	Affected HSTCs											
	Cognitive - Simple	Cognitive - Complex	Communications	Inter-personal Skills	Vision	Hearing	Cardio-pulmonary	Dentition	GI	GU		
Treated Best Case (TBC)												
Untreated Best Case (UTBC)						44						
Treated Worst Case (TWC)												
Untreated Worst Case (UTWC)		664				44						
	Affected HSTCs (Continued)								TI Calculation			TI Score

	Hand (Dom)	Hand (Any)	Upper Extremity	Lower Extremity	Ambul & Standing (g)	Translation & Stabilization (microgravity)	Don/Doff Equipment	Pressure Ops	Total Tasks Impaired By Condition	Total Human System Category Tasks Full Mission	TI Decimal	TI %
Treated Best Case (TBC)									0	3763	0	0
Untreated Best Case (UTBC)									44	3763	0.0116928	1.17
Treated Worst Case (TWC)									0	3763	0	0
Untreated Worst Case (UTWC)	132							211	1051	3763	0.279298	27.93

TABLE 8 KEY
Human System Task Category (HSTC) Definitions: Cognitive-Simple: Tasks requiring simple cognitive involvement (low levels of attention, following simple checklists, and not requiring extensive decision making) in conjunction with inputs from other systems. Cognitive-Complex: Tasks requiring complex cognitive involvement (requiring constant attention, frequent interpretation of outside stimuli to inform real-time situations) in conjunction with inputs from other systems. Communication: Tasks requiring primarily communication, via hearing and speaking. Interpersonal Skills: Tasks requiring interpersonal, social interaction between crew including complex technical tasks that require extended crew interaction. Vision: Tasks in which visual information is required. Hearing: Tasks in which primarily auditory information is required, excluding communication, e.g. hearing alarms, medical auscultation, OOHAs. Cardiopulmonary: Tasks requiring greater-than-baseline cardiopulmonary effort, e.g. physically strenuous activities. Dentition: Tasks requiring use of teeth for mastication. GI (Gastrointestinal): Tasks requring use of the alimentary sytem, e.g. solids/liquids consumption and solids excretion. GU (Genitourinary): Tasks requiring use of the male/female genitourinary systems. Hand (Dominant): Tasks performed using primarily the hand, requiring use of the dominant hand (piloting, medical procedures, dental procedures). Hand (Any): Tasks performed using primarily the hand(s), with no preference for dominance, with equivalent bilateral effectiveness. Upper Extremity: Tasks requiring specific use of the upper extremities, excluding hands. Lower Extremity: Tasks requiring specific use of the lower extremities (excluding ambulation and standing in the presence of gravity), e.g. using exercise equipment. Ambulation and Standing (g): Tasks requiring use of both lower extremities to accomplish ambulation or standing in the presence of gravity. Translation and Stabilization (microgravity): Tasks requiring use of either the upper or lower extremities to accomplish translational movement and stabilization (securing oneself to remain stationary) in the setting of microgravity. Don/Doff Equipment: Tasks requiring the donning of personal equipment (including pressure suit, exercise harness, EVA equipment, etc). Pressure Ops: EVA/contingency tasks performed while pressurized in a suit.

Criteria for Assignment of Conditions to HSTCs (any of the following):
1) Is affected crew member physically incapable of performing the human system task category, without impairment, with the condition?
2) Would the treatment (e.g. medications) impair the crewmember's ability to perform the human system task category? (Does not apply to UTx)
3) Does the condition have a high likelihood of causing a significant aeromedical contraindication with an associated human system task category
4) Would performing tasks in an associated task category worsen the condition? (If so, it is affected).
5) Does pain associated with the condition impair any further human system categories?

TASK IMPAIRMENT COMMENTS

While most levels of Task Impairment increase from treated best case to untreated worst case, the CP2 TI warrants explanation. In the treated scenarios, there is a high level impairment for the very short duration (<30 minutes) of treatment while astronauts are likely undergoing irrigation or manual disimpaction. For untreated best case scenarios, the TI is 0 given neither the best case cerumen impaction itself or treatment is significantly interfering with tasks. For untreated worst case scenarios, treatment is not interfering, however symptoms may be interfering with some tasks (and for a much longer duration 5-14 days rather than < 30 minutes).

EVIDENCE COLLECTION PROCESS

Mesh terms that most closely resembled the best-case and worst-case scenarios, and associated Conditions Included but Not Explicitly Stated (CNES), were utilized to build incidence, duration, RTDC, and LOCL searches by best- and worst-case.

Incidence:
Databases searched for spaceflight and analog incidence data included: PubMed, Google Scholar, NASA Technical Reports Server (NTRS) public search, Defense Technical Information Center (DTIC), and Barratt MR, Baker E, Pool SL. Principles of Clinical Medicine for Space Flight. New York, NY: Springer; 2019. 2nd Edition. Databases searched for terrestrial incidence included: DynaMed, PubMed, and Google Scholar.

Duration, RTDC, LOCL:
Databases searched for duration, RTDC, and LOCL included: Dynamed, Cochrane, PubMed, and Google Scholar. Note, that if duration, RTDC, or LOCL data was found in a DynaMed search, the other search engines were not included. Relevant articles were selected and reviewed. If applicable, the article was included in the CLiFF.

LEVEL OF CONFIDENCE (LOC) SCORING

Articles obtained to update the evidence behind this CLiFF were scored by ExMC editors, based on their applicability to the Exploration Spaceflight environment using the following grading scale:

4 – Confident
3 – Somewhat confident
2 – Neutral
1 – Somewhat unconfident
0 – Not confident

The following considerations factor into the grading scale above:

• How closely does the paper describe the medical condition as defined by the IMPACT 1.0 Condiltion List (relevance)?
• How closely does the population included resemble the astronaut population?
• Quality of the paper (number of subjects, methods, etc.)
• How much does the editor trust the source of the evidence?
• How closely does the editor think that the data represents the exploration spaceflight environment?
• Other considerations, at the discretion of the editor, supported in the comments for LOE scoring.

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ACRONYMS

ACRONYM	PHRASE
AAOMS	American Association of Oral and Maxillofacial Surgeons
AMA	American Medical Association
ARCL	All Remaining Conditions List
ARS	Acute Radiation Sickness
BHP	Behavioral Health and Performance
CAC	Coronary Artery Calcium
CHS	Crew Health and Safety
CL	Condition List
CliFF	Clinical Finding Form
CMO	Crew Medical Officer
COMFORT	Clinical Outcome Metrics for Optimization of Robust Training
CP1	Clinical Phase 1
CP2	Clinical Phase 2
CP3	Clinical Phase 3
CRL	Clinical Resource Level

CRT	Capability Resource Table
CST	Clinical Science Team
DCS	Decompression Syndrome
DRM	Design Reference Mission
ED	Emergency Medicine Doctor
EL	Evidence Library
EMCL	Exploration Medical Condition List
EMT	Emergency Medical Technician
EVA	Extravehicular Activity
EXMC	Exploration Medical Capability
HRP	Human Research Program
ICD	International Classification of Disease
ICL 1.0	IMPACT 1.0 Medical Conditions List
ICU	Intensive Care Unit
IMCL	iMED Condition List
iMED	Integrated Medical Evidence Database
IMM	Integrated Medical Model
IMPACT-MD	Impact Medical Database
IP	Incidence Proportion
IR	Incidence Rate
ISS	International Space Station
IV	Intravenous
JSC	Johnson Space Center
LEO	Low-Earth orbit
LEVA	Lunar Extravehicular Activity
LOCL	Loss of Crew Life
LOM	Loss of Mission
LSAH	Lifetime Surveillance of Astronaut Health
LSO	Lunar Surface Operations
MCL	Master Condition List
MEVA	Medical Extravehicular Activity
NASA	National Aeronautics and Space Administration
N/A	Not Applicable
NP	Nurse Practitioner
OBGYN	Obstetrics and Gynecology
OR	Occurrence Rate
PA	Physician Assistant
PDQ	Pain Disability Questionnaire
PFCL	Proposed Future Conditions List
PPE	Personal Protective Equipment
PTRS	Project Technical Requirements Specification
PRL	Pharmaceutical Resource Level
QTL	Quality Time Lost

RCL	Removed Conditions List
REP	Rochester Epidemiology Study
RTDC	Removal to Definitive Care
SANS	Spaceflight-Associated Neuro-ocular Syndrome
SAS	Space Adaptation Syndrome
SEVA	Spaceflight Extravehicular Activity
SME	Subject Matter Expert
SoP	Standard Operating Procedure
SPE	Solar Particle Event
TBD	To Be Determined
TI	Task Impairment