

Clinical Finding Form (ClIFF)

Branch

Baseline

ICL61_Gravity Well - Entry Sensorimotor/Neurovestibular Disturbance

Gravity well sensorimotor neurovestibular disturbances are the collection of physiologic changes during the initial postflight period when the astronaut is readapting to Earth's gravity or a partial gravity environment following adaptation to weightlessness. It is a state of diminished health in response to reacclimating from a microgravity environment, to which the astronaut has adapted to, back to a gravitational field, requiring readaptation. This includes the possibility for symptoms regarding the lunar gravitational field of 1/6th g. Symptomatic presentation is highly variable and includes vertigo as well as postural, vestibular and ocular disturbances and orientation issues. (Ortega, 2019, Clark, 2019) It is usually a self-limited condition, mild in severity for shorter missions and "unlikely to have a significant impact on the mission." (Bacal, 2003)

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

The incidence of gravity well neurovestibular disturbance (specifically defined as readaptation occurring on return to a gravitational field from microgravity one) has been estimated based on astronaut inflight data and limited lunar mission (Apollo) data. There have been no documented cases of neurovestibular disturbance among the 12 Apollo astronauts that have walked on the moon as they transitioned from microgravity to the 1/6 G environment of the moon. However, there may have been under-reporting of symptoms related to neurovestibular disturbance among the Apollo astronauts. In addition, the Apollo astronauts who walked on the moon did not undergo neurovestibular testing when they landed on the moon. Astronauts who have prolonged exposed to the microgravity environment undergo extensive neurovestibular testing when they return to Earth.

ANALOG LITERATURE

Not applicable. No analog literature search completed due to this being a space adaptation condition.

TERRESTRIAL LITERATURE

Not applicable. No terrestrial literature search completed due to this being a space adaptation condition.

OVERALL INCIDENCE SUMMARY

INCIDENCE

mean 0.07191 and SD 0.06703

INCIDENCE SUMMARY

The Bayesian posterior distribution for the incidence proportion given the spaceflight evidence (0 events over 12 astronaut moon landings) under an uninformative prior is Beta(shape1=0.9962, shape2=12.8577) with mean 0.07191 and SD 0.06703. Evidence: Spaceflight – Moon Landings – 0 events over 12 crew. IP: 0 (95%CI: 0, 0.2647).

TABLE 1. INCIDENCE MODEL

Incidence Details

Incidence Type

UNK

Segment

Gravity Well Transition

Env. Exposure

NA

Sex

Any

Crowns

Any

Contacts

Any

Pregnancy

Any

Incidence Distribution

Occurrence Dist

Binomial

Incidence Dist.

Beta

Mean

0.0719075

SD

0.067029

Beta

(Alpha): 0.9962

(Beta): 12.8577

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Paloski, 1999	Spaceflight	1
Bacal, 2003	Spaceflight	1

Incidence is given an LOC = 1 (somewhat unconfident) since the incidence is based on limited astronaut inflight data. There have been 0 documented sensorimotor neurovestibular events among the 12 astronauts that have walked on the moon compared to documented events among astronaut return shuttle flights. The incidence distribution is based on the lunar mission data (Apollo) of no documented medical events of sensorimotor neurovestibular disturbance among the 12 astronauts who landed and walked on the moon.

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

There are no specific reentry preventive measures for this condition.

BEST CASE SCENARIO DEFINITION

Gravity well sensorimotor neurovestibular disturbance that results in mild balance deficits or orientation difficulty, but does not prevent the operation of machinery or piloting.

WORSE CASE SCENARIO DEFINITION

Gravity well sensorimotor neurovestibular disturbance that results in moderate or severe balance deficits and orientation difficulty, and prevents the operation of machinery or piloting.

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

None

BEST CASE/WORST CASE PROBABILITY COMMENTS

Since the gravity transition will be from 0g to 1/6th g or 3/8 g instead of 1 g, it is anticipated that all sensorimotor neurovestibular events will be best case scenarios. There have been 0 documented events among the 12 astronauts that have walked on the moon compared to the documented events among astronaut shuttle flights. Therefore, best case percentage is estimated as 100% and the worst case percentage is 0%.

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

Citation	Source	LOC Value
Paloski, 1999	Spaceflight	3
Bacal, 2003	Spaceflight	3
Bloomberg, 2015	Spaceflight	3
Reschke, 2017	Spaceflight	3

Incidence is given an LOC = 3 (somewhat confident) since the incidence is based on limited astronaut inflight data. There have been 0 documented sensorimotor neurovestibular events among the 12 astronauts that have walked on the moon compared to documented events among astronaut return shuttle flights.

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 0.07191 per person and SD 0.06703	100 - 100	100	0.53	11.6264	24	192	0	0	0	0	0
Treated Worst Case (TWC)		0 - 0	100	1.7	27.9564	0	0	0	0	0	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	0.53	16.1573	24	192	0	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	1.7	34.0287	0	0	0	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

This condition falls within space adaptation syndrome/readaptation phase, specifically on return from microgravity to a gravitational field. Treatment consists of symptom control until readaptation to the new gravitational environment is established. There are no RTDC and LOCL events based on case definition.

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Occurrence and duration data comes directly from spaceflight data embedded within the cited references of this CLIFF. The best case scenarios can last up to 192 hours. (Palowski, 1999) "The majority of symptoms were experienced to a mild to moderate degree, suggesting that they are unlikely to have a significant impact on the mission." (Bacal, 2003) Symptoms resolve spontaneously over time with readaptation. The subject could engage in reported preventive countermeasures and/or be restricted from certain activities pending readaptation to the gravitational transition. RTDC probability is estimated at 0% and LOCL is estimated at 0%.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

Not applicable.

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

Occurrence and duration data comes directly from spaceflight data embedded within the cited references of this CLIFF. The best case scenarios can last up to 192 hours. (Palowski, 1999) "The majority of symptoms were experienced to a mild to moderate degree, suggesting that they are unlikely to have a significant impact on the mission." (Bacal, 2003) Symptoms resolve spontaneously over time with readaptation to the gravitational transition. RTDC probability is estimated at 0% and LOCL is estimated at 0%.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

Not applicable.

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

Citation	Source	LOC Value
Paloski, 1999	Spaceflight	3
Bacal, 2003	Spaceflight	
Bloomberg, 2015	Spaceflight	
Reschke, 2017	Spaceflight	
Clark (Barrett) 2019	Spaceflight	

Clinical Phase II durations are given an LOC = 3 (somewhat confident) based on Earth reentry data. "Preflight stability levels were achieved in all subjects by 8 days after wheels stop." (Paloski, 1999)

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
case definitions	case definitions	4

RTDC is given an LOC = 4 (confident) based on the case definitions.

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
case definitions	case definition	4

LOCL is given an LOC = 4 (confident) based on the case definitions.

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Capabilities and Resourcing Scope Overview This condition occurs during transitions between gravity environments. The first category is largely motion sickness with the second relating to vestibular disorientation. CNES: NONE Diagnostic Scope and Resourcing Diagnosis relies on history and physical exam within the context of the transition into or out of a gravity well. Lunar crew may experience this on launch from Earth, descent to Luna, and Launch from Luna. Earth return will not be handled by the medical system on board the spacecraft. 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 for history given the context of spaceflight and the self resolving nature CP1 WC (Treated or Untreated): 1.7 hours including set up time, history, and physical exam including a focused neurological exam and careful attention to rule out mimic conditions like decompression sickness (DCS). This condition requires a Scope of Practice 4 to manage and rule out other similar presenting conditions. Treatment Scope and Resourcing The best case requires antiemetics and anti-vertigo medications. The worst case adds functional task testing and virtual reality simulation. This is because vestibular disorientation may put the crew at risk immediately after landing. To mitigate this, evaluation to ensure recovery using functional testing in a protected environment will be needed prior to EVA or construction tasks. Virtual reality systems can be used for both assessment and reorientation therapies for more complex tasks such as driving and/or flight. Since the BC definition has no affect on these complex tasks it is not considered necessary but was included as a zero percent necessity as it would be "nice to have." In the WC definition these tasks are affected so a simulation to assess the astronaut's ability prior to task performance would be essential. Physical therapy is included to represent occupational therapy and rehabilitation as a consult with experts on the ground. This is the terrestrial mainstay of treatment and is likely to be the extraterrestrial standard as well. Communications and Support Needs; Ground based communication will be necessary to assist with the treatment phase (CP2) in the second category ("worst case") for this condition References Barratt, Michael R., Ellen S. Baker, and Sam L. Pool. 2019. "Principles of clinical medicine for space flight." In. New York, NY: New York, NY : Springer.

IMM CLIFF RECONCILIATION COMMENTS

LIMITATIONS SUMMARY

The primary limitation pertains to the limited number of subjects that have walked on the moon. The incidence distribution is based on the lunar mission data (Apollo) of no documented medical events of sensorimotor neurovestibular disturbance among the 12 astronauts who landed and walked on the moon.

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)		664										
Untreated Best Case (UTBC)		664					145					
Treated Worst Case (TWC)		664			854				13			
Untreated Worst Case (UTWC)	223	664		89	854		145		13			
	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)								211	875	3763	0.232527	23.2527
Untreated Best Case (UTBC)					196			211	1216	3763	0.323146	32.3146
Treated Worst Case (TWC)	132				196		34	211	2104	3763	0.559128	55.9128
Untreated Worst Case (UTWC)	132				196		34	211	2561	3763	0.680574	68.0574
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)												
Treated Worst Case (TWC)												
Untreated Worst Case (UTWC)												
	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	T1 Decimal	T1 %
Treated Best Case (TBC)									0	3763	0	0
Untreated Best Case (UTBC)									0	3763	0	0
Treated Worst Case (TWC)									0	3763	0	0
Untreated Worst Case (UTWC)									0	3763	0	0

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 requiring use of the alimentary system, 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

Although this CLIFF has assigned a 100% probability to the best-case scenario, TI was calculated for worst-case scenario so that future iterations of IMPACT can use this value should evidence from Artemis Missions reveal an incidence for the worst-case scenario. CP2: In the worst-case scenarios, this condition would be exacerbated by tasks requiring greater than baseline cardiopulmonary effort. CP3: No comment.

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 Condition 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.

REFERENCES

Reference

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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