

Clinical Finding Form (ClIFF)

Branch

Baseline

ICL122_Gravity Well Entry Motion Sickness

Entry Motion Sickness is the collection of physiologic changes during the initial postflight period of motion sickness when the astronaut is readapting to Earth's gravity or a partial gravity environment after adaptation to a period 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. (Ortega, 2019) It is usually a self-limited condition, mild in severity for shorter missions, resembling acute terrestrial motion sickness. Longer missions could possibly, though unlikely, pose an operational risk with respect to astronaut reentry tasks such as piloting and egress. (Heer 2006, 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 entry motion sickness (specifically defined as readaptation occurring on return to a gravitational field from microgravity one) has been estimated based on LSAH inflight data and the limited lunar mission (Apollo) data. There is no documented evidence of entry motion sickness among the 12 Apollo astronauts who 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 the entry motion sickness symptoms by the Apollo astronauts who walked on the moon. The incidence distribution for this condition is based on the lunar mission data (Apollo) of no documented medical events of entry motion sickness among the 12 astronauts who landed and walked on the moon.

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

0.07191 events/person 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
Ortega, 2019	Spaceflight	1
Scheuring, 2007	Spaceflight	1

Incidence is given an LOC = 1 (somewhat unconfident) since the incidence is based on limited applicable data. There have been 0 documented EMS events among the 12 astronauts that have walked on the moon compared to the 228 documented events among 664 astronaut shuttle flights. The incidence distribution for this condition is based on the lunar mission data (Apollo) of no documented medical events of entry motion sickness 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. Medications such as meclizine given prior to reentry may mitigate symptoms of reentry motion sickness.

BEST CASE SCENARIO DEFINITION

Entry motion sickness that results in nausea/vomiting that responds to behavior modifications and/or medications.

WORSE CASE SCENARIO DEFINITION

Entry motion sickness that results in nausea/vomiting and does not respond to behavior modifications and/or medications.

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 3/8g instead of 1g, it is anticipated that all EMS events for lunar will be best case scenarios. There have been 0 documented EMS events among the 12 astronauts that have walked on the moon compared to the 228 documented events among 664 astronaut shuttle flights. Therefore, best case percentage is estimated at 100% with worst case 0%.

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

Citation	Source	LOC Value
Ortega, 2019	Spaceflight	3
Scheuring, 2007	Spaceflight	3

Probabilities are given an LOC = 3 (somewhat confident) based on the assumption that severe EMS will not be seen due to mild gravity transitions during exploration missions. Since the gravity transition will be from 0g to 1/6th g or 3/8g instead of 1g, it is anticipated that all EMS events will be best case scenarios.

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	0.5	13.38	0	48	0	0	0	0	0
Treated Worst Case (TWC)		0 - 0	100	0	0	0	0	0	0	0	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	0.5	19.265	0	48	0	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	0	0	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 phase, specifically on return from microgravity to a gravitational field. The treatment does not differ significantly to that of the terrestrial equivalent and can usually be treated in a fashion similar to Space Motion Sickness (SMS).

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Occurrence and duration data comes directly from spaceflight data (LSAH) embedded within the cited references of this CLiFF. The best case scenarios can last up to 48 hours, typically with the strongest symptomatology initially, then tapering off. (Ortega, 2019) They either resolve spontaneously or require isolated/limited anti-motion sickness countermeasures/drugs. 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 (LSAH) embedded within the cited references of this CLiFF. The best case scenarios can last up to 48 hours, typically with the most notable symptoms initially, then tapering off. (Ortega, 2019) A portion of these resolve spontaneously but others linger without intervention. RTDC probability is 0% and LOCL probability is 0%.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

Not applicable.

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

Citation	Source	LOC Value
Ortega, 2019	3	3

Durations are given an LOC = 3 (somewhat confident) based on Earth reentry data. "Complete recovery time from frank EMS symptoms can be expected within a day or two." (Ortega, 2019)

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
N/A	Case definition	4

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

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
N/A	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. There is only a BC definition since the gravity transition will be from 0g to 1/6th g or 3/8g instead of 1g and it is anticipated that all EMS events will be best case scenarios. 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): 0.5 hours for history given the context of spaceflight and the self resolving nature This condition requires a Scope of Practice 4 to manage and rule out other similar presenting conditions. Treatment Scope and Resourcing Treatment requires antiemetics and anti-vertigo medications. It is expected to be a brief and self limited condition but potentially quite debilitating until the symptoms subside. Communications and Support Needs; Ground based communication will not be necessary since it is brief, self limited, and largely anticipated. It is expected that routine medical communications will be available to support as needed 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

Not applicable. There is no IMM CLIFF for this condition.

LIMITATIONS SUMMARY

The primary limitation pertains to the limited number of subjects that have walked on the moon. The incidence distribution for this condition is based on the lunar mission data (Apollo) of no documented medical events of entry motion sickness 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		89			145		13			
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	TI Decimal	TI %
Treated Best Case (TBC)	132							211	1007	3763	0.267606	26.7606
Untreated Best Case (UTBC)	132				196			211	1450	3763	0.385331	38.5331
Treated Worst Case (TWC)										3763	0	0
Untreated Worst Case (UTWC)										3763	0	0
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

CP2: No comment. 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

1. Clark JB, Bloomberg JJ, Bacal K. Neurologic concerns. In: Barratt's Principles of Clinical Medicine for Space Flight. 2019.
2. Heer M, Paloski WH. Space motion sickness: Incidence, etiology, and countermeasures. *Autonomic Neuroscience: Basic and Clinical*. 2006;129:77-79.
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4. Reschke MF, Bloomberg JJ, Harm DL, Paloski WH, Layne C, McDonald V. Short review Posture, locomotion, spatial orientation, and motion sickness as a function of space flight. *Brain Research Reviews*. 1998;28:102-117.
5. Reschke M, Good E, Clement G. Neurovestibular Symptoms in Astronauts Immediately after Space Shuttle and International Space Station Missions. *OTO open*. 2017;1(4).
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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