Clinical Finding Form (CliFF)

Branch Baseline

ICL45_Eva Related Shoulder Injury

There are multiple factors associated with the mechanism of shoulder injury related to the EVA such as suit fit, donning and doffing, body position, pre-existing injury, tool mass and configuration, age, in-suit activity, and training density. Notably, EVA density has been correlated with shoulder injury. For each EVA performed in spaceflight, crewmembers undergo 6-10 NBL training runs (Scheuring et al, 2012). The likelihood of symptoms increases with increased NBL test-runs with the following proportions of runs complaining of shoulder symptoms: 2.7% (0-9 runs), 5% (10-91 runs) and 15.8% (92 or more runs). Similarly, training volume is correlated with surgical shoulder injuries, with crewmembers who have performed more than 92 training runs (in either the planar or the pivoted hard upper torso suit) being 5.9 more likely to have shoulder surgery compared to crewmembers who have performed 0-9 training runs. (Scheuring et al, 2012) Suit design has been implicated in shoulder injuries. The Scye (arm openings) on both the planar hard upper torso (HUT) and pivoted HUT suits restrict normal shoulder motion, but the planar HUT to a greater degree. The planar HUT limits shoulder range of motion to the following approximates (Abduction 60-90°, Flexion 90°, Internal Rotation 40°, External rotation 35°). (Scheuring et al, 2012)

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

Scheuring et al. (2009) was used to inform the incidence distribution for this condition. The study evaluated the incidence musculoskeletal in-flight injuries among astronauts in a review spanning Mercury - Expedition 13 of the ISS Program. 6 shoulder injuries were attributed to the EVA suit during that timeframe. Of note, these data are based on the Extravehicular Mobility Unit (EMU) suit used on the ISS – not the planned xEMU suit for Lunar surface EVAs. Also of note, the study reports a total of 21 shoulder injuries from Mercury - ISS Expedition 13. As previously stated, 6 are attributed to the EVA suit, 5 are attributed to exercise, an unknown amount are attributed to repetitive injury from contact with the glove box during science experiments, and the remainder are attributed to general activities within the ISS. The following data sources were utilized in this review: post-flight medical debriefs, the LSAH medical record database, the Johnson Space Center (JSC) electronic medical record system, including ASCR specialist assessment and treatment logs, and the JSC Flight Medicine Clinic vault records. Musculoskeletal injury data in the ISS program was extracted from the private medical conferences held between the ISS crewmembers and their flight surgeon up to and including Expedition 13, as well as from the ASCR specialists supervising the crewmember's in-flight training regimen. Lastly, several entries came directly from personal communications with astronaut crewmembers or flight surgeons and the authors when not otherwise duplicated. Information collected on each injury included location, type, and a detailed narrative on the mechanism of injury, the type of exercise the crewmember performed during the flight, previous history of injury, treatment, and post-flight outcome. The term " in-flight" included lunar surface operations. This article notes small lacerations and abrasions to the hands are among the most common injuries occurring throughout the U.S. space program.

ANALOG LITERATURE

Analog data regarding shoulder injuries that occur during EVA training is readily available. Laughlin et al, 2014 is a retrospective review poster presentation which reviewed all astronaut medical records (n = 330) for training injuries that occurred at the Weightless Environment Training Facility (WETF) or Neutral Buoyancy Laboratory (NBL) in active astronauts. They report an overall incidence of 9.67 injuries per 100 astronauts over 10 years in the EVA training environment. There was a non-statistically significant difference in incidence between male (8.88 injuries per 100 astronauts over 10 years) and females (13.97 injuries per 100 astronauts over 10 years). Viegas et al, 2004 presents retrospective data from an NBL study of 83 astronauts, comprising 548 test-runs from July 19, 2002 - July 18, 2003. During the year-long study 66 shoulder injuries were reported during these 548 test runs. Of note, while EVA training in water can achieve neutral buoyancy, the effect of gravity is still in place. Injuries seen in the NBL, not seen in spaceflight have been attributed to gravity shifting inside the suit (Chappell et al, 2017).

TERRESTRIAL LITERATURE

It was assumed that terrestrial data would be inadequate for providing input that drives the incidence of this spaceflight specific condition. No terrestrial data searches were performed.

OVERALL INCIDENCE SUMMARY

INCIDENCE

Mean: 0.0282 SD: 0.0107

INCIDENCE SUMMARY

In incidence distribution for this condition is informed by Scheuring et al, 2009. This reports 6 EVA-related shoulder injuries from Mercury through ISS Expedition 13. Total EVAs Mercury through Expedition 13 was 247. Total events 6 over 247 person-EVAs. IP: 0.0243 (95%CI: 0.009, 0.0521). The Bayesian posterior distribution for the incidence proportion given the spaceflight data (6 events over 247 person-EVAs) under an uninformative prior is Beta(shape1=6.722, shape2=231.64) with mean 0.0282 and SD 0.0107.

TABLE 1. INCIDENCE MODEL

Incidence Details

Incidence Type
EVA

Segment
EVA All

Env. Exposure
NA

Sex
Any

Crowns
Any

Contacts
Any

Pregnancy
Any

Incidence Distribution

Occurrence Dist
Binomial

Incidence Dist.
Beta

Mean
0.0282008

SD
0.0107002

Beta
(Alpha): 6.722
(Beta): 231.64

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Scheuring et al, 2009	Spaceflight	4
Viegas et al, 2004	Analog	3
Laughlin et al, 2014	Analog	3

Scheuring et al, 2009 is a retrospective review of musculoskeletal injuries in U.S. Astronauts from Mercury - ISS Expedition 13. It reports 6 inflight shoulder injuries secondary to the EVA suit. It was used to inform the incidence for this condition and given that it is spaceflight data, was ranked with a level of confidence of 4. Viegas et al, 2004 presents retrospective data from an NBL study of 83 astronauts, comprising 548 test-runs. There were 66 shoulder injuries reported during these 548 test runs. Laughlin et al, 2014 is a retrospective review poster presentation which reviewed all astronaut medical records (n = 330) for training injuries that occurred at the Weightless Environment Training Facility (WETF) or Neutral Buoyancy Laboratory (NBL) in active astronauts. They report an overall incidence of 9.67 injuries per 100 astronauts over 10 years in the EVA training environment. Viegas et al, 2004 presents retrospective data from an NBL study of 83 astronauts, comprising 548 test-runs. 66 shoulder injuries were reported during these 548 test runs.

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

Prevention methods include optimizing suit fit, crew training including avoiding work outside of the normal work envelop, the application of suit padding and pressure absorbing dressings to known affected body areas. (Strauss, 2004)

BEST CASE SCENARIO DEFINITION

Suit related overuse injury or Grade I or II strain/sprain (minimal or partial muscle or ligamentous tearing) in which symptoms can be readily managed with oral or topical medications and supportive care (physical therapy is encouraged).

WORSE CASE SCENARIO DEFINITION

Suit related overuse injury or Grade III strain/sprain (full thickness muscle or ligamentous tearing), instability, or suspected labral tear that requires additional treatment. Physical therapy is mandatory.

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

Shoulder - Labral Tear

BEST CASE/WORST CASE PROBABILITY COMMENTS

Scheuring et al, 2012 is a presentation from the Aerospace Medical Association National Conference which presents data on shoulder injuries in US Astronauts related to EVA suit design. NBL training data and spacesuit design data from 1995-2011 were analyzed. Shoulder surgery data was acquired from JSC medical records. Causal mechanisms were obtained via personal interview with crewmembers who underwent surgery. An analysis of the hard upper torso of the EMU was performed as it related to normal shoulder biomechanics. This study reviewed 330 US astronauts. Data was unavailable for 176 astronauts. Of the remaining 154 which records were available for, 103 had performed at least 1 EVA prior to shoulder surgery. Of these 103 crewmembers, there were 11 shoulder surgeries. Laughlin et al, 2014 is a retrospective review poster presentation which reviewed all astronaut medical records (n = 330) for training injuries that occurred at the Weightless Environment Training Facility (WETF) or Neutral Buoyancy Laboratory (NBL) in active astronauts. They report a total of 40 shoulder injuries. Using the 40 total shoulder injuries from Laughlin et al, 2014 in the cohort of 330 crewmembers as the denominator for total shoulder injuries and the 11 shoulder surgeries from Scheuring et al, 2012 as the numerator for worst-case scenario EVA related shoulder injuries, the worst-case probability was assigned as 27.5%. The best-case scenario probability was assigned as 72.5%. Note, there are considerations that were not able to be factored into this best and worst-case scenario, such as EVA volume per crewmember. Scheuring et al, 2012 concluded that crewmembers who had more than 92 total training runs (in either the planar or pivoted hard upper torso (HUT) suit) were 5.9 times more likely to have shoulder surgery compared to crewmembers who had 0-9 training runs. The study also supported that training in the planar HUT only may decrease the risk of shoulder injury requiring surgery. Given that this is based on NBL data, where higher severity shoulder injuries are more common than in spaceflight, to account for uncertainty the best and worst-case scenarios were assigned a range: Best-case scenario 72.5%-100% and worst-case scenario 0-27.5%.

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

Citation	Source	LOC Value
Scheuring et al, 2012	Analog	3
Laughlin et al, 2014	Analog	3

Scheuring et al, 2012 is a presentation from the Aerospace Medical Association National Conference which presents data on shoulder injuries in US Astronauts related to EVA suit design. NBL training data and spacesuit design data from 1995-2011 were analyzed. Shoulder surgery data was acquired from JSC medical records. Causal mechanisms were obtained via personal interview with crewmembers who underwent surgery. An analysis of the hard upper torso of the EMU was performed as it related to normal shoulder biomechanics. This study reviewed 330 US astronauts. Data was unavailable for 176 astronauts. Of the remaining 154 which records were available for, 103 had performed at least 1 EVA prior to shoulder surgery. Of these 103 crewmembers, there were 11 shoulder surgeries. Laughlin et al, 2014 is a retrospective review poster presentation which reviewed all astronaut medical records (n = 330) for training injuries that occurred at the Weightless Environment Training Facility (WETF) or Neutral Buoyancy Laboratory (NBL) in active astronauts. They report a total of 40 shoulder injuries.

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: 0.0282 SD: 0.0107	86 - 86	100	1.48	8.75631	504	2232	0	0	0	0	0
Treated Worst Case (TWC)		14 - 14	100	1.48	19.2665	2232	8928	17.5126	0	0	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	1.48	22.5884	2232	8928	6.51076	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	1.48	29.2719	8760	87600	17.5126	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

The RTDC surrogate selected was need for surgical intervention. See details for specific scenarios below.

TREATED BEST CASE (TBC) SCENARIO COMMENTS

The duration for this scenario was assigned a range of 504-2232 hours (3 weeks - 3 months). The minimum duration was informed by the Hand to Shoulder Center of Wisconsin, a private clinic website that states the average healing time for an upper extremity sprain/strain is 3 weeks (note this source was also used in the Upper Extremity Sprain/Strain CLiFF). The maximum duration is based on a conservative/non-operative treatment length of 3-6 months in patients with partial thickness rotator cuff tears (Deore et al, 2016; Matthewson et al, 2015). The RTDC probability was assigned 0%. The RTDC surrogate selected was the need for surgical intervention. Most partial thickness tears (Grade I and II) can successfully be treated non-operatively (Matthewson et al, 2015). Literature searches (Dynamed and NTRS) did not reveal any studies indicating mortality due to best-case EVA-Related Shoulder injury. Therefore, the LOCL probability was assigned 0%.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

The duration was assigned a range of 2232-8928 hours (3-12 months). The minimum duration was informed by Osborne et al, 2016 which reports a healing time of 3-6 months after rotator cuff repair surgery. The maximum duration was informed by Morgan et al, 1998 in which the majority of athletes with SLAP (Superior Labrum Anterior Posterior) tears were able to return to the same level of play at 1-year post-op. This range was corroborated by Casagranda and Thurlow (2016) who present a range of 4-9 months for return to play in athletes after surgical rotator cuff repair. The RTDC surrogate for this Cliff was initially assigned as need for surgical intervention. Typically, patients present to the hospital due to pain. Pain control could be provided during spaceflight, so this is not a realistic surrogate for RTDC. While a Grade III sprain/strain requiring surgical intervention is possible in spaceflight, it is unlikely that RTDC would be executed for surgical intervention. Rather, pain control and PT would be the mainstay of treatment inflight and surgical intervention would be pursued post-flight. Lack of prompt surgical intervention will be reflected in TI. Thus, the RTDC probability was accordingly assigned as 0%. Literature searches (Dynamed and NTRS) did not reveal any studies indicating mortality due to worst-case EVA-Related Shoulder injury. Therefore, the LOCL probability was assigned 0%.

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

The duration was assigned a range of 2232-8928 hours (3-12 months). The minimum duration was informed by conservative (non-operative treatment times) for rotator cuff tears (Deore et al, 2016;Matthewson et al, 2015). Despite this being an untreated scenario, it is feasible that symptoms would plateau as early as 3 months without treatment. The maximum duration (12 months) was informed by Maman et al, 2009. This was a retrospective review that followed rotator cuff tears radiographically (MRI) to assess for progression. At 12 months 87.5% of partial thickness tears were asymptomatic. The RTDC surrogate for this Cliff was initially assigned as need for surgical intervention. Typically, patients present to the hospital due to pain. Pain control could be provided during spaceflight, so this is not a realistic surrogate for RTDC. While a Grade III sprain/strain requiring surgical intervention is possible in spaceflight, it is unlikely that RTDC would be executive for surgical intervention. Rather, pain control and PT would be the mainstay of treatment inflight and surgical intervention would be pursued post-flight. Lack of prompt surgical intervention will be reflected in TI. Thus, the RTDC probability was according assigned as 0%. Literature searches (Dynamed and NTRS) did not reveal any studies indicating mortality due to best-case EVA-Related Shoulder injury. Therefore, the LOCL probability was assigned 0%.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

A duration of 8760-87600 hours (1-10 years) was assigned to this scenario. The minimum duration was informed by a Cochran review comparing survey vs. placebo for full thickness rotator cuff tears (note that the "untreated arm" represents non-operative treatment with or without glucocorticoid injection. The follow-up period was 1 year, at which time operative and non-operative outcomes were not statistically different. (Karjalainen et al, 2019) The maximum duration was informed by American Academy of Orthopedic Surgery Guidelines for the Management of Rotator Cuff Injuries (March 11, 2019) which states that despite physical therapy improving patient satisfaction, in non-operatively treated full thickness rotator cuff tears, the size of the tear, muscle atrophy, and fatty infiltration progress for a period of 5-10 years. Two studies showed intermediate duration lengths. Both were based on MRI surveillance of non-operatively treated full-thickness rotator cuff tears. Kim et al, 2016 found that over 100 months 82.4% of full-thickness rotator cuff tears enlarged in size, whereas Fucentense et al, 2012 found that at 3.5 years, isolated full thickness supraspinatus tears that were treated non-operatively had not increased in size and had good outcomes. The RTDC surrogate for this Cliff was initially assigned as need for surgical intervention. Typically, patients present to the hospital due to pain. Pain control could be provided during spaceflight, so this is not a realistic surrogate for RTDC. While a Grade III sprain/strain requiring surgical intervention is possible in spaceflight, it is unlikely that RTDC would be executive for surgical intervention. Rather, pain control and PT would be the mainstay of treatment inflight and surgical intervention would be pursued post-flight. Lack of prompt surgical intervention will be reflected in TI. Thus, the RTDC probability was according assigned as 0%. Literature searches (Dynamed and NTRS) did not reveal any studies indicating mortality due to worst-case EVA-Related Shoulder injury. Therefore, the LOCL probability was assigned 0%.

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

Citation	Source	LOC Value
Hand to Shoulder Center of Wisconsin, 2021	Terrestrial	3
Deore et al, 2016	Terrestrial	
Matthewson et al, 2015	Terrestrial	
Osborne et al, 2016	Terrestrial	
Morgan et al, 1998	Terrestrial	
Casagranda and Thurlow, 2016	Terrestrial	
Maman et al, 2009	Terrestrial	
Karjalainen et al, 2019	Terrestrial	
Kim et al, 2016	Terrestrial	
Fucentense et al, 2012	Terrestrial	
AAOS Guidelines for "Management of Rotator Cuff Injuries" March 11, 2019	Terrestrial	

Durations were provided from terrestrial data including sprains/strains and partial rotator cuff tears (best-case scenario) and full-thickness rotator cuff tears and labral tears (worst-case scenario).

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Maman et al, 2009	Terrestrial	3
Matthewson et al, 2015	Terrestrial	
Scheuring et al, 2012	Terrestrial	
Minagawa et al, 2013	Terrestrial	

The RTDC surrogate selected was need for surgical intervention. Terrestrial data was used to inform indications for surgery. The most agreed upon criteria is Grade III tears (> 50% tendon thickness). Therefore, data regarding progression of partial thickness tears (best-case scenario) to large tears was used to inform the best-case scenario RTDC probabilities. This is unchanged by conservative management. For the worst-case scenario data regarding crewmember surgical shoulder injuries and rate of full-thickness tears in a terrestrial population was used to inform the RTDC probability.

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
N/A	N/A	4

Literature searches in Dynamed ("Rotator Cuff Tear" and "SLAP Tear") as well as subsequent secondary references from the primary references listed, and NTRS did not reveal any literature that indicates mortality as a result of EVA Related Shoulder Injury. Thus the LOCL probability was assigned 0% for all scenarios.

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Capabilities and Resourcing Scope Overview EVA Related Shoulder Injury – This condition represents a spectrum of strains and sprains of the shoulder that can occur during EVAs. Clinically the condition is similar to shoulder injuries incurred terrestrially without unique clinical features, although the design of the suit's torso coupled with the atypical and repetitive motions of an EVA make this a likely source of injury. Shoulder

dislocations, tendinopathies, and other sprains/strains are not included in this outline as they are addressed elsewhere. CNES: N/A Diagnostic Scope and Resourcing This condition in the best-case and worst-case is diagnosed by history and a focused musculoskeletal examination. A neurological examination is also included to evaluate for corresponding nerve injury or impingement. Ultrasound has been included in the diagnostic suite to look for muscle tears, dislocation, and fracture. 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): 1.48 hours CP1 WC (Treated or Untreated: 1.48 hours This CRT includes a scope of practice code of 5 (which correlates to an “Experienced procedure trained generalist attending” and was included for the performance and interpretation of specialized diagnostic ultrasounds. Treatment Scope and Resourcing The major difference in spaceflight evaluation compared to that on Earth is the lack of specific diagnostic testing, namely x-rays and MRIs. Terrestrially, shoulder sprains and strains would be treated with medications and physical therapy which is effective for many of the milder cases. Refractory symptoms would prompt an MRI study that would provide a definitive diagnosis and severity, thus driving additional treatments (to include surgery). Ultrasound offers some additional diagnostic capability, primarily to look for alternate and more significant diagnoses, although it is very limited in this situation. MSK ultrasound typically requires specialized training and frequent practice, which most generalist physicians do not have. Similar to terrestrial treatment, in spaceflight we can provide oral NSAIDs, topical medications, hot and cold packs, and physical therapy for this condition. In the worst case, a sling may be required to provide short term stabilization and pain relief. Surgical repair of severe shoulder strains and sprains is not available in spaceflight. Communications and Support Needs Additional ground communication capability is indicated here primarily for physical therapy consultation and guidance. REFERENCES Vaughan A, Hulkower S. Evaluation of the adult with shoulder complaints. UpToDate 2021. Holmes RE, Barfield WR, Woolf SK. Clinical evaluation of nonarthritic shoulder pain: diagnosis and treatment. Phys Sportsmed 43:262.

IMM CLIFF RECONCILATION COMMENTS

EVA Related Shoulder Injury is a unique condition to IMPACT 1.0. Therefore, the incidence, duration, and outcomes (RTDC, LOCL) are appropriately unique in this CLiFF.

LIMITATIONS SUMMARY

• The CLiFF is heavily informed by rotator cuff tears. Best-case scenario data included sprains/strains and partial thickness tears (Grade I-II). Worst-case scenario data included full thickness tears (Grade III). Labral tears were incorporated in the worst-case scenario as available literature allowed. In the NBL most shoulder injuries involve the rotator cuff and/or labrum but shoulder injuries on orbit generally are more mild in nature.

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)												
Untreated Best Case (UTBC)		664										
Treated Worst Case (TWC)												
Untreated Worst Case (UTWC)		664		89								
	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)			414				34	211	659	3763	0.175126	17.5126
Untreated Best Case (UTBC)	132		414				34	211	1455	3763	0.38666	38.666
Treated Worst Case (TWC)	132		414				34	211	791	3763	0.210205	21.0205
Untreated Worst Case (UTWC)	132		414				34	211	1544	3763	0.410311	41.0311

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	TI Decimal	TI %
Treated Best Case (TBC)									0	3763	0	0
Untreated Best Case (UTBC)							34	211	245	3763	0.0651076	6.51076
Treated Worst Case (TWC)			414				34	211	659	3763	0.175126	17.5126
Untreated Worst Case (UTWC)			414				34	211	659	3763	0.175126	17.5126

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

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 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