Clinical Finding Form (CliFF)

Branch Baseline

ICL102_Sprain/Strain - Lower Extremity

Sprains and strains are common musculoskeletal injuries. The most common injury in the United States is Ankle Sprain (MedicineNet, 2010). Sprain/Strain – Lower Extremity is a broad condition including strains (muscle/tendon) or sprains (ligaments) anywhere in the lower extremity. This includes, but is not limited to, the hip, thigh, knee, ankle, Achilles tendon, and foot.

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 2017 IMM CLiFFs for Ankle, Hip, and Knee Sprain/Strains present the most up to date data regarding incidence of inflight lower extremity sprains/strains. Cumulatively, they report 55 lower extremity sprains/strains from Mercury - ISS Expedition 40: 11 ankle sprain/strains (NASA, Ankle Sprain/Strain CLiFF, 2017), 17 Hip Sprain/Strains (NASA, Hip Sprain/Strain CLiFF, 20170, and 27 Knee Sprain/Strains (NASA, Knee Sprain/Strain CLiFF, 2017). This represents the most up to date in-flight lower extremity sprain/strain data available and will be used to inform the incidence for this CLiFF. It may be an underestimate of all lower extremity sprains/strains since it is limited to the ankle, hip, and knee, but is felt to be representative given the data available. Antonsen et al, 2017 is a retrospective review, utilizing LSAH data, of in-flight events for ankle sprain/strain (11), knee sprain/strain (7), and hip sprain/strain (assumed to be 0 as not reported) spanning Mercury - ISS Expedition 13. This corroborates the data from this time period presented in the IMM CLiFFs, but does not include the update through Expedition 40. Scheuring et al, 2009 is a retrospective review of musculoskeletal injuries in US Spaceflight from Mercury - ISS Expedition 13. 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. It reports 54 sprain/strain injuries in this timeframe, but does not specify how many occurred in the lower extremities. It has a separate category for "lower extremity injury" (approximately 40), which presumably includes other diagnoses beyond sprain/strain.

ANALOG LITERATURE

A comprehensive study of all active duty service members across the United States Army, Navy, Air Force, and Marine Corps reported a lower extremity sprain/strain/rupture incidence of 0.00784 per person year during the calendar year 2006 (U.S. Army, 2008). A similar injury epidemiology report published by the Department of Defense Military Injury Prevention Priorities Working Group reported a lower extremity sprain/strain incidence of 0.1496 per person-year during the calendar year 2004 (Ruscio et al, 2006). It is anticipated that military analogs will be an overestimate of the spaceflight incidence of lower extremity sprains/strains due to occupational demands of the military.

TERRESTRIAL LITERATURE

Hikers, mountain climbers, and backpackers were a terrestrial population of consideration because they experience an austere, uneven, rocky environment that may be similar to Lunar and Martian surfaces. A 5-year study of more than 43,000 hikers and mountain climbers in Grand Teton National Park, USA, recorded only 15 cases of lower extremity sprain/strain injuries during the investigative period, an incidence of 0.0000687 per person-year (Schussman et al, 1990). While hikers and mountaineers would be expected to have a higher incidence of lower extremity sprains/strains than crewmembers during spaceflight due to their activities, this is likely an underestimation of the true incidence of lower extremity sprains/strains in the mountaineering population because it only represents injuries that were reported to park rangers. Presumably, a large number of sprain/strain injuries go unreported.

OVERALL INCIDENCE SUMMARY

INCIDENCE

Mean: 1.233 SD: 0.1683

INCIDENCE SUMMARY

The 2017 IMM CLiFFs for Ankle, Hip, and Knee Sprain/Strains present the most up to date data regarding incidence of inflight lower extremity sprains/strains. Cumulatively, they report 55 lower extremity sprains/strains from Mercury - ISS Expedition 40: 11 ankle sprain/strains (NASA, Ankle Sprain/Strain CLiFF, 2017), 17 Hip Sprain/Strains (NASA, Hip Sprain/Strain CLiFF, 20170, and 27 Knee Sprain/Strains (NASA, Knee Sprain/Strain CLiFF, 2017). This represents the most up to date in-flight lower extremity sprain/strain data available and will be used to inform the incidence for this CLiFF. The Bayesian posterior distribution for the incidence rate given the LSAH spaceflight data (55 events over 44.58 person-years) under an uninformative prior is Gamma(shape=53.67, rate=43.53) with mean 1.233 and SD 0.1683.

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
1.23294

SD
0.168297

Gamma
(Shape): 53.67
(Rate): 43.53

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
U.S. Army, 2008	Analog	2
Schussman et al, 1990	Terrestrial	1
Ruscio et al, 2006	Analog	2
Scheuring et al, 2009	Spaceflight	3
Antonsen et al, 2017	Spaceflight	3
NASA, Ankle Sprain/Strain CLiFF, 2017	Spaceflight	4
NASA, Hip Sprain/Strain CLiFF, 2017	Spaceflight	4

Citation	Source	LOC Value
NASA, Knee Sprain/Strain CLiFF, 2017	Spaceflight	4

The 2017 IMM CLiFFs for Ankle, Hip, and Knee Sprain/Strains present the most up to date data regarding incidence of inflight lower extremity sprains/strains. Cumulatively, they report 55 lower extremity sprains/strains from Mercury - ISS Expedition 40. Antonsen et al, 2017 is a retrospective review, based on LSAH data only, of the number of lower extremity sprains and strains that occurred from Mercury missions - Expedition 13 of the ISS program. Note, this is restricted to sprains/strains for which IMM conditions existed at the time (Ankle, Knee, and Hip). However, given that ankle sprains are the most common lower extremity sprain, this data is considered applicable for this condition. This source corroborates the data presented in the 2017 IMM CLiFFs. Scheuring et al, 2009, is a retrospective review of inflight musculoskeletal injuries over the same time period (Mercury - Expedition 13 of ISS) and includes more comprehensive data sources beyond only LSAH. However, the injuries are classified as "lower extremity injuries" rather than sprains/strains. Given that Antonsen et al, 2017 specifies sprain/strain injuries, it is felt to be the more appropriate source to inform this incidence. Two military analog sources (U.S. Army, 2008; Ruscio et al, 2006) that included over one million active duty service members across the four major branches of the United States military (i.e., Army, Navy, Air Force, Marine Corps) provided retrospective analysis data for lower extremity sprains/strains. This is likely an overestimate of the true spaceflight incidence of lower extremity sprains/strains due to the occupational demands of the military. Schussman et al, 1990 is a retrospective analysis of mandatory accident reports from Grand Teton National Park rangers. It had a large sample size (more than 43,000 individuals). Similar to the analog literature, it is likely that hikers and mountaineers will have a higher incidence of lower extremity sprains/strains than what is expected in the spaceflight environment.

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

Lower extremity injuries have been known to occur in-flight due to exercise (Scheuring et al, 2009). The Astronaut Strength, Conditioning and Rehabilitation (ASCR) program and Astronaut gym at Johnson Space Center are strategic to providing pre-flight strengthening in attempts to prevent or mitigate injuries as well as post-flight rehabilitation. The Strength Coach's primary role is to provide an exercise plan designed to achieve flight physical readiness and prevent musculoskeletal injuries during spaceflight training.

BEST CASE SCENARIO DEFINITION

A Grade I or II strain/sprain in which there is minimal or partial muscle or ligamentous tearing.

WORSE CASE SCENARIO DEFINITION

A Grade III strain/sprain in which there is full thickness muscle or ligamentous tearing, and/or instability.

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

Sprain/Strain - Hip, Sprain/Strain - Knee, Sprain/Strain - Ankle, Sprain/Strain - Foot, Sprain/Strain - Medial gastrocnemius muscle strain, Sprain/Strain - Achilles tendon injury

BEST CASE/WORST CASE PROBABILITY COMMENTS

Two military analog sources inform the best and worst-case probabilities for this condition. Ruscio et al, 2006 is a retrospective analysis of all active duty service members across the United States Army, Navy, Air Force, and Marine Corps in the year 2004 that reports the incidence of lower extremity sprains/strains. Hospitalization for sprain/strain was considered a surrogate for the worst-case scenario. Of the 134,619 lower extremity sprain/strain events, 482 required hospitalization, for a worst-case scenario probability of 0.358%. An updated retrospective analysis across the United States Army, Navy, Air Force, and Marine Corps in the year 2006 reported 8,984 lower extremity sprain/strain events, 535 of which required hospitalization, for a worst-case scenario probability of 5.96%. Thus, the worst-case scenario was assigned a probability of 0.358-5.96% and the best-case scenario was assigned a probability of 94.04-99.64%.

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

Citation	Source	LOC Value
U.S. Army, 2008	Analog	4
Ruscio et al, 2006	Analog	4

Ruscio et al, 2006 is a retrospective analysis of all active duty service members across the United States Army, Navy, Air Force, and Marine Corps in the year 2004 that reports the incidence of lower extremity sprains/strains. Hospitalization for sprain/strain was considered a surrogate for the worst-case scenario. Of the 134,619 lower extremity sprain/strain events, 482 required hospitalization, for a worst-case scenario probability of 0.358%. An updated retrospective analysis across the United States Army, Navy, Air Force, and Marine Corps in the year 2006 reported 8,984 lower extremity sprain/strain events, 535 of which required hospitalization, for a worst-case scenario probability of 5.96%.

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: 1.233 SD: 0.1683	94 - 94	100	1.3	5.70024	168	672	0	0	0	0	0
Treated Worst Case (TWC)		6 - 6	100	1.66	17.6189	840	4380	23.8374	0	0	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	1.3	16.2769	192	2160	0	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	1.66	29.8299	840	8760	23.8374	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 probability for best-case scenarios was pre-determined by the ExMC Clinical and Science Team to be 0%. For worst-case scenarios, the RTDC surrogate selected was surgical intervention. See specific comments for each scenario below.

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Lower extremity sprain/strain encompasses any sprain or strain in the lower extremity. Different locations of sprain/strain have different recovery timelines. Therefore, the duration is estimated as the range with minimum duration representing healing time for an isolated Grade I MCL injury (168 hours, Kim et al, 2016), and the maximum duration representing healing time for a Grade II hamstring strain (Pollock et al, 2016) or an isolated Grade II MCL injury (Kim et al, 2016), both of which as estimated to be 672 hours. Ankle sprain is the most common lower extremity sprain terrestrially (MedicineNet, 2010). The American Academy of Family Physicians clinical practice guideline for ankle sprains states that, unlike other acute joint injuries, clinical grading of acute ankle sprains is often subjective and variable between clinicians because few ankle sprain injuries undergo MRI imaging; as a result, the timeline for recovery reported in the literature is not stratified by Grade of injury and is instead reported as a single range for all ankle sprains (Tiemstra, 2012). Because of this, it was determined that the upper limit of ankle sprain recovery (6 weeks) more accurately represents a treated worst-case scenario sprain, and has therefore been excluded from the treated best-case scenario estimates listed here. The RTDC probability was pre-determined to be 0% for best-case scenarios by the ExMC Clinical and Science Team, therefore no RTDC literature searches were performed. No reports of mortality due to lower extremity sprain/strain were found in a DynaMed literature search. Thus, the LOCL probability was assigned 0%.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

Lower extremity sprain/strain encompasses any sprain or strain in the lower extremity. Different locations of sprain/strain have different recovery timelines. Therefore, the duration is estimated as the range with minimum duration representing healing time for an isolated Grade III MCL injury (840 hours, Kim et al, 2016), and the maximum duration representing the average healing time for a Grade III Achilles tendon rupture (4,380 hours, Zellers et al, 2016). Experts debate whether surgical intervention (the RTDC surrogate selected for worst-case scenario lower extremity sprains/strains) improves outcomes in Grade III lower extremity sprain/strain injuries (Tiemstra, 2012; Kim et al, 2016; DeWitt and Vidale, 2014). Some experts suggest that operative management should be considered for patients with Grade III injuries that have caused functional impairment or structural instability, but even these indications are not universally accepted in the current literature. 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 according assigned as 0%. No reports of mortality due to lower extremity sprain/strain were found in a DynaMed literature search. Thus, the LOCL probability was assigned 0%.

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

A prospective cohort study of acute ankle sprains managed only by elevation, early mobilization, and weight-bearing as tolerated reported that 67% of patients were able to walk without pain after 8 days, and 99% of patients were able to walk without pain after 3 months (Linde et al, 1986). From this data, the minimum duration was assigned as 8 days (192 hours) and the maximum duration was assigned as 90 days (2,160 hours). Although an argument can be made that the resting and elevation of an injured lower extremity may be considered treatment by some clinicians, it is noted that resting and elevating an extremity does not require resources that would otherwise consume mass and volume during a spaceflight mission the way other conservative treatments would (i.e., compression bandages, splinting material, medication, etc.), and therefore represents the study population that is most similar to an untreated best-case population based on the literature available. It is important to note that the only available data was exclusively related to ankle sprains, and that the untreated best-case duration of sprain/strain injuries that occur throughout the rest of the lower extremity may differ. The RTDC probability was pre-determined to be 0% for best-case scenarios by the ExMC Clinical and Science Team, therefore no RTDC literature searches were performed. No reports of mortality due to lower extremity sprain/strain were found in the literature via PubMed and Google Scholar searches. Thus, the LOCL probability was assigned 0%.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

The minimum duration for the treated worst-case scenario was assigned as 840 hours (based on an isolated Grade III MCL injury; Kim et al, 2016). This value will be repeated for the untreated worst-case scenario. The maximum duration was assigned 1 year (8760 hours) based on 18% of patients experiencing residual symptoms (pain and instability) after one year in a prospective cohort study of 137 ankle sprains (Linde et al, 1986). 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 according assigned as 0%. No reports of mortality due to lower extremity sprain/strain were found in PubMed and Google Scholar literature searches. Thus, the LOCL probability was assigned 0%.

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

Citation	Source	LOC Value
Tiemstra, 2012	Terrestrial	3
Kim et al, 2016	Terrestrial	
Pollock et al, 2016	Terrestrial	
Zellers et al, 2016	Terrestrial	
Linde et al, 1986	Terrestrial	
Brooks et al, 1981	Terrestrial	

Different locations of sprains/strains in the lower extremity have different recovery timelines depending on the joint, ligament, or tendon involved (Tiemstra, 2012; Kim et al, 2016; Pollock et al, 2016; Zellers et al, 2016). The untreated scenarios are informed primarily by data relatign to the ankle as opposed to the entire lower extremity, which limits the relevance of this data (Linde et al, 1986; Brooks et al, 1981). Despite this, the study populations were physically active adults, with a mix of male and female patients, which is a reasonable approximation of the astronaut population.

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Tiemstra, 2012	Terrestrial	3
DeWitt and Vidale, 2014	Terrestrial	
Linde et al, 1986	Terrestrial	
DynaMed, Record No. T116632, 2018.	Terrestrial	

The RTDC probability for best-case scenarios was pre-determined by the ExMC Clinical and Science Team to be 0% and no literature searches were performed for these scenarios. Regarding worst-case scenarios: experts debate whether surgical intervention (the selected RTDC surrogate) improves outcomes of lower extremity sprain/strain injuries (Tiemstra, 2012; DeWitt and Vidale, 2014). Some experts suggest that operative management should be considered for patients with Grade III injuries that have caused functional impairment or structural instability of the affected joint, but even these indications are not universally accepted in the current literature. The majority of available data were related to the ankle as opposed to the entire lower extremity, which limits the relevance of this data (Tiemstra, 2012; Linde et al, 1986). There paucity of literature to inform the untreated worst-case RTDC for this condition, as nearly all reviewed studies that discuss surgical management attempted some form of conservative treatment before intervening surgically. Despite this, the study populations were physically active adults, with a mix of male and female patients, which is a reasonable approximation of the astronaut population. Lower extremity sprain/strain injuries may occur less in a microgravity environment, meaning these data may prove to be an overestimation of the true RTDC probability.

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
N/A	N/A	4

Dynamed, PubMed, and Google Scholar database searches yielded no relevant reported cases of death caused by this condition for any scenario.

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Capabilities and Resourcing Scope Overview WC Definition: A Grade III strain/sprain in which there is full thickness muscle or ligamentous tearing, and/or instability. BC Definition: A Grade I or II strain/sprain in which there is minimal or partial muscle or ligamentous tearing. Sprain/Strain refers to tearing of the muscle or ligament in the region for the condition (i.e. the leg), with the best-case scenario representing uncomplicated tearing or instability and the worst-case scenario representing full thickness tearing and instability. Any strain or sprain, if left untreated, could result in further complications or continued pain and poor functioning of the affected muscle. Both Sprains and Strains are classified according to three degrees of injury. Sprains break down as follows: a first-degree sprain is one in which the ligament fibers are over-stretched but intact, second-degree sprain is one in which some fibers are actually torn, and third-degree sprain is one in which the ligament is completely torn and non-functioning. First-degree strains indicate over-stretching, second-degree indicating partial tear, and third-degree indicating complete tear (rupture) (Reed, 1994). In-flight

sprains have generally been mild and self-limited. Diagnostic Scope and Resourcing In the best-case scenario, diagnosis is based on history, and physical examination (musculoskeletal and neurologic). Musculoskeletal ultrasound was considered but it was decided that it would not be necessary to determine if a partial thickness tear was present. It may be a useful adjunct in diagnosis for some cases, but it was not considered a necessary capability to diagnose a partial thickness tear. In the worst-case scenario, diagnosis is based on history, physical examination (musculoskeletal, neurologic), and imaging. The utility of musculoskeletal ultrasound would be determined on a case-by-case basis. It was included as a non-necessary capability. This diagnostic framework is consistent with the terrestrial workup for sprains/strains with the exception of the inability to perform plain film X-Ray (and if warranted CT or MRI), and thereby using Musculoskeletal Ultrasound as a possible surrogate. 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): 1.3 hours This is the longest reasonable time to complete this task for an experienced clinician adjusted for being in the spaceflight environment to do the following: 1 - Take a proper history of the patient 2 - Perform a focused neurological and musculoskeletal physical exam on the patient CP1 WC (Treated or Untreated): 1.66 hours This is the longest reasonable time to complete this task for an experienced clinician adjusted for being in the spaceflight environment to do the following: 1 - Take a proper history of the patient 2 - Perform a complete neurological and musculoskeletal physical exam on the patient 3 - Perform a musculoskeletal ultrasound exam The highest scope of practice code used in this CRT which includes interpretation of diagnosis, performing diagnostic tests and performing treatment would be a four: this is at a intern level. Treatment Scope and Resourcing Most best-case sprains/strains in terrestrial populations resolve with reduction in weight loading and symptomatic relief. An initial period of wrapping may be beneficial. Physical therapy is recommended post-immobilization. Pain is variable depending on the patient. NSAIDs and Acetaminophen were included in the best-case and worst-case treatment scenario. Terrestrially all worst-case sprain/strains would offload weight from leg. We are assuming that on surface operations they could use a makeshift weight bearing capability and are therefore not resourcing crutches. Additional, non-weightbearing/partial weight bearing status may be used as part of treatment terrestrially for a worst-case lower extremity sprain/strain. If the sprain/strain were to occur in microgravity phases of flight, non-weightbearing status is already achieved. Should the sprain/strain occur during surface operations, it was assumed that partial gravity combined with improvised mobility assistance utilizing materials available during surface operations would sufficiently provide partial weight-bearing/non-weightbearing status (i.e. crutches were not included in this CRT). Wrapping and Splinting were resourced for a worst-case and Physical therapy is recommended post-immobilization. Pain is variable depending on the patient. NSAIDs and Acetaminophen were included in the best-case and worst-case treatment scenario. 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 may be helpful for the ultrasound portion of CP1 but not needed for the rest of the condition. REFERENCES - Reed P. The Medical Disability Advisor. 2nd ed. Horsham, PA: 1994. - Kerstman EL. Conversation with Dr. Kerstman. Saile L, editor. 2011.

IMM CLIFF RECONCILATION COMMENTS

Sprain/Strain – Lower Extremity is a new condition. IMM had separate conditions for lower extremity sprains/strains in the following anatomic locations: hip, knee, and ankle. These were combined into one condition for ICL 1.0 to allow for more breadth of conditions within the 120 allowed conditions on the list. For this reason, the incidence, best-case/worst-case probabilities, duration, RTDC, and LOCL are unique to this condition.

LIMITATIONS SUMMARY

• The incidence of this condition is based on spaceflight data regarding in-flight ankle, knee, and hip sprains/strains. Ankle sprains are the most common lower extremity sprain/strain which makes this approximation reasonable, but the incidence of all lower-extremity sprains/strains may be underestimated due to the limited incidence data. • The maximum duration for the treated worst-case scenario is based on a systematic review of poorly defined return to play criteria after Achilles tendon rupture (Zellers et al, 2016). Terrestrially, return-to-play takes longer than return to normal activity or work activity because the dynamic forces on the tendon during athletic activity (particularly sharp stops/starts and jumping) put it at risk for re-injury. The average return to play time was used, but this may still be an overestimate of the duration since it is based on return to play. • For the untreated scenarios, the data is limited to primarily ankle sprains.

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)				22	196			211	429	3763	0.114005	11.4005
Untreated Best Case (UTBC)	132			22	196			211	1225	3763	0.325538	32.5538
Treated Worst Case (TWC)				22	196			211	429	3763	0.114005	11.4005
Untreated Worst Case (UTWC)	132			22	196		34	211	1348	3763	0.358225	35.8225

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)		664										
Untreated Worst Case (UTWC)		664										
	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)									0	3763	0	0
Treated Worst Case (TWC)				22				211	897	3763	0.238374	23.8374
Untreated Worst Case (UTWC)				22				211	897	3763	0.238374	23.8374

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.

REFERENCES

Reference
1. Antonsen E, Blue TBR, Daniels V, Hailey M, Hussey S, Kerstman E, et al. Risk of Adverse Health Outcomes and Decrements in Performance Due to In-flight Medical Conditions. Human Research Program Exploration Medical Capabilities Element. 2017.
2. DeWitt J, Vidale T. Recurrent hamstring injury: consideration following operative and non-operative management. Int J Sports Phys Ther. 2014;9(6):798-812. Epub 2014/11/11. PubMed PMID: 25383248; PubMed Central PMCID: PMCPMC4223289.
3. DynaMed [Internet]. Ipswich (MA): EBSCO Information Services. 1995 - . Record No. T116632, Achilles Tendon Rupture; [updated 2018 Nov 30, cited 2021 Mar 28]. Available from https://www.dynamed.com/topics/dmp~AN~T116632. Registration and login required.
4. Linde F, Hvass I, Jürgensen U, Madsen F. Early mobilizing treatment in lateral ankle sprains. Course and risk factors for chronic painful or function-limiting ankle. Scand J Rehabil Med. 1986;18(1):17-21. Epub 1986/01/01. PubMed PMID: 3715426.
5. Questions and Answers About Sprains and Strains: MedicineNet; 2010 [updated 3/2/2010; cited 2021 June 28]. Available from: https://www.medicinenet.com/script/main/art.asp?articlekey=113898.
6. NASA. Ankle Sprain/Strain Clinical Information Findings Form. Integrated Medical Database of the Human Health and Performance Contract Integrated Medical Model Project. 2017;v6.5.
7. NASA. Hip Sprain/Strain Clinical Information Findings Form. Integrated Medical Database of the Human Health and Performance Contract Integrated Medical Model Project. 2017;v6.5.
8. NASA. Knee Sprain/Strain Clinical Information Findings Form. Integrated Medical Database of the Human Health and Performance Contract Integrated Medical Model Project. 2017;v6.5.
9. Ruscio J, Amoroso P, Anslinger J, Bullock S, Burnham B, Campbell J, Chervak M, Garbow K, Garver R, Godwin E, Harvey M, Hooper T, Jones B, Reinhard D, Phillips J, Rennix C, Riddle J, Scott J, Seibert J, Smith R, Thomas D, Trone D, Webster P, Wells T,
Wilkening R. DoD Military Injury Prevention Priorities Working Group: Leading Injuries, Causes, and Mitigation Recommendations. 2006.
10. Scheuring RA, Mathers CH, Jones JA, Wear ML. Musculoskeletal injuries and minor trauma in space: incidence and injury mechanisms in U.S. astronauts. Aviat Space Environ Med. 2009;80(2):117-24. Epub 2009/02/10. doi: 10.3357/asem.2270.2009. PubMed PMID: 19198198.
11. Schussman L, Lutz L, Shaw R, Bohnn C. The epidemiology of mountaineering and rock climbing accidents. Journal of Wilderness Medicine. 1990;1(4):235-48.
12. Tiemstra JD. Update on Acute Ankle Sprains. Am Fam Physician. 2012;85(12):1170-6.
13. US Army Center for Health Promotion and Preventive Medicine APG, MD. Preventing Injuries in the U.S. Military: The Process, Priorities, and Epidemiologic Evidence. 2008.

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