Clinical Finding Form (CliFF)

Branch: Baseline

ICL1_Abdominal Wall Hernia

Defects or weak points in the abdominal wall lead to the development of abdominal hernias. Hernias are relatively common, as groin (inguinal and femoral) hernia prevalence is estimated to be 5-10% in the United States. The white male population is at the highest risk for both development of a hernia and need for repair. The most common hernia types are inguinal, umbilical, incisional, and femoral. However, umbilical hernias are most common in the very young and the elderly or in the obese population (Dabbas, 2011). As current astronauts are medically qualified and, therefore, outside of these affected populations, this CliFF will focus on the more likely etiologies of inguinal, incisional, and femoral hernias. The clinical spectrum of presentations and complications related to abdominal hernias is variable, ranging from uncomplicated identification of an asymptomatic hernia to incarceration and strangulation of bowel resulting in intestinal ischemia and even perforation (Fitzgibbons, Jr., 2006). Symptoms can range from the patient noticing a bulge in the groin region or at an old incisional site, with or without pain, to a severe and emergent presentation of acute bowel strangulation, with severe pain, signs of bowel obstruction, and even signs and symptoms of acute shock. Diagnosis can be made with ultrasound imaging, with indirect inguinal hernias identified with a 97% sensitivity and 87% specificity, and identification of femoral hernias with reported rates of 100% sensitivity and specificity (Bradley, 2003). Hernias are more common in males and can occur at any age, though femoral hernias are more common in women particularly over the age of 60 (Dabbas, 2011)(Naude, 1997). Elective surgical repair of hernias has become quite common, with surgical procedures ranging from open laparotomy and suture or mesh repair to laparoscopic and minimally invasive surgery (Anon., 2000). There are no documented episodes of inflight abdominal wall hernias. Therefore, terrestrial studies are used to estimate the incidence and outcomes of abdominal wall hernia during spaceflight.

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

Berry 1975 and Barratt 2019 analyze the incidence of various medical conditions and risks throughout candidate selection and spaceflight history. No hernia has occurred during the course of a mission. Several candidates and astronauts have been noted to have a medical history of hernia, which early in the selection process led to disqualification for missions and have since been corrected prior to flight with no reports of complications (Berry 1975). Subsequent review by Barratt 2019 identify 30 class IIb medical conditions present in astronauts, including hernias, but does not specify the number or status of hernia repair.

ANALOG LITERATURE

A terrestrial military population is used as an analog for astronauts in spaceflight.

TERRESTRIAL LITERATURE

Large population retrospective studies show a wide range of hernia incidence over time, based on comorbidities, age, sex, and health status. Ruhl 2007 does the best job of analyzing subgroups and accounting for these variables, reporting a 9.3% incidence in men aged 24-59, which is the closest in age to the astronaut cohort. Ruhl 2007 also notes a 7.3% incidence risk over 20 cumulative years in the 24-39 year old male demographic, which is likely the closest to astronauts on exploration missions. Stephenson 2012 cites a 27% male and 3% female cumulative lifetime risk of developing a hernia. Fitzgibbons Jr. 2015 reports an annual repair rate of 0.25% by age 18 and an incidence of repair in the US of 23/100,000.

OVERALL INCIDENCE SUMMARY

INCIDENCE

Males = mean 3.95E-3 and SD 1.911E-5. Females = mean 6.4E-4 and SD 1.774E-5.

INCIDENCE SUMMARY

The Bayesian posterior distributions for the sex-specific incidence rates given the analog evidence data under uninformative priors is Gamma(shape=42724.09, rate=10816225) for males with mean 3.95E-3 and SD 1.911E-5 and Gamma(shape=1301.526, rate=2033634) for females with mean 6.4E-4 and SD 1.774E-5. Evidence: Analog – Active U.S. Armed Forces – Stahlman 2020. Incidence of Inguinal Hernia and Repair Procedures and Rate of Subsequent Pain Diagnoses, Active Component Service Members, U.S. Armed Forces, 2010-2019. Sex-specific rates were reported: Males - 43580 cases with incidence rate 39.5 per 10kpy. This implies 11032911 person-years. IR: 39.5E-4 (95%CI: 39.13E-4, 39.87E-4). Females: 1318 cases with incidence rate 6.4 per 10kpy. This implies 2059375 person-years. IR: 6.4E-4 (95%CI: 6.062E-4, 6.753E-4)

TABLE 1. INCIDENCE MODEL

Incidence Details

Incidence Type
General
Segment
All
Env. Exposure
NA

Sex
Male
Crowns
Any
Contacts
Any

Pregnancy
Any

Incidence Distribution

Occurrence Dist
Poisson
Incidence Dist.
Gamma
Mean
0.00395
SD
1.911E-05

Gamma
(Shape): 42724.1
(Rate): 1.08162E+07

Incidence Details

Incidence Type
General
Segment
All
Env. Exposure
NA

Sex
Female
Crowns
Any
Contacts
Any

Pregnancy
Any

Incidence Distribution

Occurrence Dist
Poisson
Incidence Dist.
Gamma
Mean

0.00064
SD
1.774E-05

Gamma
(Shape): 1301.53
(Rate): 2.03363E+06

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Shauna, et al. 2020	Military Analog	3

LOC = 3 (somewhat confident). Based on the incidence rates of inguinal hernia, active component, U.S. Armed Forces, 2010–2019.

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 preflight preventive measures.

BEST CASE SCENARIO DEFINITION

Asymptomatic or mildly symptomatic hernia not requiring surgery.

WORSE CASE SCENARIO DEFINITION

Hernia requiring either non-emergent surgery or emergent surgery due to complications.

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

None

BEST CASE/WORST CASE PROBABILITY COMMENTS

Best case/worst case percentages = 96%-98%/2%-4% based on the percentage of abdominal wall hernias requiring surgical treatment. References: (Fitzgibbons, Jr., 2015) and (Primatesta, 1996).

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

Citation	Source	LOC Value
Primatesta, 1996	Terrestrial population	3
Fitzgibbons Jr., 2015	Terrestrial	2

Primatesta 1996: 9% of all hernia admissions considered an emergency, though that reduces to 3.6% when excluding ages <1 and >65. Elective repairs are reportedly performed primarily for pain and occur at higher frequency in older patients. Emergency surgery is noted to be associated with a higher risk of mortality, though the authors note hernia itself is only attributed to 17% of the deaths following repair. Ruhl 2007: No breakdown of best case and worst case, simply incidence and risk factors. Stephenson 2012: 2,000 operations/million population annually. It is not specified what percentage are emergent vs. elective. LeBlanc 2013: Level C evidence (usual practice guidelines) to determine when to recommend surgical repair. No analysis of best case vs. worst case or incidence of emergent vs. elective repair. Fitzgibbons Jr. 2015: 35-40% of femoral hernias present as with worst case findings requiring emergent surgical repair. Femoral hernias account for <5% of all groin hernias (2% groin hernias presenting emergently). Watchful waiting did not convert any patients to emergent surgical repair with only 3/880 patients developing acute symptoms. Surgical correction occurs at 10/100,00 in the UK and 28/100,000 in the US, though this includes elective and emergent indications. This paper provides good incidence for best and worst case in femoral hernias, but does not clearly delineate inguinal hernias.

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)	Males = mean 3.95E-3 and SD 1.911E-5. Females = mean 6.4E-4 and SD 1.774E-5.	96 - 98	100	0.583	2.80361	0.5	24	0	0	0	0	0
Treated Worst Case (TWC)		2 - 4	100	1.416	50	120	1092	0	25	25	0.02	7
Untreated Best Case (UTBC)	N/A	N/A	N/A	0.583	21.047	0.5	24	21.047	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	1.416	100	120	1092	100	25	25	0.02	7

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 definition of best case scenario is as follows: asymptomatic or mildly symptomatic hernia not requiring surgery. The definition of worst case scenario is as follows: hernia requiring either non-emergent surgery or emergent surgery due to complications. These definitions work quite well in stratifying the data, especially as hernia treatment is often a watchful waiting approach until symptoms develop or a complication arises. I made no use of the surrogate searches due to the abundance of literature involving hernia surgery, complications, and outcomes. In addition, the Clinical Science Team defined the best case scenario RTDC as 0, which makes sense as there would be no need to emergently cancel a mission for a non-symptomatic uncomplicated hernia. Treatment, given the relative incidence of best case vs. worst case (~97% vs. ~3%) will most often be a watchful waiting approach. For any emergent or acute indications requiring surgical repair, the procedure is extremely well documented with clinical outcomes and can be managed surgically from multiple approaches, depending on resource availability.

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Given the definition of best case scenario of asymptomatic or mildly symptomatic hernia not requiring surgery, and the only definitive treatment for abdominal wall hernia being surgical repair, there is no criteria for best case treated incidence. By definition, best case scenarios preclude the need for treatment and would simply be left alone. If they were to develop symptoms or criteria that would warrant treatment, the patient would cross over from best case to worst case. Therefore, by definition, best case scenarios necessitate no loss of crew life and no need for return to definitive care. Duration of treatment was defined as watchful waiting and use of a truss/binder in asymptomatic/mildly symptomatic abdominal wall hernias after discussion with the clinical science team. Although these are not definitive treatments for hernias, they do provide temporizing or management efforts in dealing with a hernia. Duration for placement of a truss or binder was defined as how long it would take to place rather than the length of the mission.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

Worst case scenario requires surgical treatment. RTDC = 25% based on 25% of cases requiring emergent surgery. LOCL = 0.02% - 7% based on mortality rates for elective hernia repairs and emergent hernia repairs, respectively.

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

As the best case scenario definition includes abdominal wall hernias only that have no symptoms or mild symptoms and that do not require intervention, by defintion, all best case scenarios are untreated. As such, these categories are left blank as there is no consideration to make. Should an asymptomatic or mildly symptomatic abdominal wall hernia develop acute symptoms or otherwise require intervention, then the scenario enters the worst case categories and will be defined by such risks and incidences. Watchful waiting and application of trusses were considered in the best case treated category as these mark management strategies to temporize symptoms.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

Worst case scenario requires surgical treatment. RTDC = 25% based on 25% of cases requiring emergent surgery. LOCL = 0.02% - 7% based on mortality rates for elective hernia repairs and emergent hernia repairs, respectively.

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

Citation	Source	LOC Value
Bansal, 2013	Terrestrial	
Burns, 1990	Terrestrial	
Canonico, 2013	Terrestrial	
de Goede, 2018	Terrestrial	
Fitzgibbons Jr., 2006	Terrestrial	

Citation	Source	LOC Value
HerniaSurge, 2018	Terrestrial	1
Jones, 2001	Terrestrial	
Koning, 2012	Terrestrial	
McIntosh, 2000	Terrestrial	
O'Dwyer, 2006	Terrestrial	

After discussion, it was decided that the duration of treatment for best case scenarios would analyze the effectiveness of watchful waiting and the use of trusses/abdominal binders in mitigating symptoms. These criteria would allow an astronaut on a long term mission to manage mild symptoms until mission completion. Further, the duration of treatment for a truss or abdominal binder is estimated to take 10 - 30 minutes, accounting for time to retrieve the equipment from storage, undress, apply the equipment, and result. Watchful waiting is estimated as 24 hours. LOC for CP2 durations = 1 (somewhat unconfident) since there is a large degree of uncertainty regarding these durations.

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Bay-Nielsen, 2001	Terrestrial	3
Chung, 2011	Terrestrial	
Fitzgibbons Jr., 2006	Terrestrial	
HerniaSurge, 2018	Terrestrial	
Leubner, 2007	Terrestrial	
Naude, 1997	Terrestrial	
O'Dwyer, 2006	Terrestrial	

The Clinical Science Team defined best case RTDC as 0 by definition. Fitzgibbons Jr. 2006 is a pivotal study cited by nearly all subsequent studies due to the power of its results. HerniaSurge 2018 is the most comprehensive meta-analysis of hernia studies. Based on the discrepancy between elective and emergent surgical repairs and the underlying pathologies, I separated the results based on type of repair. All of the included studies had consistent data about the prevalence of emergent indications for surgery and repair with overall low levels of incidence. Unfortunately, some of the studies (Bay-Nielsen 2001, Fitzgibbons Jr. 2006, O'Dwyer 2006) remark upon the difference in age groups as to complications and rates of emergencies, but do not stratify the data based on age. Therefore, the results are likely higher than what would be seen in the select astronaut population while being accurate for a general population. Due to limited data regarding untreated symptomatic abdominal wall hernias, the same CP2 durations are used for the treated and untreated scenarios.

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Bay-Nielsen, 2001	Terrestrial	2
Chung, 2011	Terrestrial	
Fitzgibbons Jr, 2006	Terrestrial	
HerniaSurge, 2018	Terrestrial	
Martinez-Serrano, 2010	Terrestrial	
Naude, 1997	Terrestrial	
Scott, 2002	Terrestrial	
Simons 2009	Terrestrial	
Stabilini, 2020	Terrestrial	
Beadles, 2015	Terrestrial	

The studies are widely consistent across populations regarding the mortality rate related to abdominal wall hernias. Bay-Nielsen 2001 has a higher

incidence at 7% than other studies, though this agrees with the higher death rate associated with emergency surgery for acute symptoms. However, the meta-analyses (HerniaSurge 2018, Simons 2009, and Stabilini 2020) that guide national surgical treatment guidelines do not provide for leaving symptomatic hernias untreated. In addition, by definition of best case scenario developed by the Clinical Science Team, there can be no loss of crew life in the treated or untreated best case situations. Therefore, the only real data comes from the treated worst case scenario. Given this limited applicability of data, I downgraded the evidence, especially with no data for the mortality surrounding untreated symptomatic/emergent hernias, which would be the most valuable to know in case a crew member developed this on an exploration mission.

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Capabilities and Resourcing Scope Overview Abdominal hernias may be classified as groin hernias (femoral or inguinal) and ventral hernias (umbilical, epigastric, Spigelian, lumbar, and incisional). The most common complications of abdominal wall hernias are bowel obstruction secondary to the hernia, incarceration (irreducible sac), and strangulation (compromised blood supply; Neblett 1988). Bowel obstruction is covered by ICL-90. Incarceration and strangulation remain a significant challenge as they are sometimes difficult to diagnose by physical examination and require urgent surgical intervention. Early surgical intervention of a strangulated hernia with obstruction is crucial as delayed diagnosis can result in the need for bowel resection with prolonged recovery and increased complication rate. Further, strangulated hernias can also lead to bacterial translocation, intestinal wall necrosis, and bowel perforation. Less severe complications include herniation of intraabdominal organs including solid (ex. liver, kidneys) and nonsolid (ex. stomach, bladder) organs. CNES: None Diagnostic Scope and Resourcing In the best-case scenario, diagnosis is based on history, physical examination (namely abdominal). Imaging is likely not needed. In the worst-case scenario, diagnosis is also largely based on history and physical examination (vital signs and abdominal exam). Serum labs like a lactate (De Simone 2020) and abdominal ultrasound imaging (Rettenbacher 2001) can help with diagnosing worst-case complications such as strangulation and incarcerated hernia. Other labs like a CPK, D-dimer, or advanced imaging like a computed tomography are unlikely to be available and thus are not scoped for this condition. 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): 0.583 hours CP1 WC (Treated or Untreated): 1.416 hours The highest diagnostic scope of practice is 4 (experienced procedural-trained generalist attending). Treatment Scope and Resourcing Terrestrially, most hernias require surgery to prevent complications from arising. The best-case scenario involves either asymptomatic or mildly symptomatic abdominal wall hernias that do not require surgery. Thus, management may include symptom management with non-narcotic pain medications, antiemetics, and manual reduction of the hernia. A cold compress can be used to reduce swelling prior to the reduction. Abdominal mechanical support such as a truss, an abdominal binder, or tying other clothing tight around the area may also assist with symptom control and prevention of escalation to the worst case. The worst-case scenario involves abdominal wall hernias that are surgical or leading to complications such as bowel obstruction, incarceration, or strangulation. However, all complicated hernias are surgical by definition. Bowel obstruction management is considered in ICL-90, however, is managed with bowel rest and symptom control. Unfortunately, surgery will not be an option during spaceflight for these complications, and thus the management remains similar to the best-case scenario: pain control, anti-emetics, and manual reduction of the hernia. In worst-case scenarios, narcotic pain medications, IV hydration, and possibly sedation during the attempted manual reduction may be additional capabilities. Communications and Support Needs For the WC, consultation with ground specialists to facilitate treatment and healing was considered necessary given the limited diagnostic and treatment capabilities in-flight. Pictures or video are unlikely necessary. REFERENCES Neblett WW 3rd, Pietsch JB, Holcomb GW Jr. Acute abdominal conditions in children and adolescents. Surg Clin North Am1988; 68: 415–430. De Simone B, et al. Emergency repair of complicated abdominal wall hernias: WSES guidelines. Hernia 2020 Apr;24(2):359-368. Rettenbacher T. Abdominal wall hernias: cross-sectional imaging signs of incarceration determined with sonography. AJR Am J Roentgenol. 2001 Nov;177(5):1061-6.

IMM CLIFF RECONCILATION COMMENTS

There is an IMM CliFF for this condition (Abdominal Wall Hernia). However, the data from this CliFF has been updated in an attempt to provide more current and relevant input data. For example, the IMM CliFF incidence rate is based only on data for hospital discharges which probably results in an underestimation of the true incidence of all abdominal wall hernias. The updated estimated incidence rate is based on a military analog population and uses all incident cases of abdominal wall hernia. An incident case of inguinal hernia was defined as having an inguinal hernia diagnosis in any diagnostic position of an inpatient or outpatient encounter.

LIMITATIONS SUMMARY

No cases of abdominal wall hernias have occurred in-flight. Terrestrial outcomes for abdominal wall hernias are difficult to apply to the spaceflight environment since surgical treatment is unlikely to be an available treatment option in spaceflight. It is uncertain if abdominal wall hernias would present differently or have different outcomes in microgravity and partial gravity environments than terrestrially.

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)							145					
Treated Worst Case (TWC)	223	664	113	89	854	44	145	5	13	6		
Untreated Worst Case (UTWC)	223	664	113	89	854	44	145	5	13	6		
	Affected HSTCs (Continued)								TI Calculation			TI Score
	Hand (Dom)	Hand (Any)	Upper Extremity	Lower Extremity	Ambul & Standing (g)	Translation & Stabilization (microgravity)	Don/Doff Equipment	Pressure Ops	Total Tasks Impaired By Condition	Total Human System Category Tasks Full Mission	TI Decimal	TI %
Treated Best Case (TBC)								211	211	3763	0.0560723	5.60723
Untreated Best Case (UTBC)			414	22				211	792	3763	0.21047	21.047
Treated Worst Case (TWC)	132	564	414	22	196	34	34	211	3763	3763	1	100
Untreated Worst Case (UTWC)	132	564	414	22	196	34	34	211	3763	3763	1	100

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)							145					
Treated Worst Case (TWC)												
Untreated Worst Case (UTWC)	223	664	113	89	854	44	145	5	13	6		
	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)			414	22				211	792	3763	0.21047	21.047
Treated Worst Case (TWC)									0	3763	0	0
Untreated Worst Case (UTWC)	132	564	414	22	196	34	34	211	3763	3763	1	100

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
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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