Clinical Finding Form (CliFF)

Branch Baseline

ICL52_Fracture - Cervical Spine

There is no IMM Cervical Spine Fracture CliFF. No cervical spine fractures have occurred in spaceflight. Ideally, the likelihood and outcomes for this condition would be determined based on a biomechanical mathematical model. This was done for several fracture conditions in IMM. However, since there is no biomechanical mathematical model for cervical spine fracture, terrestrial data must be used. This is not a very good analog population for this condition and will likely result in an overestimation of the incidence and associated outcomes for cervical spine fracture. For best case/worst case percentages, 24% of cervical spine fractures required surgery in 2017. (Ponkilainen, 2020).

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

No cervical spine fractures have occurred during spaceflight.

ANALOG LITERATURE

This study focuses on young divers with cervical injuries and the probability of a cervical fracture in divers with cervical injuries. Mean age was 26 years old (Chan-Seng et al., 2013). The other article cites the incidence of cervical fractures in the US Military from years 2000-2009 and a total of 13,813,333 US Military service personnel (Schoenfeld et al., 2012).

TERRESTRIAL LITERATURE

The terrestrial articles highlights incidence of cervical fractures among adults ages 18-49 in a region of Minnesota over three years (Farr et al., 2017).

OVERALL INCIDENCE SUMMARY

INCIDENCE

mean 1.71E-7 and SD 4.345E-9

INCIDENCE SUMMARY

Relevant reference is Ponkilainen 2019 –Incidence of Spine Fracture Hospitalization and Surgery in Finland in 1998-2017. IR for hospitalization 17.1 per 100kpy and IR for surgery 4.1 per 100kpy in 2017. The population of Finland over age 20 in 2017 was estimated from: https://www.statista.com/statistics/521152/population-of-finland-by-age/ There were 4326651 persons. If we considered that the total number of person-years, the expected case counts is 740. IR 1.71E-4 (95%CI: 1.59E-4, 1.84E-4). The Bayesian posterior distribution for the probability of having an event during a 6-hour surface-ops EVA is Beta(shape1=725.4, shape2=6200206112) with mean 1.17E-7 and SD 4.344E-9 given the terrestrial reference data under an uninformative prior.

TABLE 1. INCIDENCE MODEL

Incidence Details

Incidence Type
EVA
Segment
EVA Surface
Env. Exposure
NA

Sex
Any
Crowns
Any
Contacts
Any

Pregnancy
Any

Incidence Distribution

Occurrence Dist
Binomial
Incidence Dist.
Beta
Mean
1.16996E-07
SD
4.34393E-09

Beta
(Alpha): 725.4
(Beta): 6.20021E+09

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Farr, Joshua N. et al., 2017	Terrestrial	1
Ponkilainen, V. et al., 2020	Terrestrial	1
Schoenfeld, A. et al., 2012	Terrestrial	1
Chan-Seng, E. et al., 2013	Terrestrial	1

All terrestrial data related to incidence is LOC 1 (somewhat unconfident).

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

No preflight preventive medical measures regarding cervical spine fractures. Preventive measures based on vehicle and equipment design, and safety training.

BEST CASE SCENARIO DEFINITION

A non-displaced fracture with no dislocation, and mild to moderate pain that responds to analgesics and conservative treatment.

WORSE CASE SCENARIO DEFINITION

A displaced fracture or dislocation resulting in spinal instability, severe pain, or requiring surgery. (Spinal cord injury covered by "spinal cord injury.")

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

None

BEST CASE/WORST CASE PROBABILITY COMMENTS

Best case based on (Ponkilainen, 2020). Worst case - 24% of cervical spine fractures required surgery in 2017. (Ponkilainen, 2020).

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

Citation	Source	LOC Value
Ponkilainen, V. et al., 2020	Terrestrial	1

Large epidemiologic cohorts available; however, the populations do not represent the Astronaut Corps. Generally easy to separate date between those younger or older than 50. Low risk of bias and fair consistency.

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 1.17E-7 SD 4.344E-9	76 - 76	100	1.5	13.8719	1544	2016	0	0	0	0	0
Treated Worst Case (TWC)		24 - 24	100	2	57.5073	2016	2016	24.8738	100	100	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	1.5	33.8825	1544	2016	0	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	2	72.4953	2016	2016	72.4953	100	100	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

Excellent, accessible data from the European spine registries as well as non-surgical outcomes, which may be used as a surrogate for UT. Bias towards high cervical fractures (C1/C2). Much incidence risk is likely overstated in the microgravity environment, where high mass risks are engineered out. More unpredictable for launch/landing and surface ops. T&O outcomes are more translatable.

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Searches needed to go beyond Dynamed for duration and RTDC. Nevertheless, excellent data from the neurosurgical literature was obtained: Cochrane review for duration; Cooper et al and Passias et al for RTDC; and Fredo for LOCL.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

Excellent data from the Neurosurgical literature on the three parameters. Some confounding with comorbidities and other injuries; the Norwegian National Registry provides excellent data for RTDC.

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

Decent reporting of non-operative management from spine registries, particularly from the European health systems. Some bias here on the anatomy (C1 & C2) which confounds dta on other trauma to lower cervical.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

Untreated cases of significant cervical neck fracture is uncommon, for purposes of this CLiFF, the primary focus will be on delay of care vs timely treatment, and minimal treatment/ extremely conservative treatment.

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

Citation	Source	LOC Value
Shears E, et al. 2008	Terrestrial	3
Croce, et al. 2001	Terrestrial	
Fiedler, et al. 2020	Terrestrial	
Kim, et al. 2019	Terrestrial	

Wide degree in variability for cervical fractures, mainly dependent on whether the fracture is "stable" or "unstable." Even recent Cochrane Review was unable to identify studies comparing surgery versus conservative management of specific cervical spine injury (odontoid). Not representative of Astronaut Corps and overall difficult to apply data to expectations and management in long-duration spaceflight

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Cooper, et al. 1979	Terrestrial	
Passias, et al. 2018	Terrestrial	
Fredo, et al. 2014	Terrestrial	

Citation	Source	LOC Value
Dvorak, et al. 2010	Terrestrial	4
Butler, et al. 2010	Terrestrial	
Koivikko, et al. 2004	Terrestrial	
Wang, et al. 2018	Terrestrial	

There is a wide variability in the patient populations, the hospital systems they were treated in, and the specific subsets of cervical injuries. Ultimately, there is a consistent and significant risk that a cervical fracture will result in RTDC for our astronauts.

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Fredo, et al. 2014	Terrestrial	0
Fiedler, et al. 2020	Terrestrial	
Pull ter Gunne, et al. 2010	Terrestrial	
Koivikko, et al. 2004	Terrestrial	
Pull ter Gunne, et al. 2010	Terrestrial	

Primary issues related to treatment in different healthcare systems and with populations not analogous to astronauts. Data somewhat consistent with mortality expected between 2-18%, but this really hinges on the sub-type of cervical spine fracture.

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Capabilities and Resourcing Scope

Overview

Cervical spine fracture encompasses any spinal fracture in the cervical region, with the best-case scenario representing uncomplicated fractures and the worst-case scenario representing complicated fractures. Note that this CRT was not scoped for open spinal fractures. Any fracture, if left untreated, could result in further complications such as malunion, loss-of function, and/or chronic pain. A worst-case scenario, left untreated, could result in additional significant complications. Note that spinal cord injury is a separate condition, and resources for this are not covered in this CRT.

CNES: N/A

Diagnostic Scope and Resourcing

In both best and worst-case scenarios, diagnosis is based on history, physical examination (musculoskeletal, neurologic, and vital signs), and imaging. Plain film (X-Ray), CT, and MRI will be unavailable inflight. Musculoskeletal ultrasound was included in the CRT as it may serve as a useful adjunct in diagnosis for some cases, but it was not considered a necessary capability to diagnose a cervical spine fracture. This diagnostic framework is consistent with the terrestrial workup for cervical spine fracture 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. Note that nerve blocks are not included in the scope of this CRT.

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): 1.5 hours
CP1 WC (Treated or Untreated: 2 hours

This CRT includes a scope of practice code of 5 (which correlates to an “Experienced procedure trained generalist attending (ED attending)” and was included for musculoskeletal ultrasound and interpretation.

Treatment Scope and Resourcing

Terrestrially, best-case cervical spine fractures are managed with immobilization, followed by physical therapy. Soft and rigid cervical spine bracing was included in this CRT. Worst-case scenario fractures would require orthopedic surgery, which is not a capability included in this CRT. Therefore, they would be splinted in the same fashion as cervical spine fractures. Although 3D printing offers potential for splinting of musculoskeletal injuries, it remains a largely experimental process and it is not within the scope of this CRT. Note, treatment for open spinal fractures is outside the scope of this CRT. Physical therapy is included post-immobilization. Exercise modification is also recommended, but not built into the CRT as this does not represent a clinical resource. Pain is variable. NSAIDs and acetaminophen were included in the best-case treatment scenario, narcotics were additionally included in the worst-case scenario.

Communications and Support Needs

While real-time video and audio loop communications are desired for diagnosis and treatment, they were not considered a necessity in the best-case scenario. For the worst-case scenario, consultation with ground specialists to facilitate treatment and healing was considered necessary given the limited diagnostic and treatment capabilities in-flight.

IMM CLIFF RECONCILATION COMMENTS

NO IMM CLIFF FOR THIS CONDITION

LIMITATIONS SUMMARY

There is limited data to inform untreated scenarios. Non-operative treatment is not the same as untreated. The incidence from the most relevant terrestrial article was applied to surface EVA only. This will most likely be an overestimate given the lower gravitational field during lunar and Martian EVA's and absence of major terrestrial risk factors for cervical spine fractures. Because of the large sample size, the study used to compute the composite incidence most likely overestimates the confidence we have in the assigned value. Ideally, the likelihood and outcomes for this condition would be based on a biomechanical mathematical model. This was done for several fracture conditions in IMM as well as for IMPACT. However, since there is no biomechanical mathematical model for cervical spine fracture, terrestrial data must be used. This CLIFF will need to be updated for IMPACT 2.0 when non-EVA surface operations are considered.

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)							145					
Untreated Best Case (UTBC)		664		89			145					
Treated Worst Case (TWC)		664					145					
Untreated Worst Case (UTWC)	223	664		89			145					
	Affected HSTCs (Continued)								TI Calculation			TI Score
	Hand (Dom)	Hand (Any)	Upper Extremity	Lower Extremity	Ambul & Standing (g)	Translation & Stabilization (microgravity)	Don/Doff Equipment	Pressure Ops	Total Tasks Impaired By Condition	Total Human System Category Tasks Full Mission	TI Decimal	TI %
Treated Best Case (TBC)	132						34	211	522	3763	0.138719	13.8719
Untreated Best Case (UTBC)	132						34	211	1275	3763	0.338825	33.8825
Treated Worst Case (TWC)	132	564	414				34	211	2164	3763	0.575073	57.5073
Untreated Worst Case (UTWC)	132	564	414	22	196	34	34	211	2728	3763	0.724953	72.4953

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)							145					
Untreated Worst Case (UTWC)	223	664		89			145					
	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)	132		414				34	211	936	3763	0.248738	24.8738
Untreated Worst Case (UTWC)	132	564	414	22	196	34	34	211	2728	3763	0.724953	72.4953

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

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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