Clinical Finding Form (CliFF)

Branch: Baseline

ICL82_Respiratory Tract Infection - Upper

Respiratory tract infections in this CLIFF include the common cold and rhinitis (viral and bacterial). Upper respiratory tract infection (URI) represents the most common acute illness evaluated in the outpatient setting. The common cold is typically a mild, self-limited, catarrhal syndrome of the nasopharynx. URIs involve direct invasion of the mucosal lining the upper airway. Person-to-person spread of viruses accounts for most URIs. (Meneghetti, 2011). Respiratory infections have been reported in space in spite of efforts to mitigate this risk with a 7 day pre-launch quarantine. The diagnosis can be challenging since similar symptoms have been attributed to a cephalad fluid shift and the dry spacecraft cabin atmosphere. Susceptibility to infection is increased due to an impaired immune response seen in astronauts during space missions. (Marshburn, 2008)

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

Crucian et al. reports 1.0 events/flight year of "prolonged congestion, rhinitis, sneezing" and 0.1 events/flight year of pharyngitis, on board the ISS. Wotring et al. discusses medication use on the ISS and reports 43 cases of medication taken for congestion or allergy, over 10 years.

ANALOG LITERATURE

Thomas et al. reports ICD-9 data from isolated US Navy submarine crews, sorted by age and rank. The group of officers over age 30, the closest analog to astronauts, had 8.8 upper respiratory infections/100 person-years, and less specifically 9.2 "respiratory system disorders" per 100 person-years. Cameron et al reported in 1968 about a crew of Australian researchers to Antarctica; 13 out of 27 initially developed URIs but they did not have another URI for 1 year in isolation. Both of these studies are relevant analogs because the population studied is healthy working-age males under conditions of group isolation.

TERRESTRIAL LITERATURE

Simasek et al reports that the average American has 2-4 upper respiratory infections per year. There is not further discussion about the demographic breakdown of this data.

OVERALL INCIDENCE SUMMARY

INCIDENCE

mean: 2.126 SD: 0.2642

INCIDENCE SUMMARY

Incidence Distribution - Gamma(shape=64.75, rate=30.46) mean: 2.126 SD: 0.2642

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
2.126

SD
0.2642

Gamma
(Shape): 64.75
(Rate): 30.46

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Simasek, 2007	Terrestrial	2
Pleis, 2010	Terrestrial	2
Crucian B, 2016	Spaceflight	4
Wotring, 2015	Spaceflight	4
Thomas, 2003	Analog	2
Cameron, 1968	Analog	2

Studies are overall not representative of the Astronaut Corps. These studies are potentially biased due to lack of either methodology or due to recall bias; however, the data is consistent with other studies regarding URIs in adults. Incidence is generally dependent on surveys.

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

Pre-flight quarantine program was established to limit viral or bacterial infections to crew members; however, breaches are possible. Pulmonary problems unique to space flight include exposure to exotic atmospheric and environmental contaminants which may cause irritation of the upper airways. (Marshburn, 2008

BEST CASE SCENARIO DEFINITION

Uncomplicated viral or allergic rhinosinusitis, non-strep pharyngitis, or the common cold that are treated successfully with first line treatment.

WORSE CASE SCENARIO DEFINITION

Bacterial rhinosinusitis requiring antibiotics.

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

Respiratory Tract Infection (Upper) - Rhinitis, Acute Respiratory Tract Infection (Upper) - Sinusitis, Acute Respiratory Tract Infection (Upper) - Pharyngitis, Non-strep

BEST CASE/WORST CASE PROBABILITY COMMENTS

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

Citation	Source	LOC Value
Simasek, 2007	Terrestrial	2
Pleis, 2010.	Terrestrial	2
Crucian B, 2016	Spaceflight	4
Wotring, 2015	Spaceflight	4
Thomas, 2003	Analog	2
Cameron, 1968	Analog	2

Studies are overall not representative of the Astronaut Corps. These studies are potentially biased due to lack of either methodology or due to recall bias; however, the data is consistent with other studies regarding URIs in adults. Incidence is generally dependent on surveys

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: 2.126 SD: 0.2642	98 - 98	100	0.5	2.80361	24	504	0	0	0	0	0
Treated Worst Case (TWC)		2 - 2	100	0.5	13.3803	168	360	0	0	0	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	0.5	14.5628	24	504	0	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	0.5	17.4329	153.6	408	5.60723	0.067	0.1192	1.25	75

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

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Best case is URI without bacterial infection requiring antibiotics; treatments are supportive/symptomatic and do not impact duration of illness.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

TWC = bacterial sinusitis treated with antibiotics

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

Since there is no definitive treatment for viral URI, this scenario is the same as TBC

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

Bacterial rhinosinusitis requiring antibiotics which is not treated

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

Citation	Source	LOC Value
Heikkinen, 2003	Terrestrial	3
Harris, 2016	Terrestrial	
Rosenfeld, 2015	Terrestrial	
Lindbaek, 1996	Terrestrial	
Varonen H, 2003	Terrestrial	

Harris, Lindebaek, and Rosenfeld appropriately address a population that is similar to crew (adults only) while focusing on treatment. Heikkinen was offering a somewhat dated and broader scope of the treatment of the common cold which is too broad for our purposes to get a higher level of confidence than given. Varonen's focus is on the efficacy of ultrasound as a diagnostic modality and has some passing use for antibiotic efficacy, thus the current confidence it use.

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Heikkinen, 2003	Terrestrial	3
Fokkens WJ, 2012	Terrestrial	
Hansen, 2012	Terrestrial	
Petersen, 2007	Terrestrial	

Fokkens not particularly helpful because these patients have polyps and are refractory to treatment. This population is unlike crew who would have been screened for this. Hansen helps to address some of the worst case scenarios (treated and untreated) statistically and is therefore somewhat gives us confidence in the data provided. Petersen is a good broad paper on the state of stewardship and treatment complications, but does not address our patient population or our concerns well.

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Heikkinen, 2003	Terrestrial	3
Hansen, 2012	Terrestrial	
Williams, 1937	Terrestrial	
Richards, 1931	Terrestrial	

Williams is a decent attempt to capture the UTWC data. Richards does not address the appropriate population

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Capabilities and Resourcing Scope Overview Worst Case Definition: Bacterial rhinosinusitis requiring antibiotics. Best Case Definition: Uncomplicated viral or allergic rhinosinusitis, non-strep pharyngitis, or the common cold that are treated successfully with first line treatment. Essentially this is an upper respiratory infection that either does or does not require antibiotics to resolve within weeks. Terrestrially, the cutoff is considered roughly 7 days before potential "conversion" to a bacterial infection that will necessitate antibiotic therapy. Diagnostic Scope and Resourcing In the best-case scenario, diagnosis is based on history and physical examination. In the worst-case scenario, diagnosis is based on history and physical examination. Clinical Phase 1 Duration and Rationale This version of IMPACT presumes physician level knowledge, skill, and ability will be present on the mission. The CRT working group SME consensus duration is as follows: CP1 BC (Treated or Untreated): 0.5 hours 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 physical on the patient CP1 WC (Treated or Untreated): 0.5 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 physical on the patient The highest scope of practice code used in this CRT which includes interpretation of diagnosis, performing diagnostic tests and performing treatment would be a three, or nursing level. Treatment Scope and Resourcing In the best-case scenario, treatment is limited to management of the symptoms which includes mild pain medications and decongestant therapy. The worst case scenario, where conservative management fails, antibiotics are added to resolve the bacterial infection. Terrestrially, even most bacterial causes of upper respiratory infections resolve eventually. Communications and Support Needs In the best-case and worst-case scenario, diagnosis and course of treatment is uncomplicated and likely within the scope of care of onboard crew members.

IMM CLIFF RECONCILATION COMMENTS

The conditions across IMM and IMPACT are not very similar. The distinction drawn in IMM was between Respiratory infections and Sinusitis while the distinction in IMPACT was between upper and lower respiratory tract infections. It was therefore, a little difficult to fully reconcile the two systems. However, data for the current delineation (upper vs lower infection) is more easily found in the literature and is more important clinically to make. Therefore, data gathering was easier. The data comparison however with IMM was reasonable and a good correlation between the conditional definitions could be made regardless of this distinction difference.

LIMITATIONS SUMMARY

The UTWC data is extremely sparse but that may be expected as treatment is generally readily available and the course of untreated disease is usually self-limited anyway. Analog and Terrestrial data is somewhat not helpful in this study because the spaceflight environment or patient populations are so different than studies available. On-orbit data may have an under-reporting bias as this condition is generally mild and self-limited, so crew may not be motivated to report the condition.

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		89								
Treated Worst Case (TWC)		664										
Untreated Worst Case (UTWC)		664		89				5				

	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)	132							211	1096	3763	0.291257	29.1257
Treated Worst Case (TWC)	132							211	1007	3763	0.267606	26.7606
Untreated Worst Case (UTWC)	132							211	1101	3763	0.292586	29.2586

Clinical Phase 3: Condition End State

	Affected HSTCs											
	Cognitive - Simple	Cognitive - Complex	Communications	Inter-personal Skills	Vision	Hearing	Cardio-pulmonary	Dentition	GI	GU		
Treated Best Case (TBC)												
Untreated Best Case (UTBC)												
Treated Worst Case (TWC)												
Untreated Worst Case (UTWC)												

	Affected HSTCs (Continued)								TI Calculation			TI Score
	Hand (Dom)	Hand (Any)	Upper Extremity	Lower Extremity	Ambul & Standing (g)	Translation & Stabilization (microgravity)	Don/Doff Equipment	Pressure Ops	Total Tasks Impaired By Condition	Total Human System Category Tasks Full Mission	TI Decimal	TI %

	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)									0	3763	0	0
Untreated Worst Case (UTWC)								211	211	3763	0.0560723	5.60723

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: Interpersonal skills were considered to be impaired due to the risk of crewmembers spreading infection in close contact in untreated scenarios (i.e. they likely would be self-isolating to try to prevent infecting the rest of the crew). In the worst case, untreated scenario dentition was impaired due to assumed maxillary pain from the infection. URI was considered an aeromedical contraindication to EVA. CP3: In a worst case, untreated scenario, chronic sinusitis would present a continued aeromedical contraindication to EVA.

EVIDENCE COLLECTION PROCESS

Mesh terms that most closely resembled the best-case and worst-case scenarios, and associated Conditions Included but Not Explicitly Stated (CNES), were utilized to build incidence, duration, RTDC, and LOCL searches by best- and worst-case.

Incidence:
Databases searched for spaceflight and analog incidence data included: PubMed, Google Scholar, NASA Technical Reports Server (NTRS) public search, Defense Technical Information Center (DTIC), and Barratt MR, Baker E, Pool SL. Principles of Clinical Medicine for Space Flight. New York, NY: Springer; 2019. 2nd Edition. Databases searched for terrestrial incidence included: DynaMed, PubMed, and Google Scholar.

Duration, RTDC, LOCL:
Databases searched for duration, RTDC, and LOCL included: Dynamed, Cochrane, PubMed, and Google Scholar. Note, that if duration, RTDC, or LOCL data was found in a DynaMed search, the other search engines were not included. Relevant articles were selected and reviewed. If applicable, the article was included in the CLiFF.

LEVEL OF CONFIDENCE (LOC) SCORING

Articles obtained to update the evidence behind this CLiFF were scored by ExMC editors, based on their applicability to the Exploration Spaceflight environment using the following grading scale:

4 – Confident
3 – Somewhat confident
2 – Neutral
1 – Somewhat unconfident
0 – Not confident

The following considerations factor into the grading scale above:

• How closely does the paper describe the medical condition as defined by the IMPACT 1.0 Condiltion List (relevance)?
• How closely does the population included resemble the astronaut population?
• Quality of the paper (number of subjects, methods, etc.)
• How much does the editor trust the source of the evidence?
• How closely does the editor think that the data represents the exploration spaceflight environment?
• Other considerations, at the discretion of the editor, supported in the comments for LOE scoring.

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ACRONYMS

ACRONYM	PHRASE
AAOMS	American Association of Oral and Maxillofacial Surgeons
AMA	American Medical Association
ARCL	All Remaining Conditions List
ARS	Acute Radiation Sickness
BHP	Behavioral Health and Performance
CAC	Coronary Artery Calcium
CHS	Crew Health and Safety
CL	Condition List
CliFF	Clinical Finding Form
CMO	Crew Medical Officer
COMFORT	Clinical Outcome Metrics for Optimization of Robust Training
CP1	Clinical Phase 1

CP2	Clinical Phase 2
CP3	Clinical Phase 3
CRL	Clinical Resource Level
CRT	Capability Resource Table
CST	Clinical Science Team
DCS	Decompression Syndrome
DRM	Design Reference Mission
ED	Emergency Medicine Doctor
EL	Evidence Library
EMCL	Exploration Medical Condition List
EMT	Emergency Medical Technician
EVA	Extravehicular Activity
EXMC	Exploration Medical Capability
HRP	Human Research Program
ICD	International Classification of Disease
ICL 1.0	IMPACT 1.0 Medical Conditions List
ICU	Intensive Care Unit
IMCL	iMED Condition List
iMED	Integrated Medical Evidence Database
IMM	Integrated Medical Model
IMPACT-MD	Impact Medical Database
IP	Incidence Proportion
IR	Incidence Rate
ISS	International Space Station
IV	Intravenous
JSC	Johnson Space Center
LEO	Low-Earth orbit
LEVA	Lunar Extravehicular Activity
LOCL	Loss of Crew Life
LOM	Loss of Mission
LSAH	Lifetime Surveillance of Astronaut Health
LSO	Lunar Surface Operations
MCL	Master Condition List
MEVA	Medical Extravehicular Activity
NASA	National Aeronautics and Space Administration
N/A	Not Applicable
NP	Nurse Practitioner
OBGYN	Obstetrics and Gynecology
OR	Occurrence Rate
PA	Physician Assistant
PDQ	Pain Disability Questionnaire
PFCL	Proposed Future Conditions List
PPE	Personal Protective Equipment

PTRS	Project Technical Requirements Specification
PRL	Pharmaceutical Resource Level
QTL	Quality Time Lost
RCL	Removed Conditions List
REP	Rochester Epidemiology Study
RTDC	Removal to Definitive Care
SANS	Spaceflight-Associated Neuro-ocular Syndrome
SAS	Space Adaptation Syndrome
SEVA	Spaceflight Extravehicular Activity
SME	Subject Matter Expert
SoP	Standard Operating Procedure
SPE	Solar Particle Event
TBD	To Be Determined
TI	Task Impairment