

Clinical Finding Form (CLiFF)

Branch

Baseline

ICL77_Prostatitis, Acute

The incidence for this CLiFF uses the same study as the IMM LD68 CLiFF Acute Prostatitis. Best case/ worst case percentages, CP2 durations, and RTDC are based on different studies. No events have occurred among U.S. astronauts in spaceflight. 1 anecdotal event during spaceflight (Russian event). Therefore, terrestrial studies are used.

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 events have occurred among U.S. astronauts in spaceflight. 1 event/nonfatal significant medical events during spaceflight 1961-2013 (Russian event).

ANALOG LITERATURE

1% incidence of medical evacuation events from McMurdo Station, Antarctica, 1992-1996 (total 71).

TERRESTRIAL LITERATURE

4.9 events/1,000 person-years. Clemens, J Quentin et al. "Incidence and clinical characteristics of National Institutes of Health type III prostatitis in the community." The Journal of urology vol. 174,6 (2005): 2319-22. doi:10.1097/01.ju.0000182152.28519.e7. (Clemens, 2005). LOC = 3.

OVERALL INCIDENCE SUMMARY

INCIDENCE

mean 4.895E-3 and SD 1.653E-4

INCIDENCE SUMMARY

The Bayesian posterior distribution for the incidence rate given the terrestrial data (891 cases of newly diagnosed prostatitis over 181,949 person-years – IR: 4.9E-4) under an uninformative prior is Gamma(shape=876.92, rate=179145.9) with mean 4.895E-3 and SD 1.653E-4. Evidence: Clemens 2005 – Incidence and Clinical Characteristics of National Institutes of Health Type III Prostatitis in the Community. 1223 events over 181,949 person-years. After chart review of a subset, the overall rate of newly diagnosed prostatitis was estimated as 4.9 per 1kpy. This translates to about 891 events. 891 events over 181,949 person-years. IR: 6.722E-3 (95%CI: 4.583E-3, 5.227E-3)

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
0.004895
SD
0.0001653

Gamma
(Shape): 876.92
(Rate): 179146

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Clemens et al., 2005	Terrestrial	3

Terrestrial general population study. LOC = 3 (somewhat confident).

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 specific preflight prevent measures for acute prostatitis.

BEST CASE SCENARIO DEFINITION

Prostatitis that responds to treatment with analgesics and antibiotics.

WORSE CASE SCENARIO DEFINITION

Prostatitis that requires more than one course of antibiotics or develops an abscess.

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

Prostatic Abscess.

BEST CASE/WORST CASE PROBABILITY COMMENTS

Best case/worst case percentage = 76%/24%. Based on 24% of cases with bacterial failure at follow-up. (Etienne, 2008). LOC = 3.

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

Citation	Source	LOC Value
Etienne et al., 2008	Terrestrial study.	3

Based on 24% of cases with bacterial failure at follow-up.

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 4.895E-3 and SD 1.653E-4	76 - 76	100	1.56	4.63726	240	336	0	0	0	0	0
Treated Worst Case (TWC)		24 - 24	100	1.56	15.3867	672	1008	0	0	0	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	1.56	18.27	336	2160	5.76668	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	1.56	32.9923	2160	2160	26.92	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

This condition will be treated with analgesics and antibiotics. RTDC surrogate is hospitalization due the inability to treat with available resources. Details regarding diagnosis and treatment are contained in the CRT.

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Treated best case scenario should not result in RTDC or LOCL.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

Treated worst case scenario should not result in RTDC or LOCL.

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

Untreated best case scenario should not result in RTDC or LOCL. Untreated best case prostatitis is not likely to cause hospitalization in the healthy astronaut population.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

Untreated worst case scenario is very likely to result in RTDC (based on RTDC surrogate of hospitalization). LOCL is not expected. LOCL in worst case scenarios would be secondary to sepsis. Sepsis is a separate condition.

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

Citation	Source	LOC Value
Coker, 2016	Terrestrial	3
Brede, 2011	Terrestrial	
Sharp, 2010	Terrestrial	
Sutcliffe, 2014	Terrestrial	

Treated best case CP2 duration = 240 hours - 336 hours. (Coker, 2016). Treated worst case CP2 duration = 672 hours - 1008 hours. (Brede, 2011). Untreated best case CP2 duration = 336 hours - 2160 hours. (Coker, 2016) and (Sharp, 2010). Untreated worst case CP2 duration = 2160 hours (Sutcliffe, 2014).

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
N/A	Case Definitions	4
N/A	RTDC Surrogate	

RTDC is not expected in the best case scenarios or the worst case treated scenario. RTDC is 100% in the untreated worst case scenario based on

worst case definition and RTDC surrogate of hospitalization.

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
N/A	Case Definitions	4

LOCL = 0% for all scenarios. LOCL is not expected in best case scenarios. LOCL in the worst case scenarios would be secondary to sepsis. Sepsis is a separate condition.

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Capabilities and Resourcing Scope Overview Acute prostatitis refers to an episode of acute, bacterial prostatitis with the best-case scenario responding to treatment with analgesics and oral antibiotics and the worst-case scenario requiring prolonged antibiotic treatment or developing an abscess. CNES: Prostatic abscess Diagnostic Scope and Resourcing: In the best- and worst-case scenario, diagnosis is based on history, physical examination (abdominal, genitourinary, rectal, and vital signs), imaging with ultrasound (a post-void residual is standard of care), and urinalysis. Terrestrially, standard of care also includes a urine culture, but urine culture was considered outside the scope of medical capabilities for this CRT. Trans-rectal ultrasound was not included as a capability (to assess for prostatic abscess) because drainage was beyond the scope of the medical capabilities in this CRT and it was felt without this capability, the ultrasound would not change medical management. Clinical Phase 1 Duration and Rationale This version of IMPACT presumes physician level knowledge, skill, and ability will be present on the mission. This CRT includes a scope of practice code of 4 (which correlates to an "Intern/PA/NP." The CRT working group SME consensus Clinical Phase 1 duration: Best Case CP1: 1.56 hours Worst Case CP1: 1.56 hours Treatment Scope and Resourcing: For a best-case acute prostatitis, terrestrial standard of care is 2-4 weeks of oral antibiotics (Ciprofloxacin, Levofloxacin, or Bactrim) and analgesics PRN. Given the best-case definition states that the prostatitis is "responds to treatment," a 2-week course of these oral antibiotic agents was included for the best-case scenario, as well as NSAIDs, and acetaminophen PRN for pain. Terrestrially a urine culture would guide antibiotic treatment, but this was considered outside the scope of medical capabilities for this CRT, so treatment would be empiric. In a worst-case acute prostatitis, treatment is prolonged. Meropenem IV was chosen as the antibiotic of choice for empiric treatment of a worst-case acute prostatitis due to its broad coverage, including pseudomonas. There has been one case of acute bacterial prostatitis in spaceflight and the bacterial agent was thought to be pseudomonas. Notably, Meropenem is not currently included on the spaceflight formulary, but the benefit of its inclusion was considered for this CRT. The dose is Meropenem 1000mg IV every 8 hours. It is a powder that requires reconstitution. The 1g dose for reconstitution requires dilution with normal saline for a 1-20mg/ml concentration (i.e. 50ml NS minimum for a dose of 1g). Prior to reconstitution, it has a shelf-life of 4 years, but after reconstitution, it is only stable at room temperature for 3 hours. 14 days of Meropenem IV have been included in the worst-case scenario, followed by an additional 4 weeks of oral antibiotics. Communications and Support Needs: While real-time video and audio loop communications are desired for diagnosis and treatment, they were not considered a necessity, particularly in the best-case scenario. For the WC, consultation with ground specialists to facilitate treatment and healing was considered necessary given the limited diagnostic and treatment capabilities in-flight. References 1. Clinical Practice Guideline. Retrieved 19 December 2020 from <http://www.asams.org/guidelines/Completed/NEW%20Prostatitis.htm> 2. Coker T.J, Dierfeldt DM. Acute Bacterial Prostatitis: Diagnosis and Management. AFP 2016; 93:114–20. 3. Karah N, Rafei R, Elamin W, Ghazy A, Abbata A, Hamze M, et al. Guideline for Urine Culture and Biochemical Identification of Bacterial Urinary Pathogens in Low-Resource Settings. Diagnostics (Basel) 2020; 10. Retrieved 20 December 2020 from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7602787/> 4. Meropenem 500 mg powder for solution for injection or infusion - Summary of Product Characteristics (SmPC) - (emc). Retrieved 7 May 2021 from <https://www.medicines.org.uk/emc/product/5070/smpc#gref> 5. Microbiology - 007 - Carbohydrate Fermentation Test | Microbiology Undergraduate Program. Retrieved 20 December 2020 from <https://www.micro.iastate.edu/video/microbiology-007-carbohydrate-fermentation-test>

6. URINE CULTURES ** | Student Health Center Manuals. Retrieved 20 December 2020 from <http://shs-manual.ucsc.edu/policy/urine-cultures>

7. Meropenem. IBM Micromedex. <https://www.micromedexsolutions.com>

IMM CLIFF RECONCILIATION COMMENTS

The incidence for this Cliff uses the same study as the IMM LD68 Cliff Acute Prostatitis. Best case/ worst case percentages, CP2 durations, and RTDC are based on different studies.

LIMITATIONS SUMMARY

Limited data available regarding untreated scenarios. Terrestrial studies do not account for the possible increased virulence of pathogens in spaceflight, the possible decreased immune system response of astronauts in spaceflight, and the possible decreased effectiveness of medications in spaceflight. Also, terrestrial general population studies do not account for the healthy astronaut population.

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)										6		
Untreated Best Case (UTBC)		664					145			6		
Treated Worst Case (TWC)		664					145			6		
Untreated Worst Case (UTWC)	223	664		89			145			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)	132							211	349	3763	0.0927452	9.27452
Untreated Best Case (UTBC)	132							211	1158	3763	0.307733	30.7733
Treated Worst Case (TWC)	132							211	1158	3763	0.307733	30.7733
Untreated Worst Case (UTWC)	132							211	1470	3763	0.390646	39.0646
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)										6		
Treated Worst Case (TWC)												
Untreated Worst Case (UTWC)		664								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	T1 Decimal	T1 %
Treated Best Case (TBC)									0	3763	0	0
Untreated Best Case (UTBC)								211	217	3763	0.0576668	5.76668
Treated Worst Case (TWC)									0	3763	0	0
Untreated Worst Case (UTWC)	132							211	1013	3763	0.2692	26.92

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 requiring use of the alimentary system, 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 Condition 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
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