

Clinical Finding Form (CLiFF)

Branch

Baseline

ICL99_Space Adaptation - Urinary Incontinence

The International Continence Society defines urinary incontinence as "the complaint of any involuntary leakage of urine." (Abrams P, 2002) The demarcation between incontinence as a symptom and incontinence as a disease is far from clear. (Nygaard, 2007) Space Adaptation Syndrome (SAS) related urinary incontinence is an involuntary leakage of urine. It has been reported by several female crewmembers during the early phases of flight, and is thought to be secondary to overflow from a distended bladder secondary to SAS-related urinary retention. Urinary incontinence in flight can also occur secondary to a urinary tract infection. (Jones, 2008a) A urologist who is a NASA flight surgeon reports that of the cases of urinary incontinence which have occurred in-flight most have been stress incontinence, a few cases were of post-void dribbling which was categorized as a minor nuisance, and one case was over flow incontinence secondary to urinary retention. (Jones, 2008b) Irritation of the perineal skin due to continuous contact with wet undergarments or absorbent pads is possible and it is addressed in the Skin Rash CLiFF. Incontinence secondary to urine retention is addressed in the Urinary Retention CLiFF.

INCIDENCE DATA INCLUDED IN THE MODEL

The model imports the following incidence information from the MEDPRAT Evidence Library Database: incidence data category, space adaption status, EVA status, incidence data type, incidence and occurrence distribution data and incidence data characteristics. Data category defines the type of data available for incidence calculations (i.e. raw data vs. adjusted data). Space adaptation identifies medical events that where onset occurs in the first 5-7 days of flight and does not reoccur. EVA-related incidence values identify medical events that occur only during an EVA. Incidence values types vary by data category and define the number of medical events per person-year (rates) or medical events per person at-risk (proportion) for each medical condition. Incidence values can be modified by crew characteristics such as gender sex and certain crew medical history characteristics. Modifying characteristics are noted below and incidence values are listed individually for each characteristic. Distributions are assigned to medical events incidence values and occurrences in the model. For each crewmember in a given trial, the incidence and number of occurrences of each medical condition are randomly selected from these probability distributions. Detailed descriptions of the distributions are included in the MEDPRAT Technical Description Document.

INCIDENCE DATA

SPACEFLIGHT LITERATURE

The incidence of space adaptation urinary incontinence (specifically defined as occurring within the first 5 days of spaceflight) has been estimated based on LSAH inflight data.

ANALOG LITERATURE

Not applicable. No analog literature search completed due to this being a space adaptation condition.

TERRESTRIAL LITERATURE

Not applicable. No terrestrial literature search completed due to this being a space adaptation condition.

OVERALL INCIDENCE SUMMARY

INCIDENCE

Male: mean 0.001415, sd 0.001391 and female: mean 0.05101, sd 0.02027

INCIDENCE SUMMARY

Incidence proportion distributions depend on sex. Males: Bayesian posterior distribution for the incidence proportion using the spaceflight data of 0 events over 692 person-missions under a uniform(0,1) prior is Beta(shape1=1.032, shape2=728.24) mean: 0.001415 and SD: 0.001391. Females: Bayesian posterior distribution for the incidence proportion using the spaceflight data of 5 events over 115 person-missions under a uniform(0,1) prior is Beta(shape1=5.959, shape2=110.86) mean: 0.05101 and SD: 0.02027

TABLE 1. INCIDENCE MODEL

Incidence Details

Incidence Type

SAS

Segment

Space Adaptation

Env. Exposure

NA

Sex

Male

Crowns

Any

Contacts

Any

Pregnancy

Any

Incidence Distribution

Occurrence Dist

Binomial

Incidence Dist.

Beta

Mean

0.00141511

SD

0.00139106

Beta

(Alpha): 1.032

(Beta): 728.24

Onset Timing (Hours)

(Min): 1

(Max): 120

(Most Likely): 12

Incidence Details

Incidence Type

SAS

Segment

Space Adaptation

Env. Exposure

NA

Sex

Female

Crowns

Any

Contacts

Any

Pregnancy

Any

Incidence Distribution

Occurrence Dist

Binomial

Incidence Dist.

Beta

Mean

0.0510105

SD

0.02027

Beta

(Alpha): 5.959

(Beta): 110.86

Onset Timing (Hours)

(Min): 1

(Max): 120

(Most Likely): 12

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Saile, 2017	LSAH	4

LOC = 4 (confident) based on spaceflight data.

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 preventive measures for this condition.

BEST CASE SCENARIO DEFINITION

The best case scenario is defined as having an uncomplicated course of urinary incontinence which resolves by itself or causes minimal discomfort.

WORSE CASE SCENARIO DEFINITION

Not applicable.

CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

None

BEST CASE/WORST CASE PROBABILITY COMMENTS

Since there is no worst case scenario for this medical condition, the worst case and best case percentages are estimated at 0% and 100% respectively.

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

Citation	Source	LOC Value
Saile, 2017	LSAH	3

LOC = 3 (somewhat confident) based on limited spaceflight data. No worst case scenarios have been recorded to date.

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: 0.001415 and SD: 0.001391/male, mean: 0.05101 and SD: 0.02027female	100 - 100	100	0.75	15.9	0	24	0	0	0	0	0
Treated Worst Case (TWC)		0 - 0	100	0	0	0	0	0	0	0	0	0
Untreated Best Case (UTBC)	N/A	N/A	N/A	0.75	15.9	0	24	0	0	0	0	0
Untreated Worst Case (UTWC)	N/A	N/A	N/A	0	0	0	0	0	0	0	0	0

TABLE 4 KEY

Composite Incidence: The same composite incidence will be used for both TBC and TWC. For EVA conditions: events per EVA (events/EVA). For space adaptation conditions: events per person (events/person). For non-spaceflight conditions: events per person year (events/py).

Condition Probability: The probability that CLIFF condition progresses to a worst case scenario. Best case scenario: 100%-Worst Case.

Clinical Phase General Comments:

- TI% = Task Impairment %. Task Impairment is the % of tasks that the crewmember is incapable of performing without impairment secondary to the medical condition.
- Durations are defined in hours.
- Removal to Definitive Care (RTDC): The probability the entire crew aborts the mission and returns to earth. This is considered as a condition end state result if any of the following criteria are met: 1) the potential for LOCL, 2) potential for significant permanent task impairment, or 3) potential for intractable pain.
- Loss of Crew Life (LOCL): The probability of death of affected crewmember due to medical condition.

Clinical Phase 1: Initial Assessment and Diagnosis:

- Covers only the initial assessment and diagnosis of the affected crewmember to define his or her medical condition. While the affected crewmember is being assessed, he or she is not able to perform any assigned tasks, thus Task Impairment (TI) during this phase is considered 100%. In the untreated case, there is no diagnosis performed, therefore Task Impairment and Duration will always be "not applicable."

Clinical Phase 2: Stabilization, Treatment, and Convalescence:

- The affected crewmember is receiving any appropriate initial or follow-on treatment for his or her medical condition to allow the crewmember to recover as much as he or she is able to recover in the spaceflight environment. Clinical phase 2 also encompasses relapses or recurrences of the same original medical condition in Clinical Phase 1. The duration of Clinical Phase 2 is expressed as minimum and maximum hours.

Clinical Phase 3: Condition End State:

- Reached once the affected crewmember has recovered from the medical condition as much as he or she is able to recover in the spaceflight environment amongst treated and untreated best and worst case scenarios. This may or may not be recovery from the given medical condition to the full extent possible. If this "recovered" state results in Removal to Definitive Care (RTDC) or Loss of Crew Life (LOCL) this will be noted in the condition end state results.

SCENARIO OVERVIEW COMMENTS

This condition falls within space adaptation syndrome phase specifically. The treatment does not differ significantly to that of the terrestrial equivalent and can usually be treated inflight with adequate training and supplies.

TREATED BEST CASE (TBC) SCENARIO COMMENTS

Occurrence and duration data comes directly from spaceflight data (LSAH) in the prior IMM CLIFF. These best case Clinical Phase II scenarios are up to 24 hours maximum with known cause/quick treatment, with minimal discomfort or intrusiveness, or spontaneously resolves, based on LSAH data. As a result, RTDC and LOCL probabilities are deemed 0%.

TREATED WORST CASE SCENARIO (TWC) COMMENTS

Not applicable.

UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

Occurrence and duration data comes directly from spaceflight data (LSAH) in the prior IMM CLIFF. These best case Clinical Phase II scenarios are up to 24 hours maximum with minimal discomfort or intrusiveness, and spontaneously resolve. The RTDC and LOCL probabilities are deemed 0%.

UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

Not applicable.

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

Citation	Source	LOC Value
Saile, 2017	LSAH	3

LOC = 3 (somewhat confident) based on limited spaceflight data.

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Saile, 2017	LSAH	4

LOC = 4 (confident) based on best case and worst case definitions.

TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)

Citation	Source	LOC Value
Saile, 2017	LSAH	4

LOC = 4 (confident) based on best case and worst case definitions.

CAPABILITY RESOURCE TABLE (CRT) OVERVIEW

Overview

Urinary incontinence is the involuntary leakage of urine and can be caused from a wide variety of etiologies. As this condition is exclusive to space adaptation, it is not including chronic stress incontinence, urgency incontinence, overflow incontinence, anomalies, or neurologic, pharmacologic, or metabolic issues. Space adaptation syndrome-related urinary incontinence is believed to be secondary to the overflow from a distended bladder secondary to acute urinary retention versus acute stress incontinence.

CNES: None

Diagnostic Scope and Resourcing

The medical history should review any personal history of incontinence in the past as well as any concerning differential diagnostic questions like UTI for example. Workup begins with an abdominal exam and urinalysis. More advanced exams, labs, or imaging are felt to be beyond the scope of SAS-related urinary incontinence. Cough stress tests, urethral mobility testing, cystourethroscopy, post void residual testing would all be performed terrestrially as part of the differential for chronic incontinence.

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): 0.75

CP1 WC (Treated or Untreated): N/A as there is no WC definition.

The highest scope of practice required for diagnosis includes the interpretation of the ultrasounds which is SOP 3 (experienced ED/ICU nurse).

Treatment Scope and Resourcing

As this condition is specific to space adaptation, the treatment only includes absorbance pads. Kegel exercises, pharmacologic management, pessaries, neuromodulation, and urethral bulking are all beyond the scope of SAS-related incontinence.

Communications and Support Needs

Ground communication is not required. References

ACOG Practice Bulletin No. 155 Summary: Urinary Incontinence in Women. Obstet Gynecol. 2015 Nov;126(5):1120-1122. doi: 10.1097/AOG.0000000000001143. PMID: 26488516.

IMM CLIFF RECONCILIATION COMMENTS

This updated CLIFF is based on the prior IMM CLIFF documentation with no changes. The prior CLIFF is based on direct astronaut spaceflight data/LSAH data.

LIMITATIONS SUMMARY

The primary limitations of the data retrieved consists of a limited number of subjects/sample size, previous and current vehicle platforms and differing mission profiles. The Clinical Phase II durations for this CLIFF were all taken from the IMM CLIFF which is based on LSAH data. The ExMC composer/editor of this CLIFF does not have access to that primary source, but felt after looking through multiple other sources that these estimates for duration were reasonable given they are spaceflight specific.

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)										6		
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 %
Treated Best Case (TBC)									6	3763	0.00159447	0.159447
Untreated Best Case (UTBC)									6	3763	0.00159447	0.159447
Treated Worst Case (TWC)									0	3763	0	0
Untreated Worst Case (UTWC)									0	3763	0	0
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 %
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)									0	3763	0	0

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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2. Inflight Compilation Lockdown. In-flight medical events for Apollo, MIR, ISS, Skylab, and STS. 7-10-2008. Houston, Texas, NASA, Johnson Space Center.
3. International Space Station Integrated Medical Group. Medical Checklist ISS- All Expeditions. Houston: National Aeronautics and Space Administration; 2008.
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5. Jones JA, Pietrzyk RA, Whitson PA. Renal and Genitourinary Concerns. In: Barratt M, Pool S, editors. Principles of Clinical Medicine for Space Flight. New York: Springer; 2008a. p. 273-91.
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7. Nygaard I, Thom DH, Calhoun EH. Urinary Incontinence in Women. In: Litwin MS, Saigal CS, editors. Urologic Diseases in America. Washington DC: US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Washington, DC: US Government Printing Office; 2007. p. 159-91.
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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