Urinary Incontinence (space adaptation) Cliff

Branch Baseline

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, 2008)

Incidence Data Included in the Model

The model imports the following incidence information from the IMM database: incidence data category, space adaption status, incidence data, 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. fixed data). Space adaptation identifies medical events that onset occurs in the first 5 days of flight and does not reoccur. Incidence values vary by data category and define the number of medical events per person-year or medical events per person-at-risk for each medical condition. Incidence values can be modified by crew characteristics such as gender. 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 crew member 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 IMM Technical Description Document.

Incidence	
Data Category:	In-flight
Space Adaptation:	Yes
Incidence Type:	Proportion

Distribution Data	
Incidence:	Beta
Occurrence:	Bernoulli

Female Data Characteristics	
Occurrence Hour Range:	24 to 216
Peak Occurrence Hours:	24
Events:	5
Persons At Risk:	115
Space Flight Incidence Rate (Events / Persons at Risk):	5 / 115 = 0.0434782608695652

Incidence Comments

Source of incidence data is a compilation of available in flight medical events. (Inflight Compilation Lockdown, 2008)

Added 25 persons at risk (9 ISS and 16 STS) to the existing data (Saile, 2017)

Information Regarding Prevention

Disqualifying genitourinary conditions include: disease, injury, or other disorders of the kidneys or GU tract that could require emergency medical treatment or interfere with successful mission completion; diseases interfering with micturition and potentially requiring emergency medical treatment such as prostatitis, any disabling disorders of the reproductive system or associated anatomical structures that could potentially require emergency medical care (International Space Station Program, 2009). Screening includes evaluation of voiding symptoms such as polyuria, oliguria, frequency, urgency, dysuria, nocturia, diminished force and caliber of urine stream, spraying of stream, hesitancy, dribbling, straining , sense of residual urine after voiding, and incontinence (Jones, 2008).

Vehicle requirement(s): Conditions affecting urinary health are prelaunch, launch and entry suit. (Jones, 2008)

Other: Mission schedules, inadequate fluid intake, and redistribution of body fluids may affect urinary output. Some medications used for motion sickness may cause urinary retention or have anticholinergic side effects. (Jones, 2008) Atropine, Vicodin, metaxalone (Skelaxin). (International Space Station Integrated Medical Group, 2006)

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, 2008) Refer to the Urinary Retention Clinical Findings Form for resources, treatment and outcomes.

Incidence Level of Evidence (LOE)

The IMM level of evidence appropriate assessment of the quality of the IMM input data. Since IMM incorporates input data from a wide variety of sources including astronaut population, terrestrial or analog populations, and external models, an innovative approach to assess the quality of input data was required. Information obtained from the astronaut population and/or space flight is the more relevant so it is assigned the highest level of evidence and less relevant data sources are assigned a lower level of evidence.

Citation	LOE Value	LOE Category
Inflight Compilation Lockdown, 2008	1	Incidence
Saile, 2017	1	Incidence

Incidence data not included in the model

The model pulls the incidence information from the IMM database ... the information shown below does not go into the model.

Incidence	
Data Category:	Fixed
Space Adaptation:	Yes
Incidence Type:	Rate

Distribution Data	
Incidence:	Fixed
Occurrence:	Poisson

Female Data Characteristics	
Occurrence Hour Range:	to
Peak Occurrence Hours:	
Fixed Rate:	11.1

Incidence Comments

The Study of Women's Health Across the Nation (SWAN) defined prevalent incontinence as at least monthly incontinence reported at baseline and incident incontinence as at least monthly incontinence first reported over follow-up. They used multiple logistic regression for their comparison. The age range of their cohort at baseline was 20 to 59; the mean age was 45.8 years, 2.7 years standard deviation. Prevalent incontinence was 46.7% and the average incidence was 11.1 per year. During a 5 year period, from 1995 to 2001, 801 or 55.7% of 1439 women reported first incidence of incontinence, 717 women reported occasional (monthly to weekly) and 84 reported frequent (weekly to daily), 49.8% and 5.7% respectively. 638 or 44.3% reported no incontinence. P value is 0.07 for incident incontinence, from chi-square tests evaluating differences in rates of each incontinence type across racial/ethnic groups.

They concluded that incontinence described as occurring less than weekly is responsible for the midlife prevalence peak of incontinence in previous epidemiologic studies. Parity was not an important factor in the development of any type of incident incontinence over the 5 years of follow-up.

General health status based on self description for 2818 participants in the follow up cohort ranged from excellent to good, excellent 599, very good 1010, and good 744; while 313 reported fair and poor status. (Waetjen, 2007)

Incidence data not included in the model

The model pulls the incidence information from the IMM database ... the information shown below does not go into the model.

Incidence	
Data Category:	Fixed
Space Adaptation:	Yes
Incidence Type:	Rate

Distribution Data	
Incidence:	Fixed
Occurrence:	Poisson

Female Data Characteristics	
Occurrence Hour Range:	to
Peak Occurrence Hours:	
Fixed Rate:	5.9

Incidence Comments

Townsend calculated incidence rates of urinary incontinence by frequency and type over 4 years in Asian, black, and white women in the United States. Prospective analyses included 76,724 participants aged 37 to79 years in the Nurses' Health Study cohorts with no incontinence at baseline. The age range was 54 to 79 for NHS and 37 to 54 years for NHS II. Considering each cohort separately the authors found that patterns of incontinence across racial groups were similar despite the age difference between cohorts. The 4-year incidence of incontinence at least monthly was higher in white women 7.3/100 person-years (95% CI 7.2-7.4) P value 0.001, compared with Asian 5.7/100 person-years; (95% CI 4.8-6.6) P value .003 and black women 4.8/100 person-years (95%CI 4.1-5.5); P value < .001. The average for all ethnic groups was 5.9. The incidence of at least weekly stress incontinence was significantly lower in black compared with white women (0.1 vs. 0.8 per 100 person-years; P < .001). The difference between black and white women in the incidence of any incontinence and stress incontinence remained significant after adjusting for known risk factors (P < .001 for both). Baseline year was 2000 for NHS and 2001 for NHS II. (Townsend, 2009)

Incidence data not included in the model

The model pulls the incidence information from the IMM database ... the information shown below does not go into the model.

Incidence	
Data Category:	Fixed
Space Adaptation:	Yes
Incidence Type:	Rate

Distribution Data	
Incidence:	Fixed
Occurrence:	Poisson

Female Data Characteristics	
Occurrence Hour Range:	to
Peak Occurrence Hours:	
Fixed Rate:	9.37

Incidence Comments

In the Tennstedt study looking at races, the commulative incidence across blacks, hispanic, and white men and women is 9.3. The Boston Area Community Health (BACH) Survey, an epidemiologic survey conducted in a population-based random sample of Black, Hispanic, and White men (2,301) and women (3,205) aged 30–79 years, recruited from April 2002 to June 2005. The overall prevalence of weekly urine leakage was 8 percent. Women were twice as likely as men (10.4 percent vs. 5.3 percent) to report weekly urine leakage across all racial/ ethnic groups. For both genders, prevalence was highest among Whites and lowest among Hispanics. Prevalence rates among Blacks of both genders were closer to the rates for Whites than to the rates for Hispanics. The BACH Survey is the most recent publication presenting comparable prevalence data for both genders. (Tennstedt, 2008)

Treatment and Outcomes

Based on the best evidence available best and worst case percentage ranges are assigned. The medical condition is divided into three clinical phases in all three clinical phases a functional impairment is assigned. The clinical phase I and II's functional impairments remain for the duration for that respective clinical phase. The function impairment in clinical phase III represents final impairment for this medical condition and remains for the rest of the mission. Other mission end states include evacuation and loss of crew life.

The IMM checks medical resource availability once the number of medical events and scenarios has been established. If there is not sufficient essential resources called out in the CliFF, then the medical condition will go down an untreated best or worst case scenario pathway.

The table below summarizes the treated and untreated best and worst case scenarios.

	Clinical Phase I Diagnosis & Initial Treatment[1]		**Clinical Phase II On-going Treatment / Convalescence[2]**		**Clinical Phase III Recovered / Mission End State[3]**		
	FI* (%)	**Duration (hrs)**	**FI* (%)**	**Duration (hrs) (Min - ML - Max)**	**FI* (%)**	**EVAC** (%)**	**LOCL** (%)**
ISS-based Treatment (best case scenario %: 83 - 100)	100	0.33	0 - 9	0 - 12 - 24	0	0	0
ISS-based Treatment (worst case scenario %: 0 - 17)	100	0.33	1 - 19	24 - 72 - 120	0	0	0
Untreated Best Case	0	0	1 - 19	0 - 12 - 24	0	0	0
Untreated Worst Case	0	0	11 - 29	24 - 72 - 120	0	0	0

[1]Clinical Phase I: Clinical phase I covers only the initial assessment of the affected crew member to define his or her medical condition, and completion of appropriate initial treatment to stabilize the crew member. While the affected crew member is being assessed, he or she is not able to perform any assigned tasks, thus Functional Impairment during this phase is considered 100%. In the untreated case, there is no diagnosis performed or treatment given, therefore Functional Impairment and Duration will always be "not applicable".

[2]Clinical Phase II: On-going Treatment and Convalescence- During clinical phase II, the affected crew member is receiving any appropriate follow-on treatment for his or her medical condition to allow the crew member to recover as much as he or she is able to recover in the ISS environment. Clinical phase II also encompasses relapses or reoccurrences of the same original medical condition in clinical phase I necessitating additional treatment or recovery time due to unsuccessful primary treatment response. The duration in Clinical Phase II is expressed in minimum, most likely (ML) and maximum hours. This was updated for future capabilities in IMM but is currently not being used by the model.

[3]Clinical Phase III: Recovered/Mission End State- Clinical phase III is reached once the affected crew member has recovered from the medical condition as much as he or she is able to recover in the ISS environment. This may or may not be recovery from the given medical condition to the full extent possible. If this "recovered" state results in an evacuation or loss of the crew member, this will be noted in the mission end state results.

*Functional Impairment (FI) is a measure of the affected crew member's health and performance ability.

**Two mission end state results are addressed in the CliFF: 1) Evacuation (EVAC) - crew and patient are evacuated from the spacecraft due to the medical condition, and 2) Loss of crew (LOCL) - death of affected crew member due to medical condition. EVAC is considered as an end state result if any of the following criteria are met: 1) potential LOCL, 2) potential significant permanent impairment, or 3) potential intractable pain. Probability distributions are assigned for each range of values within the Table of Treatments and Outcomes.

Refer to the Integrated Medical Model Technical Document for more information on how risk is reported by the IMM, Crew Health Index (CHI) and Quality Adjusted Mission Time calculations.

Definition and Probability of Best and Worst Case Scenario: (includes definitions of best and worst case scenarios and identifies the probability of those scenarios.)

Scenario Comments

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

The **worst case scenario** is defined as having a moderate to severe course of urinary incontinence.

The **percentages of how often best versus worst case scenario occur** are determined using the in-flight incidence data (Inflight Compilation Lockdown, 2008). All cases have been best cases. In order to account for uncertainty, we assume the next case will be either a best or a worst case. If a best case, the probability is 100%; if a worst case, the risk is estimated to be 1 in 6, or 17% worst cases. Thus, the probability of best case is 83 to100%.

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.

Best Case Comments

During **Clinical Phase I,** Functional Impairment (FI) is 100%. Duration time of following ISS procedures for diagnosis is 20 minutes. During **Clinical Phase II,** FI is estimated to be 0 to 9%. Class 0 or 0% FI is prior history of bladder disease with no residuals and no signs of bladder disease. Class 1 or 1 to 9% FI is occasional mild to moderate symptoms, such as frequency, nocturia, or dribbling, with normal function between episodes(American Medical Association, 2008). Duration is estimated to be 0 to 24 hours for best case based on in-flight data (Inflight Compilation Lockdown, 2008). During **Clinical Phase III** best case scenario, incontinence will resolve making functional impairment 0%. Based on in-flight data, EVAC or LOCL is not estimated to occur (Inflight Compilation Lockdown, 2008).

Worst Case Comments

During **Clinical Phase I,** FI and duration are similar to the best case scenario. During **Clinical Phase II,** FI is estimated to be 1 to 19% or class 1 to 2. Class 1 is occasional mild to moderate symptoms, such as frequency, nocturia, or dribbling, with normal function between episodes. Class 2 is moderate symptoms such as pain or incontinence despite continuous treatment, or continuous mild signs or intermittent moderate findings despite treatment (American Medical Association, 2008). Duration is estimated to be 24 to 120 hours based in our definition of space-adaptation conditions. During **Clinical Phase III** worst case scenario, Space Adaptation Urinary incontinence is expected to resolve and FI is Class 0 or 0% (American Medical Association, 2008). EVAC or LOCL is not estimated to occur based in in-flight data (Inflight Compilation Lockdown, 2008).

Untreated Best Case Comments

During **Clinical Phase II,** FI is estimated to be 1 to 19% or class 1 to 2, similar to the treated worst case scenario. Class 1 is occasional mild to moderate symptoms, such as frequency, nocturia, or dribbling, with normal function between episodes. Class 2 is moderate symptoms such as pain or incontinence or continuous mild signs or intermittent moderate findings. In this scenario there is no treatment available (American Medical Association, 2008). Duration is estimated to be 0 to 24 hours for best case based on in-flight data (Inflight Compilation Lockdown, 2008). During **Clinical Phase III** best case scenario, untreated incontinence will resolve making functional impairment 0% (American Medical Association, 2008). Based on in-flight data, EVAC or LOCL is not estimated to occur (Inflight Compilation Lockdown, 2008).

Untreated Worst Case Comments

During **Clinical Phase II,** FI is estimated to be 11 to 29% or class 2 to 3. Class 2 is moderate symptoms such as pain or incontinence or continuous mild signs or intermittent moderate findings. Class 3 is little to no voluntary control of micturition or severe symptoms. In this scenario there is no treatment available (American Medical Association, 2008). Duration is estimated to be 24 to 120 hours based in our definition of space-adaptation conditions. During **Clinical Phase III** untreated worst case scenario, incontinence will resolve making functional impairment 0% (American Medical Association, 2008). Based on in-flight data, EVAC or LOCL is not expected to occur (Inflight Compilation Lockdown, 2008).

Treatment and Options Level of Evidence (LOE)

The IMM level of evidence appropriate assessment of the quality of the IMM input data. Since IMM incorporates input data from a wide variety of sources including astronaut population, terrestrial or analog populations, and external models, an innovative approach to assess the quality of input data was required. Information obtained from the astronaut population and/or space flight is the more relevant so it is assigned the highest level of evidence and less relevant data sources are assigned a lower level of evidence.

Citation	LOE Value	LOE Category
Inflight Compilation Lockdown, 2008	1	EVAC
	1	BCWC
American Medical Association, 2008	3	FI

The Resource Table (RT)

Resource	Units Required Best Case	Units Required Worst Case	Units Available At Start Of Mission	Consumable	Essential	Rationale
Maximum Absorbency Garment (MAG)	0	1	1	Yes	No	Under garment collection

Resource Comments

Resources included in this table that are not part of the medical kit and are kept as placeholders. The source of the resource table data was derived from ISS Space Medicine document including the checklist and protocols. (International Space Station Integrated Medical Group, 2006)

There are several drugs for Overactive Bladder in terrestrial care, but none of them is currently included in the ISS list, e.g. Detrol LA, Ditropan XL, also available as a patch called Oxytrol and gel called Gelnique, Enablex, Sanctura, Vesicare, and Toviaz.

Required Resources Level of Evidence (LOE)

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Citation	LOE Value	LOE Category
International Space Station Integrated Medical Group, 2008	2	Resources

Level Of Evidence

Input Data	LOE Average
Incidence	1
Functional Impairment	3
Best Case / Worst Case	1
EVAC / LOCL	1
Resources	2
QUALITY OF EVIDENCE	**1.6**

Description	Range
Excellent	1-2
Good	2.1-3
Fair	3.1-4
Poor	4.1-5

Reference List

Reference
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