Acute Prostatitis Cliff

Branch Baseline

Prostatitis refers to several clinical syndromes, including well-defined acute and chronic bacterial infections, poorly defined chronic pelvic pain syndrome, and asymptomatic inflammation in the prostate gland found in pathology specimens. Categories I and II refer to acute and chronic bacterial prostatitis. Together, these conditions account for approximately 5% to 10% of all cases. (McNaughton-Collins, 2007)

Acute Prostatitis is characterized by the sudden onset of fever and dysuria.

Category III, known as chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), comprises more than 90% of cases. The classification is further divided, depending on the presence (Type IIIA) or absence (Type IIIB) of white blood cells in semen, post prostate-massage urine specimens (VB3), or expressed prostatic secretions (EPS). Category IV refers to asymptomatic inflammatory prostatitis that is diagnosed incidentally during a workup or test for other disorders. (McNaughton-Collins, 2007)

Diagnosis of Category I prostatitis is primarily based on clinical findings and a positive urine culture. Categories I and II prostatitis are caused by bacteria, including E.coli, Klebsiella, Enterobacter, and Pseudomonas. Treatment of Category I (acute bacterial) prostatitis begins with antibiotic therapy to eradicate the infection. Prostatitis affects men of all ages. (McNaughton-Collins, 2007)

Prostatitis has occured rarely in space, and has not been reported among US astronauts. Adequate diagnostic capabilities are provided in the current ISS medical kits. These include urine dip stick for leukocyte esterase and nitrates, and ultrasound. Treatment for prostatitis in on board. (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:	Fixed
Space Adaptation:	No
Incidence Type:	Rate

Distribution Data	
Incidence:	Fixed
Occurrence:	Poisson

Male Data Characteristics	
Fixed Rate:	0.0049

Incidence Comments

To date, there have been no cases recorded of a US crewmember with this medical issue. One Russian crew member became ill with prostatitis and urosepsis. Return to earth was required on day 56 of a 216 days mission. (Johnston, 2008) Lacking in flight data, we are using terrestrial data for our model incidence.

A population based epidemiological study to identify new diagnoses of chronic prostatitis, International Classification of Diseases, 9th Revision, (ICD9) code 601.1) and prostatitis not otherwise specified ICD9 code 601.9 was conducted in the Kaiser Permanene Northwest (KPNW). Of the 1,223 men identified with these coded diagnoses, chart reviews were performed on a random subset of 413 (33.8%). Patients were categorized based on NIH prostatitis definitions of type I / II—evidence of pyuria and/or bacteriuria on urinalysis or culture, type III—presence of at least 1 of the pain or urinary symptoms in the NIH Chronic Prostatitis Symptom Index (pain in the perineum, testicles, tip of penis, pubic or bladder area, dysuria, ejaculatory pain, incomplete emptying, urinary frequency), type IV—inflammation on prostate biopsy and Other—symptoms other than those listed.

Of the 413 patients whose charts were reviewed, 57 were previously diagnosed with prostatitis (prevalent cases), 46 had no evidence of a prostatitis diagnosis in the medical record and 7 were treated by physicians outside of the KPNW plan. Of the remaining 303 the distribution was 58 type I / II, 189 type III, 33 type IV and 23 Other. The incidence of any prostatitis diagnosis was 4.9 per 1,000 person-years, and the incidence for each subtype was 1.26 (type I / II), 3.30 (type III) and 0.33 (type IV), respectively, per 1,000 person-years. (Clemens, 2005)

Information Regarding Prevention

Selection criteria

Exclusion criteria in the genitourinary area include: any disorder of the genitourinary tract that may interfere with the performance of duties; anatomical abnormalities of one or both kidneys and lower urinary tract producing functional impact to the urogenital system. A duplicated collecting system is considered a variant of normal anatomy and is not disqualifying unless associated with other pathology (e.g. hydronephrosis, nephrolithiasis, or recurrent episodes of infection); loss or absence of one or both kidneys; presence of acute or chronic nephropathy; history of tubular necrosis from any cause if associated with residual renal dysfunction that may interfere with the performance of duties; presence or history of urinary calculus (crystalline concretion within the urine-collecting system); history of urinary calculus formed secondary to parathyroid adenoma requires further evaluation; history of frequent infections of the urinary tract and/or persistent asymptomatic bacteriuria associated with urinary tract abnormalities unless predisposing condition is eliminated; bladder, prostate, or urethral diseases that result in urinary retention, or interfere with micturition. History of same requires further evaluation. (NASA, 2007) (International Space Station Program, 2009)

Countermeasures:

All long duration crewmembers (greater than 30 days) undergo screening ultrasound of the abdomen and pelvis about 6 weeks prior to flight. (Jones, 2008)

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
Clemens, 2005	4	Incidence

Alternative Incidence Data

Analog Populations

Prostatitis has occurred among the astronauts corps on the ground and during pre-flight period. There was 1 case of prostate congestion in Apollo along with UTI. Two cases of prostatitis of undetermined etiology were found on post flight examination. (Hawkins, 1975)

An analysis of 10 years of data collected on US Navy Polaris submarine patrols over the ten year period 1963-1973 reported a total of 1685 medical events treated. Illness rates are indicated as new/cases/1000 man-days. There were a total of 115 diseases of the urinary tract events during the 1963-73 period There were two prostatitis events; causing 11 sick days, 5.5 sick days average per event. Illness rate and rate of days lost were significantly higher than those observed in the surface population ($P < 0.05$) (Tansey, 1979). Our estimate rate per person year is 0.000165 (2 prostatitis/4,410,000 person-days). Three EVACs occurred but there is no information by condition.

There are 31 aviators in the USAF electronic waiver file approved for flight with the diagnosis of prostatitis. Fourteen of these were approved for flight while on antibiotics. Of those 43% were on antibiotics ciprofloxacin or levofloxacin, 36% for TMX/SMX and 21% for doxycycline. Three aviators were disqualified. One of 31 was diagnosed with Chronic Pelvic Pain Syndrome (CPPS). (American Society of Aerospace Medicine Specialists, 2008)

Non Analog Populations

The Urologic Diseases in America project uses multiple national databases to quantify the burden of urologic diseases on the American public. Their report is based on 1992-2000 physician office visits for prostatitis listed as any diagnosis, annual rate per 100,000 are 1,749 overall; 1,534 and 1,921 by age cohorts 35-44, and 45-54 respectively. Rates do not differentiate by prostatitis categories. Bacterial Prostatitis accounts for 5-10%, including both acute and chronic. According to the Healthcare Cost and Utilization Project (HCUP), the age-adjusted rate of inpatient hospitalizations for prostatitis in 2000 was 7.7 per 100,000. By age, 2.8, and 6.8 for the 35-44 and 45-54 age cohorts respectively. 95% Confidence intervals (CI) 2.2–3.3 and 5.9–7.8 for the same groups. According to the National Survey of Ambulatory Surgery database, visit rates were essentially stable between 1994 and 1996, with an annualized rate of 33 per 100,000 for prostatitis listed as any diagnosis. Visit rates were highest in the 55–74 age group (216 per 100,000). Men aged 35–54 had much lower rates (91 per 100,000). Three procedures were associated with ambulatory surgery visits for prostatitis—cystoscopy, prostatic biopsy, and urethral dilation. (McNaughton-Collins, 2007)

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 %: 87 - 100)	100	0.5	0 - 5	48 - 360 - 672	0	0	0
ISS-based Treatment (worst case scenario %: 0 - 13)	100	0.5	1 - 13	240 - 456 - 672	0 - 5	0 - 1	0
Untreated Best Case	0	0	1 - 13	48 - 360 - 672	0 - 5	0 - 1	0
Untreated Worst Case	0	0	7 - 15	240 - 456 - 672	1 - 15	0 - 100	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

Best case scenario is defined as a mild to moderate prostatitis that responds to treatment with analgesics and antibiotics.

Worst case scenario is defined as a severe prostatitis including development of prostatic abscess.

Best case versus worst case percentages

The percentage of worst cases is based on terrestrial data. A review article on prostatitis syndrome reported that prostatic abscess develops in about 3% of all cases of acute bacterial prostatitis (ABP). The recurrence rate for ABP is about 13%. (Wagenlehner, 2009) To allow for uncertainty the worst case percentage is estimated at 0-13%. Thus the best case percentage is 87-100%.

Concomitant urinary tract infection, urinary retention, and sepsis are addressed in the Urinary tract infection (UTI), Urinary Retention, and Sepsis CliFFs respectively.

Best Case Comments

Acute Prostatitis functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Prostate Disease ratings are based on Table 7-9, p-149 (American Medical Association, 2008).

By definition, FI during **Clinical Phase I** is 100%. Duration is estimated to be 30 minutes, to follow the procedure indicated in the ISS medical checklist for physical exam, urinalysis, analgesia and scheduling a PMC conference. During **Clinical Phase II**, FI is estimated in 0 to 5%. Duration is estimated in 48 to 672 hours, 2 to 28 days, based on time to spontaneous remission or duration of antibiotic treatment. During **Clinical Phase III**, by definition, FI is 0%, EVAC and LOCL are not expected in the best case scenario.

Worst Case Comments

Acute Prostatitis functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Prostate Disease ratings are based on Table 7-9, p-149 (American Medical Association, 2008).

By definition, functional impairment (FI) is 100% during **Clinical Phase I** Duration is estimated to be 30 minutes, to follow the procedure indicated in the ISS medical checklist for physical exam, urinalysis, analgesia, and scheduling a PMC conference. During **Clinical Phase II**, FI is estimated in 1 to 13%. Duration is estimated in 240 to 772 hours, 10 to 28 days, based in length of treatment. During **Clinical Phase III**, symptoms may or may not resolve. FI is estimated at 0 to 5%. Prostatitis is a Class IIa medical event, i.e. manageable with the HMS and not likely to require evacuation or affect mission duration, although it resulted in an early termination on one MIR mission. (Johnston, 2008) Non-US astronaut data is not considered in the model. The rate of hospitalization per prostatitis events is less than 1% in the United States. (McNaughton-Collins, 2007) EVAC is estimated at 0 to 1%. LOCL is not expected.

Untreated Best Case Comments

Acute Prostatitis functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Prostate Disease ratings are based on Table 7-9, p-149 (American Medical Association, 2008).

During Clinical Phase II, FI is estimated in 1 to 13%. Duration is estimated at 48 to 672 hours, 2 to 28 days, similar to the treated best case scenario. During **Clinical Phase III**, recovery may or may not occur without treatment, FI is estimated at 0 to 5%. By definition EVAC may be considered due to intractable pain. EVAC is estimated at 0-1% similar to the treated worst case. LOCL is not expected.

Untreated Worst Case Comments

Acute Prostatitis' functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Prostate Disease ratings are based on Table 7-9, p-149 (American Medical Association, 2008).

During **Clinical Phase II**, FI is estimated at 7 to 15%. Duration is estimated at 240 to 772 hours, 10 to 28 days, similar to the treated scenario. During **Clinical Phase III**, the infection and pain would not resolve and FI is estimated at 1 to 15% without treatment. Based on the need for definitive care and to account for uncertainty, EVAC is estimated at 0-100% for this scenario. LOCL is not expected.

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
American Medical Association, 2008	3	FI
Johnston, 2008	2	EVAC
McNaughton-Collins, 2007	4	EVAC
Wagenlehner, 2009	4	BCWC

The Resource Table (RT)

Resource	Units Required Best Case	Units Required Worst Case	Units Available At Start Of Mission	Consumable	Essential	Rationale
Bactrim DS (Sulfamethoxazole/Trimethoprim) 800 mg/160 mg tablet	56	0	40	Yes	Yes	Antibiotic
Blood Oximeter	1	1	1	No	Yes	For VS Measurement
Blood Pressure Cuff (regular, large)	0	1	2	No	Yes	Measure blood pressure
Blood Pressure Monitor	0	1	1	No	Yes	Measure blood pressure
Cotton swabs	1	2	6	Yes	No	To test urine
Ertapenem 1gm	0	14	6	Yes	Yes	Antibiotic
Lidocaine (Xylocaine) plain 1%, 10mL multi dose vial	0	14	3	Yes	Yes	Anesthetic for ertapenem injection
Motrin (Ibuprofen) 400mg	28	28	400	Yes	Yes	Pain relief/anti-inflammatory
Stethoscope	1	1	2	No	Yes	For VS Measurement
Thermometer	1	1	1	No	No	For VS Measurement
Urine chemstrips	1	2	10	Yes	Yes	Urine test for pH, leukocytes, protein, glucose, ketones, blood, and nitrites
Urine Color Chart	1	1	1	No	No	Use with urine chemstrips to test for blood in urine.
Vicodin HP (Hydrocodone/ Acetaminophen HP) 10 mg/660 mg	0	14	30	Yes	Yes	Pain managment

Resource Comments

We revised the table on 9/19/2011 and added rationales, Sharps container, and ziplock bag.

The ISS medical checklist does not address Prostatitis. There are procedures for bladder/kidney infection. The resource table is based on terrestrial clinical guidelines (Clinical Effectiveness Group. British Association for Sexual Health and HIV (BASHH, 2008) combined with ISS bladder/kidney infection treatment (Mission Operations Directorate (MOD), 2011). All required resources are available on board.

Required Resources 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
Clinical Effectiveness Group.British Association for Sexual Health and HIV (BASHH, 2008	3	Resources
NASA Mission Operations Directorate (MOD), 2011	2	Resources

Level Of Evidence

Input Data	LOE Average
Incidence	4
Functional Impairment	3
Best Case / Worst Case	4
EVAC / LOCL	3
Resources	2.5
QUALITY OF EVIDENCE	**3.3**

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

Reference List

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