

# Hemorrhoids Cliff

## Branch Baseline

Hemorrhoids are swollen blood vessels in the lower rectum. The term "hemorrhoids" refers to the pathologic presentation of hemorrhoidal venous cushions. (Thornton, 2011)

Hemorrhoids are classified as diseases of the circulatory system by ICD-9 and ICD-10, but are much more often diagnosed and treated by digestive disease specialists than by those with a primary interest in the circulatory system. Hemorrhoids are sub-classified by anatomical location (internal or external) and whether they are complicated with bleeding, prolapse, strangulation, or ulceration. Most persons with hemorrhoids do not seek medical care and are self-treated using non-prescription medications. (Everhart, 2008)

The risk of hemorrhoids on orbit are increased due to higher incidence of constipation thought to be explained by large bowel ilius, relative dehydration, and the desire of crew to reduce bowel movements. These can each contribute to straining at stool which can increase the risk of hemorrhoid events. (Marshburn, 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: | No        |
| Incidence Type:   | Rate      |

#### Distribution Data

|             |         |
|-------------|---------|
| Incidence:  | Gamma   |
| Occurrence: | Poisson |

#### Data Characteristics

|                                                      |                                 |
|------------------------------------------------------|---------------------------------|
| Events:                                              | 4                               |
| Person Years:                                        | 45.49                           |
| Space Flight Incidence Rate (Events / Person Years): | $4 / 45.49 = 0.087931413497472$ |

### Incidence Comments

Two events have occurred in flight. (Walton, 2010)

Both episodes were described as bleeding. One occurred on flight day 84, with no recurrences; and the other on flight day 4

Integrated the real world system's incidence data (Saile, 2017)

Updated the Person-Years based on the revised real world system integrated incidence data. The integrated person years changed from 18.17 to 18.13 so the conditions person years changed from 45.53 to 45.49 (Saile L., 2017)

### Information Regarding Prevention

#### Selection criteria

Disqualifying conditions in the abdomen/digestive system include: chronic diseases or disorders of the alimentary tract that interfere with performance of duties; chronic constipation requiring chronic or continuous medication or therapy; acute or chronic diseases of the rectum or anus; and external or internal hemorrhoids that cause marked symptoms that could interfere with performance. (International Space Station Program, 2009)

#### Contingency measures

Oral and rectal bowel stimulants and psyllium wafers are available on orbit for constipation (Marshburn, 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 |
|----------------|-----------|--------------|
| Walton, 2010   | 1         | Incidence    |
| Saile L., 2017 | 1         | Incidence    |

## Alternative Incidence Data

### Analog populations

An analysis of 10 years of data collected on 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 5 hemorrhoids listed under surgeries during the 1963-67 period with an illness rate of 0.030; 12 sick days. There were six events of thrombosed hemorrhoids during the 1968-1973 period with an illness rate of 0.039; 6 sick days, (Table A7). (Tansey, 1979)

Incidence rate 0.030 per 1000 man-days ( $0.030 \times 365 = 10.95 / 1000$ ) equals 0.01095 person-years for the period 1963-1967 and 0.039 per 1000 man-days ( $0.039 \times 365 / 1000$  person years) equals 0.014235 person-years for the period 1968-1973. The average of these two incidence rates is 0.0125925 per person-years. Hemorrhoids (11/269) accounted for 4.1% of total surgeries, or a rate of 0.0005162925. No other hemorrhoid events, without surgery were found among the gastrointestinal, cardiovascular, or general medicine groups

Thomas reported on health of US Navy submarine crews during periods of isolation. Hemorrhoids occurred to 4 submarine officers, which accounted for 50% (4/8) of the reported circulatory system disorders (ICD-9 codes 455, Diseases of Veins and Lymphatics, and other diseases of circulatory system). The total rate for circulatory system disorders was 1.4 for officers per 100 person years. Effect of illness was minimal 0.75 (officers) to 1 day (enlisted men). Only 4.2 officers and 7% of enlisted men had greater than 2 days illnesses. Thomas concluded that officers are most analogous to current space program participants. Majority of medical events reported were minor, non life-threatening, with little or no impact on unit mission. (Thomas, 2003) Our estimated incidence rate derived from the aforementioned events is 0.7 ( $1.4 \times 50\%$ ) per 100 person years, 0.007 per person-years.

### Non-Analog populations

In 2004 in the United States, ambulatory care visits with first-listed hemorrhoids diagnosis, age adjusted rates per 100,000 population were 569 and 1294 for the 15-44 and 45-64 cohorts respectively. Hospital discharge rates per 100,000 for the same age cohorts were 7 and 19. Mortality rates were 0.0 for both age cohorts, with a total of 2 and 8 events respectively (Everhart, 2008). Per person-years, ambulatory care visit rates are 0.00569 and 0.01294; while hospital discharge rates are 0.00019 and 0.00045.

Hemorrhoids are the fourth or fifth leading outpatient digestive system diagnosis. Age-adjusted rates were similar for males and for females. Most hospitalizations for hemorrhoids are for surgery, which is performed most often as same-day surgery; thus, the number of hospitalizations for hemorrhoids was small relative to the number of ambulatory care visits (Everhart, 2008). The proportion of surgery per total visits is 1.2 and 1.4 % (7/569 and 19/1294) for the 15-44 and 45-64 age cohorts.

Neither Everhart's nor his data sources, National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS) published standard deviations or confidence intervals. The NAMCS website provides a description of the standard error calculation methodology without the results.

## 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<br>Diagnosis & Initial<br>Treatment <sup>1</sup> |                   | Clinical Phase II<br>On-going Treatment /<br>Convalescence <sup>2</sup> |                                    | Clinical Phase III<br>Recovered / Mission End<br>State <sup>3</sup> |               |               |
|---------------------------------------------------------|-------------------------------------------------------------------|-------------------|-------------------------------------------------------------------------|------------------------------------|---------------------------------------------------------------------|---------------|---------------|
|                                                         | FI*<br>(%)                                                        | Duration<br>(hrs) | FI*<br>(%)                                                              | Duration (hrs)<br>(Min - ML - Max) | FI*<br>(%)                                                          | EVAC**<br>(%) | LOCL**<br>(%) |
| ISS-based Treatment<br>(best case scenario %: 80 - 100) | 100                                                               | 0.25              | 0 - 5                                                                   | 0 - 36 - 72                        | 0                                                                   | 0             | 0             |
| ISS-based Treatment<br>(worst case scenario %: 0 - 20)  | 100                                                               | 0.25              | 1 - 10                                                                  | 0 - 84 - 168                       | 0 - 5                                                               | 0             | 0             |
| Untreated Best Case                                     | 0                                                                 | 0                 | 1 - 10                                                                  | 0 - 36 - 72                        | 0 - 5                                                               | 0             | 0             |
| Untreated Worst Case                                    | 0                                                                 | 0                 | 6 - 20                                                                  | 0 - 84 - 168                       | 1 - 20                                                              | 0 - 1         | 0             |

<sup>1</sup>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".

<sup>2</sup>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.

<sup>3</sup>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 a mild case of hemorrhoids, which causes minimal symptoms and responds to brief topical treatment, dietary and fluid modification. (Stages I and II)

The **worst case scenario** is defined as moderate or severe case of hemorrhoids with repeated symptoms requiring prolonged treatment. (Stages III and IV)

### Percentages of best case vs. worst case scenario

Updated BC/WC percentage with the algorithm "if the next case" as to date there has not been a worst case event. So WC would be 20% (1/5) and best would be 100% (5/5). Therefore the range for WC will be 0-20% (Saile L., 2017).

### Best Case Comments

Hemorrhoid's functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Anal Disease ratings are based on Table 6-6, p-116 (American Medical Association, 2008).

By definition in Clinical Phase I, FI is 100%. Duration of physical exam as described in ISS checklist for the best case scenario is estimated in 15 minutes. During Clinical Phase II, FI is estimated in 0 to 5%. Duration is estimated in 0 to 72 hours, or 0 to 3 days. In Clinical Phase III, full recovery is expected and FI is 0%. By definition EVAC and LOCL are not expected for the best case scenario.

### Worst Case Comments

Hemorrhoid's functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Anal Disease ratings are based on Table 6-6, p-116 (American Medical Association, 2008).

By definition in Clinical Phase I, FI is 100%. Duration of physical exam as described in ISS checklist is estimated in 15 minutes similar to the best case scenario. During Clinical Phase II, FI is estimated in 1 to 10%. Duration is estimated in up to 7 days (Halverson, 2007). In Clinical Phase III, full recovery may or may not occur and FI is estimated at 0-5%. Internal hemorrhoids requiring hospitalization have occurred in the astronaut corps on the ground. They are a Class IIa medical event, manageable with the HMS and not likely to require evacuation or affect mission duration (Johnston, 2008). By definition, EVAC and LOCL are not expected for this condition.

### Untreated Best Case Comments

Hemorrhoid's functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Anal Disease ratings are based on Table 6-6, p-116 (American Medical Association, 2008).

During Clinical Phase II, FI is estimated at 1 to 10%. Duration is 0 to 72 hours, or 0 to 3 days, similar to the treated best case scenario. In Clinical Phase III, recovery may or may not occur. FI is estimated at 0-5%. By definition, EVAC and LOCL are not expected for this condition.

### Untreated Worst Case Comments

Hemorrhoid's functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Anal Disease ratings are based on Table 6-6, p-116 (American Medical Association, 2008).

During Clinical Phase II, FI is estimated at 6 to 20%. Duration is estimated in up to 7 days, similar to the treated worst case scenario. In Clinical Phase III, recovery is unlikely and FI remains 1-20%. In analog populations, hemorrhoids have required surgical treatment (Tansey, 1979). Repeated bleeding without available treatment may make EVAC a consideration. To allow for uncertainty EVAC is estimated in 0 to 1%. LOCL is not expected for this condition.

### 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           |
| Tansey, 1979                       | 2         | EVAC         |
| Johnston, 2008                     | 2         | EVAC         |
| Saile L., 2017                     | 1         | BCWC         |

## The Resource Table (RT)

| Resource                        | Units<br>Required<br>Best<br>Case | Units<br>Required<br>Worst<br>Case | Units<br>Available<br>At Start<br>Of<br>Mission | Consumable | Essential | Rationale                         |
|---------------------------------|-----------------------------------|------------------------------------|-------------------------------------------------|------------|-----------|-----------------------------------|
| Dulcolax (Bisacodyl) tablet 5mg | 2                                 | 14                                 | 40                                              | Yes        | Yes       | Laxative                          |
| Lidocaine Jelly 2% 30mL Tube    | 0.3                               | 0.3                                | 3                                               | Yes        | Yes       | For pain relief                   |
| Motrin (Ibuprofen) 400mg        | 0                                 | 28                                 | 500                                             | Yes        | Yes       | For inflammation and pain relief. |
| Water                           | 1                                 | 1                                  | 1                                               | No         | No        | Constipation relief               |

### Resource Comments

The ISS medical checklist does not address hemorrhoids. Resources included are available on board and follow terrestrial guidelines (Society for Surgery of the Alimentary Tract - SSAT, 2008), e.g. dietary modifications and topical medication. Operative treatment is reserved for symptomatic patients with Stage III or IV hemorrhoids and would need to be done on the ground.

### 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 |
|---------------|-----------|--------------|
| Unknown, 2008 | 3         | Resources    |

## Level Of Evidence

| Input Data                 | LOE Average | Description | Range |
|----------------------------|-------------|-------------|-------|
| Incidence                  | 1           | Excellent   | 1-2   |
| Functional Impairment      | 3           | Good        | 2.1-3 |
| Best Case / Worst Case     | 1           | Fair        | 3.1-4 |
| EVAC / LOCL                | 2           | Poor        | 4.1-5 |
| Resources                  | 3           |             |       |
| <b>QUALITY OF EVIDENCE</b> | <b>2</b>    |             |       |

## Reference List

### Reference

---

American Medical Association. Digestive System. In: Rondinelli R, editor. Guides to the Evaluation of Permanent Impairment. 6th ed. Chicago: American Medical Association Press; 2008. p. 101-27.

---

Everhart JE. Hemorrhoids. In: Everhart JE, editor. The Burden of Digestive Diseases in the United States. 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 ; 2008. p. 89-92.

---

Halverson A. Hemorrhoids. Clin Colon Rectal Surg 2007 May;20(2):77-85.

---

International Space Station Program. Medical Standards for ISS Crewmembers - MED Vol A. 3.2 ed. NASA; 2011.

---

Johnston S, Arenare B, Smart K. Medical Evacuation and Vehicles for Transport. In: Barratt M, Pool S, editors. Principles of Clinical Medicine for Space Flight. New York: Springer; 2008. p. 139-61.

---

Marshburn TH. Acute Care. In: Barratt M, Pool S, editors. Principles of Clinical Medicine for Space Flight. New York: Springer; 2008. p. 101-22.

---

Saile L., Boley L, Kerstman E. Integration RWS ISS STS Observed Incidence V2. 2017.

---

Saile L., Boley L, Arellano J, Kerstman E. iMED Best and Worst Case Percentage Update. 2017.

---

Saile L, Boley L, Kerstman E. Integration RWS ISS STS Observed Incidence. 2017.

---

Tansey WA, Wilson JM, Schaefer KE. Analysis of health data from 10 years of Polaris submarine patrols. Undersea Biomed Res 1979;6 Suppl:S217-S246.

---

Thomas TL, Garland FC, Mole D, Cohen BA, Gudewicz TM, Spiro RT, et al. Health of U.S. Navy submarine crew during periods of isolation. Aviat Space Environ Med 2003 Mar;74(3):260-5.

---

Thornton S. Hemorrhoids. Geibel J, editor. WebMD eMedicine . 1-7-2011. New York. 7-29-2011.

---

Unknown. Surgical Management of Hemorrhoids. Society for Surgery of the Alimentary Tract - SSAT . 10-13-2008. Beverly, MA, Society for Surgery of the Alimentary Tract - SSAT. 8-11-2011.

---

Walton M, Kerstman E, IMM. In-flight Compilation v20100414\_Incidence\_calculation. 2010.