Gastroenteritis Cliff

Branch Baseline

Gastroenteritis is a non-specific term for various pathologic states of the gastrointestinal tract. The primary manifestation is diarrhea. Diarrhea associated with nausea and vomiting is referred to as gastroenteritis. Diarrhea is one of the most common reasons patients seek medical care. Of these patients, 90% do not seek medical attention, and 1-2% require admission. Infectious agents usually cause acute gastroenteritis by adherence, mucosal invasion, enterotoxin production, and/or cytotoxin production. It leads to dehydration, and the loss of electrolytes and nutrients. (Diskin, 2009)

The evaluation of gastrointestinal disorders on orbit proves to be a challenge compared to that on the ground. Symptoms may present in a different way due to re-positioning of the organs and mesentery as well as elevation of the diaphragm. (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:	5
Person Years:	45.49
Space Flight Incidence Rate (Events / Person Years):	5 / 45.49 = 0.10991426687184

Incidence Comments

There have been 4 cases reported in flight (Walton, 2010)

Added 1 total medical event and 18.17 persons based on the real world system 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 area include: chronic diseases or disorders of the alimentary tract that interfere with performance of duties, chronic gastritis or chronic abdominal pain, chronic gastritis or chronic abdominal pain, ulcerative colitis, Crohn's disease, chronic diarrhea, regardless of cause, irritable bowel syndrome. In the infectious diseases area: Acute or chronic infectious diseases, until appropriately treated that might compromise mission operations, performance of duties, or crew health or safety; presence of pathological intestinal bacteria or parasites on laboratory stool testing. In the general category: In general, any medical condition that, in the judgment of the MSMB, may compromise mission operations, performance of duties, or crew health or safety. (International Space Station Program, 2009)

Other

Gastroenteritis is less likely than Space Motion Sickness (SMS). Diarrhea and fever are not components of SMS and thus they distinguish infectious gastric disturbances from SMS. Pre-flight quarantine reduces the incidence of viral gastroenteritis during flight, but breaches can occur. (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 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 229 gastrointestinal diseases during the 1963-73 period with an illness rate of 0.05 and 0.03; for the 1963-67 and 1968-73 periods respectively. There were 134 events of gastroenteritis; causing 212 sick days and 21 staphylococcal gastroenteritis, with 24 sick days during the 1963-1973 period. Total is 155 events and 236 sick days (Table A3). (Tansey, 1979)

Incidence rate 0.03 per 1000 man-days (0.03*365 = 10.95/ 1000) equals 0.01095 person-years for the period 1963-1967 and 0.05 per 1000 man-days (0.05 *365 / 1000 person years) equals 0.01825 person-years for the period 1968-1973. The average of these to incidence rates is 0.0146 per person-years. Gastroenteritis (155/229) accounted for 67.7% of total gastrointestinal events, or a rate of 0.0098842. Six EVACs occurred but there is no information by condition.

Thomas reported on health of US Navy submarine crews during periods of isolation. There were 12 intestinal infections among officers, and 99 among enlisted men. Reported as ICD-9 code 008. The incidence rate for intestinal infections was 2.0 for officers and 1.9 for enlisted crew, per 100 person years. Effect of illness was minimal 0.75 (officers) to 1 day (enlisted men). Digestive was the second most common cause of limited or no duty. Only 4.2 officers and 7% of enlisted man 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) The incidence rate per person-years is 0.02 (2.0/100) and 0.019 (1.9/1000).

Of the major diagnostic categories associated with medical communications, 17% were for digestive system and it is the second diagnostic category associated with medical communications. Digestive system MEDEVACs were 17%, primarily for dental conditions. Percentage for gastroenteritis, if any, is not included. (Nice, 1987)

A health assessment survey was collected from US military personnel deployed to the Middle East taking part in the “Rest and Recuperation” program or on temporary assignment to Camp As Sayliyah Doha, Qatar, from January to December 2004. In addition, a concurrent clinic-based observational study was conducted to determine pathogen etiology and potential risk factors between may and November 2004. Self-reported incidence of diarrhea was 4.9 cases per 100 person-months. For the clinic-based observational study the calculated minimal incidence estimate was 12.6 (95% CI, 10.5–14.9) episodes of diarrhea per 100 person-months among those who had been deployed for at least 7 days. (Monteville, 2006) Rates per person-year are 0.588 (4.9 * 12 /100) and 1.512 (12.6 * 12 /100), for self report and observational respectively.

In 2004 in the United States, ambulatory care visits with first-listed gastrointestinal infections diagnosis, age adjusted rates per 100,000 population were 460 and 377 for the 15-44 and 45-64 cohorts respectively. Hospital discharges rates per 100,000 for the same age cohorts were 31 and 34. Mortality rates were 0.0 and 0.5 for the same age cohorts, with a total of 49 and 353 deaths respectively. (Everhart, 2011) Per person-years, ambulatory care visit rates are 0.0046 and 0.00377 for the 15-44 and 45-64 cohorts respectively. The proportion of hospital admissions per ambulatory visits is 6.73 and 9.01 % (31/460 and 34/377) 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 NACMS website provides a description of the standard error calculation methodology without the results.

In the Netherlands, a prospective population-based cohort study estimated the incidence of gastroenteritis as 283 per 1000 person-years. Bacterial pathogens accounted for 5% of the cases, parasites for 6%, bacterial toxins for 9%, and viral pathogens for 21% with Norwalk virus as the leading pathogen (de Wit, 2001). Per person year, the rate is 0.283.

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 %: 83.33 - 100)	100	0.25	0 - 17	24 - 48 - 72	0	0	0
ISS-based Treatment (worst case scenario %: 0 - 16.67)	100	0.25	2 - 36	24 - 72 - 120	0 - 17	0 - 1	0
Untreated Best Case	0	0	2 - 36	24 - 48 - 72	0 - 17	0	0
Untreated Worst Case	0	0	23 - 62	24 - 72 - 120	2 - 62	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

The **best case scenario** is defined as having an uncomplicated course of gastroenteritis which resolves spontaneously or causes minimal disturbance; with mild nausea/vomiting, diarrhea, or abdominal pain requiring only symptomatic treatment.

The **worst case scenario** is defined as having a severe course of gastroenteritis or prolonged symptoms refractory to treatment.

Dehydration or hypovolemic shock is addressed in the Hypovolemic Shock Clinical Findings Form.

Percentage of best versus worst case scenario is based on the Real World Systems data there were no worst cases so to integrate this data into the BC/WC percentage the algorithm developed with the original data set was used for all the medical events in both data sets. Therefore, if the next case is a worst case we would 1/6 or 17% of cases as worst cases. If the next case is best case, we would have 6/6 or 100%. Thus the percentage for worst case is 0-17% (Saile L., 2017)

Best Case Comments

Gastroenteritis functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Upper Digestive Tract ratings are based on Table 6-4, p-107. Colonic & Rectal Disorders ratings are based on Table 6-5, p-114 (American Medical Association, 2008). Total FI ratings are calculated combining the mentioned tables using the Combined Values Chart as indicated in Appendix A, pp 604-606 (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 to be 15 minutes. During Clinical Phase II, FI is estimated in 0 to 17%. Duration is estimated to be 24 to 72 hours, or 1 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

Gastroenteritis functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Upper Digestive Tract ratings are based on Table 6-4, p-107. Colonic & Rectal Disorders ratings are based on Table 6-5, p-114 (American Medical Association, 2008). Total FI ratings are calculated combining the mentioned tables using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008).

By definition in Clinical Phase I, FI is 100%. Duration of physical exam as described in ISS checklist is estimated to be 15 minutes similar to the best case scenario. During Clinical Phase II, FI is estimated in 1 to 10%. Duration is estimated to be 24 to 120 hours, 1 to 5 days (Monteville, 2006). In Clinical Phase III, full recovery may or may not occur and FI is estimated at 0-17%. Infectious colitis and abdominal pain with bloody diarrhea requiring hospitalization have occurred in the astronaut corps on the ground. Class IIa medical event, manageable with the HMS and not likely to require evacuation or affect mission duration. Class IIC is expected to be manageable with HMS, but may necessitate emergent evacuation if condition does not improve or worsens (Johnston, 2008). To allow for uncertainty EVAC is estimated at 0-1%. By definition, LOCL is not expected for this condition.

Untreated Best Case Comments

Gastroenteritis functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Upper Digestive Tract ratings are based on Table 6-4, p-107. Colonic & Rectal Disorders ratings are based on Table 6-5, p-114 (American Medical Association, 2008). Total FI ratings are calculated combining the mentioned tables using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008).

During Clinical Phase II, FI is estimated at 2 to 36%. Duration is expected to be 24 to 72 hours, or 1 to 3 days, similar to the treated best case scenario. In Clinical Phase III, recovery may or may not occur without treatment. FI is estimated at 0-17%. By definition, EVAC and LOCL are not expected for this condition.

Untreated Worst Case Comments

Gastroenteritis functional impairments (FI) calculation follows the IMM mild non-space adaptation template. Upper Digestive Tract ratings are based on Table 6-4, p-107. Colonic & Rectal Disorders ratings are based on Table 6-5, p-114 (American Medical Association, 2008). Total FI ratings are calculated combining the mentioned tables using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008).

During Clinical Phase II, FI is estimated at 23 to 62%. Duration is estimated to be up to 7 days, similar to the treated worst case scenario. In Clinical Phase III, recovery is unlikely and FI is estimated at 2-62%. Dehydration without available treatment may require EVAC. To allow for uncertainty EVAC is estimated at 0-100%. LOCL is not expected for this scenario.

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
American Medical Association, 2008	3	FI
Johnston, 2008	2	EVAC
Saile L., 2017	1	BCWC

The Resource Table (RT)

Resource	Units Required Best Case	Units Required Worst Case	Units Available At Start Of Mission	Consumable	Essential	Rationale
Blood Pressure Cuff (regular, large)	1	1	2	No	Yes	Measure blood pressure
Blood Pressure Monitor	1	1	1	No	Yes	Measure blood pressure
BZK wipes	0	1	60	Yes	No	Cleanse skin.
CMRS	0	1	1	No	No	Restrain crew member to ensure safety
Gauze pads (4x4)	0	2	50	Yes	No	To absorb blood or fluids from skin
Imodium (loperamide HCL) 2 mg tablet	3	9	40	Yes	Yes	Anti-diarrhea
IV administration set	0	1	3	Yes	Yes	IV Fluids infusion
IV Cap	0	1	5	Yes	No	To attach IV fluids to Y-type catheter
IV Catheter (18G, 20G, or 22G)	0	1	14	Yes	Yes	IV fluid administration
IV Fluid 1L (1000mL)	0	2	5	Yes	Yes	To replenish fluids
IV Fluid Air Filter	0	1	3	Yes	No	To filter air from IV line
IV pressure infuser	0	1	1	No	No	IV Fluids infusion
Medical tape	0	0.03	5	Yes	No	Single-coated tapepressure adhesive tape
Nitrile gloves (large, medium, and small) (pair)	0	1	30	Yes	No	Personal Protective equipment for CMO
Promethazine (Phenergan) 25mg/mL 1 mL injectable	0	4	24	Yes	Yes	Nausea relief
Sharps container	0	1	40	No	No	To dispose of medical waste such as used medical needles, scalpels, IV catheters, razors, vials
Stethoscope	1	1	2	No	Yes	To evaluate bowel sounds
Thermometer	1	1	1	No	No	To measure temperature
Tourniquet	0	1	1	No	No	To stop blood flow and engorge vein, this facilitates IV insertion
Water	1	0	1	No	No	Oral rehydration
Zofran (Ondansetron) 8 mg tablet	0	6	30	Yes	Yes	For nausea/vomiting

Resource Comments

The Resource table was revised and updated on 8/12/2011. We added BP/ECG, blood pressure cuff, Simethicone, and stethoscope.

Dehydration causing hypovolemic shock is addressed in the Hypovolemic Shock CliFF.

Gastroenteritis is not included as a condition in the ISS Medical checklist. The ISS Medical checklist's treatment for abdominal pain, including medications for nausea, vomiting, and diarrhea (Mission Operations Directorate (MOD), 2011).

Comparison of ISS medical Checklist versus terrestrial guidelines

The ISS Medical checklist is comparable to terrestrial guidelines (Guerrant, 2001), addressing symptomatic treatment and oral or intravenous hydration. IMM includes Sulfamethoxazole/Trimethoprim (Bactrim DS) as per terrestrial guidelines. Fecal testing is not 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
NASA Mission Operations Directorate (MOD), 2011	2	Resources
Guerrant, 2001	3	Resources

Level Of Evidence

Input Data	LOE Average
Incidence	1
Functional Impairment	3
Best Case / Worst Case	1
EVAC / LOCL	2
Resources	2.5
QUALITY OF EVIDENCE	**1.9**

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

Reference List

Reference
American Medical Association. Guides to the Evaluation of Permanent Impairment. 6th ed. Chicago: American Medical Association Press; 2008.
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.
de Wit MA, Koopmans MP, Kortbeek LM, Wannet WJ, Vinje J, van LF, et al. Sensor, a population-based cohort study on gastroenteritis in the Netherlands: incidence and etiology. Am J Epidemiol 2001 Oct 1;154(7):666-74.
Diskin A. Gastroenteritis in Emergency Medicine . Dronen S, editor. WebMD - Medscape Reference . 10-22-2009. New York, WebMD. 8-12-2011.
Everhart JE. Gastrointestinal Infections. 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.
Guerrant RL, Van GT, Steiner TS, Thielman NM, Slutsker L, Tauxe RV, et al. Practice guidelines for the management of infectious diarrhea. Clin Infect Dis 2001 Feb 1;32(3):331-51.
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.
Monteville MR, Riddle MS, Baht U, Putnam SD, Frenck RW, Brooks K, et al. Incidence, etiology, and impact of diarrhea among deployed US military personnel in support of Operation Iraqi Freedom and Operation Enduring Freedom. Am J Trop Med Hyg 2006 Oct;75(4):762-7.
NASA Mission Operations Directorate (MOD). International Space Station Integrated Medical Group Medical Checklist. Mission Operations Directorate (MOD), Systems Operations Data File (SODF) . 6-24-2011. Houston, TX, National Aeronautics and Space Administration (NASA).
Nice DS. U.S. Navy medical communications and evacuations at sea. Mil Med 1987 Sep;152(9):446-51.
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.
Walton M, Kerstman E, IMM. In-flight Compilation v20100414_Incidence_calculation. 2010.