Acute Sinusitis Cliff

Branch Baseline

The American Academy of Otolaryngology– Head and Neck Surgery Foundation developed the clinical practice guideline on adult sinusitis and provided the following definitions. (Rosenfeld, 2007)

Rhinosinusitis is defined as symptomatic inflammation of the paranasal sinuses and nasal cavity. Because sinusitis is almost always accompanied by inflammation of the contiguous nasal mucosa the term rhinosinusitis is preferred. Rhinosinusitis without clinically evident extension of inflammation outside the paranasal sinuses and nasal cavity at the time of diagnosis (e.g., no neurological, ophthalmological, or soft tissue involvement is defined as uncomplicated

Based on its duration rhinosinusitis may be further classified as acute, sub acute, or chronic, with or without acute exacerbations. Durations are less than 4 weeks, 4 to12 weeks, and more than 12 weeks respectively.

Based on symptom pattern acute rhinosinusitis may be classified into acute bacterial rhinosinusitis (ABRS) or viral rhinosinusitis (VRS).

Sinusitis, although not a prominent disorder among space flight crew can be promoted by cephalad fluids shift that causes engorgement of the sinus mucosal vasculature. It is important to distinguish true bacterial sinusitis from sinus congestion. Sonography may be useful in determining sinuses partially or fully filled. (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:	6
Person Years:	45.49
Space Flight Incidence Rate (Events / Person Years):	6 / 45.49 = 0.131897120246208

Incidence Comments

Incidence data includes 6 in flight events (Walton, 2010): 5 in STS, 1 in Apollo, 0 in ISS, 0 in Skylab, 0 in MIR

Incidence = 6 events/27.36 person-years (0.2193 events/person-year)

Of the 6 incidence events reported, 1 acute maxillary sinusitis, was found and treated on Apollo re-entry (Johnston, 1975). If found upon re-entry examination, we may assume that it started while on board.

One case presented as sinus congestion with low grade fever.

Integrated 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 events in the nose and sinuses category include: Chronic sinusitis (greater than 3 months), unless surgically or medically treated more than 3 years prior to exam with no evidence of recurrence. Any chronic disorder or defect that interferes with normal ventilation of paranasal sinuses or middle ear. **{**International Space Station Program, 2009 3074 /id**}**

Other

Flight Crew health Stabilization Program (pre-flight quarantine) in place to reduce the risk of illness from pre-flight exposure to persons with upper respiratory infectious diseases.

Ultrasound is a reliable diagnostic test for assessing fluid levels; recent experiments demonstrate the technique can be used during microgravity conditions with attention to altered fluid behavior in the absence of gravity (Benninger, 2009)

In November 2010 an animal model of acute sinusitis was developed in anesthetized swine. Ultra sound (US) examinations were performed in normal and microgravity environments, on control and sinusitis conditions, and recorded these for later interpretation. The US appearance of fluid in nasal sinuses during microgravity is characterized in the large animal model. On the introduction of microgravity, the typical air-fluid interface disassociates, and fluid lining the sinus can be observed. Such fluid behavior can be used to develop diagnostic criteria for acute bacterial rhinosinusitis in the microgravity environment. (Benninger, 2010)

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

Sinusitis is one of the most common disease conditions in the United States, affecting millions of Americans each year. (Anand, 2004)

In 2004, there were 30,789,000 cases or 14.2 percent (standard error 0.25). Respondents were asked in three separate questions if they had been told by a doctor or other health professional in the past 12 months that they had sinusitis 14% of adults 18 years and over had ever been told by a doctor or other health professional they had sinusitis. (Lethbridge-Cejku, 2006)

Sinusitis was reported by 13,976 and 11769 by age groups 18-44 and 45-64 respectively Age-adjusted percentages (with standard errors) of sinusitis were12.7 (0.33) and 16.8 (0.46) for these age groups. Estimates are age adjusted to the 2000 U.S. standard population using four age groups: 18–44 years, 45–64 years, 65–74 years, and 75 years and over. These calculations used the Sample Adult Weight variable, which is calibrated by National Center for Health Statistics (NCHS) staff to produce numbers consistent with estimates of the adult civilian non institutionalized population of the United States, based on projections from the 2000 U.S. Census.

The percentage of adults with sinusitis was higher in the South than in any other region of the United States. Survey methodology does not distinguish between acute and chronic sinusitis, so no further distinction between these diagnoses is possible.

A meta analysis by the Agency for Healthcare Research and Quality (AHRQ) ((Ip, 2005) found that overall, antibiotics were more effective than placebo, reducing the risk of clinical failure by about 25% to 30% 7 to 14 days after treatment initiation; risk ratio (RR) 0.69, 95% confidence interval (CI) 0.53-0.89. Nevertheless, symptoms improved or were cured in 65% of patients without any antibiotic treatment at all (95% CI 40-91%).

Analog populations

A total of 7 cases of acute sinusitis occurred on 10 years of Polaris health data resulting in 14 sick days (Tansey, 1979), 1963-1973, representing 0.042 of Ear Nose and Throat (ENT) diseases and 0.0041 of the total illness rate. Information on evacuations (transfers at sea) is not provided by specific diseases.

A nine month survey by the Naval Health Research Center (Nice, 1987) including 529 surface ships and submarines and 54 ships from the Military Sealift Command found that nervous system and sense organs accounted for 5% of medical communications and 8% infectious diseases. About 62% of medical communications results in MEDEVACs, ENT were not associated in the principal diagnostic categories associated with MEDEVACs while infectious diseases were. No specific information is provided on ICD codes

A study on health of US Navy submarine crew during periods of isolation, used data obtained from onboard automated medical system, which contains information on crewmembers serving aboard U.S. Navy submarines. IDCs are required to make an entry for each medical event requiring a prescription medication, a medical procedure, or crewmember assignment to limited or no duty. From 1 January 1997 through 30 September 2000. By ICD-9 code 461, acute sinusitis is classified under Upper respiratory infections. Total 55, rate 9.3/100 person years among officers and 502, rate 9. 4 per 100 person-years. No further details are provided within the Upper respiratory infections. (Thomas, 2003)

A longitudinal study of disease and non battle injuries (NDBI) by US Army brigade combat team during Operation Iraqi Freedom reported that of 4122 soldiers deployed, there were 58 total events (n=58) in the Head ears & nose (HEENT) body system. The only death (n=1, rate 1.7%) was due to trauma not to medical illness. The MEDEVAC rate was 19.0 (n=11, while the RTD was 79.3 (n=46). ICD-9 codes are not provided; thus it is possible that HEENT do not include sinus infections. Upper respiratory infections are not included. (Belmont, 2010)

Complications

There is a dearth of recent literature on sinus infection complications.

A recent study in Switzerland recruited acute rhinosinusitis subjects during four winter seasons (November 1 to April 30) of 1997 to 2001 from 24 general practices in Basel, Switzerland, and surroundings and in the internal medicine and otolaryngology outpatient clinics of the University Hospital Basel. In the placebo group, there was 1 serious disease-related adverse event. After 2 weeks of symptomatic treatment, the patient was then treated for 1 week with amoxicillin-clavulanate (1 g twice daily) but experienced a brain abscess caused by an amoxicillin-clavulanate–sensitive strain of *Streptococcus milleri*. The patient was operated on and recovered but has a frontal syndrome. (Bucher, 2003) We estimated the incidence of complications to be 0.004 (1/251) to 0.008 (1/127) for the total population and for the placebo group.

Complications of paranasal sinusitis constitute true surgical and medical emergencies. These complications appear to be more prevalent and seem to present in a more fulminant manner in the pediatric age group. The most common complication of paranasal sinusitis is orbital cellulitis followed collectively by all the intracranial complications. (Durand, 1998)

A retrospective chart review of all patients (n = 649) admitted for acute or chronic sinusitis to the University of Minnesota Hospital and to the University of Michigan Medical Center during a 13-year period (1975 to 1988) determined the incidence of complications as 3.7%, or 24 subjects (Clayman, 1991)

A Russian study (Voronkin, 1999) examined 2251 patients with paranasal sinusitis and detected various rhino sinusogenic orbital and intracranial complications in 75 of them (3.3% of overall number of sinusitis patients). The complications were caused by acute and chronic paranasal sinusitis in 49 and 26 patients, respectively. 55 patients (2.44%) had orbital and 20 (0.9 %) different intracranial complications. The treatment in most cases consists of emergency surgery and antibiotics.

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 %: 84 - 100)	100	0.25	0 - 9	72 - 120 - 168	0	0	0
ISS-based Treatment (worst case scenario %: 0 - 16)	100	0.25	1 - 27	168 - 252 - 336	0 - 9	0 - 1	0
Untreated Best Case	0	0	1 - 27	72 - 120 - 168	0 - 9	0	0
Untreated Worst Case	0	0	11 - 42	168 - 252 - 336	1 - 42	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 is defined as uncomplicated viral or bacterial rhinosinusitis that responds to initial treatment.

Worst case is defined as acute complicated bacterial rhinosinusitis causing severe headache, pain and/or fever and requires antibiotic treatment.

Percentages of how often best versus worst case scenarios occur were calculated based on in flight data. (Walton, 2010). Of 6 in flight events, only one presented with fever, and none with other complication symptoms. 4 cases presented between days 1-5, and 2 after. Our percentage for worst case is estimated at 0-16% (1/6), thus best case is 84-100%

Complicated sinusitis may present with severe headache, propotosis, cranial nerve palsies, facial swelling, or other clinical findings. (Rosenfeld, 2007)A severe complication of sinus infection it is not included here and it would be treated as Sepsis, addressed in the Sepsis CliFF

Best Case Comments

Sinus Infection functional impairments (FI) calculation follows the IMM mild non space adaptation template. Air passage deficits are based on Table 11-6, p.267 (American Medical Association, 2008). For further description of gradings refer to the CliFF Appendix

By definition in Clinical Phase I, FI is 100%. Duration to follow procedures specified in ISS checklist, i.e. nasal exam, and providing medications is estimated in 15 minutes. During Clinical Phase II, FI is estimated in 0 to 9%. Duration is estimated in 72 to 168 hours, or 3 to 7 days based on space flight data (In-flight Compilation Lockdown revised, 2010). In Clinical Phase III, by definition, full recovery is expected and FI is 0%. By definition EVAC and LOCL would not be expected for the best case scenario.

Worst Case Comments

Sinus Infection functional impairments (FI) calculation follows the IMM mild non space adaptation template. Air passage deficits are based on Table 11-6, p.267 (American Medical Association, 2008). For further description of gradings refer to the CliFF Appendix

By definition in Clinical Phase I, FI is 100%. Duration to follow procedures specified in ISS checklist, i.e. nasal exam, and providing medications is estimated in 15 minutes. During Clinical Phase II, FI is estimated in 1 to 27%. Terrestrial clinical guidelines (Rosenfeld, 2007)presume acute bacterial rhinosinusitis if symptoms are present for 10 or more days or double worsening within 10 days after initial improvement. Duration is estimated in 168 to 336 hours, or 7 to 14 days, to cover both presentations. In Clinical Phase III, recovery is expected but some symptoms may persist. FI is estimated at 0 to 9%. Both Viral and Bacterial acute rhinosinusitis are considered self-limited processes (Meltzer, 2004). Faced with the lack of available data for serious complications of sinusitis, a model created to examine cost effective strategies for management of acute bacterial sinusitis derived a disease complication rate of 1 in 10,000 cases. The model used hospital admission rates for brain abscess in 1994, percentage of abscesses caused by sinus infections, and all cases of acute bacterial sinusitis, including those who do not seek health care. (Balk, 2001) To allow for uncertainty we estimated 0 to 1% for EVAC. LOCL is not expected.

Untreated Best Case Comments

Sinus Infection functional impairments (FI) calculation follows the IMM mild non space adaptation template. Air passage deficits are based on Table 11-6, p.267 (American Medical Association, 2008). For further description of gradings refer to the CliFF Appendix

During Clinical Phase II, FI is estimated in 1 to 27%. Duration is 72 to 168 hours, or 3 to 7 days, similar to the treated best case scenario. In Clinical Phase III, based on Bucher's study (Bucher, 2003)where 76.6% in the placebo group were cured, we expect that best case scenario infections will resolve. FI is estimated at 0-9%. By definition EVAC and LOCL are not expected for the untreated best case scenario.

Untreated Worst Case Comments

Sinus Infection functional impairments (FI) calculation follows the IMM mild non space adaptation template. Air passage deficits are based on Table 11-6, p.267 (American Medical Association, 2008). For further description of gradings refer to the CliFF Appendix.

During Clinical Phase II, FI is estimated in 11 to 42%. Duration is 168 to 336 hours, or 7 to 14 days, similar to the treated worst case scenario. In Clinical Phase III, based on Bucher's study (Bucher, 2003)where 74% in the placebo group were cured, we expect that majority of worst case scenario infections will resolve. FI is estimated at 1-42%. No hospitalization for sinusitis was found on the LSAH astronauts on the ground data. (Johnston, 2008). EVAC may be considered based on potential intractable pain. To allow for uncertainty we are considering 0 to 100% EVAC rate. 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
Balk, 2001	3	EVAC
Walton, 2010	1	BCWC

Additional Comments

PubMed searches were conducted using the terms sinusitis or sinus infection, and microgravity, astronauts, epidemiology, and incidence

The Resource Table (RT)

Resource	Units Required Best Case	Units Required Worst Case	Units Available At Start Of Mission	Consumable	Essential	Rationale
Levaquin (levofloxacin) 500mg	0	10	30	Yes	Yes	Antibiotic
Sudafed 12 Hour (Pseudoephedrine) 120 mg	6	12	125	Yes	Yes	Relief of nasal congestion (oral)
Thermometer	1	1	1	No	No	To measure temperature
Tylenol (Acetaminophen) 325 mg	18	48	250	Yes	Yes	pain relief, first line

Resource Comments

ISS checklist includes sinus problems, and addresses symptomatic relief and treating the infection if present. All resources included for this condition are included in the ISS medical checklist (Mission Operations Directorate (MOD), 2011).

Terrestrial guidelines treatments are comparable to ISS with pain relief as a major goal.

Because of evidence limitations, particularly heterogeneity in trial design, initial observation of acute bacterial rhinosinusitis (ABRS) is considered an “option” and is not a “recommended” approach in all circumstances. Most favorable clinical outcomes for non severe ABRS, however, result from natural history, not antibiotics, and randomized trials of comparative efficacy do not support superiority of any single agent for initial empirical therapy. (Rosenfeld, 2007)

Adjunctive treatments for rhinosinusitis that may aid in symptomatic relief include decongestants (alpha-adrenergic), corticosteroids, saline irrigation, and mucolytics. None of these products has been specifically approved by the Food and Drug Administration for use in acute rhinosinusitis (as of February 2007), and few have data from controlled clinical studies supporting this use. ISS includes decongestants and mucolytics. Use of saline irrigation will have operational limitations.

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

Level Of Evidence

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

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

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