Nasal Congestion (space adaptation) Cliff

Branch Baseline

A few minutes to a few hours after being weightless a sensation of fullness in the head is commonly reported along with nasal congestion. Subjectively crew members complain of discomfort feeling of facial fullness, especially behind the eyes and the in the maxillary and frontal sinus areas. This last from a few hours to a few days, and it usually resolves to a tolerable level when new set points for fluid regulation are established. (Baker, 2008)

Although nasal congestion poses minimal risk to the crew, it can distract from mission tasks and increase insensible fluid loss from mouth breeding (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:	Yes
Incidence Type:	Proportion

Distribution Data	
Incidence:	Beta
Occurrence:	Bernoulli

Data Characteristics	
Occurrence Hour Range:	24 to 120
Peak Occurrence Hours:	24
Events:	458
Persons At Risk:	807
Space Flight Incidence Rate (Events / Persons at Risk):	458 / 807 = 0.567534076827757

Incidence Comments

All events are from space flight data (Walton, 2010).

IMM considers space adaptation events as events starting during days 1 to 5 (IMM, 2009). In reviewing the data, it became evident that nasal congestion occurs beyond the 5 initial days. We considered for this condition events occurring during the first two weeks, days 1 to 15 and events with no start day were all considered for this condition. This change is supported by Skylab (Gibson II, 1975)and Apollo (NASA, 1975)crew reports.

Early in the flight we experienced a sensation of head fullness. This is caused by a shift of the body fluids to the upper part of the body when one first enters into zero-g. One notices that the eyes turn red which, in my case, happened after about a day or so. The eye sockets themselves become a little puffy, the face a little rounder and a little redder, veins in the neck and forehead become distended and one's sinuses feel congested. These **conditions did not change significantly in-flight, they just tapered off.**

The most frequently reported subjective sensation associated with initial orbital insertion was a feeling of fullness in the head. This sensation, reported by all but two crewmen**,** persisted for four hours to three days. Concomitantly, crewmen noticed a roundness of the face in one another and engorgement of the veins of the head and neck. One crewman reported that head fullness was similar to the feelings elicited by standing on one's head or hanging upside down. (Johnston, 1975)

Putcha's study of pharmaceutical use in spaceflight, included decongestants, the frequency of use was low but constant througout the mission. (Putcha, 1999) Specific findings were that decongestant are the third most used drug, after medications for sleep and headache. Also sinus congestion drugs were taken consistently for 9 flight days.

The incidence for Apollo was 0.94 (31/33), for Skylab 1.0 (9/9), and 0.58 for STS (346/600)

Integrated the real world system incidence data. Added 9 ISS events and 60 STS events tot he previous 2 and 346, respectively. Added 144 persons at risk for a total of 808 persons at risk (Saile, 2017).

Updated the Persons at Risk based on the revised real world system integrated incidence data. The integrated RWS persons at risk from 144 to 143 so the conditions integrated iMED value went from 808 to 807. (Saile L., 2017)

Information Regarding Prevention

Vehicle requirements

It has become apparent from crew comments and flight surgeon observations that adequate filtering of the spacecraft air lessens nasal congestion (Marshburn, 2008)

Contingency measures

Exercise improves the head fullness sensation and eating lessens the feeling to some degree (Gibson II, 1975)

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

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 %: 99.56 - 99.78)	100	0.25	0 - 9	0 - 36 - 72	0	0	0
ISS-based Treatment (worst case scenario %: 0.22 - 0.44)	100	0.25	1 - 27	72 - 120 - 168	0	0	0
Untreated Best Case	0	0	1 - 27	0 - 36 - 72	0	0	0
Untreated Worst Case	0	0	11 - 42	72 - 120 - 168	0	0	0

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

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

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

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

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

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

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

Scenario Comments

Best case scenario is defined as mild to moderate nasal congestion, partial nasal obstruction

Worst case scenario is defined as severe nasal congestion, complete nasal obstruction

Best case vs. worst case percentage rationale

Based on space flight data from the Real World System, there was 69 events and of those 1 was worst case. Therefore, the worst case is caculated to 1.45% (1/69) and the best cases are 98.55% (Saile L., 2017)

Best Case Comments

Nasal congestion functional impairments (FI) calculation follows the IMM 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 is estimated in 15 minutes. During Clinical Phase II, FI is estimated in 0 to 9%. Duration is estimated in 0 to 72 hours, based on description of in flight events. In Clinical Phase III, full recovery is expected and FI is 0%. By definition EVAC and LOCL would not be expected for the best case scenario. Nasal congestion could be classified as a Class I Medical Event with no mission impact, or a Class IIa, manageable with the HMS and not likely to require evacuation or affect mission duration (Johnston, 2008)

Worst Case Comments

Nasal congestion functional impairments (FI) calculation follows the IMM 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 is estimated in 15 minutes. During Clinical Phase II, FI is estimated in 1 to 27%. Duration is estimated in 72 to 168 hours or 3 to 7 days. In Clinical Phase III, by definition full recovery is expected for a space adaptation condition and FI is 0%.

Untreated Best Case Comments

Nasal congestion functional impairments (FI) calculation follows the IMM 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 1-27%. Duration is 0 to 72 hours, similar to the treated best case scenario. In Clinical Phase III, by definition full recovery is expected for a space adaptation condition and FI is 0%.

Untreated Worst Case Comments

Nasal congestion functional impairments (FI) calculation follows the IMM 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 at 11 to 42%. Duration is 72 to 168 hours, similar to the treated worst case scenario. In Clinical Phase III, by definition full recovery is expected for a space adaptation condition and FI is 0%.

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
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
Afrin (Oxymetazoline) 0.05% 15mL bottle	0.25	0.5	12	Yes	Yes	Relief of nasal congestion (topical)
Saline Nose Spray 22mL bottle	0	0.3	1	Yes	Yes	Relief of nasal dryness/irritation (topical)
Sudafed 12 Hour (Pseudoephedrine) 120 mg	0	14	125	Yes	Yes	Relief of nasal congestion (oral, long-acting)

Resource Comments

All resources to treat nasal congestion are included in the ISS medical checklist (MOD, 2011).

The treatment described is comparable to the treatment guidelines for non allergic rhinitis, i.e. oral decongestants and intranasal agents (Wallace, 2008).

Required Resources Level of Evidence (LOE)

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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	2
Resources	2
QUALITY OF EVIDENCE	**1.8**

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

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