

# Clinical Finding Form (CLiFF)

Branch

Baseline

## ICL25\_Choking/Obstructed Airway

"Foreign body aspiration can be a life-threatening emergency. An aspirated object may lodge in the larynx or trachea. If the object is large enough to cause near or complete obstruction of the airway, asphyxia may rapidly cause death. Lesser degrees of obstruction or passage of the obstructive object beyond the carina can result in less severe signs and symptoms." (Warszawsky, 2020) These can result in recurrent infections. Objects that descend beyond the trachea are more often found in the right endobronchial tree than in the left. (Warszawsky, 2020) "Possible mechanisms for choking and obstructed airway on orbit may include food that is partially swallowed that, due to microgravity, obstructs or irritates the upper airway. During exercise or while working near small floating objects, they may be inhaled. Also talking or laughing while eating or drinking may increase the risk of choking or obstructed airway." (NASA, Choking/Obstructed Airway CLiFF, 2017)

INCIDENCE DATA INCLUDED IN THE MODEL

The model imports the following incidence information from the MEDPRAT Evidence Library Database: incidence data category, space adaption status, EVA status, incidence data type, 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. adjusted data). Space adaptation identifies medical events that where onset occurs in the first 5-7 days of flight and does not reoccur. EVA-related incidence values identify medical events that occur only during an EVA. Incidence values types vary by data category and define the number of medical events per person-year (rates) or medical events per person at-risk (proportion) for each medical condition. Incidence values can be modified by crew characteristics such as gender sex and certain crew medical history characteristics. 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 crewmember 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 MEDPRAT Technical Description Document.

INCIDENCE DATA

SPACEFLIGHT LITERATURE

There have been 3 events of foreign body inhalation have been reported in space flight. (NASA, Choking/Obstructed Airway CLiFF, 2017) All events have been mild and self-limited. One event was described as aspiration of lint which occurred on the evening of flight day 7. The astronaut drank fluids and milk to help clear the lint. All symptoms were cleared by the next morning. A second inhaled hair while exercising, which caused the astronaut to "hack" for about one hour. The third occurred while working near an old vent that was blowing on the astronaut. The astronaut felt something go down into the upper airway. The astronaut coughed for 5 minutes, then cleared. No treatment was required. (NASA, Choking/Obstructed Airway CLiFF, 2017).

ANALOG LITERATURE

A literature search (September, 2021) did not obtain any studies with data analogous to spaceflight.

TERRESTRIAL LITERATURE

Terrestrially, the true incidence of best-case foreign body airway obstruction is difficult to determine due an unknown amount of cases being managed without the need for emergency services (Pavitt et al, 2017). It is known that foreign body aspiration has a bimodal distribution with most occurrences in children less than 5 years of age and adults over 75 years of age (National Safety Council, 2019). Data for worst-case scenario choking episodes is more readily available. According to the National Safety Council, there were 200 deaths in adults aged 25-44 in the United States related to worst-case scenario choking in 2019 (National Safety Council, 2019). Other studies attempt to determine incidence through EMS records in various locations, but are similarly skewed towards worst-case scenario episodes of choking given the need for EMS intervention.

OVERALL INCIDENCE SUMMARY

INCIDENCE

Mean: 0.06589 SD 0.03826

INCIDENCE SUMMARY

The incidence for this CLiFF is taken directly from the IMM CLiFF which reported 3 best-case scenario episodes of choking/obstructed airway in

spaceflight through 2017. The Bayesian posterior distribution for the incidence rate given the spaceflight evidence (3 events over 45.49 person-years), under an uninformative prior, is Gamma(shape=2.966, rate=45.012) with mean 0.06589 and SD 0.03826.

TABLE 1. INCIDENCE MODEL

|                                                         |
|---------------------------------------------------------|
| <b>Incidence Details</b>                                |
| Incidence Type<br><b>General</b>                        |
| Segment<br><b>All</b>                                   |
| Env. Exposure<br><b>NA</b>                              |
| Sex<br><b>Any</b>                                       |
| Crowns<br><b>Any</b>                                    |
| Contacts<br><b>Any</b>                                  |
| Pregnancy<br><b>Any</b>                                 |
| <b>Incidence Distribution</b>                           |
| Occurrence Dist<br><b>Poisson</b>                       |
| Incidence Dist.<br><b>Gamma</b>                         |
| Mean<br><b>0.0658935</b>                                |
| SD<br><b>0.0382611</b>                                  |
| Gamma<br><b>(Shape): 2.966</b><br><b>(Rate): 45.012</b> |

TABLE 2. INCIDENCE LEVEL OF CONFIDENCE (LOC)

| Citation                                    | Source      | LOC Value |
|---------------------------------------------|-------------|-----------|
| National Safety Council, 2019               | Terrestrial | 2         |
| Pavitt et al, 2017                          | Terrestrial | 1         |
| NASA, Choking/Obstructed Airway CLiFF, 2017 | Spaceflight | 4         |
| Sakai et al, 2014                           | Terrestrial | 1         |
| Soroudi et al, 2007                         | Terrestrial | 2         |

National Safety Council, 2019 presents statistics regarding choking related deaths in the US by age. It does not adjust for risk factors (neuromuscular disease, etc.). Pavitt et al, 2017 is a study of EMS encounters for foreign body airway obstruction in London, UK in 2016. It provides data regarding incidence by age, however does not adjust for comorbidities similar to the National Safety Council data. NASA, Choking/Obstructed Airway CLiFF, 2017 provides incidence taken directly from spaceflight records and therefore has the strongest level of confidence. Sakai et al, 2014 is incidence data from EMS records in Osaka, Japan. This population is distinct from the US population and does not adjust for comorbidities. Soroudi et al, 2007 is incidence data from San Diego records and is adjusted for age, making these data more representative of the NASA astronaut population relative to other EMS studies.

## CREWMEMBER SELECTION/PREVENTION

### DISQUALIFYING CONDITIONS

Refer to Medical Evaluation Documents (MED) Volume A, Medical Standards for ISS Crewmembers, International Space Station Program, Rev 3.4 (2016).

### PREFLIGHT PREVENTATIVE MEASURES

Vehicle air filters minimize foreign object debris floating in the cabin that could be aspirated.

### BEST CASE SCENARIO DEFINITION

Choking and cough that resolve spontaneously, or obstructed airway that responds to the Heimlich maneuver.

### WORSE CASE SCENARIO DEFINITION

Choking and obstructed airway that requires instrument extraction or advanced life support.

### CONDITIONS INCLUDED, BUT NOT EXPLICITLY STATED (CNES)

None

## BEST CASE/WORST CASE PROBABILITY COMMENTS

In the prehospital setting in Osaka, Japan, Magill forceps were used to remove aspirated foreign bodies in 16.3% of cases (Sakai et al, 2014). According to Soroudi et al, in San Diego, the Heimlich maneuver was about 86.5% effective in removing aspirated foreign objects. Instrumentation with suction or Magill forceps were utilized in about 5.6% of cases. (Soroudi et al, 2007) Of the three cases of choking that have occurred in spaceflight, all were best-case scenarios (NASA, Choking/Obstructed Airway CLiFF, 2017). Terrestrial studies will over-estimate the incidence of worst-case scenarios because only worst-case scenarios present for care. The best-case scenario includes spontaneous resolution with coughing, for which there are no available data. Interpretation of terrestrial data are further limited because the majority of the population that required EMS services for foreign body aspiration were elderly with comorbidities, thus not representative of the astronaut population. Young, healthy astronauts are expected to have a lower overall incidence and higher percentage of best-case scenario cases than terrestrial studies. To account for the skewed terrestrial data towards an overestimation of the worst-case scenario, the current incidence of worst-case scenarios in spaceflight (0%) and the lowest predicted value (5.6%) from the terrestrial data (Soroudi et al, 2007) were utilized. The 5.6% WC upper limit came from the Soroudi study that showed that 5.6% of subjects who presented to the hospital required suction (presumably during bronchoscopy) or Magill forceps to remove a foreign body. The problem with this study that it only includes patients who actually presented to the hospital; it does not include subjects who cleared the foreign body on their own and never presented to the hospital. We did a quick search of articles that estimate the total number of cases of choking in the US per year (including those who don't present to the hospital). This would be a difficult statistic to find because very mild choking that self-resolves (our best case) would never be reported. (We were hoping to find the percentage of all cases of choking that present to the hospital. We could this percentage to correct the 5.6% figure which only applies to patients who go to the hospital with choking.) Therefore, SME opinion was used that approximately 80% of choking episodes are self-resolving without hospital intervention, then 20% go to the hospital or call 911. Using this, we will adjust the 5.6% WC upper limit by the percentage who actually present. This would be  $5.6\% \times .2 = 1.2\%$ . Thus, our range for WC would be 0 – 1.2%

TABLE 3.BEST/WORST CASE PROBABILITY LEVEL OF CONFIDENCE (LOC)

| Citation                                    | Source      | LOC Value |
|---------------------------------------------|-------------|-----------|
| Sakai et al, 2014                           | Terrestrial | 1         |
| Soroudi et al, 2007                         | Terrestrial | 2         |
| NASA, Choking/Obstructed Airway CLiFF, 2017 | Spaceflight | 4         |
| CST SME Opinion                             | SME         | 1         |

The worst-case scenario probability in terrestrial data is based on EMS encounters documented as foreign body aspiration or obstruction requiring instrumentation. The majority of the population that required EMS services for foreign body aspiration were elderly with comorbidities, making them less representative of the Astronaut Corps. This accounts for the lower scores for level of confidence for Soroudi et al, 2007 and Sakai et al, 2014. Young, healthy astronauts have a lower overall incidence and higher percentage of best case scenario cases than reported here. Spaceflight data provides an incidence of 3 choking episodes, all of which were best-case scenario (NASA, Choking/Obstructed Airway CLiFF, 2017).

**TABLE 4. CLIFF TREATMENT & OUTCOME TABLE BY CLINICAL PHASE**

| Case Scenario               | Composite Incidence         | Condition Probability % | CP1: Diagnosis |          | CP2: Treatment |          |       | CP3: Condition End State |      |      |      |      |
|-----------------------------|-----------------------------|-------------------------|----------------|----------|----------------|----------|-------|--------------------------|------|------|------|------|
|                             |                             |                         | TI%            | Duration | TI%            | Duration |       | TI%                      | RTDC | LOCL |      |      |
|                             |                             |                         | Preset         | Preset   | Preset         | Min      | Max   | Preset                   | Min% | Max% | Min% | Max% |
| Treated Best Case (TBC)     | Mean: 0.06589<br>SD 0.03826 | 98.8 - 100              | 100            | 0.06     | 50             | 0.008    | 0.2   | 0                        | 0    | 0    | 0    | 0    |
| Treated Worst Case (TWC)    |                             | 0 - 1.2                 | 100            | 0.5      | 50             | 0.02     | 360   | 0                        | 0    | 18   | 0    | 93   |
| Untreated Best Case (UTBC)  | N/A                         | N/A                     | N/A            | 0.06     | 50             | 0.008    | 0.2   | 0                        | 0    | 0    | 0    | 0    |
| Untreated Worst Case (UTWC) | N/A                         | N/A                     | N/A            | 0.5      | 100            | 0.17     | 85440 | 100                      | 0    | 100  | 0    | 100  |

**TABLE 4 KEY**

**Composite Incidence:** The same composite incidence will be used for both TBC and TWC. For EVA conditions: events per EVA (events/EVA). For space adaptation conditions: events per person (events/person). For non-spaceflight conditions: events per person year (events/py).

**Condition Probability:** The probability that CLIFF condition progresses to a worst case scenario. Best case scenario: 100%-Worst Case.

**Clinical Phase General Comments:**

- TI% = Task Impairment %. Task Impairment is the % of tasks that the crewmember is incapable of performing without impairment secondary to the medical condition.
- Durations are defined in hours.
- Removal to Definitive Care (RTDC): The probability the entire crew aborts the mission and returns to earth. This is considered as a condition end state result if any of the following criteria are met: 1) the potential for LOCL, 2) potential for significant permanent task impairment, or 3) potential for intractable pain.
- Loss of Crew Life (LOCL): The probability of death of affected crewmember due to medical condition.

**Clinical Phase 1: Initial Assessment and Diagnosis:**

- Covers only the initial assessment and diagnosis of the affected crewmember to define his or her medical condition. While the affected crewmember is being assessed, he or she is not able to perform any assigned tasks, thus Task Impairment (TI) during this phase is considered 100%. In the untreated case, there is no diagnosis performed, therefore Task Impairment and Duration will always be "not applicable."

**Clinical Phase 2: Stabilization, Treatment, and Convalescence:**

- The affected crewmember is receiving any appropriate initial or follow-on treatment for his or her medical condition to allow the crewmember to recover as much as he or she is able to recover in the spaceflight environment. Clinical phase 2 also encompasses relapses or recurrences of the same original medical condition in Clinical Phase 1. The duration of Clinical Phase 2 is expressed as minimum and maximum hours.

**Clinical Phase 3: Condition End State:**

- Reached once the affected crewmember has recovered from the medical condition as much as he or she is able to recover in the spaceflight environment amongst treated and untreated best and worst case scenarios. This may or may not be recovery from the given medical condition to the full extent possible. If this "recovered" state results in Removal to Definitive Care (RTDC) or Loss of Crew Life (LOCL) this will be noted in the condition end state results.

## SCENARIO OVERVIEW COMMENTS

The best-case and worst-case scenarios for the condition do not fit perfectly with available literature. They were created because the current best-case scenario is reflective of all prior episodes of choking/obstructed airway in spaceflight. This is important to capture. The literature, however, naturally breaks choking into complete vs. partial airway obstruction (both of which are accounted for in both the best and worst-case scenarios). Literature searches were not performed for the RTDC and LOCL probabilities of best-case scenarios as the choking/obstructed airway was assumed to resolve spontaneously based on the scenario definitions. In worst-case scenarios the RTDC surrogate was hospitalization due to cardiac arrest secondary to complete airway obstruction from choking. See details for individual scenarios below.

## TREATED BEST CASE (TBC) SCENARIO COMMENTS

In a best-case scenario, the crewmember would clear the airway obstruction before losing consciousness (loss of consciousness, indicates a worst-case scenario). Time to loss of consciousness in complete airway obstruction is "less than 1 minute" (Walls, 2012), 30 seconds was therefore selected as the minimum duration. The maximum duration assumed the aspiration resulted in a partial airway obstruction with signs and symptoms of cough, dyspnea, and wheeze that self-resolves. According to EMS data in San Diego from 2000-2007, in 43.5% of calls for foreign body aspiration, the aspiration event had resolved by paramedic arrival (Soroudi et al, 2007). A report from the Grand Jury of San Diego County indicated that for high priority medical calls the obligated contractual time to response is 12 minutes and that this has been fulfilled in the large majority of cases (approximately 95-98% of cases) in 2011-2013 (San Diego County Grand Jury, 2014). From this, the maximum duration for partial airway obstructions resolution was assigned 12 minutes. Literature searches were not conducted for RTDC and LOCL because by definition all best-case scenarios resolve either with the Heimlich or spontaneously resulting in no need for RTDC, and no LOCL would occur.

## TREATED WORST CASE SCENARIO (TWC) COMMENTS

Assumptions were made to determine the duration for the treated worst-case scenario. A complete airway obstruction was assumed for the minimum duration. After failed attempts at removal through backblows and the Heimlich maneuver, the astronaut would lose consciousness. It was assumed that after loss of consciousness it may be possible to immediately remove the foreign body. Thus, time to loss of consciousness in a complete airway obstruction (1 minute) was used for this duration (Walls, 2012). For the maximum duration, a partial airway obstruction was assumed, resulting in signs and symptoms of cough, dyspnea, and wheezing. In this situation, the flight surgeon or crew medical officer (CMO) would decide when it is appropriate to pursue instrumentation based on practice guidelines. Early flexible bronchoscopy should be pursued as a diagnostic and therapeutic intervention for patients without symptoms of acute asphyxiation (Shepherd et al, 2021). Terrestrial data from a study of 40 partially obstructed patients undergoing flexible bronchoscopy between 2009-2011, average age 52y (18-88y), at the University of Sao Paulo School of Medicine Hospital das Clinicas in Brazil reported a median length of obstruction prior to removal of 15 days (12h-10 years) (Rodrigues et al, 2012). Thus, 360 hours (15 days) was used as the maximum duration for this scenario. RTDC was assumed to be necessary in treated worst-case scenarios in which the foreign body could not be successfully removed. The CRT for this condition includes both instrument removal and flexible bronchoscopy. Although the CRT includes the capability for a surgical airway, it was assumed that this would be a lifesaving maneuver, followed by RTDC. Thus, the RTDC for this scenario is based on failure rates of instrument removal or bronchoscopy. In a study by Soroudi et al (2007), 29/29 patients were symptomatically improved after suctioning or forceps removal. The complication rate of flexible bronchoscopy is insignificant (Stahl et al, 2015). The failure rate of acute foreign body (present for a week or less) removal using flexible bronchoscopy was 0% in a retrospective study of 47 adult patients in Taiwan (Lan, 1994). Therefore the minimum RTDC percentage was assigned 0%. In the aforementioned study (Rodrigues et al, 2012) of 40 partially obstructed patients undergoing flexible bronchoscopy at the University of Sao Paulo School of Medicine Hospital das Clinicas in Brazil, 33 (82.5%) were successfully treated with flexible bronchoscopy. The remaining patients required rigid bronchoscopy (6 patients) or surgical bronchotomy (1). Based on these data the minimum RTDC probability was assigned 0% and the maximum RTDC probability was assigned 17.5%. The worst-case scenario includes choking/obstructed airway episodes requiring "advanced life support." The minimum probability of 0% for LOCL was assigned to this scenario as there are partial obstructions that never result in death. Near 0% probability has been reported in the literature. A retrospective analysis of data from the San Diego County pre-hospital database, 3.3% (17/513) of adult foreign body airway obstruction patients died (Soroudi et al 2017). The mean age for this study was 65 years. The maximum probability for LOCL was informed by data from Japan. Two studies provided 1 month survival after cardiac arrest due to choking (Kiyohara et al, 2018; Sakai et al, 2014). Kiyohara et al (2018) reported a 17.2% 1 month survival in 314 out of hospital cardiac arrest secondary to choking on rice cake patients in Osaka, Japan. Notably, the average age of subjects was 78 years. In a similar study, Sakai et al (2014), reported a one month survival rate after out of hospital cardiac arrest due to witnessed choking on food of 17%, which improved to 26.7% in patients who received attempted removal with forceps enroute to the hospital. The average age of subjects was 74 years in the forceps group and 78 years in the non-instrumented group. This study was also in Osaka, Japan. Inasuma et al (2010) reported a survival to hospital discharge of only 7% in cardiac arrest patients secondary to witnessed food asphyxiation in 69 cases over a 4 year period in Japan. The average age of subjects was 78 years. Therefore the maximum probability of LOCL of 93% was assigned (Inasuma et al, 2010). It should be noted that all included studies had an average age which is older than the astronaut corps, particularly the studies from Japan. The studies informing the maximum probability were all from Japan. Japanese food (like rice cakes) were indicated as having a higher risk for choking. These data from Japan may, therefore, be less generalizable to the diet of crewmembers on an exploration mission.

## UNTREATED BEST CASE (UTBC) SCENARIO COMMENTS

The duration from the treated best-case scenario is repeated for this scenario as it remains applicable regardless of intervention with the Heimlich maneuver. In a best-case scenario, the crewmember would clear the airway obstruction before losing consciousness (loss of consciousness, indicates a worst-case scenario). Time to loss of consciousness in complete airway obstruction is "less than 1 minute" (Walls, 2012), 30 seconds was therefore selected as the minimum duration. The maximum duration assumed the aspiration resulted in a partial airway obstruction with signs and symptoms of cough, dyspnea, and wheeze that self-resolves. According to EMS data in San Diego from 2000-2007, in 43.5% of calls for

foreign body aspiration, the aspiration event had resolved by paramedic arrival (Soroudi et al, 2007). A report from the Grand Jury of San Diego County indicated that for high priority medical calls the obligated contractual time to response is 12 minutes and that this has been fulfilled in the large majority of cases (approximately 95-98% of cases) in 2011-2013 (San Diego County Grand Jury, 2014). From this, the maximum duration for partial airway obstructions resolution was assigned 12 minutes. Literature searches were not conducted for RTDC. An best-case scenario obstruction that clears spontaneously would have an RTDC and LOCL of 0%. In a complete obstruction that required the Heimlich Maneuver but this was not used, it would be assumed to revert to a worst-case scenario. Therefore, the RTDC and LOCL for this scenario reflect obstruction that resolved spontaneously and were assigned 0% probabilities.

#### UNTREATED WORST CASE (UTWC) SCENARIO COMMENTS

The minimum duration assumed completed airway obstruction, followed by loss of consciousness and subsequent cardiac arrest due to lack of treatment. In a retrospective analysis of the outcomes of patients who experienced out of hospital cardiac arrest secondary to foreign body airway obstruction, patients with an asphyxiation-ROSC time of greater than 10 minutes had 0% long term survival (Inamasu et al, 2010). Additionally, after 15 minutes of global ischemia with cardiac arrest, 95% of brain tissue is damaged (Busl and Greer, 2010). Therefore, the shortest duration is between 10-15 minutes. The minimum duration was thus assigned 10 minutes. The maximum duration assumed partial airway obstruction. Terrestrial data indicates that there can be a range of hours to years delay from diagnosis to treatment (Dong et al, 2012; Nguyen et al, 2010; Baharloo, 1997; Rodrigues et al, 2012). The longest duration identified in the literature was 10 years (Rodrigues et al, 2012). Thus, 85440 hours (10 years) was assigned as the maximum duration. Since some patients were able to continue their lives with partial airway obstructions for as long as 10 years before having the foreign body removed, the minimum untreated RTDC probability was assigned 0%, indicating it may be possible to defer treatment until after the mission (Rodrigues et al, 2012). Without treatment in cases of complete airway obstruction, cardiopulmonary arrest was assumed to occur. Out of hospital cardiac arrest caused by choking, requiring subsequent hospitalization, was used as a surrogate for RTDC for this scenario. In a study examining the incidence and outcomes of choking on Japanese rice cakes, Kiyohara et al (2018) reported 66.9% of cardiac arrests due to rice cake aspiration required subsequent hospitalization. Notably, this was with treatment. To account for lack of treatment, the RTDC maximum probability was assigned 100%. In the setting of a complete airway obstruction, if untreated, a mortality rate of 100% is expected. For a partial airway obstruction, LOCL may not occur. Thus, LOCL was assigned a probability of 0-100%. Note, no literature search was performed.

TABLE 5. CLINICAL PHASE II DURATION LEVEL OF CONFIDENCE (LOC)

| Citation                          | Source      | LOC Value |
|-----------------------------------|-------------|-----------|
| Walls, 2012                       | Terrestrial | 3         |
| Soroudi et al, 2007               | Terrestrial |           |
| San Diego County Grand Jury, 2014 | Terrestrial |           |
| Sakai et al, 2014                 | Terrestrial |           |
| Shepherd et al, 2021              | Terrestrial |           |
| Dong et al, 2012                  | Terrestrial |           |
| Nguyen et al, 2010                | Terrestrial |           |
| Baharloo et al, 1999              | Terrestrial |           |
| Inamasu et al, 2010               | Terrestrial |           |
| Rodrigues et al, 2012             | Terrestrial |           |
| Busl and Greer, 2010              | Terrestrial |           |

All relevant studies included in discussion of duration were retrospective analyses. For the best-case scenarios, time to loss of consciousness in a complete airway obstruction was used as a surrogate for the maximum length of time for spontaneous resolution. For the worst-case scenario, the durations varied considerably based on whether the obstruction was partial vs. complete. Multiple studies corroborated that partial obstructions involving the distal airways can persist for hours to years. Complete airway obstruction in the worst-case scenario would require immediate intervention, or result in cardiac arrest. Thus the maximum durations were driven by studies regarding cardiac arrest after choking. These were all from Japan. The average age of participants in these studies was in the 70s. Further, the diet in Japan may vary significantly from crewmembers in spaceflight. Regardless of these concerns, it is felt that the studies provide an accurate portrayal of the duration of this condition.

TABLE 6. RTDC LEVEL OF CONFIDENCE (LOC)

| Citation              | Source      | LOC Value |
|-----------------------|-------------|-----------|
| Stahl et al, 2015     | Terrestrial | 3         |
| Soroudi et al, 2007   | Terrestrial |           |
| Kiyohara et al, 2018  | Terrestrial |           |
| Lan, 1994             | Terrestrial |           |
| Rodrigues et al, 2012 | Terrestrial |           |

All relevant studies included in discussion of RTDC were retrospective analyses. For best-case scenarios, the RTDC was assumed to be 0% based on spontaneous resolution in the definition. (In cases in which the Heimlich maneuver was required, but the episode did not resolve, the scenario would revert to a worst-case scenario). Thus, no RTDC searches were performed for best-case scenarios. For the worst-case scenario, both partial and complete obstruction were considered.

**TABLE 7. LOCL LEVEL OF CONFIDENCE (LOC)**

| Citation             | Source      | LOC Value |
|----------------------|-------------|-----------|
| Sakai et al, 2014    | Terrestrial | 2         |
| Kiyohara et al, 2018 | Terrestrial |           |
| Inamasu et al, 2010  | Terrestrial |           |
| Soroudi et al, 2007  | Terrestrial |           |

All relevant studies included in discussion of LOCL were retrospective analyses. For best-case scenarios, the LOCL was assumed to be 0% based on spontaneous resolution in the definition. (In cases in which the Heimlich maneuver was required, but the episode did not resolve, the scenario would revert to a worst-case scenario). Thus, no LOCL searches were performed for best-case scenarios. For the worst-case scenario, both partial and complete obstruction were considered. Studies indicating worst-case LOCL probability, secondary to cardiac arrest after complete obstruction of the airway, were all from Japan. The diet in Japan may differ significantly from the diet of the crewmembers (e.g. rice cakes were indicated as a culprit of choking in one study). The average age of participants was also in the 70s for most of these cases. Therefore the generalizability is questionable.

#### **CAPABILITY RESOURCE TABLE (CRT) OVERVIEW**

**Capabilities and Resourcing Scope Overview** This is an emergency condition relating to a compromised airway and the maneuvers and resources needed to dislodge an obstructing object. The condition was interpreted to include up to the point of airway stabilization but not the resources needed to treat aspiration pneumonitis/pneumonia and no thoracic surgery. CNES: NONE Diagnostic Scope and Resourcing The Best Case definition involves an obstructed airway dislodged spontaneously or with Heimlich maneuvers. Diagnosis is emergent and done by a primary assessment type exam alone. The worst case is similar however, a realistic diagnosis for a more complicated case will take additional time to attempt the best case maneuvers. For this reason the diagnostic time is extremely fast in the best case and much longer in the worst case. Clinical Phase 1 Duration and Rationale This version of IMPACT presumes physician level knowledge, skill, and ability will be present on the mission. The CRT working group SME consensus duration is as follows: CP1 BC (Treated or Untreated): 0.06 hours CP1 WC (Treated or Untreated): 0.5 hours The highest scope of practice in these is 5 representing the worst case decision making process as commensurate with an attending physician and the surgical airway, bronchoscopy, and the fitness for duty assessment. The best case however represents a skill level of 1 since this is a required EMT level skill. Treatment Scope and Resourcing Best case treatment is the Heimlich maneuver. Communications and Support Needs For the BC definition, there are no extra communications needed as the condition requires immediate intervention and resolves completely after the Heimlich maneuver. There is no time for consult ground teams before intervening and no need after beyond a routine notification. For the WC definition ground communications would be needed with streaming video to support to complex interventions and decision making that must occur during this event. REFERENCES Walls, Ron M, Murphy, F. Foreign body in the adult airway. In: Manual of Emergency Airway Management, Fourth Ed., Wolters Kluwer/Lippincott Williams and Wilkins, Philadelphia p.419-423. Lund ME. Foreign body removal. In: Principles and Practice of Interventional Pulmonology, 2013. ECC Committee, Subcommittees and Task Forces of the American Heart Association. 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation 2005; 112:IV1.

#### **IMM CLIFF RECONCILIATION COMMENTS**

The best and worst-case scenario definitions are unchanged from the IMM CLIFF. The incidence used for this CLIFF was provided from the IMM CLIFF. The durations of this CLIFF vary considerably from the durations in the IMM CLIFF. The LOCL probabilities in this CLIFF are almost exactly the same as the EvAC probabilities in the IMM CLIFF. The LOCL probabilities are similar for all scenarios except the treated worst-case scenario which has a substantially higher maximum LOCL probability based on cardiac arrest secondary to obstructed airway from choking. Because Task Impairment is a new paradigm, these values are unique from the Functional Impairment values in the IMM CLIFF.

## LIMITATIONS SUMMARY

- The best-case and worst-case scenarios for the condition do not fit perfectly with available literature. They were created because the current best-case scenario is reflective of all prior episodes of choking/obstructed airway in spaceflight. This is important to capture. The literature, however, naturally breaks choking into complete vs. partial airway obstruction (both of which are accounted for in both the best and worst-case scenarios). Duration, RTDC, and LOCL values are affected by this inconsistency between our definitions and the literature.
- In partial airway obstructions in the bronchial tree that can await definitive removal (such as seen in the 10-year duration of the untreated worst-case scenario), patients often present with concomitant issues like pneumonia, granulomas, etc. It is important to keep that in mind for the SIN network project going forward.

TABLE 8. TASK IMPAIRMENT CALCULATION BASED ON AFFECTED HUMAN SYSTEMS TASK CATEGORIES (HSTC)

| Clinical Phase 2: Treatment           |                            |                     |                 |                       |                      |                                            |                    |              |                                   |                                                |            |      |
|---------------------------------------|----------------------------|---------------------|-----------------|-----------------------|----------------------|--------------------------------------------|--------------------|--------------|-----------------------------------|------------------------------------------------|------------|------|
|                                       | Affected HSTCs             |                     |                 |                       |                      |                                            |                    |              |                                   |                                                |            |      |
|                                       | Cognitive - Simple         | Cognitive - Complex | Communications  | Inter-personal Skills | Vision               | Hearing                                    | Cardio-pulmonary   | Dentition    | GI                                | GU                                             |            |      |
| Treated Best Case (TBC)               | 223                        | 664                 | 113             | 89                    | 854                  | 44                                         | 145                | 5            | 13                                | 6                                              |            |      |
| Untreated Best Case (UTBC)            | 223                        | 664                 | 113             | 89                    | 854                  | 44                                         | 145                | 5            | 13                                | 6                                              |            |      |
| Treated Worst Case (TWC)              | 223                        | 664                 | 113             | 89                    | 854                  | 44                                         | 145                | 5            | 13                                | 6                                              |            |      |
| Untreated Worst Case (UTWC)           | 223                        | 664                 | 113             | 89                    | 854                  | 44                                         | 145                | 5            | 13                                | 6                                              |            |      |
|                                       | Affected HSTCs (Continued) |                     |                 |                       |                      |                                            |                    |              | TI Calculation                    |                                                | TI Score   |      |
|                                       | Hand (Dom)                 | Hand (Any)          | Upper Extremity | Lower Extremity       | Ambul & Standing (g) | Translation & Stabilization (microgravity) | Don/Doff Equipment | Pressure Ops | Total Tasks Impaired By Condition | Total Human System Category Tasks Full Mission | TI Decimal | TI % |
| Treated Best Case (TBC)               | 132                        | 564                 | 414             | 22                    | 196                  | 34                                         | 34                 | 211          | 3763                              | 3763                                           | 1          | 100  |
| Untreated Best Case (UTBC)            | 132                        | 564                 | 414             | 22                    | 196                  | 34                                         | 34                 | 211          | 3763                              | 3763                                           | 1          | 100  |
| Treated Worst Case (TWC)              | 132                        | 564                 | 414             | 22                    | 196                  | 34                                         | 34                 | 211          | 3763                              | 3763                                           | 1          | 100  |
| Untreated Worst Case (UTWC)           | 132                        | 564                 | 414             | 22                    | 196                  | 34                                         | 34                 | 211          | 3763                              | 3763                                           | 1          | 100  |
| Clinical Phase 3: Condition End State |                            |                     |                 |                       |                      |                                            |                    |              |                                   |                                                |            |      |
|                                       | Affected HSTCs             |                     |                 |                       |                      |                                            |                    |              |                                   |                                                |            |      |
|                                       | Cognitive - Simple         | Cognitive - Complex | Communications  | Inter-personal Skills | Vision               | Hearing                                    | Cardio-pulmonary   | Dentition    | GI                                | GU                                             |            |      |
| Treated Best Case (TBC)               |                            |                     |                 |                       |                      |                                            |                    |              |                                   |                                                |            |      |
| Untreated Best Case (UTBC)            |                            |                     |                 |                       |                      |                                            |                    |              |                                   |                                                |            |      |
| Treated Worst Case (TWC)              |                            |                     |                 |                       |                      |                                            |                    |              |                                   |                                                |            |      |
| Untreated Worst Case (UTWC)           | 223                        | 664                 | 113             | 89                    | 854                  | 44                                         | 145                | 5            | 13                                | 6                                              |            |      |
|                                       | Affected HSTCs (Continued) |                     |                 |                       |                      |                                            |                    |              | TI Calculation                    |                                                | TI Score   |      |

|                             | Hand (Dom) | Hand (Any) | Upper Extremity | Lower Extremity | Ambul & Standing (g) | Translation & Stabilization (microgravity) | Don/Doff Equipment | Pressure Ops | Total Tasks Impaired By Condition | Total Human System Category Tasks Full Mission | T1 Decimal | T1 % |
|-----------------------------|------------|------------|-----------------|-----------------|----------------------|--------------------------------------------|--------------------|--------------|-----------------------------------|------------------------------------------------|------------|------|
| Treated Best Case (TBC)     |            |            |                 |                 |                      |                                            |                    |              | 0                                 | 3763                                           | 0          | 0    |
| Untreated Best Case (UTBC)  |            |            |                 |                 |                      |                                            |                    |              | 0                                 | 3763                                           | 0          | 0    |
| Treated Worst Case (TWC)    |            |            |                 |                 |                      |                                            |                    |              | 0                                 | 3763                                           | 0          | 0    |
| Untreated Worst Case (UTWC) | 132        | 564        | 414             | 22              | 196                  | 34                                         | 34                 | 211          | 3763                              | 3763                                           | 1          | 100  |

#### TABLE 8 KEY

Human System Task Category (HSTC) Definitions: Cognitive-Simple: Tasks requiring simple cognitive involvement (low levels of attention, following simple checklists, and not requiring extensive decision making) in conjunction with inputs from other systems. Cognitive-Complex: Tasks requiring complex cognitive involvement (requiring constant attention, frequent interpretation of outside stimuli to inform real-time situations) in conjunction with inputs from other systems. Communication: Tasks requiring primarily communication, via hearing and speaking. Interpersonal Skills: Tasks requiring interpersonal, social interaction between crew including complex technical tasks that require extended crew interaction. Vision: Tasks in which visual information is required. Hearing: Tasks in which primarily auditory information is required, excluding communication, e.g. hearing alarms, medical auscultation, OOHAs. Cardiopulmonary: Tasks requiring greater-than-baseline cardiopulmonary effort, e.g. physically strenuous activities. Dentition: Tasks requiring use of teeth for mastication. GI (Gastrointestinal): Tasks requiring use of the alimentary system, e.g. solids/liquids consumption and solids excretion. GU (Genitourinary): Tasks requiring use of the male/female genitourinary systems. Hand (Dominant): Tasks performed using primarily the hand, requiring use of the dominant hand (piloting, medical procedures, dental procedures). Hand (Any): Tasks performed using primarily the hand(s), with no preference for dominance, with equivalent bilateral effectiveness. Upper Extremity: Tasks requiring specific use of the upper extremities, excluding hands. Lower Extremity: Tasks requiring specific use of the lower extremities (excluding ambulation and standing in the presence of gravity), e.g. using exercise equipment. Ambulation and Standing (g): Tasks requiring use of both lower extremities to accomplish ambulation or standing in the presence of gravity. Translation and Stabilization (microgravity): Tasks requiring use of either the upper or lower extremities to accomplish translational movement and stabilization (securing oneself to remain stationary) in the setting of microgravity. Don/Doff Equipment: Tasks requiring the donning of personal equipment (including pressure suit, exercise harness, EVA equipment, etc). Pressure Ops: EVA/contingency tasks performed while pressurized in a suit.

#### Criteria for Assignment of Conditions to HSTCs (any of the following):

- 1) Is affected crew member physically incapable of performing the human system task category, without impairment, with the condition?
- 2) Would the treatment (e.g. medications) impair the crewmember's ability to perform the human system task category? (Does not apply to UTx)
- 3) Does the condition have a high likelihood of causing a significant aeromedical contraindication with an associated human system task category?
- 4) Would performing tasks in an associated task category worsen the condition? (If so, it is affected).
- 5) Does pain associated with the condition impair any further human system categories?

#### TASK IMPAIRMENT COMMENTS

CP2: No comment. CP3: No comment.

#### EVIDENCE COLLECTION PROCESS

Mesh terms that most closely resembled the best-case and worst-case scenarios, and associated Conditions Included but Not Explicitly Stated (CNES), were utilized to build incidence, duration, RTDC, and LOCL searches by best- and worst-case.

#### Incidence:

Databases searched for spaceflight and analog incidence data included: PubMed, Google Scholar, NASA Technical Reports Server (NTRS) public search, Defense Technical Information Center (DTIC), and Barratt MR, Baker E, Pool SL. Principles of Clinical Medicine for Space Flight. New York, NY: Springer; 2019. 2nd Edition. Databases searched for terrestrial incidence included: DynaMed, PubMed, and Google Scholar.

#### Duration, RTDC, LOCL:

Databases searched for duration, RTDC, and LOCL included: Dynamed, Cochrane, PubMed, and Google Scholar. Note, that if duration, RTDC, or LOCL data was found in a DynaMed search, the other search engines were not included. Relevant articles were selected and reviewed. If applicable, the article was included in the CLIFF.

#### LEVEL OF CONFIDENCE (LOC) SCORING

Articles obtained to update the evidence behind this CLIFF were scored by ExMC editors, based on their applicability to the Exploration Spaceflight environment using the following grading scale:

- 4 – Confident
- 3 – Somewhat confident
- 2 – Neutral
- 1 – Somewhat unconfident
- 0 – Not confident

The following considerations factor into the grading scale above:

- How closely does the paper describe the medical condition as defined by the IMPACT 1.0 Condition List (relevance)?
- How closely does the population included resemble the astronaut population?
- Quality of the paper (number of subjects, methods, etc.)
- How much does the editor trust the source of the evidence?
- How closely does the editor think that the data represents the exploration spaceflight environment?
- Other considerations, at the discretion of the editor, supported in the comments for LOE scoring.

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## ACRONYMS

| ACRONYM | PHRASE                                                  |
|---------|---------------------------------------------------------|
| AAOMS   | American Association of Oral and Maxillofacial Surgeons |
| AMA     | American Medical Association                            |
| ARCL    | All Remaining Conditions List                           |
| ARS     | Acute Radiation Sickness                                |
| BHP     | Behavioral Health and Performance                       |

|                  |                                                              |
|------------------|--------------------------------------------------------------|
| <b>CAC</b>       | Coronary Artery Calcium                                      |
| <b>CHS</b>       | Crew Health and Safety                                       |
| <b>CL</b>        | Condition List                                               |
| <b>Cliff</b>     | Clinical Finding Form                                        |
| <b>CMO</b>       | Crew Medical Officer                                         |
| <b>COMFORT</b>   | Clinical Outcome Metrics for Optimization of Robust Training |
| <b>CP1</b>       | Clinical Phase 1                                             |
| <b>CP2</b>       | Clinical Phase 2                                             |
| <b>CP3</b>       | Clinical Phase 3                                             |
| <b>CRL</b>       | Clinical Resource Level                                      |
| <b>CRT</b>       | Capability Resource Table                                    |
| <b>CST</b>       | Clinical Science Team                                        |
| <b>DCS</b>       | Decompression Syndrome                                       |
| <b>DRM</b>       | Design Reference Mission                                     |
| <b>ED</b>        | Emergency Medicine Doctor                                    |
| <b>EL</b>        | Evidence Library                                             |
| <b>EMCL</b>      | Exploration Medical Condition List                           |
| <b>EMT</b>       | Emergency Medical Technician                                 |
| <b>EVA</b>       | Extravehicular Activity                                      |
| <b>EXMC</b>      | Exploration Medical Capability                               |
| <b>HRP</b>       | Human Research Program                                       |
| <b>ICD</b>       | International Classification of Disease                      |
| <b>ICL 1.0</b>   | IMPACT 1.0 Medical Conditions List                           |
| <b>ICU</b>       | Intensive Care Unit                                          |
| <b>IMCL</b>      | iMED Condition List                                          |
| <b>iMED</b>      | Integrated Medical Evidence Database                         |
| <b>IMM</b>       | Integrated Medical Model                                     |
| <b>IMPACT-MD</b> | Impact Medical Database                                      |
| <b>IP</b>        | Incidence Proportion                                         |
| <b>IR</b>        | Incidence Rate                                               |
| <b>ISS</b>       | International Space Station                                  |
| <b>IV</b>        | Intravenous                                                  |
| <b>JSC</b>       | Johnson Space Center                                         |
| <b>LEO</b>       | Low-Earth orbit                                              |
| <b>LEVA</b>      | Lunar Extravehicular Activity                                |
| <b>LOCL</b>      | Loss of Crew Life                                            |
| <b>LOM</b>       | Loss of Mission                                              |
| <b>LSAH</b>      | Lifetime Surveillance of Astronaut Health                    |
| <b>LSO</b>       | Lunar Surface Operations                                     |
| <b>MCL</b>       | Master Condition List                                        |
| <b>MEVA</b>      | Medical Extravehicular Activity                              |
| <b>NASA</b>      | National Aeronautics and Space Administration                |
| <b>N/A</b>       | Not Applicable                                               |

|              |                                              |
|--------------|----------------------------------------------|
| <b>NP</b>    | Nurse Practitioner                           |
| <b>OBGYN</b> | Obstetrics and Gynecology                    |
| <b>OR</b>    | Occurrence Rate                              |
| <b>PA</b>    | Physician Assistant                          |
| <b>PDQ</b>   | Pain Disability Questionnaire                |
| <b>PFCL</b>  | Proposed Future Conditions List              |
| <b>PPE</b>   | Personal Protective Equipment                |
| <b>PTRS</b>  | Project Technical Requirements Specification |
| <b>PRL</b>   | Pharmaceutical Resource Level                |
| <b>QTL</b>   | Quality Time Lost                            |
| <b>RCL</b>   | Removed Conditions List                      |
| <b>REP</b>   | Rochester Epidemiology Study                 |
| <b>RTDC</b>  | Removal to Definitive Care                   |
| <b>SANS</b>  | Spaceflight-Associated Neuro-ocular Syndrome |
| <b>SAS</b>   | Space Adaptation Syndrome                    |
| <b>SEVA</b>  | Spaceflight Extravehicular Activity          |
| <b>SME</b>   | Subject Matter Expert                        |
| <b>SoP</b>   | Standard Operating Procedure                 |
| <b>SPE</b>   | Solar Particle Event                         |
| <b>TBD</b>   | To Be Determined                             |
| <b>TI</b>    | Task Impairment                              |