Acute Radiation Syndrome Cliff

Branch Baseline

The biological effects of space radiation, including Acute Radiation Syndrome (ARS), are a significant concern. High doses of radiation can induce profound radiation sickness and death. Lower doses of radiation induce symptoms that are much milder physiologically, but that pose operational risks that are equally serious. Both scenarios have the potential to seriously affect crew health and/or prevent the completion of mission objectives (Wu, 2009).

The two cosmic sources of radiation that could impact a mission outside the Earth's magnetic field are solar particle events (SPE) and galactic cosmic radiation (GCR). Either can cause acute and chronic medical illness. (Epelman, 2006)

Radiation can exert its damaging effects through multiple mechanisms. It causes the breaking of double stranded DNA and proliferating cells such as those in the immune system; bone marrow and less differentiated cells that line the gastrointestinal tract are particularly radiosensitive due to their high turnover. Chromosome alterations in lymphocytes can be seen through multiple techniques and can, in fact, be used to estimate the dose (Sv) that has been absorbed for long duration missions. Radiation can also interact with water, resulting in the production of free oxygen radicals. Free radicals can readily interact with DNA and other molecules, causing cell damage and death. (Epelman, 2006)

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:	Fixed
Space Adaptation:	No
Incidence Type:	Rate

Distribution Data	
Incidence:	Fixed
Occurrence:	Poisson

Data Characteristics	
Fixed Rate:	0.05

Incidence Comments

Acute radiation syndrome (ARS) has not occurred in space flight.

Kim determined that there have been 7 major solar particle events from 1954 to 2007, a 53 years period. Of these events, only 3 showed levels of radiation high enough to cause any acute clinical symptoms (Kim, 2009)(and only with the lowest level shielding, 0.5 g/cm-2). According to the Medical Management of Radiological Casualties Handbook (Armed Forces Radiobiology Research Institute (AFRRI), 2011); (Goans, 2010), the threshold for nausea and vomiting (5% risk) is 100-200 cGy and the threshold for death (0-80% risk) is 200 cGy. These values will act as our threshold doses for best and worst case scenarios.

Of the 7 large solar particle events 3 exceeded the NASA 30 day limit for Blood forming organs (BFO) of 250 mGy-Eq (Kim, 2009) The rate of symptomatic solar particle events is estimated at 0.0566 (3/53 years). Our threshold was a 5% risk of illness in the event of a solar particle event, the actual incidence of disease would be **5% or 0.05** given the exposure to solar particle event.

This level of shielding is higher than the shielding of an EVA suit and may prove important for future lunar exploration missions when a large portion of the mission will be spent performing EVAs.

Information Regarding Prevention

In general, any medical condition that, in the judgment of the MSMB, may compromise mission operations, performance of duties, or crew health or safety is disqualifying.

A candidate for a specific flight is not eligible for selection for that flight if the sum of the astronaut's career occupational exposure to date plus the projected mission exposure, as determined by the Radiation Health Officer (RHO), associated with that flight exceeds the career limits. The career effective dose limit, based on age at first exposure and gender, over all organs ranges from 0.4 to 3.0 sieverts (Sv). Occupationally related sources of exposure throughout the career of any USA crewmember shall result in no more than 3% probability of lifetime excess cancer mortality risk. (International Space Station Program, 2009)

Vehicle requirements

Acute radiation (SPE) storm shelter.

Reliable radiation dosimeters that can transmit to Mission Control and provide a self-alert to astronauts are required. Such instrumentation has been available for many years, including during the Apollo missions.(NCRP, 1989) cited in (Wu, 2009)

Other

Mission planning at appropriate times to minimize risk of event occurrence.

In the US astronauts have been classified as radiation workers and as dictated by the US Code of Federal Regulations, a program must be in place to protect excessive radiation exposure. Radiation health officers summarize each astronaut radiation exposure. Exposure calculations and age and gender of the crewmember are used to generate estimates of the risk of developing cancer. Flight surgeons review these reports with each crew member once a year. (Jones, 2008)

Incidence Level of Evidence (LOE)

The IMM level of evidence appropriate assessment of the quality of the IMM input data. Since IMM incorporates input data from a wide variety of sources including astronaut population, terrestrial or analog populations, and external models, an innovative approach to assess the quality of input data was required. Information obtained from the astronaut population and/or space flight is the more relevant so it is assigned the highest level of evidence and less relevant data sources are assigned a lower level of evidence.

Citation	LOE Value	LOE Category
Kim, 2009	2	Incidence
Armed Forces Radiobiology Research Institute (AFRRI), 2011	3	Incidence
Goans, 2010	3	Incidence

Alternative Incidence Data

Globally the number of persons involved in radiation accidents, between 1944 and March 2005, has been 134,311, of which 1347 were in the United States. Significant exposures were 3328 globally and 799 in the US, 2.5% and 59.3% of total exposures respectively. Fatalities reported were 169 globally, and 30 in the US, 5.1% and 3.8% of the significant exposures. Source: REAC/TS, Oak Ridge Institute for Science and Education, Oak Ridge, TN, USA, cited in (Berger, 2006)

A flight is impacted if an SPE occurs that reaches the “alert” stage or it reaches the “significant dose” criterion—says that it is impacted if an SPE occurs with an accumulated free-space dose of 10e8 particles cm e-2 (omnidirectional fluence) and energies above 10 MeV. Converted into a dose to tissue, this corresponds to about 0.6 Gy, the actual number depending on the energy spectrum of the SPE particles. (Committee on Solar and Space Physics and Committee on Solar-Terrestrial Research, National ResearchCouncil, 2000)

To predict the severity of the SPE radiation risk, one also needs to know the dose rates that would represent a worst-case scenario. The great solar particle event of August 4, 1972, is a commonly used benchmark for worst case estimates. The peak dose rate lasted about 8 hours, which gives a total dose of between 1.2 Sv and 2.4 Sv, depending on which dose-rate estimate is used. There is more than one protocol for calculating dose rates, and the results using different protocols do not always agree. (Committee on Solar and Space Physics and Committee on Solar-Terrestrial Research, National Research Council, 2000)

The Space Radiation Standing Review Panel (SRP) met at the NASA Johnson Space Center (JSC) on December 9-11, 2009 to discuss the areas of current and future research targeted by the Space Radiation Program Element (SRPE) of the Human Research Program (HRP). The charge to the Space Radiation SRP was to review the gaps, evaluate whether the tasks addressed these gaps and to make recommendations to NASA’s HRP Science Management Office regarding the SRP's review. This task is only looking at prodromal syndrome and possibly skin (2Gy dose). It appears unlikely any astronaut would suffer ARS under present radiation exposure constraints. Therefore, this part of the gap should be a low priority.(Woloschak, 2010)

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 - 100)	100	0.5	5 - 73	6 - 15 - 24	0	0	0
ISS-based Treatment (worst case scenario %: 0 - 1)	100	1	43 - 94	24 - 96 - 168	0 - 94	100	5 - 100
Untreated Best Case	0	0	43 - 94	6 - 15 - 24	0 - 73	0 - 100	0
Untreated Worst Case	0	0	78 - 100	24 - 96 - 168	78 - 100	100	100

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

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

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

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

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

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

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

Scenario Comments

The **best case scenario** is defined as receiving a dose ranging from 1 to less than 2 Gray (Gy) causing a mild course of acute radiation syndrome, e.g. mild constitutional symptoms such as fatigue and weakness, time to emesis of 4 hours after the event, and/or infection and is completely relieved by symptomatic treatment and/or resolves by itself .

The **worst case scenario** is defined as receiving a dose of 2 Gy or greater causing a moderate to severe course of acute radiation syndrome, e.g. symptoms such as abdominal pain, intractable vomiting and/or diarrhea, dehydration, hemorrhage, skin peels, severe burns, superimposed infection, bone marrow suppression, and cardiovascular or central nervous system involvement. These symptoms are not entirely relieved by symptomatic treatment and may ultimately lead to death.. Refer to the CliFF Appendix for more information.

The **percentage of how often best versus worst case scenario occur** was estimated based on EVA duration time as a proportion of mission time.

For typical ISS missions, less than 1% of mission time involves EVAs and these missions are in low earth orbit (LEO) with some protection from solar particle events provided by the geomagnetic fields of earth.

No astronaut has performed more than 3 lunar EVAs (Gernhardt, 2009)). In accordance with flight rules, EVA s should not exceed 6.5 hours (NASA, 1997)). IMM estimated the percentage of EVA times at 0.0056 (8 hours x 3 EVAs/ 6 month mission = 4320 hours). Therefore, the worst case scenario for ISS missions is estimated at 0-1%; thus the best case is estimated at 99-100%

Best Case Comments

Acute Radiation Syndrome's functional impairments (FI) calculation follows the IMM severe non-space adaptation template. Skin Disorder ratings are based on Table 8-2, p-166-167 (American Medical Association, 2008). Upper Digestive Tract ratings are based on Table 6-4, p 107 (American Medical Association, 2008). Colonic and Rectal Disorders ratings are based on Table 6-9, p 114 (American Medical Association, 2008) Anemia is based on Table 9-5, p.189 (American Medical Association, 2008). Consciousness and Awareness ratings are based on Table 13-4, p 327 (American Medical Association, 2008)Final FI ratings are calculated combining the mentioned tables using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008). For further information refer to the CliFF Appendix.

By definition during **Clinical Phase I**, FI is 100% and duration is estimated to be 30 minutes for periodic Health Status (PHS) –EVA exam. During **Clinical Phase II**, Functional Impairment is estimated at 5-73%. Duration is estimated at 6-24 hours based on the prodromal phase (Merck Manual for Health Care Professionals, 2009). During **Clinical Phase III,** by definition complete recovery is expected with no EVAC or LOCL. FI is 0%.

Worst Case Comments

Acute Radiation Syndrome's functional impairments (FI) calculation follows the IMM severe non-space adaptation template. Skin Disorder ratings are based on Table 8-2, p-166-167 (American Medical Association, 2008). Upper Digestive Tract ratings are based on Table 6-4, p 107 (American Medical Association, 2008). Colonic and Rectal Disorders ratings are based on Table 6-9, p 114 (American Medical Association, 2008) Anemia is based on Table 9-5, p.189 (American Medical Association, 2008). Consciousness and Awareness ratings are based on Table 13-4, p 327 (American Medical Association, 2008)Final FI ratings are calculated combining the mentioned tables using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008). For further information refer to the CliFF Appendix.

By definition during **Clinical Phase I**, FI is 100% and duration is estimated to be 60 minutes. Including physical exam, blood count and starting intravenous fluids. During **Clinical Phase II**, Functional Impairment is estimated at 43-94%. Duration is estimated at 24-168 hours, or 1 to 7 days based on prodromal phase for moderate to severe radiation syndrome (Merck Manual for Health Care Professionals, 2009). During **Clinical Phase III,** recovery is not expected, although symptoms may decrease during the latent phase, FI is estimated at 0-94%. EVAC is estimated at 100% based on need for hospitalization (Merck Manual for Health Care Professionals, 2009). LOCL is expected and it has been estimated at 5-100%. (Merck Manual for Health Care Professionals, 2009) Some medical care can be provided at the ISS but resources are limited.

Untreated Best Case Comments

Acute Radiation Syndrome's functional impairments (FI) calculation follows the IMM severe non-space adaptation template. Skin Disorder ratings are based on Table 8-2, p-166-167 (American Medical Association, 2008). Upper Digestive Tract ratings are based on Table 6-4, p 107 (American Medical Association, 2008). Colonic and Rectal Disorders ratings are based on Table 6-9, p 114 (American Medical Association, 2008) Anemia is based on Table 9-5, p.189 (American Medical Association, 2008). Consciousness and Awareness ratings are based on Table 13-4, p 327 (American Medical Association, 2008)Final FI ratings are calculated combining the mentioned tables using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008). For further information refer to the CliFF Appendix.

During **Clinical Phase II**, Functional Impairment is estimated at 43-94%. Duration is estimated at 6-24 hours similar to the treated best case scenario. During **Clinical Phase III,** FI is 0-73%. Recovery is unlikely without treatment; EVAC is estimated at 0-100%. LOCL is estimated at 0-5%.(Merck Manual for Health Care Professionals, 2009)

Untreated Worst Case Comments

Acute Radiation Syndrome's functional impairments (FI) calculation follows the IMM severe non-space adaptation template. Skin Disorder ratings are based on Table 8-2, p-166-167 (American Medical Association, 2008). Upper Digestive Tract ratings are based on Table 6-4, p 107 (American Medical Association, 2008). Colonic and Rectal Disorders ratings are based on Table 6-9, p 114 (American Medical Association, 2008) Anemia is based on Table 9-5, p.189 (American Medical Association, 2008). Consciousness and Awareness ratings are based on Table 13-4, p 327 (American Medical Association, 2008)Final FI ratings are calculated combining the mentioned tables using the Combined Values Chart as indicated in Appendix A, pp 604-606 (American Medical Association, 2008). For further information refer to the CliFF Appendix.

During **Clinical Phase II**, Functional Impairment is estimated at 78-100%. Duration is estimated at 24 to 168 hours similar to the treated worst case scenario. During **Clinical Phase III,** FI remains 78 to 100%. EVAC and LOCL are expected at 100% without available treatment. (Merck Manual for Health Care Professionals, 2009)

Treatment and Options Level of Evidence (LOE)

The IMM level of evidence appropriate assessment of the quality of the IMM input data. Since IMM incorporates input data from a wide variety of sources including astronaut population, terrestrial or analog populations, and external models, an innovative approach to assess the quality of input data was required. Information obtained from the astronaut population and/or space flight is the more relevant so it is assigned the highest level of evidence and less relevant data sources are assigned a lower level of evidence.

Citation	LOE Value	LOE Category
American Medical Association, 2008	3	FI
American Medical Association, 2008	3	FI
American Medical Association, 2008	3	FI
American Medical Association, 2008	3	FI
American Medical Association, 2008	3	FI
Merck Manual for Health Care Professionals, 2009	3	EVAC
Gernhardt, 2009	2	BCWC
NASA, 1997	2	BCWC

The Resource Table (RT)

Resource	Units Required Best Case	Units Required Worst Case	Units Available At Start Of Mission	Consumable	Essential	Rationale
Bacitracin 500 units/gm. 28 gm tube	0	0.25	34	Yes	Yes	Topical antibiotic
Blood Oximeter	1	1	1	No	Yes	monitors the oxygen saturation of a patient's blood
Blood Pressure Cuff (regular, large)	1	1	2	No	Yes	Measure blood pressure
Blood Pressure Monitor	1	1	1	No	Yes	Measure blood pressure
BZK wipes	4	6	60	Yes	No	Cleanse skin.
Camera	0	1	1	No	No	To document wounds/skin
CMRS	0	1	1	No	No	Restrain crew member to ensure safety
Dilaudid (Hydromorphone) 2mg/mL, 1mL syringe	0	12	18	Yes	Yes	Pain management
ECG Monitor (Device, USB Charge Cable, Lead Set Cable, Cue Card)	0	1	1	No	Yes	Measure and monitor ECG
Ertapenem 1gm	0	3	6	Yes	Yes	Antibiotic
Gauze pads (4x4)	0	35	50	Yes	No	to absorb blood or fluids from skin
Iodine Swab Stick	0	8	14	Yes	No	to clean wound surrounding area
IV administration set	0	1	3	Yes	Yes	IV Fluids infusion
IV Cap	0	1	5	Yes	No	IV administration
IV Catheter (18G, 20G, or 22G)	0	1	14	Yes	Yes	IV fluid administration
IV Fluid 1L (1000mL)	0	4	5	Yes	Yes	to replenish fluids
IV Fluid Air Filter	0	1	3	Yes	No	To filter air from IV set
IV pressure infuser	0	1	1	No	No	IV Fluids infusion
Lidocaine (Xylocaine) plain 1%, 10mL multi dose vial	0	3	3	Yes	Yes	Anesthetic for ertapenem injection
Medical tape	0	0.1	5	Yes	No	single-coated tapepressure adhesive tape
Motrin (Ibuprofen) 400mg	3	0	400	Yes	Yes	Pain relief
Needle (23G)	0	25	20	Yes	Yes	For medication administration and to flush IV
Nitrile gloves (large, medium, and small) (pair)	3	15	30	Yes	No	Personal Protective equipment for CMO
Nonstick Bandage (Telfa pads)	0	6	20	Yes	No	Used to dress a wound by applying next to skin so as not to stick.
Pack of 12 ECG electrodes	0	1	5	Yes	Yes	Measure and monitor ECG

Resource	Units Required Best Case	Units Required Worst Case	Units Available At Start Of Mission	Consumable	Essential	Rationale
Promethazine (Phenergan) 25mg/mL 1 mL injectable	0	18	24	Yes	Yes	Nausea relief
Sharps container	0	1	40	No	No	To dispose of medical waste such as used medical needles, scalpels, IV catheters, razors, vials
Stethoscope	0	1	2	No	Yes	to listen to lung,heart, and bowel sounds, to blood flow in arteries and veins
Syringe (3cc)	0	25	20	Yes	Yes	For medication administration and to flush IV
Thermometer	1	1	1	No	No	To measure temperature
Tourniquet	0	1	1	No	No	To stop blood flow and engorge vein, this facilitates IV insertion
Valium (Diazepam) 5 mg/mL, 2 mL syringe	0	2	2	Yes	Yes	To treat severe nausea, anxiety
Variable Oxygen System	0	1	1	No	Yes	To provide respiration
Zofran (Ondansetron) 8 mg tablet	2	2	30	Yes	Yes	anti nausea

Resource Comments

Acute Radiation Syndrome (ARS) is not listed in the ISS Medical checklist (Mission Operations Directorate (MOD), 2011) but the resource for treatment were generated from the ISS Med Kit. All resources included in the table are available on board. Treatment is based on military guidelines , (Goans, 2010)

PCBA contains an EC-8 cartridge that allows measuring hemoglobin and hematocrit. Lymphocyte count/CBC are not available on board (ISS Medical Operations, 2009). Colony stimulating factors are not available on board. Beta-carotene is available only on the Russian supplies. (International Space Station Integrated Medical Group, 2008)

The table was updated on November 2011. Resources for BP/ECG (electrodes, acetone pads, razor, and adhesive tape remover pads), sharps container, Ziploc bag, oxygen tubing, Ilma rod, Ilma cue card, endotracheal tube, endotracheal tube connector, Fluconazole, and Valtrex were added. Medication doses were changed to provide antibiotic, anti viral, anti fungal and diarrhea medications for both scenarios. Rationales for medication inclusion were added.

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
Goans, 2010	3	Resources

Level Of Evidence

Input Data	LOE Average
Incidence	2.66666666666667
Functional Impairment	3
Best Case / Worst Case	2
EVAC / LOCL	3
Resources	2.5
QUALITY OF EVIDENCE	**2.63333333333333**

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

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