Office of
INTERNATIONAL
MEDICAL POLICY
School of Public Policy
George Mason University

Extreme Environments

Development of Decision Processes and Training Programs for Medical Policy Formulation

Report from the Second and Third Workshops

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INTRODUCTION

The School of Public Policy at George Mason University held the first workshop on "Medical Policy Formulation Process for Expeditions into Extreme Environments" in Tyson's Corner, Virginia on July 24 - 25, 2003. This workshop brought together a group of preeminent international experts on operations in extreme environments and in health and safety policy formulation. The workshop was by invitation only and discussions were on a non-attribution basis.

The lack of a uniform approach to health and medical policy formulation, including considerations for quality of life over time, was a consistent finding of this workshop. Poor understanding of and low priority given to health issues, as opposed to safety issues, is common practice. Though safety is an important element in the success of any exploration activity, equating safety with health is misleading, since health represents a continuum, spanning the life of an explorer, and can be affected by many variables. Illness can become manifest long after the successful completion of an expedition. Current policies are simply inadequate to meet the needs of the international community engaged in space exploration or other extreme environments.

In addition, there is an urgent need for the proper education of decision makers, stakeholders, and expedition participants on medical risks and their possible impact on the overall quality of life for explorers. Health literacy and the medical knowledge base for exploration of extreme environments must be improved. The GMU research team's plan to achieve this goal is to develop a framework and training process for medical policy formulation for expeditions into extreme environments.

The workshop participants endorsed the model as well as the policy formulation process presented by the research team with only minor modifications. It was recommended that a "Bill of Rights" be developed for each mission that would clearly spell out, in addition to the safety procedures and occupational health hazards, the following information:

- the extent and quality of healthcare provisions prior, during and after the expedition;
- handling of medical emergencies and limitations; and,
- rescue and evacuation capabilities.

The GMU research team incorporated the above recommendations into its study process following the first workshop. Several promising tools for health and medical policy formulation were evaluated, and pertinent information was incorporated into the development of concepts for a health and medical policy formulation process for extreme environments. Additional internal reviews of the literature were conducted. Professor Ted Woodcock's analytical tool was adapted to assess combined health risks over time and was presented as part of the policy formulation process decision package. All of this information was presented at the second workshop for expert discussion and evaluation.

The second workshop was also held in Fairfax, Virginia at George Mason University on November 7, 2003. The workshop's two goals were to develop:

1. Analytical and predictive tools; and,
2. Policy frameworks for health and medical decision making, adaptable across various types of extreme environments.

In order to preserve continuity, most of the second workshop's participants were selected from the first workshop. The workshop participants were asked to identify a standard process for policy formulation, and to define best health and medical policy practices for extreme environments. One of the concepts presented at the workshop was a health and medical risk assessment based on Type I and II error evaluations. A Type I error is more serious in nature. It can lead to death, injury or illness. A Type II error, on the other hand, refers to wasted resources and/or an increased level of risk.

There were concerns that such a concept was primarily oriented toward risk assessment, with a potential for bias introduced by a user-defined rating system. However, if an adequate amount of accurate biomedical data is available for each individual scenario, the policy formulation process could integrate many potential risks and display how different elements respond to them. This could be helpful in those instances when the risks are unknown and the analytical tools could provide decision makers with an approximate set of risks, as well as integrated risk assessment over time.

The GMU research team asked the workshop participants to provide examples of scenarios to be used in the testing of the adopted policy formulation process. It was recommended that any decision process be a tool to assist with decision making, but also that it should not be entirely relied upon without additional expert evaluation to generate policy.

The participants commended the GMU research team for developing and selecting a process that can collect data on the environmental, human and system impact of operations in extreme environments. It was recommended that, following the second workshop, the team would identify appropriate scenario(s) to test the process and present the results at the third and final workshop.

The final workshop took place on March 5, 2004 at George Mason University. The purpose of the workshop was to test the premise that the proposed process can help develop rational medical policies for operations in extreme environments. The GMU research team chose to use the Australian National Antarctic Research Expedition (ANARE) Program's medical policy to test the model. The ANARE policy requires an appendectomy to be performed on all wintering physicians.

The exercise testing the process integrates the three elements of human space flight architecture model: human, system, and environment. The environment poses challenges to an exploration mission, and the system provides means and resources to overcome challenges to human life (problems and risks) and allows teams to effect their mission. The humans will operate the system to perform and enhance the mission capacity.[1]

The participants concluded that the ANARE exercise, and the policy formulation process presented by the research team was appropriate and useful. While the process is intended as just one of a range of tools to use in decision making, there is a certain level of assumption built in when the unknown enters into a specific scenario or setting. For example, in a new exploration location such as Mars, the ability of individuals to assess risk is only based on what is proven and available. However, the process users should recognize that results are not guaranteed, and that this is only one of the tools in the toolbox for evaluating risk in a systematic and organized fashion. The GMU research team was encouraged to continue testing the process and distributing it to potential private sector users for evaluation. In addition, should the model continue to demonstrate its applicability to other settings, training programs should be set up for end-users. The workshop participants felt that this research was very useful in addressing an important area of health and medicine and that GMU should proceed with developing a prototype training module for field testing by NASA.

[1] Nicogossian, A. "The future of space medicine." *Acta Astronautica* Vol 49, No 3-10, page 529.

WORKSHOP OVERVIEW AND DISCUSSION

The second and third workshops on "Medical Policy Formulation in Extreme Environments" focused on:

1. The development of analytical and predictive models;
2. Policy frameworks for health and medical decision making, adaptable across various types of extreme environments;
3. Impacts of potential changes in resources, technology, laws, or political climate on the decision process;
4. Testing of the premise that the proposed model(s) can be used to develop rational medical policies for extreme environments. (This goal resulted from feedback from the second workshop); and,
5. The proposed concept for development of training modules.

Participants of both workshops were experts in the fields of policy, management, medicine, science and exploration, some of them representing GMU faculty and NASA. Presenting for the GMU research team were Dr. Arnauld Nicogossian, Dr. Ted Woodcock (second workshop only), and Dr. Tom Zimmerman. The Workshop Agenda, list of participants, evaluations and presentations are included in Appendices A through G.

Workshop Two: Introducing the Model and the Health and Medical Policy Formulation Process

The second workshop focused primarily on describing the model and policy formulation process and their use in the collection of data and the analysis of risk predictors as inputs into health and medical policy development. The objective was to determine an effective policy formulation process and to identify major parameters for analytical and predictive tools. The workshop participants worked to identify a standard policy formulation process, and to define best practices for operations in extreme environments. Consensus was reached on a standard definition of risk and the means for communicating its significance.

The main recommendation from the first workshop was for the research team to identify a proper medical policy formulation process and to develop a training program for policy makers. This process should be generic, so that with minor modifications it could be adapted to individual needs and special circumstances. Such a process using historical data was to be presented at the second workshop as an exercise for validation. The following represents some of the guiding principles for the process:

- Health is an important part of the human dimension when considering expedition risks;
- Both short and long term health outcomes should be considered in the process of preparing for an expedition and/or introducing a novel technology;
- It is especially important to address both the safety and the health of the individuals while maintaining an acceptable level of productivity;
- The effectiveness and reliability of the protective systems/technology designed to enable and safeguard the expedition in an extreme environment should be carefully factored into the overall risk assessment; and
- In principle, systems and technology are engineered to protect the individuals and substitute for physiological adaptation, thus having minimal impact on the health and well being of the explorers.

It was determined that the policy formulation process must be systematic, auditable, and as much as possible guided by evidence-based knowledge. There must be uniformity of terms in order to improve communication and reduce errors. Solutions should be communicated carefully with sensitivity to and awareness of the context of individual stakeholders. The second workshop participants were presented with a matrix describing the types of errors that can occur when a policy decision is made without considering and weighing all of the above factors. A Type I error can lead to death, injury or illness, and a Type II error results in wasted resources and increased level of risk.

The policy formulation process, described by Dr. Thomas Zimmerman, included a number of factors that influence the decision making process. This data capturing methodology is designed to evaluate risks and protect against Type I and II errors. The analysis of the risks and policies addressed fell into three general categories:

1. The operational environment, including the hazards faced during travel to and from the destination and during the time at the destination;
2. The human element, subject to injury, illness or death, and usually requiring biological and/or technological adaptation for survival; and
3. The systems/technology, designed to protect the human element, extend the human capabilities and perform useful work.

Dr. Nicogossian proposed to categorize risk as follows:

None=0	no known risks
Low=1	small probability of life threatening events
Moderate=2	probability of injury or disease which can be life threatening
High=3	significant probability of injury or disease
Catastrophic=4	loss of life or significant impairment
Unknown =5	non-quantifiable risk which can range from 0-infinite

This categorization will allow expedition planners and participants to log experiences and estimate the risks as they learn more about their environment. This information then can be translated into decisions facilitating follow-up expeditions. The data collected could also be used to estimate risk in a new environment and help explorers prepare for potential threats by developing proper protective tools and enabling systems. For example, there may be several short-term health effects of space travel, but a process like this could help determine if those risks add up to long-term consequences, which could affect the Quality of Life Years.

The discussion of the three-element model prompted several suggestions. First, it was suggested that the environment element be separated into at least two categories to include ecology and location (global positioning). Second, if this process is successful, the checklist(s) could be incorporated into several Global Positioning System programs under development that would allow information to be relayed to a collection and monitoring center. Concerns were expressed that the process was primarily oriented toward risk assessment, with potential for bias introduced by the user defined rating system. If the significance of risk is overstated, a Type II error could occur causing resources to be wasted. If the risks are understated, a Type I error could occur with loss of life or injury.

The second part of the presentation involved a mathematical and visual representation of the issues identified in the process. Mathematical analysis and modeling can be used to predict risk over time. This type of analytical tool could simplify the complex decision-making process as much as possible, thereby involving less guesswork.

The prototype risk impact assessment tool calculates the human, environmental, and systems factors, including uncertainties contributing to the risks of extreme environments, and then computes the composite risk. This tool is based on STELLA™, a commercial-off-the-shelf program. It also contained a relatively simple representation of the impact of individual elements on the mission as a whole.

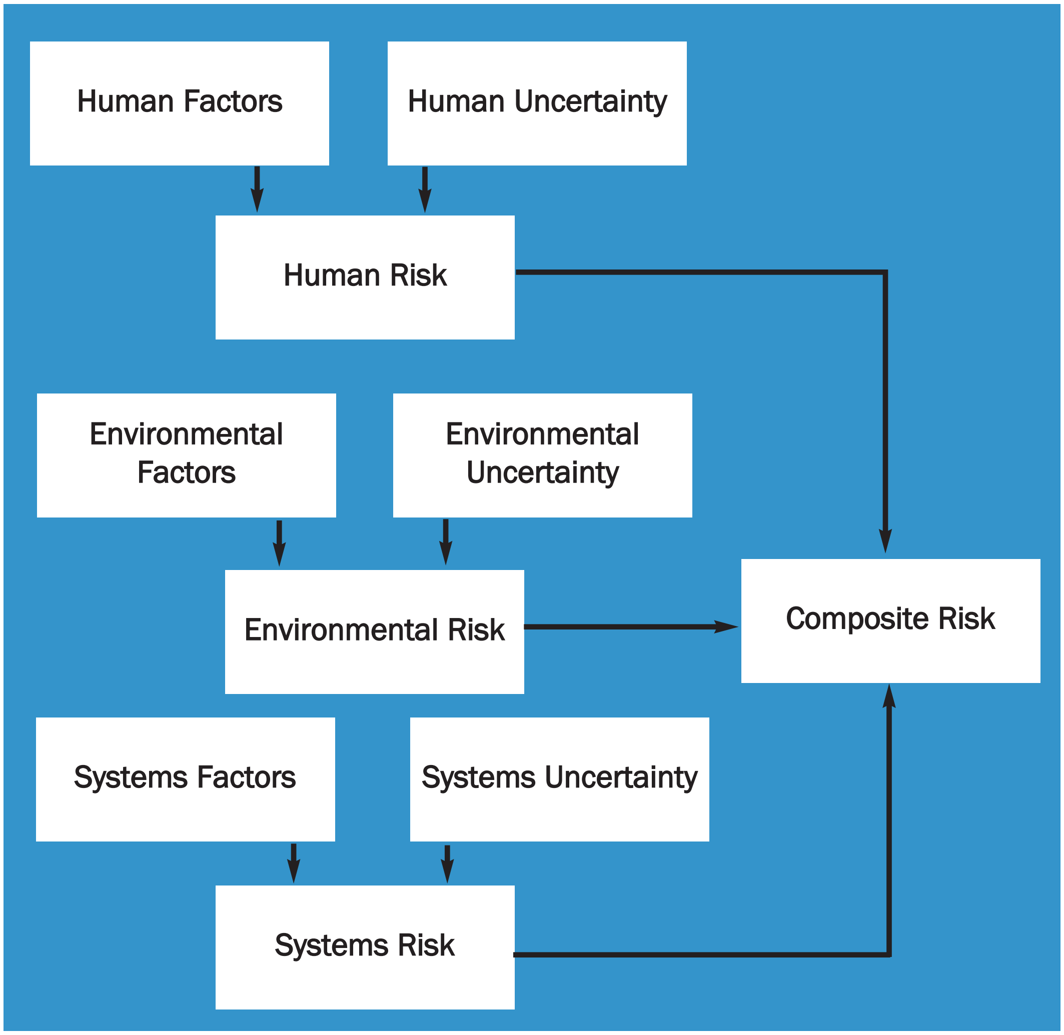


Figure 1. *The analytical tool breaks down the elements and then with simplified data returns to the composite view to analyze risk at stages of impact.*

The tool uses a 5-point Likert scale that corresponds with the original model as the starting point and requires data of risks within each element (environment, human, system) to determine the point of error (None-0, Low-1, Moderate-2, High-3, Catastrophic-4, Unknown-5). Using the data collected in the first risk-based part of the model as described by Dr. Zimmerman, the program plots data over an estimated period of time showing how each data element could impact the other elements. With the combined approaches, resources are available to test potential scenarios in a more complete manner. If accurate data is available for individual scenarios, the analytical tool could integrate many potential risks and display how different elements respond to individual or aggregate risks. A relatively simple systems dynamics-based analytical tool representing the process of disease infection, recovery, and death as well as the impact of public health measures aimed at preventing the spread of disease is presented in Figure 2.

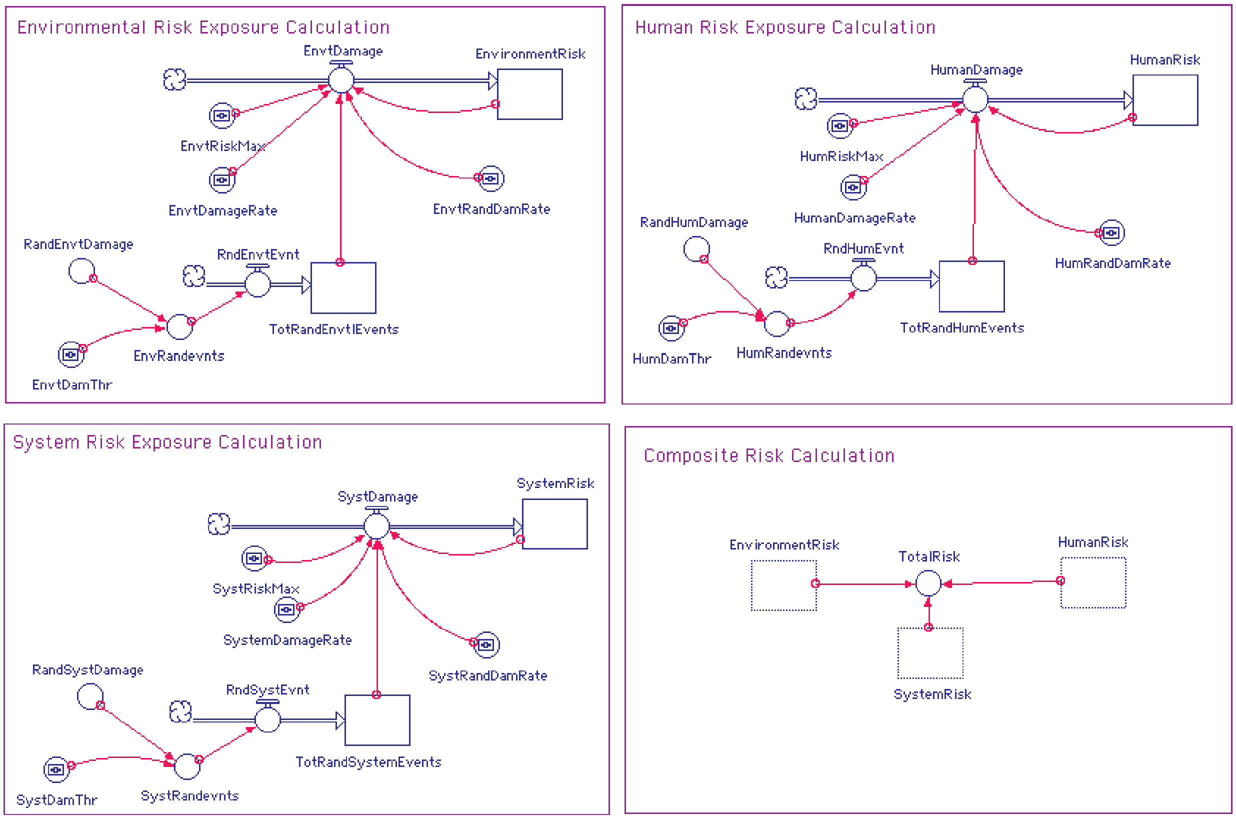
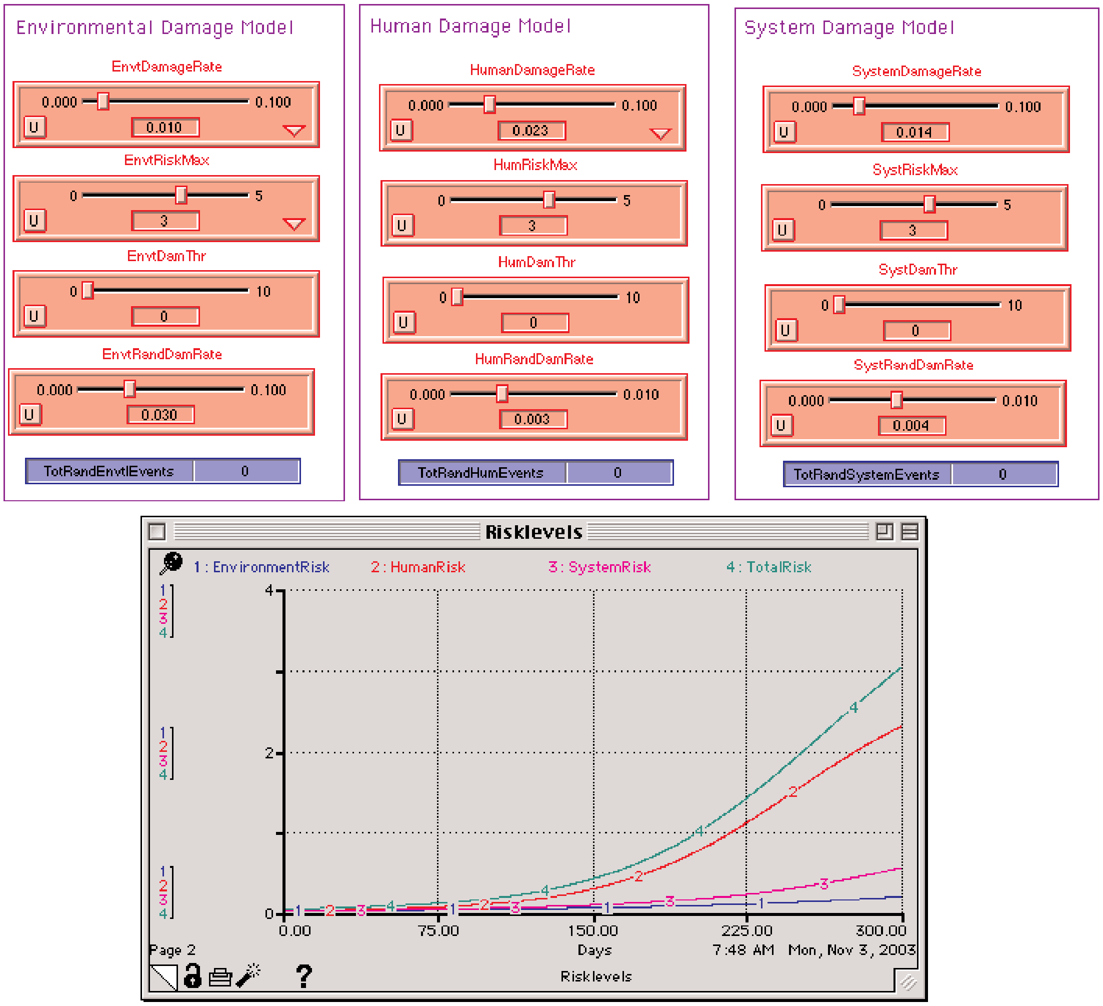


Figure 2. *A systems dynamics-based analytical tool representing the impact of events on any particular element of a mission or expedition.*

Again, using the elements of an extreme environment, the human beings as individuals or as a team, the environment, and the protective systems (i.e. space shuttle or cold weather gear), all must work together for a successful mission. The tool seeks to determine where scenarios might cause a hazardous event to occur. For example, in space exploration, addressing issues in the vehicular system, human interaction and the environment, the model could compile data on each of the three elements describing how it would respond to particular risks, or could display the compiled results with all elements in place. The model can show which preventative measures will buy the most time on particular elements affected by different risks.

Elapsed time for each of the sample runs was assumed to be 300 days, but the analysis can be set to work over greater periods of time as well. Actual values used in the following discussion do not represent any specific incident, and are used here for demonstration purposes only. No actual results should be assumed based on the analytical output. Selected outputs are presented and discussed below. In the case shown below in Figures 3 and 4, random incidents were applied at different levels of severity. As events occur, the total risk increases over time with more incidents.



Environmental Damage Model

EnvtDamageRate
0.000 0.100
0.010

EnvtRiskMax
0 5
3

EnvtDamThr
0 10
0

EnvtRandDamRate
0.000 0.100
0.030

TotRandEnvtlEvents 0

Human Damage Model

HumanDamageRate
0.000 0.100
0.023

HumRiskMax
0 5
3

HumDamThr
0 10
0

HumRandDamRate
0.000 0.010
0.003

TotRandHumEvents 0

System Damage Model

SystemDamageRate
0.000 0.100
0.014

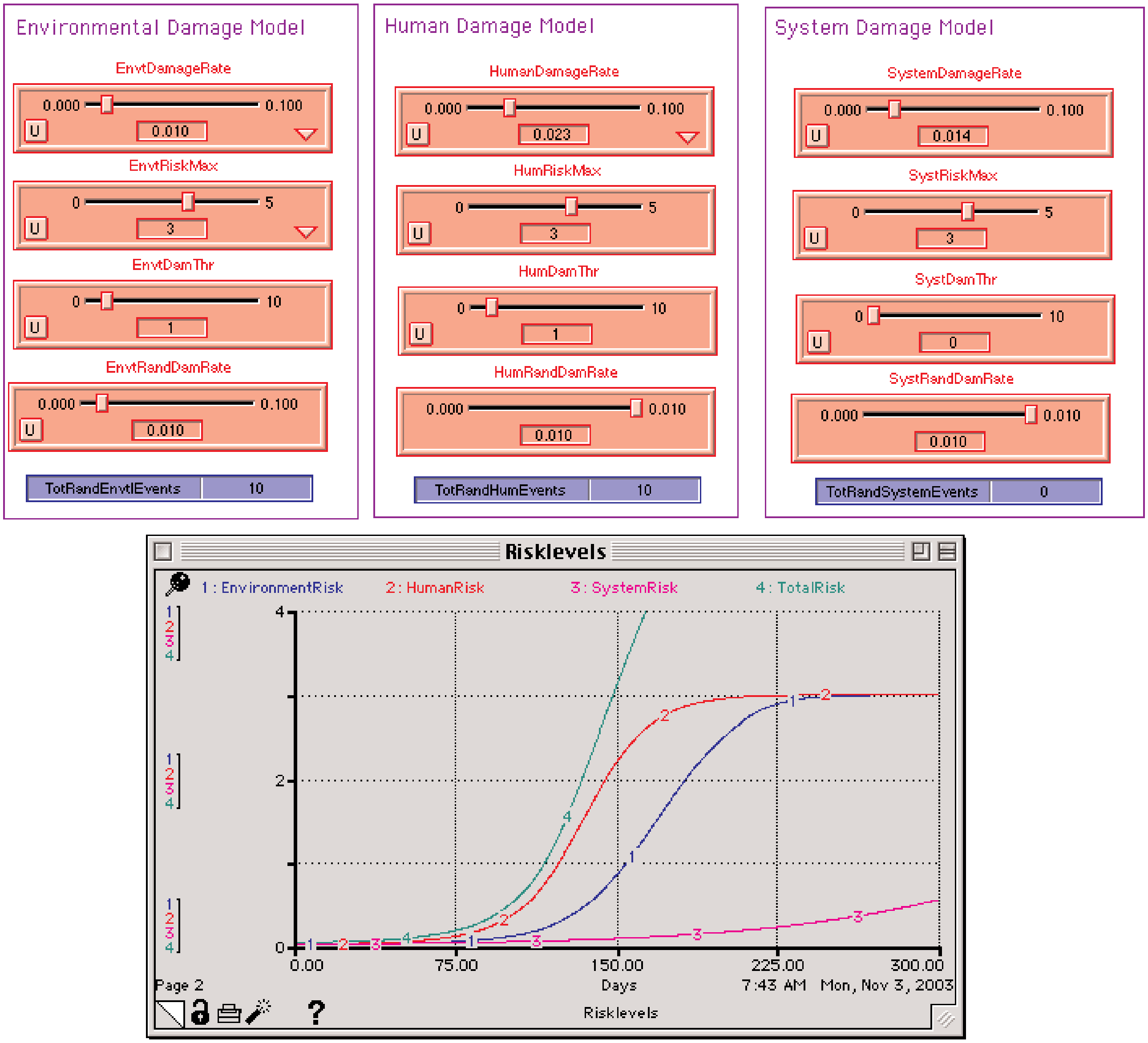
SystRiskMax
0 5
3

SystDamThr
0 10
0

SystRandDamRate
0.000 0.010
0.004

TotRandSystemEvents 0

Figure 3. *A baseline with no events shows the human element within a stable system, and an understood extreme environment faces increased deterioration around 175 days and reaches level 2 (moderate danger) at 275 days which brings the total mission to a high level of risk after 300 days.*



Environmental Damage Model

EnvtDamageRate 0.000 – 0.100: 0.010

EnvtRiskMax 0 – 5: 3

EnvtDamThr 0 – 10: 1

EnvtRandDamRate 0.000 – 0.100: 0.010

TotRandEnvtlEvents 10

Human Damage Model

HumanDamageRate 0.000 – 0.100: 0.023

HumRiskMax 0 – 5: 3

HumDamThr 0 – 10: 1

HumRandDamRate 0.000 – 0.010: 0.010

TotRandHumEvents 10

System Damage Model

SystemDamageRate 0.000 0.100 0.014

SystRiskMax 0 – 5: 3

SystDamThr 0 – 10: 0

SystRandDamRate 0.000 – 0.010: 0.010

TotRandSystemEvents 0

Figure 4. *Even with the system functioning as expected, random human and environmental events cause the mission to be catastrophic within 175 days. This shows the system was not able to protect the human under poor environmental conditions.*

The prototype risk assessment tool can be used to study the impact of different deterioration rates of the human, environmental, and systems components. This tool could also be used to assess the effect of uncertainties in the nature and protective capabilities associated with those components. For unknown situations, it could factor in a random generation of risk which could estimate the level or type of unknown risk the mission could handle on top of the known risks. The key is that the analytical tool must be populated with systematically documented strings of data or records.

The next step in the development of the analytical tool will be to test retrospective cases with known outcomes to determine the level of complexity it can handle while still producing accurate results. Without this step, it is difficult to predict if it will work in a real situation.

The GMU research team requested from the participants examples of scenarios to be used on the policy formulation process and associated analytical tools. Examples from real life health and medical policies should be drawn from areas where sufficient historical base data and evidence is available. Suggestions included treatment modalities and outcomes for cardiac patients, appendectomies for doctors wintering in the Antarctic, or Department of Defense experiences with different environmental exposures and/or vaccination policies.

It was recommended that if successful, consideration should be given to the Explorers Club for field trials involving other professional groups such as medical societies. It was also suggested that the insurance companies who provide coverage for explorers might be interested in this policy formulation process and may be willing to help develop or publicize it among a community interested in risk aversion with a lot at stake in covering those venturing into extreme environments.

There was also discussion on how to insert ethical considerations into the decision making process. It was agreed that the process should be a tool to assist with decision making, but should not be solely relied upon to make the decision or policy.

Workshop Two Conclusions

The GMU research team developed a process which will allow for the collection of data on the impact of environment, human health responses and system performance for operations in extreme environments. The participants felt the process developed by the research team would be effective in assessing risk but should not be used as the sole driver of decisions. In addition, it was determined the process and analytical tools would need to be tested with proven data before they could be released and deemed capable of assisting in the development of policies.

The GMU research team determined to seek out appropriate scenario(s) to test the process with and to present the policy formulation approach again at the final workshop with the test results. The team also decided to focus their efforts on the development concepts for training modules to recommend to NASA at the conclusion of the study.

Workshop Three: Testing the Policy Formulation Process

The purpose of the third workshop was to demonstrate how the proposed process can be used to develop rational medical policies for extreme environments (this goal was derived from feedback from the second workshop), and to solicit input on the proposed concept for the development of training modules.

To accomplish these goals, Dr. Nicogossian and Dr. Zimmerman prepared a scenario to be used in the exercise involving the workshop participants. The research team chose to review a policy which requires an appendectomy for physicians wintering in Antarctica. Other examples proposed by the participants, such as cardiovascular treatments and DOD policies for military deployment, were investigated and found not compatible with the intent of this project.

Data was collected and reviewed for extreme sports exotic tourism, as well as medical evaluations for submariners. The information in the literature consisted several articles, sometimes reporting contradictory results. Nevertheless relevant information was categorized and included in this policy testing process. The testing process proved to be a very revealing exercise.

Before presenting the results of the test scenario, Dr. Nicogossian led a discussion on the value of human life. Government sources have calculated the average value at $250,000 in direct and indirect costs based on potential earnings in the out-years which can reach $5 million.[2] The idea of determining the value of human life comes from a need to ration health care, and attention was drawn to this concept after 9/11 demanding a fair way to calculate the value of individuals who lost their lives or ability to function, in order to provide compensation. Such information should be made part of any medical or health policy consideration, especially when planning highly visible and risky exploration missions.

Dr. Williams commented on the current status of medical policy formulation and implementation at NASA. He explained categorization of health risks using color coded symbols with a reliance on opinion and varied experience, which can lead to biased decisions. He reiterated the importance for NASA and other groups exploring extreme environments to take a more exhaustive look at all the risks and how they interact with each other to develop a more accurate plan and resource allocation approach.

Dr. Zimmerman then presented the process and led the exercise to illustrate the approach to policy formulation. He encouraged openness and criticism, and distributed handouts and reports to the participants for review and comment. The participants proceeded to evaluate the policy process as it applied to the case of appendectomies for physicians bound for wintering in Antarctica.

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[2] David Dranove: *What Is Your Life Worth*, Pearson Ed. Inc., Prentice Hall 2003.

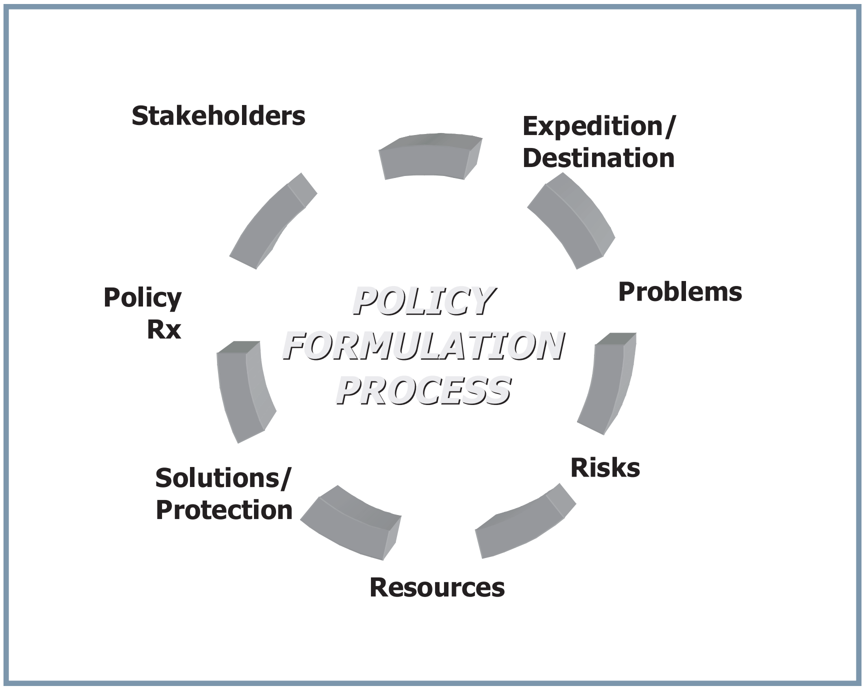
MEDICAL POLICY EXAMINATION AND FORMULATION EXERCISE

Introduction and Purpose

The GMU Office of International Medical Policy research team prepared to test the protocol developed for medical policy formulation for extreme environments. This process is based on extensive literature research and analyses, expert consultation, and expert panel workshops.

The specific purpose of this exercise was to test all steps in the policy formulation process utilizing an established single historic medical policy proposition developed to guide the conduct of human exploration in an extreme environment. The proposition selected was created for exploration of the Antarctic and is discussed in detail below.

The exercise tested this policy in light of current evidenced based research employing the policy formulation model developed by the project. The emphasis of this test was on the model and was not intended as a critique of the tested policy.



The specific purpose of this exercise was to *test all steps in the policy formulation process* utilizing an established single historic medical policy proposition developed to guide the conduct of human exploration in an extreme environment. The proposition selected was created for exploration of the Antarctic and is discussed in detail below.

The exercise tested this policy in light of current evidenced based research employing the policy formulation model developed by the project. The emphasis of this test was on the model and was not intended as a critique of the tested policy.

The policy exercise process integrates the three elements of human space flight architecture: human, system, and environment. The environment poses challenges to an exploration mission; the system provides tools to overcome challenges to human life (problems/risks) and allow teams to effect their mission.[3] A comprehensive analysis of the issues and interrelationships of these elements as they affect the mission is assured by a disciplined adherence to the formulation process.

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[3] Nicogossian, A. "The future of space medicine." *Acta Astronautica* Vol 49, No3-10, page 529.

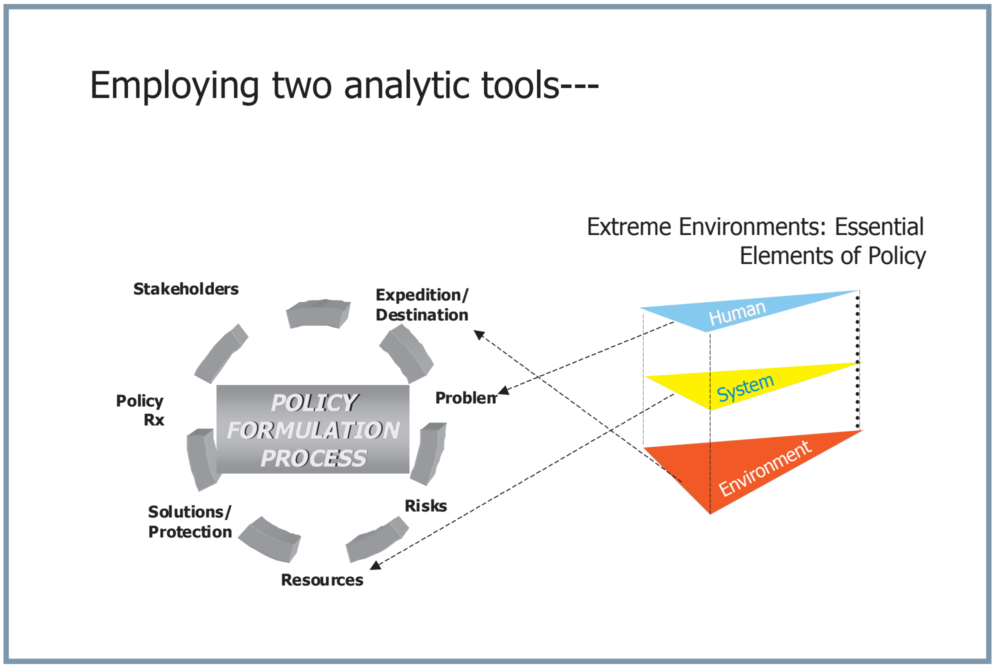

Figure 5. Adapted from Nicogossian, Hunton, and Pool, 1989.

Policy Issue Focus for Exercise

The broad context and background for the test was Antarctic exploration. The exploration team consists of scientific and support staff. The point of focus is a specific policy concerning the exploration team's sole physician member, a mission critical part of the support staff. The physician's responsibility is to address the general health and emergent medical needs of the team.

It has been mandatory for all medical officers to undergo an appendectomy before leaving for Antarctica.[4] The purpose of the usually prophylactic procedure is to avoid loss of medical support for the team, to avoid a situation in which the medical officer becomes a burden to the team, and to avoid the risks and expense of a winter emergency evacuation. The use of a prophylactic appendectomy has been considered appropriate where the physician is the sole medical person and evacuation cannot be undertaken. Should the medical member become incapacitated by appendicitis the member becomes a burden to the team, and the medical needs of the team become a critical vulnerability to the mission.

The policy raises essential questions:

1. Is the policy consistent with risks to human life posed by critical examination of Antarctic environment characteristics?

2. Does evidence-based research in Antarctic exploration and analogous extreme environments support the policy?

3. Are there other policy options recommended for consideration?

Answers for these questions will be developed employing the policy formulation protocol.

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[4] Antarctic epidemiology, page 130.

Identification of Stake Holders

Task 1: Identify and list all pertinent stakeholders---an individual or organization representing the interests and opinions of a group with an interest in the outcome of a particular decision.[5]

1. Governments (political and economic concerns)
   a. International agencies
   b. National governments

2. Academic and Scientific Organizations
   a. Australian Medical Associations-support
   b. Scientific Organizations-inability to work because of illness negatively impacts research and budgeting.
   c. American Medical Association-does not support this policy because organs should not be removed unless diseased, and risks from procedures may outweigh the benefit of mitigating risk of appendicitis during exploration.

3. Individuals and families
   a. Scientists
   b. Support Staff

4. Commercial Contractors

5. Tour operators and tourists

Destination Environment and Exploration Characteristics

Task 2: Describe the environments to which humans are exposed and in which they must survive in order to achieve the stated mission. List the characteristics of these environments that present the most salient challenges to sustaining productive life.

General Description of Antarctic Environment

Antarctica is one of the harshest environments on the planet. It is the planet's largest desert. Antarctica is a vast continent, mostly covered by ice and snow up to four kilometers thick, where the strongest winds and lowest temperatures on earth have been recorded. Animal life clings to the coastal fringe, and plant life consists of primitive mosses, algae and lichens. All animal life depends on the surrounding ocean for its food, and some birds and seals breed through the dark winter on the surface of the frozen sea.

Antarctica is the coldest continent. The lowest outdoor temperature ever recorded on earth is -89.6ºC (-129.3ºF), which was recorded in 1983 at the Russian Vostok station on the inland ice cap. At sea level, Antarctic temperatures are some 10º-17ºC (50º-63ºF) colder than the Arctic.

Antarctica is the windiest of the continents. Apart from global wind currents, Antarctica actually creates its own wind systems. Cold dense air slides from the high interior ice fields towards the lower areas along the coasts. At the edges of the ice plateau the winds accelerate, lifting and blowing clouds of snow high into the air. The strongest winds are along coastal slopes of Greater Antarctica. Katabatic winds can occur quite suddenly, and with little warning, but then die down again just as quickly. They create dramatically low effective temperatures, due to the wind-chill factor.

The harsh environment is distant and remote. There are only three airstrips each operated by a different national government. Access is primarily ship based. Travel to and from the Antarctic is expensive when it is possible. It is virtually cut off from the rest of the globe during its winter season.

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[5] *Policy, Risk, and Science*. Oxford Research Associates, Limited Report 295, 2000.

Inventory of Salient Environment Characteristics

Salient Environmental Characteristics
Arid
Average elevation: 2250m
99.6% ice covered
Winter temp -80 to -90 Celsius
Extreme wind conditions
Sun exposure and reflectivity
Profound isolation during Winter
Winter: April-September
Winter inaccessible
Winter 24 hour darkness
Remote destination
Limited transportation access
Primary access by ship
Limited aviation access and operations
3 government operated airstrips
no private or commercial airstrips
Winter operations
extremely limited
perilous
costly

Human Problems and Challenges Posed by Environment and Exploration

Task 3: Part (A): Based upon the salient environmental characteristics, list and elaborate their projected impacts on human life and the relative risk of each.

These environmental characteristics, individually and in aggregate, present risk to human life. The table below identifies the risk for human life associated with the environmental characteristic:

Environmental Impacts on Human Life and Relative Risk

Salient Environmental Characteristics	Impact	Assumed Risks
Arid	Dehydration	2
Average elevation: 2250m	Pulmonary	2
99.6% ice covered	Mobility	2
Winter temp -80 to -90 Celsius	Hypothermia	3
Extreme wind conditions	Hypothermia	3
Sun exposure and reflectivity	Skin / Vision	2
Profound isolation during Winter	Isolation	3
Winter: April-September	Isolation	3
Winter inaccessible	Isolation	4
Winter 24 hour darkness	Chronicity	2
Remote destination	Remote	3
Limited transportation access	Access	4**
Primary access by ship	Access	
Limited aviation access and operations	Access	
3 government operated airstrips	Access	
no private or commercial airstrips	Access	
Winter operations	Access	
extremely limited	Access	
perilous	Access	
costly	Access	

* Risk Scale: 0-None; 1-Low; 2-Moderate; 3-High; 4-Catastrophic; 5-Unknown
** Medical Officer incapacitation

With reference to the target policy being assessed, it is noted that there is no specific risk identified based strictly upon environmental considerations. *However, the isolation and perilous and costly evacuation for medical emergency do place emphasis on prevention of such emergencies as an important consideration of policy planning.*

Task 3: Part (B): Review and analyze available data relevant to environmental health impacts, risks and to the target policy issue.

General Population Appendicitis Factors[6]

Appendicitis affects seven percent of the US population, with an incidence of 1.1/1000 people per year. Appendicitis is the most common acute surgical condition of the abdomen.[7] The peak incidence occurs between the ages of 10 and 30 years.[8] The mortality rate in nonperforated appendicitis is less than 1 percent, but it may be as high as 5 percent or more in young and elderly patients, in whom diagnosis may often be delayed, thus making perforation more likely.[9] It is the most common reason for a child to need emergency abdominal surgery.

- Most affected by appendicitis are young people between the ages of 11 and 20.
- Most cases of appendicitis occur in the winter months -- between October and May.
- A family history of appendicitis may increase risk for the illness,
    - Especially in males. Incidence of appendicitis is approximately 1.4 times greater in men than in women.
- Having cystic fibrosis also seems to put a child at higher risk.
- May occur after a viral infection in the digestive tract
- Decreased dietary fiber and ingestion of refined carbohydrates.

Note: Incidence of appendicitis is lower in cultures with a higher intake of dietary fiber. Dietary fiber is thought to decrease the viscosity of feces, decrease bowel transit time, and discourage formation of fecaliths, which predispose individuals to obstructions of the appendiceal lumen.

General Population Mortality/Morbidity[10]

- Overall mortality rate of 0.2-0.8% is attributable to complications of the disease rather than to surgical intervention.
- Mortality rate rises above 20% in patients older than 70 years, primarily because of diagnostic and therapeutic delay.
- Perforation rates are higher in patients younger than 18 years and in patients older than 50 years, possibly because of delays in diagnosis. Appendiceal perforation is associated with an increase in morbidity and mortality rates.

Clinical Overview of Acute Appendicitis[11]

A physician is advised to maintain a high index of suspicion of appendicitis in all age groups.

Pathophysiology: Obstruction of the appendiceal lumen is the primary cause of appendicitis. Obstruction of the lumen leads to distension of the appendix due to accumulated intraluminal fluid. Ineffective lymphatic and venous drainage allows bacterial invasion of the appendiceal wall and, in advanced cases, perforation and spillage of pus into the peritoneal cavity.

Nonsurgical treatment of appendicitis: Anecdotal reports describe the success of IV antibiotics in treating acute appendicitis in patients without access to surgical intervention (e.g., submariners, individuals on ships at sea). In one prospective study of 20 patients with ultrasound-proven appen-

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[6] University of Maryland, May 2003

[7] Liu CD, McFadden DW. Acute abdomen and appendix. In: Greenfield LJ, et al., eds. Surgery: scientific principles and practice. 2d ed. Philadelphia: Lippincott-Raven, 1997:1246-61.

[8] Schwartz SI. Appendix. In: Schwartz SI, ed. Principles of surgery. 6th ed. New York: McGraw Hill, 1994:1307-18.

[9] Liu CD, McFadden DW.

[10] Sandy Craig, MD, Associate Program Director, Clinical Instructor, Department of Emergency Medicine, University of North Carolina at Chapel Hill, Carolinas Medical Center

[11] Craig, S. *Acute Appendicitis*. eMedicne.com, June 19, 2003

dicitis, 95% had resolution of symptoms with antibiotics alone, but 37% of these patients experienced recurrent appendicitis within 14 months.

The second-generation cephalosporins cefoxitin and cefotetan are the most widely used antibiotics for appendicits.[12] They have activity against enteric gram negative, gram positive and anaerobic organisms yielding their utility for intraabdominal infections. Winslow et al[13] compared placebo with preoperative cefoxitin prospectively for nonperforated appendicitis and found a significant reduction in postoperative infection. Cefotetan has the advantage of a longer half-life with better bacteroides coverage than cefoxitin. Lieberman et al[14] prospectively compared cefoxitin with cefotetan for nonperforated appendicitis. Single dose cefotetan was as effective as multiple dose cefoxitin and more effective than single dose cefoxitin for prevention of wound infection. One dose of cefotetan preoperatively would therefore seem of sufficient duration for treatment of acute nonperforated appendicitis. Patients with nonperforated appendicitis can be treated with a single dose of cefotetan.

Open versus laparoscopic appendectomy:

- Initially performed in 1987, laparoscopic appendectomy has been performed in thousands of patients and is successful in 90-94% of attempts.
- Advantages of laparoscopic appendectomy include increased cosmetic satisfaction and a decrease in the postoperative wound infection rate. Some studies find a shorter convalescent period compared to open appendectomy and a trend toward shorter hospital stays.
- Disadvantages of laparoscopic appendectomy include a slightly longer operating time (approximately 20 min) and increased cost.
- Contraindications to laparoscopic appendectomy include significant intra-abdominal adhesions and pregnancy beyond the first trimester.

Complications:

- Wound infection
- Dehiscence
- Bowel obstruction
- Abdominal/pelvic abscess
- Death (rare)

Prognosis:
Excellent.

Medical/Legal Notes:
Approximately 10% of adults who develop appendicitis are not diagnosed correctly at the first physician encounter. Failure to diagnose appendicitis is the leading cause of successful malpractice claims and the fifth most expensive source of claims against emergency physicians.

In sum, the appendectomy is a low risk procedure with an expected excellent outcome.

Surgery Statistics:

Incidence Data Relative to Antarctica Exploration

D. J. Lugg calculates the incidence of appendicitis at around nine per 1000 persons per wintering year.[15] This rate is based on data generated over the period from 1899 to 1950.

The ANARE wintering expedition's morbidity rate is 15.7 per thousand for the period 1947-1972.[16] This rate is higher than U.S. Navy and French expeditions. The incidence is higher at Russian stations than Australian stations.

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[12] Hale DA, Molloy M, Pearl R, et al. Appendectomy: A contemporary appraisal. Ann Surg 1997; 225(3):252-61

[13] Winslow RE, Dean RE, Harley JW. Acute nonperforating appendicitis. Efficacy of brief antibiotic prophylaxis. Arch Surg 1983; 118(5):651-5.

[14] Liberman MA, Greason KL, Frame S, et al. Single-dose cefotetan or cefoxitin versus multiple dose cefoxitin as prophylaxis in patients undergoing appendectomy for acute nonperforated appendicitis. J. Am Coll Surg 1995; 180:77-80.

[15] Lugg, D J Appendicitis in Polar Regions. Thesis; University of Cambridge, 1979, page 25.

[16] Antarctic epidemiology, page 141.

Direct Experience of Medical Offices in the Antarctica

In 1950, an Australian medical officer was evacuated due to appendicitis, and in 1961 another for a cerebral aneurism. A Russian physician was forced to perform a successful appendectomy on himself with the assistance of two co-workers.[17] In the past three years, three medical officers on the U.S.A. program have been subjects of emergency evacuations; one for breast cancer, one for back injury, and another for cardiovascular and gallbladder conditions.

Analogous Populations:

U. S. Navy Submarine Crews[18]

A total of 1389 officers and 11,952 enlisted crew members served aboard participating submarines for 215,086 and 1,955,521 person-days at sea, respectively, during the study period. Officers had 214 initial visits to medical staff with 79 re-visits for the same condition during these patrols, while enlisted men had 3345 initial visits and 1549 re-visits.

Among officers, categories of medical events in rank order:

- respiratory illnesses (primarily upper respiratory infections),
- injury,
- musculoskeletal conditions,
- infectious diseases,
- symptoms and ill-defined conditions, and
- skin problems.

Among enlisted men, in rank order:

- injury,
- respiratory illnesses (upper respiratory infections),
- skin problems,
- symptoms and ill-defined conditions,
- digestive disorders,
- infectious conditions,
- sensory organ problems (ear infections and eye problems), and
- musculoskeletal conditions.

Reported medical events disrupting a mission were rare, i.e., among a crew of seven officers, only one medical event would be expected to occur during a 6-month mission and result in ¾ of a day or less of limited or no duty. Among a crew of seven enlisted men, about two medical events would be expected during a 6-month mission and result in about 1 day of limited or no duty per medical event.

A careful retrospective review of the available information and peer reviewed publications did provide information on the frequency of occurrence of medical events in extreme environments. This information was categorized for several extreme environments. Information from the submarine patrol was subdivided into early and later periods based on the publications prior to and post 1979. Space flight was characterized as short (less than 3 weeks), or long (greater than one month). Commercial activities were categorized as tourism and sports in extreme environments and most of the data was obtained from the information published by the CDC or the Global Sentinel Program. The information was categorized and organized into comparative rank order of frequency of occurrence, based on the original Australian National Antarctic Research Expedition (ANARE) Program classification, for injuries, skin and subcutaneous infections and injuries, nervous system disorders, ear-nose and throat afflictions, digestive tract diseases, infections (excluding skin) and parasitosis, musculoskeletal problems, general category of other symptomatic illnesses and ill defined medical conditions, respiratory, mental and urinary tract infection problems. The researchers attempted to apply the ICD nomenclature to the information obtained from the published material without success and

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[17] Rogozov, 1964.

[18] Thomas, TL et al. Health of U.S. Navy submarine crew during periods of isolation. Aviat Space Environ Med. 2003 Mar; 74(3): 260-5.

decided to proceed with a general description of conditions related either to the type of illness or organ system. This approach provided information which in some instances made the comparison among different categories of extreme environments difficult. Additional difficulty was created by the small sample size of individuals exposed to the selected environments, ranging from 15,000 on submarine patrols to 300 individuals in space missions. This prompted the researchers to include only the data which would lend itself to comparison. The table below summarizes this information.

Medical Events for All Analog Extreme Environments by Comparative Rank Order

	ANARE[1]	U.S. Submarine		Space[4]		Commercial[5]	
Categories		*Early*[2]	*Late*[3]	*Short*	*Long*	*Tourist*	*Extreme*
Injury	1*	2	1	5	1	3	1
Skin/Subcutaneous	3	4	3	3	3		
Nervous System	4		7	1	2		
ENT				7	7		
Digestive	5	3	5				
Infectious / Parasitosis	6	5	6			1	2
Musculoskeletal	7		8	4	4		
Symptomatic Illness	8	6	4	2	5		
Respiratory	2	1	2	6	6	2**	
Mental	9	8	10	8	8		
UTI		7	9				

Notes:

[1] Lugg

[2] Tansey W.A. & al 1979 Undersea Biomed.Res.

[3] Thomas, TL, et. Al.

[4] Nicogossian & Williams in Medical Policy Board Handbook, NASA 2001

[5] Literature search papers from the glrobal sentinel program

* includes poisoning

** includes URI

Prophylactic Surgical Procedures: Extending the Question

The question logically follows, given the prophylactic appendectomy policy, are there other such surgeries that should be considered for diagnostic screening and/or prophylactic intervention?

According to the latest data from the National Center for Health Statistics, 40 million inpatient surgical procedures were performed in the United States in 2000, followed closely by 31.5 million outpatient surgeries.

Frequency surgical statistics (excluding OB) for both in- and outpatient procedures indicate these systems rankings:

Rank	System Surgeries	Number/Millions
1	Digestive	12.0
2	Musculoskeletal	7.4
3	Cardiovascular	6.8
4	Eye	5.4
5	Skin	3.7
6	Urinary	2.4
7	Head/Neck	2.4
8	Neurological	2.2
9	Pulmonary	1.4
10	Ear	.9

By far, GI surgeries lead the way and suggest consideration of other high frequency surgeries within this system. Cholecystectomy is an example.[19]

Frequency: Prevalence of cholelithiasis in the U.S. is affected by many factors, including race, ethnicity, gender, age, medical problems, and fertility. Between 10-20% of adults (approximately 20 million people) in the US, have gallstones. Each year, only 1-3% of people with stones develop symptoms of gallstones. People of Hispanic or northern European countries are more likely to have stones.

Risk Factors:[20]

- Overweight
- Between 35 and 55 years old
- Women more than men (apparently associated with metabolic changes during pregnancy)

Mortality/Morbidity:

- Asymptomatic gallstones result in morbidity and mortality when they become symptomatic.
- Complicated cholecystitis has 25% mortality (e.g., gangrene, empyema of gallbladder). Perforation of gallbladder occurs in 3-15% of patients with cholecystitis and is associated with 60% mortality.

Treatment: Historically, cholecystitis was operated on emergently, resulting in increased mortality. Currently, practice is to cool off the gallbladder and perform a cholecystectomy after several days or to readmit the patient later. Cholecystectomy may be performed after the first 48 hours or after the inflammation has subsided. Unstable patients may need more urgent intervention with ERCP, percutaneous drainage, or cholecystectomy.

Laparoscopic cholecystectomy has proven effective and with few complications. Approximately 5% must be converted to an open cholecystectomy. In acute cholecystectomy, the conversion rate can be as high as 50%.

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[19] Sanden, Sally Vanderbilt University. eMedicine.com, June 2001.

[20] American College of Surgeons. About Cholecystectomy

Whole Body Imaging

The experience data in extreme environments includes a case of cerebral aneurysm. A policy measure for consideration is a whole body MRI to detect and rule out to the extent possible such candidate conditions as aneurysms.

Frequency: The frequency of cerebral aneurysms in the U.S. is difficult to ascertain because of variation in the definitions of the size of aneurysm and modes of detection. Autopsy series cite prevalence of 0.2-7.9%. Prevalence ranges from 5-10%, with unruptured aneurysms accounting for 50% of all aneurysms. Pediatric aneurysms account for only 2% of all cerebral aneurysms. In the United States, the incidence of ruptured aneurysms is approximately 12 per 100,000 individuals or 30,000 annual cases of aneurismal Subarachnoid hemorrhage (SAH). The frequency of cerebral aneurysms has not declined in recent years. Internationally, the incidence of aneurismal SAH varies widely depending on geographic location, ranging from 3.9-19.4 per 100,000 individuals, with the highest reported rates in Finland and Japan. Overall, the incidence has been estimated at 10.5 per 100,000 individuals.

Imaging: Advances in neuroimaging techniques have altered the diagnosis of cerebral aneurysms dramatically. Noninvasive angiographic methods, such as computed tomographic angiography (CTA) and magnetic resonance angiography (MRA), allow for detection and characterization of aneurysms, further enhanced by postprocessing techniques that enable 3-dimensional evaluation of aneurysm morphology. Contemporaneous parenchymal imaging with CT scan or MRI yields a wealth of information that may assist surgical planning. However, minor aneurismal hemorrhage may not be detected with noninvasive methods.

Resources Required

Task 4: List and elaborate the technology and systems resources that are required to address the range of policy alternatives determined useful in mitigating risks to mission and to individuals. In addition, project the relative cost-benefit ratios of policy alternatives.

1. There are several resource justifications for the confirmation of the existing policy, particularly when there is a sole medical officer on an exploration team.
    - A. Emergency medical evacuation is perilous and is a multiplier of the number of lives placed at risk.
    - B. Emergency medical evacuation is a great expense.
    - C. The relative cost of the prophylactic surgery is insignificant and the mortality rate near zero. Advances in laparoscopy technology make the procedure less intrusive.
    - D. The loss of the services of the medical officer puts the health and safety of the team at risk.
    - E. Beyond the loss of service of the medical officer, that individual becomes an additional burden to the team and threatens mission and the investment of resources made in the mission.

2. A key policy consideration is redundancy of a basic level of medical skill sets within the team. There are several options for consideration:
    - A. Include at least two medical officers on the team. This option increases expense and recruitment is difficult.
    - B. Use specially trained paramedic personnel in addition to and perhaps as a substitute for a physician medical officer. This option can be implemented at lower cost and para-

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[21] David S Liebeskind, MD, Clinical Instructor, Department of Neurology, Comprehensive Stroke Center, University of Pennsylvania. eMedicine, August 2003.

medics are more available. Coupled with the use of telemedicine technology, this alternative has been demonstrated to be effective.

C. Cross training of exploration team members is an alternative. Special training in the management of medical emergencies of other team members as a secondary responsibility and skill set may be a viable option. Training can be designed and implemented at comparatively low expense.

3. Updating and making screening a more powerful tool in ruling out medical risks. A more sophisticated screening using advanced imaging technologies to detect and rule out individuals with pre-emergent medical risks. Whole body scans for the medical officer candidate (and for all the team) could prove useful in detecting a spectrum of potential risks.

4. Attention to the diet of the medical officer (and for all the team) offers the potential to mitigate the risk of appendicitis. High fiber diet for a significant period prior to the mission and during the mission may prevent and/or lower the incidence of this particular problem. There is a relatively low cost for implementing this policy alternative.

5. Increased reliance on and the use of antibiotic therapy in the treatment of appendicitis as a first line treatment. While the new generation of antibiotics is costly, the expense is relatively insignificant compared to the available alterntives.

Policy Options and Recommendations

Task 5: Frame options and alternatives as policy statements and place them in rank order of recommendation to policy makers and stakeholders.

1. Confirm existing policy of prophylactic appendectomy.

2. Given declining incidence and improved medical management, treat medically.

3. Select medical officers with no risk factors.

4. Provide high fiber diets (however the preventive aspect of this approach is inconclusive).

5. Cross train and use paramedics.

6. Increase use of advanced imaging to rule out pre-emergent medical risks.

FINDINGS AND DISCUSSION

Throughout the presentation of the report, workshop participants provided feedback. There was extensive discussion about the policy presented and the process for making complex policy decisions in general. Overall, the feedback was positive and supportive of the process.

The ANARE appendectomy practice is effective in demonstrating that policies are not always made solely on scientific or medical-based evidence. This policy has its limits, has contributed to some challenges and has been reviewed annually to ensure its appropriateness. There have been difficulties in recruiting doctors who can have appendectomies in time for a mission, especially when processing a doctor with short notice prior to departure, since a patient receiving an appendectomy needs recovery time. There has been at least one instance where doctors have gone to Antarctica without adequate recovery and at great risk of infection. It was concluded that in the case of ANARE, as long as the program relies on one physician, and total isolation during the wintering period, prophylactic appendectomies might be an acceptable solution for the time being, but should be reevaluated on a continued basis. Discussions centered on the transferability of such experiences and policies to human missions to Mars, and if additional prophylactic surgeries might be required of all crewmembers. A potential policy for consideration and based on the original model would be to select individuals which have already undergone such procedures.

Workshop participants discussed the importance of separating technical and political aspects in order to appropriately evaluate a policy. In some cases, it is not medically feasible to save the life of a person being rescued, but the political ramifications of leaving a person to die without attempts at saving life (applicable to extreme environments and highly publicized, visible, international expeditions) makes decisions daunting at best. With all the facts and evaluations available, sometimes political pressure steers a policy into a situation that ignores realistic or factual information.

Discussions were held on the possibilities of telemedicine and what to do in situations where rescuing an individual may not be immediately possible. Unfortunately telemedicine for missions beyond low Earth orbit has serious limitations imposed by the distances involved. The question was raised that if exploration is taking place in such an environment, should you eliminate potential problems prior to the mission? Or, is it necessary to send a doctor into that environment, and if that doctor was in the environment (i.e. space), would there be a situation where it was appropriate for surgery to be performed in that extreme environment? This raises great ethical questions concerning an explorer's obligation to follow measures to save an individual's life when the environment limits the ability to perform and reduces chances of survival.

In addition to concerns and prescreening for possible physiological changes or medical events which may occur on a mission, there is also the threat of harmful psychological responses to long term isolation, and removal from and then reentry into society. There is a screening test available predicting problems such as inability to sleep, alcoholism, and other behaviors which people might consider acting on out of isolation. "Retribalization," where explorers rejoin society after a voyage, was also a great concern especially when no managed transition to society is available. Retribalization difficulties include driving accidents, career changes, divorce, and increased rates of abuse, suicide, extramarital affairs, and other medical and social problems.

One of the drawbacks for using the appendectomy policy to test this model is that there is no adequate way to test the error rate. Since the appendix has been removed, there is no way to determine if the person would ever have developed appendicitis, and there is no way to predict the illness. In addition, the cost of evacuation is high and the loss of mission is greater than any risks involved in performing the appendectomy. There is also a great risk in developing a screening process for appendicitis because failure in identifying a case could lead to mission failure as well. This brings to light the ethical concern of the ability to screen out and eliminate candidates for potential problems even if there is no evidence that there will be an actual medical emergency. Such policies could lead to accusations of discrimination and resentment. However, the key is to eliminate the need for a rescue situation which would endanger more lives.

Overall, participants felt this was a good test for two useful tools, but should not be used in isolation. This model is a good tool to organize details in situations where there is no time to analyze the minutia. The group felt it should be understood that the model is based on some speculation, however it is a process and provides systematic tools to guide information gathering leading to policy formulation and estimates of the total risk rather than individual risks. This tool is useful in evaluating the important components before going into an environment for which every contingency cannot be prepared.

For future and follow up evaluation, the group suggested that emphasis should be placed on ensuring the model's portability to various environments by using commonalities of all extreme environments, and then allow for subsets that change for individual scenarios. It is also important to make sure someone outside the process could pick it up and use it without much difficulty. In addition, it would be helpful to use it for a situation where policy has not yet been established (i.e. an international exhibition, a military decision, or use of a new technology), and see if it is an accurate predictor of risk without necessarily using it to guide this particular policy decision. Once the functionality has been tested thoroughly, analyzing the model with more controversial policies will be necessary to ensure the model produces consistent results with political pressure as a potential variant. In addition, there needs to be an evaluation of the ratings of risk to ensure that biases do not sway the results significantly.

As a follow-up activity, it has been suggested that the research team approach an international trade or tourism organization, or possible travel insurance companies to generate some basic policy or guidelines used for remote travel. It would be useful to present the model with that policy in mind to get feedback from them. This could take place in the form of a pilot study as an early evaluation of the tool. Participants were supportive of creating a training element to ensure use of the model would be consistent and produce useful results. In addition, diversifying users will further test the model's ability to predict risk in multiple environments.

CONCLUSION

While the model is intended as just one of a range of tools to use in decision making, there is a certain level of assumption built in when the unknown comes into a specific scenario. For example, in a new exploration location such as Mars, the ability to assess risk is only based on what is proven and available to policy makers. However, the users recognize that results are not guaranteed and this is just one tool in the toolbox to use for evaluating risk in a systematic and organized fashion. The GMU team was encouraged to continue testing the model and distributing it to potential private sector users for evaluation. In addition, should the model continue to demonstrate its effectiveness, training programs will be set up for end-users.

The participants felt that the research was very useful in addressing an important area of health and medicine and that GMU should proceed with developing a prototype training module for field testing by NASA.

APPENDIX A. CALL TO WORKSHOP TWO

This workshop will focus on the evaluation of model(s) for medical decision making for extreme environments and validation of a process for health and safety policy formulation for exploration of and expeditions to the Extreme Environments.

Based on the outcomes of this workshop training modules and appropriate decision making tools will be developed. These tools will assist medical and safety personnel, and managers to formulate sound policies.

The Call to the Workshop

On November 7, 2003, The School of Public Policy will convene a second, one day workshop at the Finley Building, Fairfax campus of the George Mason University, to evaluate the model(s) and propose a process for health policy formulation in the planning for exploration class missions or expedition into extreme environments.

The workshop will start at 09:00 and conclude at 17:30. Additional follow up sessions might be undertaken based on the outcome of this activity The first fact finding international workshop was held on July 24-25, 2003 and concluded that development of a model and suitable process for risk assessments and medical policy formulation is essential to the success of future human undertakings in the extreme environments.

Goals of the Workshop

This workshop is dedicated to the
1. Review and agreement of analytical/predictive models for medical policy formulation
2. Validation of the parameters to be included in the processes designed to formulate health and safety policies
3. Selection of a decision making process through the conduct of simulated and/or real life exercises designed to craft appropriate health and safety policies
4. Validate the model adaptability to different exploratory and/or expeditionary activities.

Background and Opportunities

The purpose of this research is to define processes and develop training for the formulation of medical and health policies for operations in extreme environments. Four specific objectives have been identified:
- **Evaluate** best practices for formulating medical care and health policies for extreme environments.
- **Establish** a common process, if any, for policy generation, applicable and transferable to medical operations in different extreme environments, independent of prospective legal or political climate, or future changes in resources and technology
- **Develop** analytical/predictive health and policy models based on perceived complex/combined risks
- **Propose** a set of training tools and offer, if requested, periodic educational and training seminars for NASA and other personnel involved in research and operations in extreme environments in space or on the ground.

Background research on medical policy formulation for extreme environments has shown that there is no unique process or framework applicable to most extreme environments and there are no systematic activities employed by most entities responsible for medical/health policy formulation in these environments. Moreover, numerous challenges/unanswered questions have been identified:

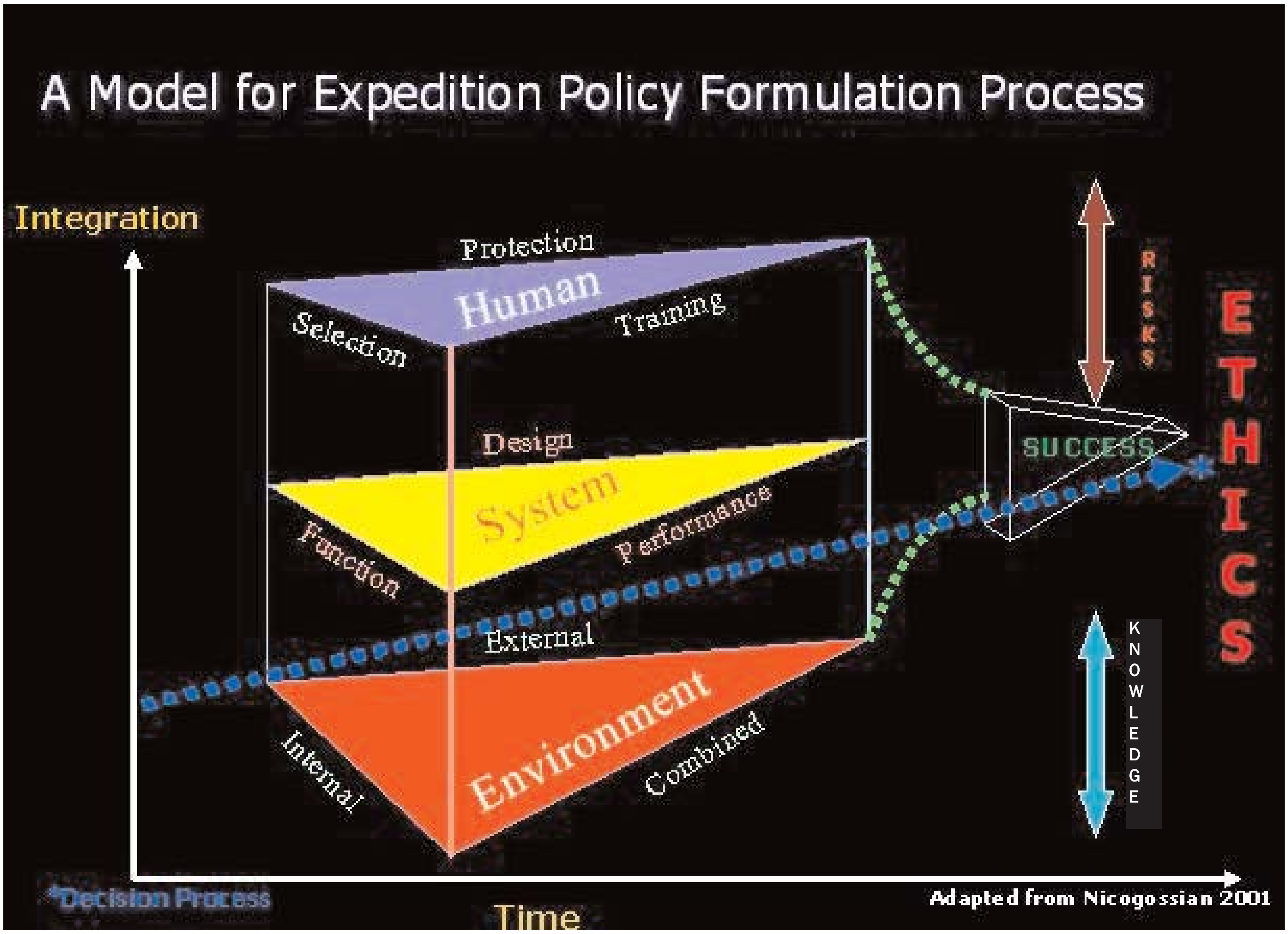
- Should the same moral standards apply in 'normal' and extreme environments?

- Do explorers have the same constitutional rights as when living in their native communities? Do they have the right to receive the same level of care?
- How do we establish the cutoff point in safety? Is there an 'acceptable risk'? What about a 'tolerable risk'? Are these risks defined similarly by all stakeholders (e.g. ordinary citizen, astronaut, medical safety team member)?
- How do we harmonize the culture, values, and standards of increasingly diverse crews (teams)?

The research team at GMU completed an initial evaluation of the health health and safety standards and policies in extreme environments. The search confirmed, however, one of the hypotheses that led to the initiation of this project: that *there are no consistent processes for formulating medical/health policies for exploration, travel, or work in extreme environments.*

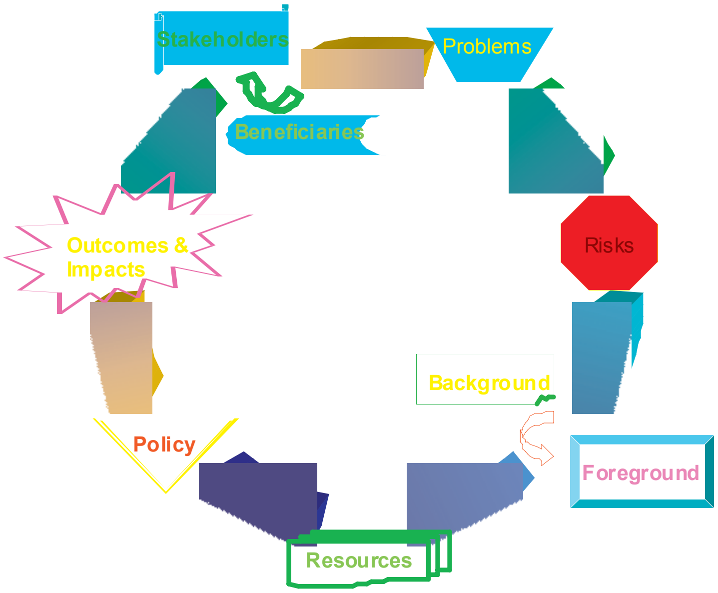
It was also concluded that decision-makers need to be educated to understand the importance of the human dimension - they need to go to their medical advisor early in the process of preparing an expedition.

The following model and process for policy formulation were endorsed by the first workshop participants.



Adapted from Nicogossian 2001

Process for policy formulation



Conduct of the Workshop

The workshop will begin with a review of the findings and recommendations from the first workshop, and presentations of different methodologies and models by the SPP Faculty to the workshop participants. A series of exercises, using hypothetical and real life examples will be conducted. The participants are encouraged to propose their own case studies to be used during the workshop (please provide a written narrative without specific individuals identifiers to comply with the Privacy Act)

The participants will be provided special questionnaires to identify satisfaction and shortcomings of the methods used by the GMU Faculty. The participants will be asked to provide recommendations for improving the process and training modules.

APPENDIX B. WORKSHOP TWO AGENDA

Medical Policy Formulation Process for Extreme Environments

Finley Bldg Large Conference Room

November 7, 2003

AGENDA

09:00	Welcome and Introductions	Arnauld Nicogossian, George Mason University
09:15	Updates on Space Medicine	Richard Williams, NASA Chief Medical Officer
09:30	Charge to the Workshop	Arnauld Nicogossian
09:45	Report on Findings and Recommendations from the first Workshop	Arnauld Nicogossian
10:00	Additional Comments	Workshop Participants
10:15	Morning Break	
10:30	Presentation of Models and Processes	Tom Zimmerman Ted Woodcock
11:00	Validation of the Process	Tom Zimmerman Ted Woodcock Workshop Participants
12:30	Working Lunch and Continued Discussions	
13:30	Continuation of Process Validation	
14:30	Afternoon Break and Refreshments	
14:45	Continuation of Process Validation	
16:00	Consensus Building	Tom Zimmerman Ted Woodcock
17:00	Summary & Recommendations	Arnauld Nicogossian
17:30	Adjournment	

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APPENDIX D. EVALUATION

The participants were surveyed on their impression of the model and the workshop preparation and accomplishments. This survey was conducted by individuals who were not part of the research team, GMU faculty or NASA staff. Of the 5 responses, there were no unsatisfactory results (1-2) in the survey. The survey tool in its entirety is available in Exhibit A, and the results are as follows:

Question	3	4	5
Pre-workshop information	1	4	0
Facilities	0	1	4
Overall Preparation	0	3	2
Accomplished Objectives	0	2	3
Adequate skill mix of participants	0	2	3
New insights from workshop	0	1	4

One comment was made which expressed concern about the time spent on discussion of the models. The individual felt there was too much time spent discussing the models. However the individual felt the concept was very good and the utility was obvious.

APPENDIX E. WORKSHOP THREE AGENDA

Extreme Environments
Development of Decision Processes and Training Programs
for Medical Policy Formulation

Friday, March 5, 2004

AGENDA

10:00	Welcoming Remarks	Dr. Roger Stough Dr. Richard Williams
10:15	Presentation: Medical Policy in Extreme Environments	Dr. Tom Zimmerman
11:45	Working Lunch and Discussions	All
13:00	Examination of the Proposed Model and Processes	Dr. Tom Zimmerman Dr. Desmond Lugg
14:00	Proposed Concepts for the Training Modules	Dr. Tom Zimmerman
14:30	Conclusions, Recommendations and Follow-Up Actions	Dr. Nicogossian All Participants

OBJECTIVE:

To test the premise that the proposed model(s) can be used to develop rational medical policies for extreme environments.

If so, comment on the proposed concept for the development of training modules.

APPENDIX F. WORKSHOP THREE PARTICIPANTS

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APPENDIX G. PRESENTATIONS

Workshop Two and Three presentations can be found online at http://policy.gmu.edu/index.htm.