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

Summary Report on Findings and Recommendations

Roger Stough, PhD
Principal Investigator
NOVA Endowed Chair, Professor of Public Policy
Associate Dean and Research Director
Mason Enterprise Center

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George Mason University, School of Public Policy
Fairfax, Virginia
http://policy.gmu.edu/oimp/index.htm

Research Team

Roger Stough, Principal Investigator

Arnauld Nicogossian, Project Coordinator

Desmond Lugg, Distinguished Research Professor

Michael Manyak, Professor and Chairman, Department of Urology, George Washington University and President of the Explorers Club

Ted Woodcock, Distinguished Research Professor

Tom Zimmerman, Senior Research Professor

Research Associates

Karen Plante, FACHE

Christine Pommerening

Sorina Vlaicu, MD, MPH

Shanea Watkins

Research Assistants

Stacey Brooks

Jill Hartsig

Joy Willingham

Associate Editor

Jeanne Geers

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Dedication

This report is dedicated to the memory of the STS 107 Columbia Crew of Explorers who devoted their lives to expanding the horizons of knowledge. Their courage and perseverance served as an inspiration to the GMU research team.

Acknowledgements

The research team would like to express their appreciation to the NASA Team and specifically Richard Williams, M.D., FACS, the NASA Chief Health and Medical Officer, who provided significant background information and support, and to the many experts named in this report who dedicated significant time and effort to make this report possible.

Office of International Medical Policy

The School of Public Policy (SPP) at GMU emphasizes interdisciplinary and alternative approaches to public policy. In addition to offering seven master's degrees and the largest PhD program in Public Policy in the nation, SPP offers a variety of hands-on research activities conducted through several research centers. From global issues, such as peacekeeping and electronic commerce, to regional issues, such as land use and transportation management in Northern Virginia, SPP is an important academic institution for inquiry into public policy formulation and recommendation of appropriate solutions.

As one of the newest disciplinary entities within SPP, the Office of International Medical Policy (OIMP) provides leadership and focus on global medical and public health processes and policies. From its inception, OIMP was intended to complement and enhance the SPP training and research portfolio. By targeting a broad spectrum of policy analysts and managers, including health professionals, OIMP aims to train a new generation of well-informed public health policy analysts and planners, prepared to face future challenges by making informed choices in the context of global socioeconomic interdependencies.

The OIMP's mission is to coordinate medical and health policy research and training activities for SPP; to provide a policy focus for professional academic activities; and to facilitate interdisciplinary research and training with international medical, health, and social science entities within and outside GMU.

Introduction

> *"...America is proud of our space program. The risk takers and visionaries of this agency have expanded human knowledge, have revolutionized our understanding of the universe, and produced technological advances that have benefited all of humanity.*
>
> *Inspired by all that has come before, and guided by clear objectives, today we set a new course for America's space program. We will give NASA a new focus and vision for future exploration. We will build new ships to carry man forward into the universe, to gain a new foothold on the moon, and to prepare for new journeys to worlds beyond our own. ...Yet for all these successes, much remains for us to explore and to learn. In the past 30 years, no human being has set foot on another world, or ventured farther upward into space than 386 miles -- roughly the distance from Washington, D.C. to Boston, Massachusetts. America has not developed a new vehicle to advance human exploration in space in nearly a quarter century. It is time for America to take the next steps."*
>
> **President George W. Bush Speech on Future of the Space Program, January 15, 2004**

Through a National Aeronautics and Space Administration grant the School of Public Policy (SPP) at George Mason University undertook research into existing health and medical policies designed to protect travelers into extreme environments, with the goal of understanding the processes governing such policy formulation (Enclosure 3).

Despite advances in medicine and technology, space exploration is still the domain of a few. However, exploration, travel and tourism into the extreme environments on Earth continue to expand. Individuals who explore and change the history of humanity are usually supported by large scale endeavors which are societal enterprises shared by many (8). Any venture into extreme environments is a risky undertaking.[1] Explorers must rely on the latest technology in order to reach their destination as quickly as possible, perform the intended tasks and return home safely. Thus, both government and private-sector chartered enterprises tend to be complex and expensive undertakings. In many instances, as the planning proceeds and expeditions are nearing commencement, resources become constrained. This results in a tendency toward primarily preserving essential life support systems, while rationing health and medical care capabilities. Emphasis is then applied on further medical screening of participants to identify and remove potential health risks. Schedules and time constraints in the planning stages of missions can also result in insufficient research into prospective health and medical risk factors. This in turn can lead to inadequate technologies, resources or logistics available to expeditions into extreme environments. Enabling research for

[1]Griffith, MD, Robert W. *The No-Risk Zone?* October 12, 2001 (Reviewed: October 15, 2003)

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human exploration is not a stable and sustained effort and as such is subject to specific mission needs, schedules, budgetary and political pressures.

In the private-sector health policies are often developed and implemented haphazardly, primarily focusing on basic safety issues. Inadequate attention given to health risks and medical care is a common practice. Recently the National Academies noted that there is a need to develop and provide adequate support to space medicine in the planning phases of exploration missions beyond the Low Earth Orbit (1).

Sojourn into an extreme environment deserves properly tailored health and medical capabilities, backed by carefully crafted policies to ensure the highest probability of mission success and explorer well-being. The U.S. Navy has been the proponent of such an approach since its inception (13). An action plan for productive and safe human enterprise into extreme environments is complex, but it must be well-thought out and comprehensive in nature. Medical and health policies need to be consistent with the best available information and practices. Planners must consider and prioritize both likely and remote scenarios explorers may encounter during their mission. The wisdom gained from past missions should be transformed into sound policy. It is important to include biomedical and environmental health expertise in this process of policy and requirements formulation practices.

Knowledge and experience are two major prerequisites for the formulation of sound health and medical policies. Medicine of Extreme Environments, and in particular Space Medicine, are still emerging specialty fields of practice in which the requisite data is often missing and in many instances simply must be extrapolated from other settings. Too often there is a tendency toward rationing medical care and services, especially given the environmental constraints, lack of supporting technology, and the assumed continued "good health status" of the participants. Fortunately, given the ability of the human physiology to compensate, such health policies rarely lead to major diseases or accidents, but they often result in the poor use of available resources and in the inadequate provisioning of exploration teams, which can be dangerous in the case of unforeseen medical emergencies. Enabling technology and systems developed to support explorations must be robust and able to protect the crews from environmental risks. Modern human exploration of the extreme environment is achieved through safe and rapid "technological adaptation" rather than slow and too often incomplete "physiological adaptations." It is generally accepted that "safe technology" should not present human explorers with additional health and medical risks. Given the above constraints, bioethical considerations should be an integral part of the health and medical care policy formulation process (11).

This research project has identified several major impediments and constraints to the development and implementation of health and medical policies for exploration of extreme environments. Tools to improve risk assessment and mission success through a systematic process of health and medical policy formulation are recommended.

Approach and Methodology

Internal and external reviews were conducted by the GMU research team in order to examine the prevailing processes and practices in health and medical policy formulation and implementation. The research team also reviewed existing models, tools and training practices for health and medical policy formulation for extreme environments. The internal evaluation was achieved through review and analysis of literature and prevailing national and international policy. The external reviews consisted of a series of three carefully structured expert workshops, held between July 2003 and March 2004. Workshop participants (Enclosure 1) were presented with research materials, models and policy formulation training concepts developed by the research team and asked to provide expert opinion, critique and recommendations. All research findings and expert recommendations were integrated by the research team into reports which were circulated among the participants for review and recommendation.

A public opinion survey to determine attitudes toward health and medical prerequisites for expeditions into extreme environments was developed by the research team and reviewed by the international experts at the first workshop. It was decided that the survey needed to be restructured or not administered at all due to the expected bias that would stem from the Space Shuttle Columbia tragedy. It was decided to indefinitely postpone the release of the survey, because of the continued inquiry into the Columbia disaster (14).

The literature review provided many different definitions for what constituted an "extreme environment." For the purpose of this research, the GMU team identified several conditions that should be met in order to earn this appellation: the destination must be isolated and/or remote, remote and hostile, or remote, isolated, and hostile.

The following definitions were adopted to facilitate the reviews, discussions and analysis conducted under this research project:

- Remoteness primarily refers to geo-spatial location;
- Isolation refers to population density or proximity to populated areas; and
- Hostility refers to specific threats and dangers posed to the expedition by physical and ecological settings.

The GMU research team completed a review of health and safety standards and policies relevant to extreme environments, and associated policy processes and recommendations. Activities included database searches (primarily web-based), such as the Government Printing Office's database of the Code of Federal Regulations (1988-2003), Lexis Nexis for related legal cases (1993-2003) and relevant action in the U.S. Congress (1993-2003), National Library of Medicine for peer-reviewed articles, and the Library of Congress for books on health policy in extreme environments. The results of these reviews were compiled in two databases, one consisting of a set of bibliographic citations, and the other summarizing regulations and policies, and relevant organizations mission statements.

For the second database more than 4500 websites were surveyed. Among those, 550 yielded significant results leading to about 35 departments or organizations that have issued health, safety, or health and safety regulations or recommendations related to exploration and/or travel in extreme environments. About 15 relevant sub-links were identified for each department/organization.

The AltaVista web search engine was used to identify a complex set of information consisting of:

- *"health and safety standards" AND "extreme environments"*
- *"safety standards" AND "extreme environments"*
- *"health standards" AND "extreme environments"*
- *"medical standards" AND "extreme environments."*

The search generated the following relevant results:

SEARCH PHRASE	RESULTS
"health and safety standards" AND "extreme environments"	6
"safety standards" AND "extreme environments"	81
"health standards" AND "extreme environments"	12
"medical standards" AND "extreme environments"	18

We also looked specifically for agencies and departments known to have had issued related regulations and policies. Overall, there are more safety than health or medical regulations and policies for extreme environments.

The primary objectives of the three workshops were to: 1) review examples of existing medical and health policy formulation and practice for various extreme environments; 2) recommend parameters to be included in a generic process of policy formulation, which can be applied to the majority of extreme environments; 3) review and select appropriate model(s), processes and retrospective examples for health and medical policy formulation; and 4) conduct a policy process validation exercise (Enclosure 3) which would lead to the development of a training program.

The attendance at the workshops was by invitation only and discussions were on a non-attribution basis. Some of the participants presented medical policy formulation and/or the decision-making process reflecting three areas of endeavor: public, commercial, and private. Selected topics addressed expeditions into space, polar regions, commercial aviation, scientific and recreational sea cruises, humanitarian relief, Himalayan and Alpine mountaineering, and rain forest expeditions. Additional presentations were received on nuclear waste disposal, radiation safety, and the Institute of Medicine's study on medical and health considerations for space exploration (1).

The international forum focused on the Australia National Antarctica Research Program, and Canadian and Russian Space Exploration activities.

This research resulted in the adoption of a model to systematically assess health risks and the development of a policy formulation process (2-4). This tool is being proposed for educating and training decision makers, stakeholders and expedition participants in the specific health and medical risks associated with such missions (Enclosure 4).

Findings

1. The workshop participants commended NASA, specifically Dr. Richard Williams, the NASA Chief Health and Medical Officer, for commissioning this research, the first of its kind in this area of health policy and medical risk management. The participants also felt that the research was very useful in addressing an important area of health and medicine.

2. The literature review revealed that *health policies for extreme environments are clearly underrepresented nationally and internationally.* The summary of these findings are presented in Figures 1 and 2. When agencies, departments, or organizations issue 'health' standards or regulations, they are primarily referring to the prevention of occupational diseases, and not necessarily preserving the explorer's long-term health and quality of life. This research also concluded that *NASA is the only agency that has specific programs in place to follow the environment's life time effect on an explorer's health. The only other profession where long-term health issues have explicitly been recognized in federal reg ulations is coal mining and the development of pneumoconiosis.*

US Regulations*, Policies & Laws

Environment	Executive Order		Public Law		Regulation		Dept. Order		Recommendation	
	H	S	H	S	H	S	H	S	H	S
Aviation					+	+			+	+
Mining			+	+	+	+			+	+
Space		+			+	+			+	+
Polar	+	+			+	+			+	+
Wilderness F & R	+	+			+	+	+			
Wilderness Tourism							+		+	+
Offshore Drilling					+				+	+
Offshore Exploration									+	+
Radiation			+	+	+	+				

Legend H = Health S = Safety

*OSHA as applicable

Figure 1. *Diagram of found regulations/laws related to health and safety and the field to which they apply.*

ENVIRONMENT	HEALTH	SAFETY
AVIATION	Yes	Yes
MINING	No	No
SPACE EXPLORATION	No	Yes
POLAR EXPLORATION	No	Yes
WILDERNESS FIRE & RESCUE	No	No
WILDERNESS TOURISM	No	No
OFFSHORE DRILLING	No	No
OFFSHORE EXPLORATION	No	No
RADIATION	No	Yes

Figure 2. *International regulations, agreements, treaties and guidance for health and safety.*

3. By virtue of its mission the NASA Office of the Chief Health and Medical Officer, given proper tools and resources, is uniquely positioned to continue to evolve and promulgate sound health and medical policies for exploration class missions. This office through its independent oversight is critical to safe and healthy human space flight.

4. General laws or regulations dealing with health and/or safety are often not specific to any environment, let alone extreme environments, and it is questionable if these existing policies can be extrapolated to fit the particular conditions of extreme environments.

5. There is a lack of any uniform approach to health and medical policy formulation, including considerations for quality of life over time.

6. A poor understanding of and a low priority given to health issues, as opposed to safety, is common practice in organizations in which health and medical care are not the primary drivers.

7. Current health and medical knowledge, experience and policies are not adequate to meet the needs of the international community engaged in space exploration beyond Low Earth Orbit.

8. A relevant medical policy formulation process and associated training program should be published and made available to policy makers. This should be a generic type process which, with minor modifications, could be tailored and adapted to individual needs and circumstances.

9. A concept for such a model (2-4) and associated process has been developed and successfully tested by the GMU research team, using a retrospective medical policy decision (see Enclosure 2).

Recommendations

1. Though safety is an important element in the success of any exploration activity, equating safety with health might be misleading, since health represents a continuum, spanning the life of an explorer, and can be affected by many variables. Illness could become manifest long after the successful completion of an expedition. In addition, it was noted that current policies are not adequate to meet the needs of the international community engaged in space exploration

2. Health literacy of travelers remains inadequate and requires improvement through intervention by medical practitioners. There is an urgent need for better training of policy and decision makers, stakeholders, and expedition participants on medical risks and their possible impact on the overall quality of life for travelers and explorers. Health literacy and the knowledge base for exploration of extreme environments must be improved. One approach to achieve this goal is to develop a training process for medical policy formulation for expeditions into extreme environments.

3. The policy process developed as the result of this research is just one of a range of tools to be used in the decision making. The users should 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.

4. For each mission a specific statement addressing the "Bill of Rights" of the explorer and/or team members should be developed and presented to the team members by the sponsor(s) of the expedition. Such a document, as a minimum, should clearly spell out, in addition to the safety procedures and occupational health hazards, the following information:

   a) medical, near and long term risks, including the extent and quality of health care;
   b) handling of medical emergencies and availability of rescue and evacuation modalities;
   c) each individual's responsibility for his or her own health care, since this can have significant impacts. For example, end of life directives, well-executed will, etc. The role and responsibility of the expedition organizers and of the team leader also need to be clarified;
   d) the use of the military medical model might be appropriate for some expeditions.

5. Bioethics should be an integral part of any health and medical decision making process leading to the policy formulation for expeditions into extreme environments.

6. The external reviewers (workshop participants) made the following recommendations:

   a.) NASA should complete the development of the training modules for the health and medical policy development process and deploy it for field testing and training purposes, including granting appropriate professional continuing education credits to the users.
   b.) The GMU research team should continue the development of the process to ensure its portability for different extreme environments and distribute it to potential private sector users for evaluation and implemen tation.

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Enclosure 1. Workshop Participants

John Allen, PhD
Program Executive, CH&S
Office of Space Flight
NASA Headquarters
Washington, DC 20546
jallen@hq.nasa.gov

George K. Anderson, MD, MPH
Major General USAF (retired)
8034 Kidwell Hill Court
Vienna, Virginia 22182
703- 748-0418
703- 748-0419 (fax)
703- 862-9683 (cellular)
docgeo@cox.net

Catherine Angotti, RD, LD
Director Occupational Health
NASA Headquarters
300 East Street SW
Washington, DC 20546
202-358-1794
cangotti@hq.nasa.gov

Stacey Brooks
Research Assistant
George Mason University
School of Public Policy
Fairfax, VA 22030
571-226-4564
sbrooks5@gmu.edu

Jeffrey R. Davis, MD, MS
Director, Space and Life Sciences
Mail code SA
NASA Johnson Space Center
Houston, Texas 77058
281-483-9393
Jeffrey.r.davis@nasa.gov

Dan Freilich, CDR, MC, USNR
Head, Hematomimetics Program
Naval Medical Research Center
503 Robert Grant Avenue
Silver Spring, MD 20910-7500
301-319-7152
freilichd@nmrc.navy.mil

Dan Hanfling, MD, FACEP
Director, Emergency Management and Disaster Medicine
Inova Health System
3300 Gallows Road
Falls Church, VA 22042
703-698-3002
703-698-2893
dan.hanfling@inova.com

Jill Hartsig
Research Assistant
School of Public Policy
George Mason University
Fairfax, VA 22030
202-729-7790
jhartsig@gmu.edu

Carolyn L. Huntoon, Ph.D
CLH Associates
20 Broadview Drive
Barrington, RI 02806
401-245-8062
clhuntoon1@aol.com

Rear Admiral Joyce M. Johnson, DO, MA
Director of Health and Safety
U.S. Coast Guard
2100 Second Street, S.W.
Washington, DC 20593
202-267-1098
jmjohnson@comdt.uscg.mil

Jim Kirkpatrick
Executive Director
American Astronautical Society
6352 Rolling Mill Place, Suite #102
Springfield, VA 22152-2354
703-866-0020
703-866-3526 (fax)
jkirkpatrick@astronautical.org

Larry Laughlin, MD, Ph.D, Capt USN
Dean, School of Medicine
Uniformed Services University of Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814-4799
301-295-3016
llaughlin@usuhs.mil

Roger Launius, Ph.D
Director
Division of Space History
MRC-311
National Air and Space Museum
P.O. Box 37012
Washington, DC 20013-7012
202-633-2428
launiusr@nasm.si.edu

Craig H Llewellyn, MD, MPH, FACPM, FRSM
Dept of Military and Emergency Medicine
Director, Center for Disaster and Humanitarian Assistance Medicine
Professor of Military Medicine, Professor of Preventive Medicine, Professor of Surgery
USUHS-School of Medicine
4301 Jones Bridge Road
Bethesda, MD 20814
301-295-3720
301-295-6773 (fax)
cllewellyn@usuhs.mil

Desmond Lugg, MD, FAFOM, FACRRM
Distinguished Research Professor
School of Public Policy
George Mason University
AM/Office of Chief Health and Medical Officer
NASA HQ 300 E Street SW
Washington, DC 20546
202-358-4790
desmond.j.lugg@nasa.gov

Harry Mahar
Safety and Health Officer
Office of Polar Programs
National Science Foundation
4201 Wilson Blvd. Rm 755.09
Arlington, VA 22230
703-292-7450
703-292-9080 (fax)
hmahar@nsf.gov

Michael J. Manyak, MD, FACS
Professor of Urology
Professor of Microbiology and Tropical Medicine
Chairman, Department of Urology
The George Washington University Medical Center
Director, The Explorers Club
2150 Pennsylvania
Washington, DC 20037
202-741-3115 secretary
202-741-3113 fax
mmanyak@mfa.gwu.edu

Ronald Merrell, MD, FACS
Professor of Surgery and
Director, MEDITAC
Virginia Commonwealth University
1200 East Broad Street
Richmond, VA 23284
804-827-1031
ronald.merrell@vcu.edu

Arnauld Nicogossian, MD, FACPM, FACP
Distinguished Research Professor
Director, Office of International Medical Policy
School of Public Policy
George Mason University
Fairfax, VA 22030
703-993-8217
anicogos@gmu.edu

Jean H. P. Paelinck, L.D.
Professor Emeritus
Oranjelaan 36
NL 3062 BT Rotterdam
Phone & Fax: 31-10-452 67 89
j.paelinck@planet.nl

Igor Pestov, MD
State and Russian Academy of Sciences Scientific Center
Institute for Biomedical Problems
76a Khoroshevskoe Shosse
Moscow, RU, 123007
256-961-6507
pestov@imbp.ru

Karen Plante, FACHE
Research Assistant
George Mason University
School of Public Policy
5217 Ballycastle Circle
Alexandria, VA 22315
703-971-2206 Home
703-203-4744 Cell
kplante@gmu.edu

Christine Pommerening, MA
Research Associate
George Mason University
School of Public Policy
Fairfax, VA 22030
cpommere@gmu.edu

Russell Rayman, MD, MPH
Executive Director
Aerospace Medical Association
320 South Henry Street
Alexandria, VA 22314
703-739-2240 Ext 103
rrayman@asma.org

Rebekah Davis Reed, Ph.D
Special Assistant for Policy
Space and Life Sciences Directorate (SA)
NASA Johnson Space Center
2101 NASA Road 1, Houston, TX 77058
281-244-1997
Rebekah.D.Reed@nasa.gov

Catherine E. Rudder, Ph.D
Professor
Director, Master's in Public Policy Program
School of Public Policy
3401 North Fairfax Drive, MS 3B1
Arlington, Virginia 22201
rudder@gmu.edu

Franceska O. Schroeder, Esq.
Partner
Pillsbury Winthrop LLP
1133 Connecticut Avenue, NW
Washington, D.C. 20036
202-775-9876
202-833-8491 (fax)
fschroeder@pillsburywinthrop.com

Marc Shepanek, PhD.
Deputy Chief of Medicine of Extreme Environments
NASA Headquarters Code AM
Office of the Chief Health and Medical Officer
Washington, DC 20546
202-358-2201
mshepanek@hq.nasa.gov

Roger Stough, Ph.D
NOVA Endowed Chair and Professor of Public Policy
Associate Dean, and Research Director, Mason Enterprise Center
Director, National Center for ITS Research
George Mason University School of Public Policy
Fairfax, VA 22030
703-993-2285
rstough@gmu.edu

Kevin Thomas
Research Associate Professor
Critical Infrastructure Protection Project
National Center for Technology and Law
George Mason University School of Law
3301 Fairfax Drive
Arlington, VA 22201
703-993-8119
kthomas2@gmu.edu

Nancy Tomich
Managing Director
U.S. Medicine Institute for Health Studies
2021 L St., NW, #400
Washington, DC 20036
202-271-5814
tomich@usminstitute.org

Sorina Vlaicu, MD, MPH
Research Associate
George Mason University
School of Public Policy
Fairfax, VA 22030
703-993-4624
svlaicu@gmu.edu

Charles Walker, Ph.D
Director, Integrated Defense Systems
NASA Systems
Boeing Company
1200 Wilson Blvd.
Arlington, VA 22209
703-465-3436
charles.walker@boeing.com

David R. Williams, MD, FRCPSC
Canadian Space Agency
Astronaut Mission Specialist
Lyndon B. Johnson Space Center
National Aeronautics and Space Administration
Houston, TX 20546
David.r.williams1@jsc.nasa.gov

Richard S. Williams, MD, FACS
NASA Chief Health and Medical Officer
AM/ NASA Headquarters
300 East Street SW
Washington, DC 20546
202-358-2390
rwillia3@hq.nasa.gov

Joy Willingham
Research Assistant
5274 Bradgen Ct.
Springfield, VA 22151
703-256-4955
jwilling@gmu.edu

Ted Woodcock, PhD
Distinguished Research Professor
School of Public Policy
George Mason University
233 Arlington O
3401 North Fairfax Drive
Arlington, VA 22201
703-993-4874
aerw@gmu.edu

Melvin Worth, MD
Senior Advisor
Institute of Medicine
National Academies
500 Fifth Street
Washington, DC 20001
mworth@nas.edu

Maj. Gen. Michael K Wyrick, USAF (Ret)
Northern Virginia Hospital Alliance
3865 Farrcroft Drive
Fairfax, VA 22030
703-359-3797
mkwyrick@cs.com

John Zapp, DDS
Managing Director
U.S. Medicine Institute for Health Studies
2021 L St., NW, #400
Washington, DC 20036
202-463-6000
zapp@usminstitute.org

James A. Zimble, M.D. Vice Admiral USN (Ret.)
President
Uniformed Services University of the Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814
301-295-3013
jzimble@usuhs.mil

Thomas Zimmerman, Ph.D
Visual Learning Systems and
Senior Research Professor (Adjunct)
School of Public Policy
George Mason University
Fairfax, VA 22030
703-993-798-6288
tfz3@aol.com

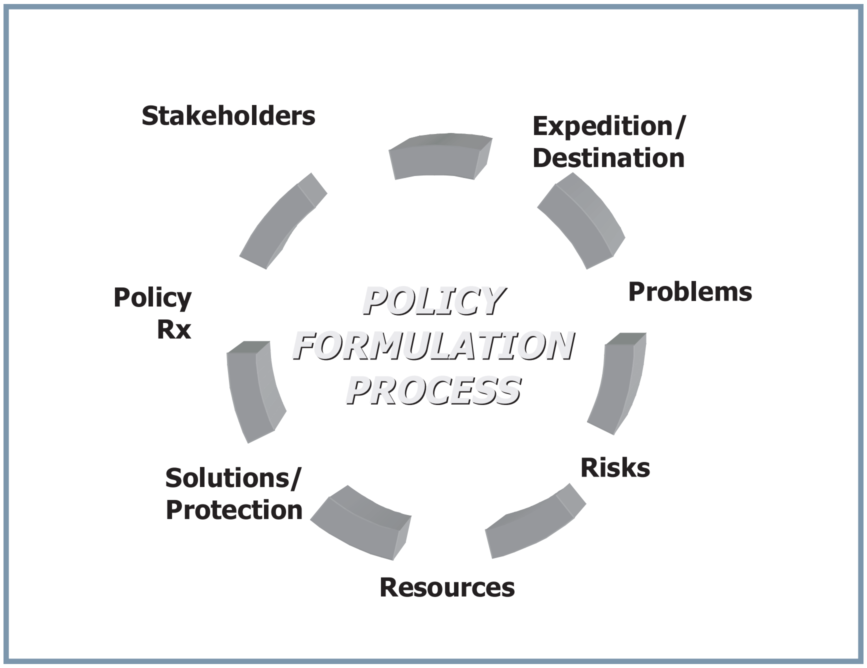
Enclosure 2. Medical Policy Examination and Formulation Exercise

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 process in light of current evidence based research employing the policy formulation model developed by the project. The emphasis of this exercise was to test the process and was not intended as a critique of the 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.[2] A comprehensive analysis of the issues and interrelationships of these elements as they affect the mission is assured by a disciplined adherence to the policy formulation process.

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

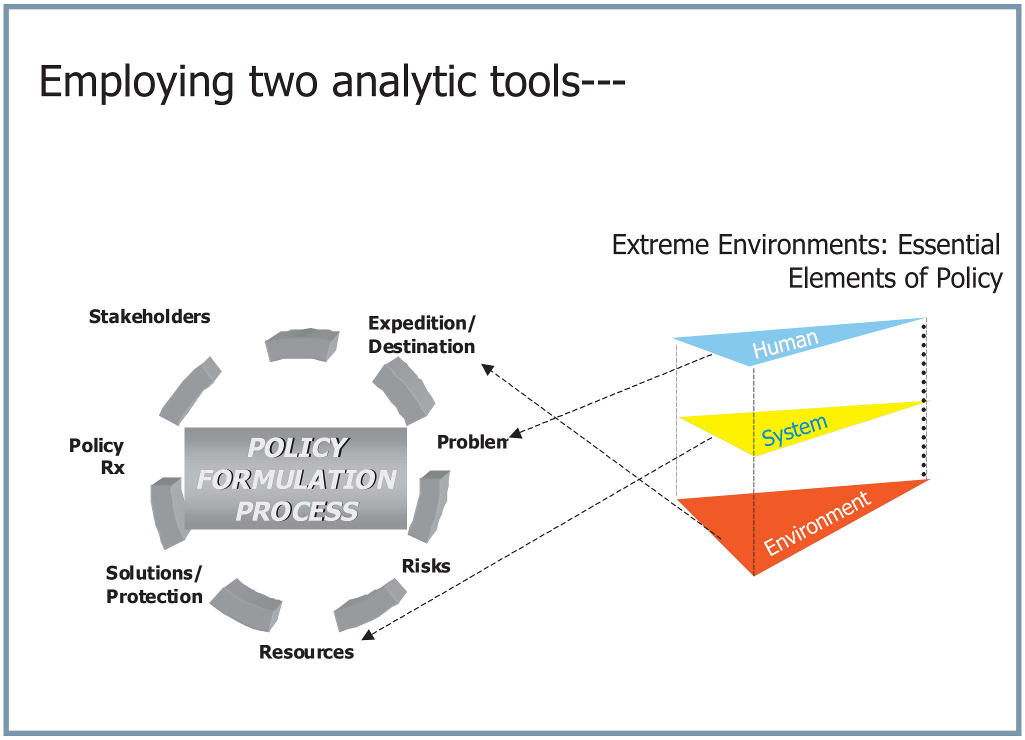


Figure 5. *Adapted from Nicogossian, Huntoon, and Pool: Space Physiology and Medicine, Lea Febiger 1989.*

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.[3] 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 to these questions were developed employing the policy formulation process.

[3] 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.[4]

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
    a. Scientists
    b. Support Staff
    c. Relatives and Families

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.

[4] 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:

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[5]

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.[6] The peak incidence occurs between the ages of 10 and 30 years.[7] 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.[8] 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[9]

- 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[10]

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 appendicitis, 95% had resolution of symptoms with

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[5] University of Maryland, May 2003
[6] 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.
[7] Schwartz SI. Appendix. In: Schwartz SI, ed. Principles of surgery. 6th ed. New York: McGraw Hill, 1994:1307-18.
[8] Liu CD, McFadden DW.
[9] Sandy Craig, MD, Associate Program Director, Clinical Instructor, Department of Emergency Medicine, University of North Carolina at Chapel Hill, Carolinas Medical Center
[10] Craig, S. *Acute Appendicitis*. eMedicne.com, June 19, 2003.

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 appendicitis.[11] They have activity against enteric gram negative, gram positive and anaerobic organisms yielding their utility for intra-abdominal infections. Winslow et al[12] 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 bactericides coverage than cefoxitin. Lieberman et al[13] prospectively compared cefoxitin with cefotetan for non-perforated 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 non-perforated appendicitis. Patients with non-perforated 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.[14] 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.[15] This rate is higher than U.S. Navy and French expeditions. The incidence is higher at Russian stations than Australian stations.

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

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

[13] 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.

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

[15] Antarctic epidemiology, page 141.

Direct Experience of Medical Offices in 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.[16] 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[17]

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, reparatory, 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 decided to proceed with a general description of conditions related either to the type of illness or organ system. This approach provided

[16] Rogozov, 1964.

[17] 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.

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 GMU research team 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 global 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.[18]

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:[19]

- 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%.

[18] Sanden, Sally. Vanderbilt University. eMedicine.com, June 2001.
[19] 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:[20] 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 post processing 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-

[20] 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 alternatives.

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.

Enclosure 3. Overview of the Research Proposal

The purpose of this study is to define policy 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 possible, for policy generation, applicable and transferable to medical operations in various extreme environments, independent of any particular legal or political climate, and sensitive to future changes in resources and technology;
- Develop analytical/predictive health and policy model(s) based on perceived complex/combined risks; and
- Propose a set of training tools and offer, if requested, periodic education 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 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 and unanswered questions have been identified:

- Should the same moral standards apply in "normal" and "extreme environments"? In this context "normal" was defined as place of residence where accessibility to services is readily available. Place of residence was considered to be a modern urban setting.

- Do explorers have the same constitutional rights as they do when living in their native communities? Do they have the right to receive the same level of care?

- How do we establish the cut-off point for 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 cultures, values, and standards of increasingly diverse crews?

To address some of these issues, the GMU research team proposed and was granted through the Office of the Chief Health and Medical Officer, National Aeronautics and Space Administration (NASA), financial support for up to one year, with the specific purpose of conducting background research and bringing experts together to help develop a generic process of policy formulation, as well as to identify appropriate training programs for policymakers.

Enclosure 4. Storyboard for Module 1: Introduction to the Health and Medical Policy Formulation Process