17 AIAA Humans in Space Symposium

Moscow, Russian Federation

Evolution of Space Medicine Policies: from Experimentation to Evidence Based Practice: The First 50 Years

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Venturing into uncharted territories carries risk to the health and well-being of the explorers. Throughout history, explorers have been considered a special breed of individuals, who contributed knowledge and wealth, and expanded the physical, boundaries of the world we live in. All new endeavors into hostile environments carry a risk to health and sometimes loss of life.

Bernardino Ramazzini, the father of occupational medicine describes challenges facing the circumnavigators, the sailors and rowers, in his famous *Diseases of the Workers*, first published in 1700:

"…chronic diseases also attack them (sailors), but they do not suffer from them as long as do those whose occupation is on land, for a ship is not a good place to ministering to chronic diseases…"[i]

Though written over 300 years ago, the observation that a "*ship is not a good place for ministering to chronic diseases"* is still relevant to the conditions and limited health care resources provided onboard the modern space ships (government operated in low Earth Orbit).

This was well understood by the renowned Soviet/Russian space medicine pioneer, Academician Oleg Georgovitch Gazenko. A military physician by trade he embarked on a large scale systematic research, both on the ground and in space, using human and surrogate test subjects. Dr. Gazenko progressively expanded the scope and breadth of the investigations using many animal subjects, including canines to prove that survival in space is possible and compatible with human physiological functions. By integrating biological missions using dogs, rodents and ultimately primates with the ongoing long duration Salyut and MIR orbital stations he was able to improve the preventive care of the cosmonauts and later on transferred that body of knowledge to the rest of the international biomedical aerospace community. One of his major accomplishments is that only a handful of missions were terminated because of the medical problems and no cosmonaut died in space because of illness or injury traceable to medical problems or errors in practice.

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Throughout the formative years of the space medicine (1959- 19750) Academician Gazenko surrounded himself with the best Russian scientific minds. He successfully identified and nurtured young talented professionals and ensured that they had the opportunity for growth and professional development. His students and colleagues are recognized around the world for their contributions to space medicine. He was a prolific writer and published extensively in Russian and international journals. His contributions to international collaboration remain unmatched in the history of space medicine and biology. He attracted scientists from at least 15 countries to collaborate on human and biological missions. Dr. Gazenko was instrumental in the development of the Cosmos series of biological research spacecraft which provided a solid base for multilateral scientific collaboration and a movement toward standardization of experimental methodologies. One of his most productive areas of collaborative research was with NASA. Dr. Gazenko opened the doors for the U.S. researcher's participation on Salyut and Russian involvement in the Space Shuttle/Spacelab missions. He was a strong proponent for the creation of the US/Russian joint working groups which are the precursors for the current ISS multilateral scientific and medical boards and working sections. He was instrumental as the head of the Soviet/Russian delegations to the UN Committee on the Peaceful Uses of Space to ensure that the NASA space medicine is represented at the annual meetings of UN and that joint presentations on the "spinoffs from the space medicine to health on Earth" are highlighted at the general assembly of the UN. Through his humanitarian efforts following the Armenia devastating earthquake international telemedicine became a part of today's complex humanitarian assistance programs.

The intent of this paper is to review the existing literature and to develop a historical understanding of the evolution of space medicine. Additional objectives are to

1. determine the evidence base of the current knowledge and its links to medical policy and practices
2. Identify the gaps in knowledge and impediments to the formulation of future policy and standards.

<u>Context</u>

To validate the evidence based policy process a critical review of the literature was conducted to
a. Determine the adequacy of the published evidence underpinning existing policies, standards and practices and
b. The usefulness of this knowledge to the formulation of medical standards and/or policies designed to protect the health of human space explorers and future travelers or tourists.

<u>Knowledge base adequacy</u>

In the 20th Century human space flight has been the domain of few individuals and primarily funded by governments. To date 838 men and 113 women have ventured into space. The 21st Century promises a multinational space tourism driven by the private sector. Establishing an evidence base health and medical policies for human spaceflight can contribute significantly to the safety and expansion of future space tourism. Space flight causes profound ***adaptive*** and ***pathophysiologic*** changes in living organisms[ii]**.** Circulatory, neuro-sensory/motor, fluid, electrolyte, and endocrine systems changes are adaptive and consistent with life in reduced gravity environments. *Pathophysiologic changes* lead to the loss of bone mineral and muscle mass and alterations in immune, metabolic, and hematology systems. Adaptive responses are manifest within hours or days following exposure to spaceflight, while pathophysiologic changes become evident over longer periods in space. The combined effects of space radiation, isolation, confinement, and psychosocial stresses of space travel contribute to these alterations. Clinical symptoms and laboratory findings such as facial puffiness, headaches, back pain, orthostatic intolerance, motion sickness, sleepiness and walking instability are self-limiting phenomena usually observed early in flight and/or upon return to the Earth's gravity. Anemia, mild dehydration, altered immune response, endocrine, fluid, electrolyte and metabolic changes, as well as loss of muscle strength and bone mass are usually documented following long duration space missions.

1. ***Evidence Acquisition, Synthesis and Utility***
   Critical assessments of the English, Chinese, and Russian language scientific and clinical space medicine literature were conducted. Medical search engines were employed using relevant terms and phrases. The search targeted primarily the *human health risks associated with space flight*. Reports and review articles from the preceding 10 years were used to identify the most cited authors and original research. Materials selected were appraised using established review criteria. These criteria assessed the literature's quality, strength of evidence, and the relevance/utility to the development of medical policy or standards. They were validated for consistency of ratings. The articles were graded for utility using a modified US Preventive Task Force classification. All materials not incorporated into the report were included in a special citation database
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2. ***Results***
   Attempts were made to quantify and document the adequacy of the published information to support the development of health standards and policies. This proved to be rather difficult due to the strength of the research. The process for selecting relevant publications and subjectivity of the evaluations may have introduced potential bias in the formulation of findings and conclusions Over 4,600 publications, addressing research in 9 disciplinary areas were identified (among 80,000) and reviewed. Of those 333 were judged to be of merit and selected for further in-depth assessments. The reviews established that 7.2 % of the authors recommended further research, 20.7% suggested possible applications to policy development for use in the clinical settings and only 10.8% recommended medical practice standards. Thus only 61% of the published research was deemed relevant to the development of a policy or a standard which could affect future practice of space medicine. The remainder of the authors did not advance policies or standards of practices in their publications. The following represents the preliminary and overarching findings:

   a. Most of the articles indicated potential threats, but did not propose a medical standard or change in the space medicine practice.
   b. Several authors proposed novel countermeasures requiring additional validation.
   c. Risks are not well defined and the epidemiological data base does not validate all the proposed medical risks

d. The majority of the authors advocate additional research or the use of analogs to validate concepts in light of constrained access to space laboratories
e. Well constructed clinical research and follow up and/or interventional studies yielding proper epidemiological data consists of
    - *Risk of kidney stones*
    - *Immunological risks*
    - *Radiation exposure surveillance*
    - *Cardiovascular risks*
    - *Negligible but not quantifiable risks for bone fractures*
    - *Risks for muscle injuries post flight*
f. Recent publications reflect trends indicating improved methodologies and statistical handling which will benefit future epidemiological and clinical studies
g. Enhanced international collaboration in standardizing flight and ground based protocols is not fully accomplished
h. A full adherence and adoption of the ICD10 among the international investigators results in the difficulty of interpreting research data
i. Only one meta analysis with no statistical handling of the data was published within the last 10 years
j. There is a need for more emphasis on clinical and operational research

Conclusions

Our preliminary review indicates a major knowledge gap in the development of preventive measures especially in the areas of the system engineering for human comfort and safety.

So far adequate progress has been achieved in establishing an understanding of the safe and healthy human exploration needs. The vision of Dr. Gazenko on the benefits and utility for international collaboration in space medicine is being realized. The next 50 years promises to be very exciting as the debate over the direction of the human exploration is again in the focus of the major space faring stakeholders. Space tourism pioneered by Russia and NASA is the new player on the scene and will play a significant role in establishing the biomedical fitness guidelines for paying customers and space crews. This will also help advancing the space medicine knowledge base. Much work still remains to prepare and educate the new stakeholders in the biomedical sciences, space medicine practices and processes addressing the formulation of medical policies and standards. Specifically space medicine policy and standards should be backed by properly researched evidence in order benefit future private investors, operators and space explorers

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[i] Bernardino Ramazzini : Diseases of the Workers. Diatribae de Artficum Morbis. DiseaSES OF THE Sailors and Rowers, Chapter X, ppgs 459-463. The Classics of Medicine Library,Gryphon Editions 1995

[ii] A. Nicogossian, Carolyn Huntoon and Sam Pool: Space Physiology and Medicine. Chapter 11: Overall Physiologic Responses to Space flight. Lea & Febiger , 1994