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Current methodological approaches assessing the health-related risks assessment in manned spaceflight missions*

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Abstract. Further development of manned space exploration requires appropriate scientific and appropriate modern methodological approaches assessing the health risks of participants in missions to an orbital station with high inclination of the orbit and interplanetary missions. The "Environmental Scanning" as well as available Internet sources (PubMed and EMBASE; 198 relevant publications) and personal messages, followed by expert discussion within the framework of an interdisciplinary working group were used to assess the contemporary approaches of manned spaceflight risk definition, classification, assessment and management. The results indicated that the term "risk" itself needs to be clarified, and mathematical models based on modern approaches other than differential calculus and providing expert support for management decisions should be developed or adapted to available evidence-based real-world data obtained in experiments using laboratory animals, ground-based simulation studies with the participation of volunteers, as well as during pre- and post-flight examinations of astronauts. It is advisable for this purpose to use interdisciplinary and interdepartmental working groups, including experts in the field of aviation, space and marine medicine, public health and health organization and control sciences as well as contemporary mathematical methods of analysis and statistics.

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Key words: risk, probability, predictive model, mathematical model, expert support for management decisions, expert assessment, manned space flights

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Современные методические подходы к оценке рисков здоровья участников пилотируемых миссий**

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Аннотация. Дальнейшее развитие пилотируемой космонавтики требует соответствующих научных и соответствующих современных методических подходов к оценке рисков для здоровья участников миссий на орбитальную станцию с большим наклонением орбиты и межпланетных миссий. Для оценки современных подходов к определению, классификации, оценке и управлению рисками пилотируемых космических полетов были использованы «Environmental Scanning», а также доступные интернет-источники (PubMed и EMBASE; 198 соответствующих публикаций) и личные сообщения с последующим экспертным обсуждением в рамках междисциплинарной рабочей группы. Результаты показали, что необходимо уточнить сам термин «риск», разработать или адаптировать математические модели, основанные на современных подходах, отличных от дифференциального исчисления, и обеспечивающие экспертную поддержку управленческих решений, к имеющимся доказательным данным реального мира, полученным в экспериментах с использованием лабораторных животных, наземных имитационных исследованиях с участием добровольцев, а также в ходе пред- и послеполетных обследований астронавтов. Для этой цели целес§ообразно использовать междисциплинарные и межведомственные рабочие группы, включающие специалистов в области авиационной, космической и морской медицины, общественного здравоохранения, организации и управления здравоохранением, а также современные математические методы анализа и статистики.

Клюевые слова: риск, вероятность, прогностическая модель, математическая модель, экспертная поддержка управленческих решений, экспертная оценка, пилотируемый космический полет

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Introduction

Risk assessment is the key factor for decision making in the areas related with human health and safety under extremal conditions. The meaning of the term can be different depending on objectives and the area of decision making. The most difficult interpretation we meet with multidisciplinary issues or with the intersection of different fields of science. It can include at the same time an uncertainty or certainty measurement (risk ratio or probability of occurrence of events), depending on the specific situation [1]. Space Life Sciences is one of the areas where we need to create a decision influencing on human health and safety based on combinations of incomplete and sometimes controversial technical, biological and social multidisciplinary data. In the space industry, the concept and evaluation of risk itself can differ significantly, for example, by using of relatively obvious tests assessing the probability of technical failures or by using rather complex and ambiguous methods of risk assessment and management in biological and social systems. The current concept and experience of space flights medical support is effective now and is based on long-term experience of orbital flights in near-Earth space at altitudes up to 55500 km. The main risk groups have been identified, both directly related to the impact of space flight factors on the human body under spaceflight, and under the influence of man-made factors [2]. The perspective spaceflight missions will be conducted beyond the boundaries of the Earth's radiation belts while the interplanetary missions are providing additional requirements for medical assistance under the conditions of communication delay and without an opportunity to return the crew to the Earth in reasonable timelines. The current concept of expert support of healthcare decision making is based on data obtained from clinical studies comparing the impact of interventions on the likelihood assessment of certain outcomes (risk ratio) [3]. This approach makes possible taking into account a limited number of measurable indicators and the relationships between them. It is justified and is used in ground-based models simulating separate space flight conditions. However, the integrated effect of multiple factors may differ significantly from the sum of separate factors outcomes. Another issue in this case is the choice of medical indicators and outcomes as well as assessing the likelihood of their occurrence, since the use of clinical outcomes (adverse or serious adverse event) is not always possible for ethical and organizational reasons. In this case, surrogate indicators are used, for example, laboratory or instrumental examination data, which, according to expert opinion, have a probabilistic and causal relationship with clinical indicators. The selection of surrogate criteria and decision-making based on them is becoming one of the urgent tasks in modern healthcare management [4, 5]. Thus, the health management of crew members in spaceflight missions and the medical support system for space flights will obviously be supplemented with new provisions related to the emergence of new risks and the need to manage them. The risk interpretation and assessment as well as the relationship of those risks (including surrogate criteria) to clinical outcomes and threats to mission failure will be the key issue for these provisions requiring establishing proper expert procedure supplied with the appropriate tools for expert decision-making support based on an assessment of the health risks during spaceflights.

Primary objective — analyses and selection of organizational approaches ensuring the process of health risks selection, evaluation and interpretation with the purpose of expert support in medical decision making related with perspective spaceflight missions.

Secondary objective — Identification of the most relevant and critical research areas for risk assessment in medical support of perspective spaceflight missions.

Materials and methods

Environmental Scanning was used for searching and analyzing the data related to the risk assessment, medical support of manned spaceflights and space industry development. As a result, key information messages were identified and then structured into a hierarchical scheme using the Analytic Hierarchy Process (AHP) by 7 experts specialized in space life sciences, population health management and control sciences.

Environmental scanning was based on the systematic review of literature (198 relevant publications) and other modes of communication including personal communication [6–8].

The obtained data was used for Analytic Hierarchy Process (AHP). First the key problem (health-related risks of perspective spaceflights) was decomposed into a hierarchy of more easily comprehended sub-problems, each of which can be analyzed independently. Nest these elements were organized into hierarchical structure by comparing them to each other two at a time, with respect to their impact on an element above them in the hierarchy. In making the comparisons, the experts assessed both concrete data about the elements and their judgments about the elements' relative meaning and importance based on “environmental scanning” data. These numerical values reflected the number of links with higher hierarchical elements and the capability of the lower element to meet needs of these higher elements [9–11].

Results

Organizational approaches ensuring the process of health risks selection, evaluation and interpretation with the purpose of expert support in medical decision making related with perspective spaceflight missions

Risk assessment of a project or process is the base for creation of probable scenarios and activities aimed at reducing or eliminating the consequences of these risks. The management of the project or process is based on selection of one of the proposed scenarios followed by appropriate redistribution of available resources. Expert support and decision-making within a single scientific area with a limited number of similar comparable indicators in the same dimensions (clinical indicators, financial costs or event probabilities) is well developed. As the complexity of the analyzed systems increases, the number of indicators increases significantly while these indicators become heterogeneous, which makes it impossible to use relatively simple predictive models based on a comparison of homogeneous indicators. In space industry we are faced with various approaches and risk assessment criteria that are traditional for various fields of science, but do not combine to develop a single integral indicator for predicting and decision-making on issues related with the success of manned space mission. Currently bioethics be an example of similar expert support of decision-making dealing with similar issues and looking for a solution influencing on human health and satisfying all parties with conflicting opinions based an interdisciplinary data. The “environmental scanning” indicated that bioethics does not have well-established and specific methodological rules differing from other areas of science as well as the similar methodological approach, providing a diversity of disciplines, tasks and quality criteria.

The goals of bioethics may differ from healthcare objectives taking into account economic and social factors [12]. Control and management of health-related risks assessment in manned spaceflight missions can also may have objectives different from common healthcare practice depending on multiple disciplines, tasks, assessment methods and quality criteria. Currently, the only practical way providing expert support for decision-making in such circumstances is an interdisciplinary and interdepartmental group of experts capable proceeding with a significant amount of information (evidence-based data) presented in various formats and generated in various areas of science[1]. Similar to bioethics there is no single methodological approach or existing interdisciplinary methods for decision-making support and providing an opportunity for analyzing and predicting human health risks associated with space missions and the primary task of such a group is to create a methodology and methods for further activities.

Identification of the most relevant and critical research areas for risk assessment in medical support of perspective spaceflight missions

The term "risk" itself in relation to medical support for manned flights needs to be clarified and supplemented, allowing the use of risk indicators to select management decisions in this area. These clarifications relate to both the definition and evaluation criteria, the relationship with other risks (including risks that go directly beyond the boundaries of medical support for manned flights), as well as possible management decisions. For the purpose of the study the experts agreed that the term "risk" was interpreted as a probability of adverse event occurrence.

[1] WHO handbook for guideline development. World Health Organization. 2012. P.1-56. ISBN 978 92 4 154844 1

Risk listing and ranking

There were 2 main groups of risks identified by experts depending on experts' priorities: threats to health and safety of the crew member and/or resulting in mission failure. Both clusters are linked and may influence each other.

1. Occurrences affecting the health of space crew mission covering 3 areas with subordinated (detailed) events occupying the lowest position in the hierarchy:

• Risks to the health of the crew members during the mission;

• Remote health risks and complications after spaceflights;

• Other health-related risks.

2. In the second case, the priority was linked to mission success or failure:

• Risks of reduced functioning and operational efficiency/ performance of crew members;

• Risks associated with technical failures that may affect health and performance;

• Risks of mission failure due to other reasons.

The health risks during the forthcoming mission are largely coincided with the factors identified during orbital flights [2] but they can also be supplemented by factors related to the specificity of the flights. The concept of radiation risk is to be revised for the flights beyond the protective action of the Earth's magnetosphere must include the assessment of long-term stochastic consequences of the new environment and functional disorders of the central nervous system [13–15]. When landing on other planets, local factors, such as lunar dust (regolith), may affect the respiratory organs and mucous membranes [16].

Long-term risks that can be identified now are associated with the accumulation of effects from exposure to adverse factors of space flight. These factors may not manifest themselves or manifest themselves slightly during the mission, but at the same time may cause delayed health effects. Although Apollo astronauts have reported mild short-term respiratory symptoms during and after the flight, the range of health effects associated with acute exposure to high doses or chronic exposure to low doses of regolith has not yet been sufficiently studied as well as of long-term effects of exposure to heavy particles of cosmic radiation [13–15].

Other health-related risks reflect those adverse opportunities that we cannot take into account now due to lack of experience, but may appear in the future as separate independent factors or as the result of the interaction of a number of factors. At the example of multimorbidity, we can expect that the integrating result will exceed the simple sum of the effects of individual factors according to the Cumulative Life Course Impairment (CLCI) concept. These conditions may occur both during the mission and throughout the life [17]. During interplanetary missions associated [18].

Interplanetary flights provide no opportunity for rapid assistance from outside the mission while functional disorders or errors in activities of one crew member can lead to a threat to the mission as a whole and the health of other crew members. This situation indicates the necessity to review the risks ranking and severity assessment of the consequences during perspective missions comparing to previous orbital flights [18].

The emergence and use of robotic systems during space flights significantly increases the list of technical failures affecting the health of crew members.

Risks associated with the failure of spacecraft technical systems have been studied in detail [6], however, the emergence of robotic human-machine systems and interactions as well the high probability of using these systems in space flight or planetary surface research increase the weight of these risk and the need to identify and manage them. The risks of the mission failure generally reflect the possibility of the development of emergency situations, which can lead to risks to human health, which in its turn can affect the possibility of successful implementation of the program, as well as the need for special requirements for the astronaut's selection and training. Since health risks, work and rest conditions and the normal functioning of on-board equipment and systems are probabilistically related, the assessment of risks to the health of an astronaut, in addition to medical indicators, must also take into account technical risks, which further complicates the integrated assessment of the possibility and probability of fulfilling the flight program.

Risk assessment and predictive models for decision making

Risk assessment methods and predictive models have been developed mainly for technical systems and technological processes with relatively low number of elements and interactions. Biological and social systems have significantly more elements and interactions between them with both positive and negative feedbacks which can also change depending on known or unknown factors. Probabilistic predictive models are used in clinical practice and are based on the use of one variable (treatment method) with fixed other parameters (inclusion criteria, other interventions, etc.) under controlled conditions (randomized clinical trials). The transfer of these data into clinical practice indicates the sound outcomes difference between results obtained under controlled conditions and Real-World Data (RWD)[2].

The influence of unknown parameters necessary for SIR or similar models creation, as well as the appearance of new characteristics (virus mutations) immediately changing all the parameters of the system led to the fact that thousands of prognostics of COVID-19 models created during the pandemic on the basis of differential functions and probabilistic data did not work properly and could only predict the facts that had been already observed by health care practitioners themselves. At the same time, the possibility of COVID-19 pandemic and the specifics of its development were described several months before its onset based on Hopkins Institute experts' opinions (event 201)[3]. Therefore, methodology and methods for prediction and assessing the health risk of crew members in the forthcoming space flights conditions remains unknown. Perhaps it should combine probabilistic (based accumulated data and available ground-based investigations) and expert assessment of events.

Basic data for risk assessment

The next issue is related to the use of available data (clinical and surrogate indicators) for risk assessment and creation of predictive scenarios for decision making. In practical healthcare, a set of consistent procedures has been developed to assess the safety, efficacy (RCT), efficiency (RWD) and economical effectiveness (health-economic studies) of medical interventions. Methodology and models for assessing of space flight "interventions" affecting the human body is similar to the methodology and models assessing the effects of medical interventions on human body. The logic of the sequence of stages of evaluating interventions in healthcare is primarily related to the safety of research participants and, secondly, to the saving of limited resources, i.e. the cost of research [20]. Animal (preclinical) studies are accompanied by an assessment of the compatibility of these data with humans (Phase I of clinical trials). With positive results, the Phase II of clinical trials is possible and the probabilistic results are based on surrogate criteria (laboratory or other examinations), which should be related to clinical outcomes (health, death, illness, disability, etc.). The choice of these indicators, the assessment of their probabilistic relationship with clinical outcomes and the possibility of using them as a justification for management decisions are the subject of separate studies [4–5]. If these stages are successfully completed, the next one is associated with the assessment of clinical outcomes, i.e. the transfer of a subject from one discrete state to another (illness, health, disability, etc.). Further, verification of the conclusions obtained in real clinical practice, systematization and integration of the information obtained, as well as an economic assessment of possi-

[2] Luca Marzano, Adam S. Darwich, Asaf Dan, Salomon Tendler, Rolf Lewensohn, Luigi De Petris, Jayanth Raghothama, Sebastiaan Meijer. Exploring the discrepancies between clinical trials and real-world data by accounting for Selection criteria, Operations, and Measurements of Outcome. MedRxiv: the Preprint Server for Health Sciences. doi: https://doi.org/10.1101/2024.01.22.24301594

[3] Meshkov D.O., Lobanov A.V., Cherkasov S.N., Isyanova A.M., Martin (Shevchenko) M.A., Oleynikova V.S. Modern Features of the Interdisciplinary Approach to Mathematical Modeling in Medicine on the Example of the COVID-19 Pandemic. In the collection: Management of Large-Scale Systems Development (MLSD'2022). Proceedings of the Fifteenth International Conference. Edited by S.N. Moscow, 2022. P. 1323-1327 (In Rus).

ble management decisions are carried out. In practice, in most cases, surrogate data on ground-based model studies involving humans (an analogue of the Phase II of RCT and data from biological studies using animals including space flights [18, 21] are available. Obtaining clinical indicators in animal studies makes it possible to partially compensate the lack of clinical indicators for the analysis of pathogenetic mechanisms, but the amount of data containing clinical outcomes in astronauts completed space flights of varying duration is not sufficient now [22, 23].

Conclusions

1. Interdisciplinary and interdepartmental expert groups in the field of aviation, space and marine medicine, public health and health organization, management theory, mathematical methods of analysis and statistics are capable ensuring the process of health risks selection, evaluation and interpretation with the purpose of expert support in medical decision making related with perspective spaceflight missions.

2. The following critical issues were identified in relation with the risk assessment in medical support of perspective spaceflight missions:

2.1. The term "risk" itself in relation to medical support for manned flights needs to be clarified and supplemented, allowing the use of risk indicators to select management decisions in this area. These clarifications relate to both the definition and evaluation criteria, the relationship with other risks (including risks that go directly beyond the boundaries of medical support for manned flights), as well as possible management decisions.

2.2. An integrated hierarchical structure of various risks interaction with both positive and negative feedback and affecting the final result (mission success or failure) or intermediate milestones (technical reliability as well as health status and functioning of the crew members). The list of these risks has been identified for current flights and will be accomplished according to the new flight objectives and research data. These risks need to be clearly identified and stratified according to their consequences, relationship with key results and milestones of the mission, taking into account the time factor.

2.3. Creation of predictive models is extremely difficult due to heterogeneity or lack of data as well as the relationships between the elements of an integrated risk assessment systems. This fact indicates the need to add the current methodology with new one covering data validation, risk interpretation, assessment and predicting.

2.4. The majority of data used for decision-making in the area is based on statistical assessment of surrogate indicators which must have (but also may not gave) the relationship with the clinical ones. Surrogate criteria utilization requires the inclusion in risk assessment and predictive models, at least, an expert assessment of the significance of these risks, as well as the development of integrated assessment methods reducing a significant amount of information to a reasonable number of possible management decisions.

2.5. The heterogeneity of data requires the creation of integrated predictive models including statistical probabilistic elements in combination with expert assessments. ICAO matrix can be taken as a very simple example of algorithms integrating probabilistic and expert assessment while the discussed perspective predictive model must be based on biological and medical data (surrogate and clinical outcomes wherever is possible) obtained in animal studies, in ground-based model experiments involving humans as well as the results of pre- and post-flight examinations of astronauts.

CONTRIBUTION OF THE AUTHORS

Alexey V. Lobanov – investigation, data collection, creating a draft of the manuscript.

Elena D. Makeeva – investigation, data collection, creating a draft of the manuscript.

Dmitry O. Meshkov – idea, methodology, project administration, creating a draft of the manuscript.

Sergey A. Ponomarev – idea, methodology, editing and revision of the manuscript.

Sergey N. Cherkasov – idea; methodology; формальный анализ; editing and revision of the manuscript.

Alexander F. Pashchenko – idea; methodology; formal analysis; writing, editing and revision the manuscript.

Yuri V. Sidelnikov – idea; methodology; formal analysis; writing, editing and revision of the manuscript.

ВКЛАД АВТОРОВ

А.В. Лобанов – исследование, сбор данных, создание черновика рукописи.

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Ю.В. Сидельников – концепция; методология; формальный анализ; написание. редактирование и доработка рукописи.

CONFLICT OF INTERESTS

The authors declare no relevant conflict of interests.

КОНФЛИКТ ИНТЕРЕСОВ

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