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PROSPECTIVE DIRECTIONS FOR INNOVATIVE DEVELOPMENT STRATEGIES IN PHARMACY IN THE MILITARY HEALTH SYSTEM OF THE RUSSIAN FEDERATION

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ABSTRART: Strengthening the readiness of the medical service system of the Armed Forces of the Russian Federation to fulfill given tasks is possible only with innovative development, which constitutes the scientific and methodological basis for the modernization of military healthcare. In this connection, researchers at the pharmacy department of the Kirov Military medical Academy considered the development of kits and equipment, medical equipment, mobile and special medical equipment, and pharmaceutical technologies as the absolute priority of their scientific development. The requirements for the equipment of different units and military medical organizations both at present conditions and in future wars include high level of mobility, shortened deployment (curtailment) terms, autonomy, increased operational efficiency of units, etc. The realization of these requirements is possible if certain issues are solved, primarily aimed at the digitalization of medical supply system of military forces, improvement of basic equipment, and entering new developments in the field of pharmaceutical technology into the medical service of the Armed Forces of the Russian Federation. The article presents the perspective directions of the innovative development of the medical supply system of the Armed Forces, which is the most important element of military healthcare. Results of the activity such as creation and acceptance for the supply of mobile units for production, accumulation (storage), delivery, distribution of medical gaseous oxygen, registration of medicinal products ("medical oxygen, 93%"), and acceptance of the corresponding pharmacopoeial article are already represented. Still at the development stage, there are innovative sets of service equipment of airborne troops, sterilization, and distillation unit, allowing the use of water from natural surface sources of domestic and drinking water supply, etc.

Keywords: automation; military health care; innovation; basic equipment; drugs; medical care; medical gases; medical equipment; scientific research; pharmacy; digitalization.

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ПЕРСПЕКТИВНЫЕ НАПРАВЛЕНИЯ ИННОВАЦИОННОГО РАЗВИТИЯ ФАРМАЦИИ В ВОЕННОМ ЗДРАВООХРАНЕНИИ РОССИИ

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Резюме. Показано, что укрепление готовности медицинской службы Вооруженных сил Российской Федерации к выполнению задач по предназначению возможно только на основе инновационного развития, составляющего научно-методическую базу модернизации военного здравоохранения. В этой связи ученые и сотрудники академии в области фармации рассматривают разработку комплектно-табельного оснащения, медицинского оборудования, подвижной и специальной медицинской техники, а также фармацевтических технологий как безусловный приоритет своей научной деятельности. Представлены требования, предъявляемые к оснащению медицинских подразделений, частей и военно-медицинских организаций как в современных условиях, так и в войнах будущего, а именно: высокий уровень мобильности, сокращенные сроки развертывания (свертывания); автономность; повышение оперативности работы подразделений и др. Показано, что реализация этих требований возможна при условии решения ряда вопросов, в первую очередь направленных на цифровизацию системы медицинского снабжения войск (сил), совершенствование комплектно-табельного оснащения, внедрение в деятельность медицинской службы Вооруженных сил Российской Федерации перспективных разработок в области фармацевтической технологии. Рассматриваются перспективные направления инновационного развития системы медицинского снабжения войск (сил), представляющей собой важнейших элемент военного здравоохранения. Представлены такие результаты деятельности, как создание и принятие на снабжение мобильной установки для получения, накопления (хранения), доставки, распределения кислорода медицинского газообразного, регистрация лекарственного средства «Кислород медицинский, 93%» и принятие соответствующей фармакопейной статьи. На этапе разработки находятся инновационные комплекты табельного оснащения Воздушно-десантных войск, стерилизационно-дистилляционной установки, позволяющей использовать воду природных поверхностных источников хозяйственно-питьевого водоснабжения и др.

Ключевые слова: автоматизация; военное здравоохранение; инновации; комплектно-табельное оснащение; лекарственные средства; медицинская помощь; медицинские газы; медицинское имущество; научные исследования; фармация; цифровизация.

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BACKGROUND

Innovative developments in the daily activities of medical units, formations, military units, and military medical organizations are important in promoting the scientific potential and expansion of the practical capabilities of Russian military healthcare (MH) [1–4]. Military pharmacy plays a significant role in this activity. It is entrusted to scientifically and methodologically support the medical supply system of troops (forces). Scientists and employees of the S.M. Kirov Military Medical Academy (MMA), in close collaboration with the specialists of the Chief Military Medical Directorate of the Ministry of Defense of the Russian Federation (CMMD MD RF), and other military authorities and leading scientific teams in Russia managed to conduct several fundamental and applied scientific studies on the priority problems of military pharmacy over a relatively short historical period [5, 6]. Initially, this refers to the formation of scientific foundations of the modern process of regulating medical stock (MS), development of a methodology for the legal regulation of activities of troops (forces), organization and implementation of advanced technologies for drug provision (DP), creation of several innovative models of technological equipment, etc.

Currently, in the interests of the Russian MH, breakthrough research is being conducted or planned in the near future, including within national projects, in various scientific pharmaceutical specialties. Thanks to their results, the efficiency of medical support for troops (forces) will increase, and the material and time costs for providing medical care to wounded (injured) troops will significantly reduce [7–11]. All this is aimed at achieving the general goal of the medical service of the Armed Forces of the Russian Federation (AFRF) to increase the availability and improve the quality of medical care for military personnel, military pensioners, and their families.

The study aimed to present promising areas of scientific research in the field of military pharmacy and demonstrate their contribution to the innovative development of the medical support system of the AFRF.

MATERIALS AND METHODS

This study used the legislative and regulatory legal acts of the RF and federal executive authorities, regulatory legal acts and official documents of the RF MD, regulating the issues of organizing the provision of MS to the troops (forces), and scientific papers on promising areas of the innovative development of pharmacy in MH.

This study used systemic, process, situational, functional, and complex methodological approaches, which were implemented using content, structural-functional, systemic, historical, and logical analyses, comparisons, and descriptive methods.

RESULTS AND DISCUSSION

Digital innovations in the medical supply system of troops (forces). In 2020, the President of the RF announced the digital transformation of social and economic life as one of the national development priorities of the country, and the "digital maturity" of healthcare and public administration was included in its target indicators. In accordance with the datasheet of the federal project "Creation of a unified digital circuit in healthcare based on a unified state informational system in the field of healthcare (USISH)", implemented in the course of the implementation of the national project "Healthcare", the plan was to increase the efficiency of healthcare functioning by creating mechanisms for interaction between medical organizations based on USISH and the implementation of digital technologies and platform solutions that form a single digital circuit until 2024 [12].

At present, the medical service of the AFRF has accumulated some experience in creating automated workplaces for individual specialists and specialized software and hardware complexes to digitalize the management of the activities of military medical organizations (medical units) [13]. All this will enable in the future the generation of a single information space and electronic document management in MH. However, scientific and methodological approaches to the digitalization of MS resource management processes in formations, military units, and military medical organizations, providing intra- and interdepartmental interaction, have not been sufficiently developed to date.

Based on the specifics of MH and medical support of the troops (forces), structure and level of morbidity of the assigned contingents, DP financing mechanisms, and need for effective control over the expediency and efficiency of spending monetary and material resources, the promptness of making appropriate management decisions with a high level of "digital security" should be provided. Thus, with the active participation of scientists

and employees of the MMA, collaboratively with CMMD MD RF specialists, a single digital circuit of the medical service of the AFRF, which implies the presence of interacting functional subsystems (modules), is being developed [14]. One of the key tasks to be solved using these modules is to automate and digitalize the processes of MS provision to formations, military units, and military medical organizations, which is expected to be implemented as follows:

- Substantiation and development of a strategy for the digitalization of MS resource management, which determines priorities, goals, objectives, mechanisms, and indicators for achieving goals, resource provision, problems and challenges of digital transformation in the short, medium, and long term.
- Application of an architectural approach that involves design creation for a digital system for managing MS resources in MH.
- Development and implementation of information subsystems for managing MS resources at different levels of MH, which allow automation of processes according to the developed algorithms and digital transformation of information.
- Development and implementation of the automated system "Register of patients having right to DP at the expense of the MD RF budget" [15].
- Application of lean-manufacturing technologies in the management of MS resources.

These will enable monitoring of the movement of MS resources in real time and accordingly making informed management decisions both at the level of formations, military units, and military medical organizations and CMMD MD RF and the National Defense Operations Center of the RF. Automation and digitalization of processes for providing MS to troops (forces) will enhance the medical supply system to a whole new level, increase the efficiency of using budget funds allocated for the purchase of MS, help maintain and strengthen the health of military personnel, and increase the readiness of the medical service of the AFRF to fulfill tasks.

Over the past years, several advanced digital technologies have been successfully introduced into the Russian MH. Thus, artificial intelligence, machine vision, and processing arrays of big data can increase the range of tasks for MS provision to troops (forces) using unmanned aircraft to facilitate not only the urgent targeted delivery of MS to the wounded and injured troops in hard-to-reach areas but also the operational provision of MS to units operating in isolation from the main forces during hostilities. The solution of tasks for the planned delivery of MS to hard-to-reach areas (Arctic zone, high mountains, etc.) will also be simplified. In addition, covert reconnaissance of routes for MS delivery and evacuation of medical equipment damaged in military conflicts and emergencies will be possible.

Improvement of complete and basic equipment (CBE). Considering the military, humanitarian, and other aspects of future wars and primarily the use of the latest means of armed struggle and weapons based on new physical principles, in the interests of medical support for troops (forces), high-tech MS models must be used predominantly. Thus, scientists and employees of the MMA, in collaboration with specialists from Russian industry enterprises, are conducting planned and initiative exploratory studies, the results of which enable the creation of qualitatively new samples of CBE. CBE occupies a special place among the extensive range of MS and forms the material basis of the medical supply system for troops (forces) in wartime. Despite the successes in the modernization of CBE for the military and ship units of the medical service, the problem of creating new sets of MS, medical equipment, and special medical devices for some branches of the AFRF and hospital units of the medical service remains unresolved [16].

In the absence of an airfield network, changing views on the use of medical units of formations and military units of Airborne Forces (ABF) predetermine the need to develop specialized MS sets that can be parachuted. The solution to this important task fully meets the requirements of the senior executives of the MD RF on improving the material and technical resources and equipment with weapons, military equipment, and special equipment of the ABF (September 2020). Based on this, on the joint initiative of the medical service of the ABF and the MMA, proposals have been prepared to conduct a set of research and development work starting in 2021. In their implementation, taking into account the medical support of the ABF in groupings of troops (forces) in strategic directions such as airborne assault forces of various compositions (operational and prestrategic) for personnel assets and medical units (medical company of the subdivision, medical detachment of the airborne assault [air assault] divisions), innovative models of first aid kits, medical bags, MS kits, and other CBE samples should be created. The implementation of the results will improve the efficiency of medical support for the ABF, based on the principles of equal survivability

and mobility with the existing elements of the combat order of units at the forefront of hostilities, and will maintain their high mobility when they are transferred in various ways, including by landing of airborne troops.

Based on the current challenges and threats, as well as views on the medical support of the troops (forces), hospital units have an exceptional role in providing specialized, including high-technology, medical care to wounded and injured patients. The existing models of CBE for military field hospitals were developed more than 30–40 years ago and are now physically and morally obsolete, as most medical interventions cannot be performed in these hospitals at the required quality level. To provide medical care at the hospital level based on advanced medical technologies, radical modernization of several MS sets, including those for operating rooms and hospital departments, special departments and offices, dentistry, laboratories and sanitary and epidemiological units, etc., is a priority. Modernizing MS kits for blood collection and processing units, pathoanatomical departments, etc., is also necessary. In the shortest possible time, it is necessary to create the most important samples of medical equipment and dual-use tools, such as devices for anesthesia and artificial lung ventilation and systems for monitoring metabolism during anesthesia, storing MS, including thermolabile drugs to provide a cold chain, evacuating and immobilizing the wounded, etc. As a result, not only the hospital level CBE nomenclature of the medical service will be optimized, but the following will also become possible:

- Providing specialized and high-tech medical care to the wounded and injured troops in military field hospitals and their high-quality preparation for evacuation.
- Maintenance of the established level of readiness of the medical service of the AFRF to perform tasks as intended.
- Unification and standardization of the norm of supply and resources of MS.
- Speed of deployment (phasing out) of functional units of military hospitals in the field.
- Prompt determination of the current and future need for MS and improvement of the provision of military hospitals with it.

Promising developments in the field of pharmaceutical technology. Over the past decades, MH has accumulated numerous problematic issues that require solutions from a pharmaceutical and technological point of view. Considering the specifics of combat pathology, mass admission of wounded and injured troops to the chains of medical evacuation and military hospitals, scientists and specialists of the MMA resolve issues related to obtaining medical oxygen, water for pharmaceutical purposes, infusion solutions, etc., in the field.

The most highly sought drugs include medical oxygen, which is significant in the provision of medical care, especially in emergency and urgent situations because many standards governing the provision of medical care to wounded and injured troops, including those with combat pathology, prescribe respiratory gas mixtures, with medical oxygen as the main component. Over the years, scientific research has aimed at developing new and improving existing technologies for its production, establishing quality indicators that determine safety (standardization), and legitimization of circulation by creating corresponding pharmacopoeial monographs (PM) [17]. In 2019, the creation of a mobile unit for the production, accumulation (storage), delivery, distribution of medical gaseous oxygen MUPK-KBA-93 was successful. On September 30, 2021, it was accepted to supply the AFRF (Order of the MD RF No. 581). To date, the MUPC-KBA-93 unit is unequaled both in Russia and other countries [18].

In January 2021, the medicinal product "Medical Oxygen, 93%" was registered, obtained from air by short-cycle non-heating adsorption, and in October, the corresponding PM was adopted. In January 2022, at a meeting of the updated Council of the Ministry of Health of the RF on the State Pharmacopoeia, a new version of the specified PM was approved under the name "Gaseous Oxygen, 93%," which was also developed with the direct participation of the MMA. The PMs "Medical Gases," "Medical Oxygen Gas 99.5%," and "Medical Liquid Oxygen 99.5%," which were created with considerable participation of the MMA, were included in the State Pharmacopoeia of the XIV edition (2018), and several PMs were included in the pharmacopoeia of the Eurasian Economic Union (2020).

Moreover, these achievements should be considered only as the beginning of subsequent research and development work related to the production, quality control, and use of other medical gases in MH [19]. Prospects for the development of this field are associated with the effective cooperation of the MMA with major scientific teams in Russia, such as the Scientific School of the Nobel Prize Winner in Physics, Academician of the Russian Academy of Sciences, Honorary Doctor

of the MMA Zh.I. Alferov; Scientific Center for Medical Products of the Ministry of Health of the Russian Federation, D. I. Mendeleev All-Russian Research Institute of Metrology, etc. Within this interaction, a complex of research works is being conducted to create a model range of multifunctional anesthesia and respiratory devices and medicines based on inert gases. Among such gases, xenon, which is currently used in medical practice as an anesthetic, is the focus of MH attention. However, considering the characteristics of its biotransformation, effect on lipid metabolism, duration of action after direct administration, and dependence of the pharmacotherapeutic effect on the concentration in the gas mixture, the indications for its use can potentially be significantly expanded. Thus, the creation of xenon-based drugs in the form of aerosols (in a portable canister), its standardization, and the study of efficacy and safety are relevant topics. The results of comprehensive research on the creation of multifunctional anesthesia and respiratory devices operating on inert gas mixtures, which can be supplied to the patient and/or generate gas–air mixtures in the gas–gas, gas–liquid, and gas–steam systems, will serve as the basis for their design and mastery of production.

Water used for pharmaceutical purposes (purified water and water for injection) is the main component (excipient) of many drugs manufactured in the field. To obtain it in the field, appropriate technical means should be developed based on advanced technological and design solutions. By using the existing scientific groundwork at the MMA, as part of the research and development work that started at the end of 2020, a modern sterilization and distillation unit is being developed, mounted on a two-axle trailer, SDP-4 (completion is scheduled for the end of 2022). This unit has several fundamental differences from the currently used SDP-3 unit, because its design takes into account current and advanced good pharmaceutical practices and aspects of operation in various climatic and geographical zones. Thus, the operation of SDP-4 will make it possible to use water from natural surface sources of drinking and household water supply in accordance with GOST 2761-84 “Sources of centralized drinking and household water supply. Hygienic, technical requirements and selection rules” (quality class 1). To purify such water and achieve the required quality indicators, an original multi-stage water treatment system is provided, manufactured using Russian components. In this system, the source water is successively purified from impurities starting from macrofiltration (inclusions with a size of 1–100 microns such as mechanical suspensions and oxidized impurities), microfiltration (inclusions with a size of 0.1–100 microns such as bacteria, colloids, and fine suspensions), ultrafiltration (inclusions with a size of 0.002–0.1 microns, such as viruses and large molecules), to nanofiltration (inclusions with a size of 0.001–0.002 microns, such as multicharged ions, molecules, and viruses) and is also exposed to ultraviolet irradiation. The SDP-4 has a reverse-osmosis unit that cleans water from particles ranging in size from 0.001 to 0.0001 microns (ions). A single passage of prepared water through a reverse-osmosis membrane provides purified water, whereas a double passage provides water for injection. The apyrogenicity of the resulting water is ensured by further distillation, and the quality control of the permeate and distillate is ensured by the conductometric method using automatic online sensors. The progressive design and technological solutions used in the SDP-4 unit enable obtaining not “distilled water” but water for pharmaceutical purposes, which are suitable for the manufacture of drugs and meet the requirements of the State Pharmacopoeia. The SDP-4 unit, in addition to a significantly increased productivity for obtaining purified water (at least 50 L/h), makes it possible to store water in a volume of 100 L for at least 24 h. Based on the latest scientific and technological achievements, the SDP-4 unit provides a “circulation loop” in the tank for storing purified water, a “hot” storage mode at a temperature of 80°C, built-in systems for automatic washing of containers and pipelines with disinfectants, and their treatment with jet steam. Moreover, the SDP-4 unit will allow thermal sterilization with steam under pressure and dry air (the method is not available in the SDP-3 unit) of various objects (drugs and dressings, medical and surgical instruments, etc.). The innovative operational and technical solutions proposed by the MMA and implemented in the course of research and development work for the creation of the SDP-4 unit have convincing theoretical foundations. However, modern requirements for pharmaceutical development require the theory to be supported by empirical research. Since 2020, this work has been conducted in a scientific study on improving the processes of water treatment and sterilization in the field. The implementation of the proposed program for studying the stability of technological and microbiological indicators of the key elements of the pre-cleaning unit of SDP-4 and validation of sterilization processes will enable future implementation of science-based modernization of mobile technical means for obtaining water for

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pharmaceutical purposes and sterilizing MS in the field. Thus, the SDP-4 unit, after its acceptance for supply by the AFRF, will create a reliable technical and technological foundation for conducting breakthrough research and development work in the near future to improve the production activities of military pharmacies in the field.

Nowadays, the Russian MH has an extensive range of effective drugs for providing medical care and treating wounded (injured) patients. According to experts, in future wars, the leading role in this arsenal will still belong to infusion solutions. With a sudden mass admission of wounded (injured) patients to the chains of medical evacuation and military hospitals, hemovolume correction will become even more significant. Its fastest implementation will be possible only in the case of rapid production of necessary infusion solutions in the field (sodium chloride 0.9%, dextrose [glucose] 5%, procaine [novocaine] of various concentrations [0.25% and 0.5%], Ringer, Ringer–Locke, etc.). Based on this, the issue of equipping military pharmacies with fundamentally new technological equipment having uniform design solutions must be addressed urgently, which will increase fundamentally the production capabilities for the manufacture of infusion solutions and, accordingly, increase their provision in medical evacuation chains and military field hospitals. Earlier, within the framework of the 2005–2008 research and development work conducted in accordance with the State Defense Order, UIR-A, an installation for the manufacture of injection solutions, was created (accepted for supply by the AFRF, 2011). However, nowadays, this installation requires serious reengineering of the medical support of troops (forces) in future wars. Thus, with all the advantages of the classical technology for the manufacture of infusion solutions, which provides for their primary packaging in glass containers (vials) sealed with an aluminum crimp cap, the expediency of using polymer bags or vials with one or more ports for additional administration of drugs and control devices for the first opening is becoming increasingly obvious. This is because the convenience of solution capping and packaging is one of the decisive conditions that determine the efficiency of infusion therapy in the provision of emergency medical care to wounded and injured patients directly on the battlefield (such as during an accident, catastrophe, and natural disaster) and at the military level of the medical service. Traditional capping and packaging means are known to have several drawbacks (e.g., glass containers are fragile and do not withstand low temperatures), but most importantly, they make it difficult to perform infusion therapy directly at the site of injury or damage, which significantly decrease the efficiency of medical care and sometimes leads to lethal outcomes. Recently, for packaging and storage of drugs, including infusion solutions, instead of traditional glass, packaging made of various polymeric materials, which have several undeniable advantages, is increasingly being used. Polymeric materials have greater impact strength, significantly less weight, and are elastic. When using polymer containers, the contamination of injection solutions with foreign particles is reduced. Thus, the use of polymer containers for packaging infusion solutions produced in the field will improve not only the quality of solutions but, also increase the efficiency of infusion therapy. The answer to this problem has been time-tested during a complex of research and development works to create a pharmacy technology for packaging and sterilizing infusion solutions in packages made of polymeric materials. These considerations were reported at a meeting of the Bureau of the Preventive Medicine Section of the Department of Medical Sciences of the Russian Academy of Sciences and were approved (2019). In accordance with the decision of the coordinating scientific and technical council of the CMMD MD RF and taking into account the support of the Russian Academy of Sciences, existing scientific and technical reserve, and accumulated experience, within the framework of the state arms program, a mobile laboratory for the manufacture of infusion solutions in the field (productivity of 500–600 l/day) is being planned. The introduction into the practice of innovative technology for the manufacture of injection solutions in the field, products, and technical means for its implementation will increase significantly the production capabilities of military pharmacies and improve the quality of injection solutions and thus increase the efficiency of medical care for the wounded (injured) in military conflicts and emergencies.

CONCLUSION

A conceptual approach to the modernization of the medical supply system for troops is the focus of scientific efforts on the priority areas of military pharmaceutics (forces) under current conditions and, most importantly, in future wars. The implementation of advanced pharmaceutical solutions and technologies into the MH is one of the promising fields of its innovative development.

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