

# State of Providing Incurably ill Patients with Opioid Analgesics at the Level of Certain Constituent Entities of Russia

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## ABSTRACT

**Background.** Palliative care is a complex of medical, social and psychological measures for the care of oncological and non-oncological seriously ill patients who need treatment for chronic pain syndrome in specific medical organizations or at home. Palliative care is based on approaches that improve the "life quality" of patients and their families when the possibilities of radical treatment have already been exhausted. Relieving the suffering of incurable patients is possible thanks to early diagnosis, assessment of the condition, adequate pain relief and full-fledged care.

**Objective.** The aim of the study was to analyze the level of palliative care for incurable patients in certain regions of the Russian Federation on the example of the Krasnodar and Stavropol territories.

**Methods.** Using content analysis, documentary observation, and statistical research methods, we studied the results of implementation of state-planned measures in certain regions and identified problems related to the availability of pain relief in incurable patients.

**Findings.** The study in both regions revealed: positive dynamics in the quality of this type of care, active implementation by regional health authorities of the developed "road map", a high degree of accessibility to pain relief, the effectiveness of measures taken, the implementation of legislative changes in the regions on palliative care. In addition to the positive results, some common problems in this area are identified not only for the studied regions, but also for the country as a whole.

**Conclusions.** The results of the study may contribute to raising awareness among health professionals about appropriate measures to improve palliative care for severe patients.

**Keywords:** Incurably ill patients, palliative care, provision of medicine

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## INTRODUCTION

These days, high healthcare standards and modern technologies have made it possible to achieve considerable success in treatment, rehabilitation and prolongation of people's lives. However, there are patients who need continuous support, including the palliative one. Palliative care got a legal status after Federal Law № 323-ФЗ "On the Fundamentals of Protection of Citizens' Health in the Russian Federation" dated 21.11.2011 came into effect [1].

Palliative care (from French *palliatif*, Latin *pallium* meaning 'cover, cloak') is an approach that allows to improve the "quality of life" of patients and members of their families who have faced a life-threatening state. Today palliative care includes two main blocks – alleviation of person's suffering throughout his/her disease and delivery of care during the last period of life. The notion of palliative care means adequate pain relief and maintenance of "life quality", psychological support of the patient and his/her relatives and medical bioethics. Leading experts in palliative care have marked out life expectancy (3-6 months) and occurring complaints (certain symptoms and pain) that require special

knowledge for therapy and treatment as the main criteria for care selection. The world knows various forms of palliative care provision, but this area is being developed in each country in a different way, depending on its healthcare system [2, 3].

In view of the outlined problems, the present study aims at considering availability and quality of pain therapy within palliative care at regional level (on the example of Krasnodar and Stavropol krais). This study was focused on examining the results of implementation of the outlined measures and identifying pain treatment problems for incurably ill patients who need palliative care. The study results can raise awareness among healthcare experts about adequate activities in the improvement of pain syndrome alleviation with regard to organizational features and capabilities of each individual region.

## Literature Review

The review of the literature did not reveal any works devoted to the analysis of the state of drug provision in palliative care in the studied regions, which confirms the relevance of this study.

## Methods

The current regulatory framework on the issues of palliative care provision in cases of cancers, that determines the patients' rights to get high-quality pain management in Russia, was analyzed through content analysis and documentary observation. The main problems of implementation of the legislation in this sphere were formulated on the basis of examination of program documents of two entities of Southern Russia in relation to patients with chronic pain syndrome.

## Results

Assessment of the cancer-related epidemiological processes and specific indicators of the morbidity and death rate among the Russian population showed that 624,709 new cases of malignant tumors were registered in 2018, and 3,762,218 patients were on record of regional oncology centres that year. The standardized ratio of cancer morbidity rate was 425.46 per 100,000 population of Russia. Krasnodar kray registered 14,248 newly diagnosed patients (269.18 per 100,000 population), while in Stavropol kray this indicator was 6,253 (246.18 per 100,000 population). The total death rate for 2018 was 1,828,910, including 293,704 people who died from tumors of different localization (the second most frequent cause of death after diseases of the blood circulatory system – 856,100). The standardized ratio of cancer morbidity rate in Russia was 108.56 per 100,000 population. In Krasnodar kray, the same indicators of death rate were 10,634 (101.57 per 100,000 population), in Stavropol kray – 4,718 (96.16 per 100,000 population). It was found out that Krasnodar kray far outstrips Stavropol kray by rate of cancer morbidity (2.28 times) and death from it (2.25) [4, 5].

As pain is one of the most widespread and devastating manifestations both of cancers and of other incurable diseases and it is becoming dominant at the end-stage of the disease, it was necessary to study the degree of its prevalence in different diseases. Table 1 presents data of the World Health Organization (WHO) [6].

**Table 1.** Assessment of the incidence of pain in various diseases (WHO, 2018)

<i>Pathology</i>	<i>Pain prevalence (%)</i>
Cancers	35-96
Cardiovascular diseases	41-77
Kidney failure	47-50
Chronic obstructive pulmonary disease	34-77
HIV/AIDS	63-80
Liver cirrhosis	67
Multiple sclerosis	43
Parkinson's disease	82
Alzheimer's disease other dementia	47
Rheumatoid arthritis	89
Diabetes mellitus	64
Multi-drug resistant tuberculosis	90

WHO data review showed that at least 12 pathologies

have pain as the guiding symptom. However, some diseases demonstrate major variation in the indicators, but the greatest one was identified in the very cancers – from 35 to 96%. Lack of accurate data on pain is one of the serious problems not only worldwide but particularly in Russia too, which is a matter, above all, for incurably ill patients. The Table shows that some diseases inside the group are accompanied by pain to varying degrees. Its prevalence in relation to cancer patients averages 51% regardless of cancer stage and 75% at the stages of disease progression and metastasis and at the terminal stage. However, in Russia there is no register of incurably ill patients, that is why it is almost impossible to determine the accurate number of people that need palliative care. In this regard, foreign statistical estimates are usually taken as a basis, where the need for palliative care falls within 37-89% of all terminal cases in the ratio of 1/3 cancer patients and 2/3 non-cancer patients. Therefore, the number of incurably ill patients in Russia who need palliative care may reach 1 million people. At the same time, the vast majority of those who already receive palliative care belongs to the category of cancer patients, while it is necessary to ensure equal access to it for the patients with other diseases, suffering from severe pains, whose share is considerably higher [7]. The calculations per this formula show that in 2018, the number of only cancer patients who needed palliative care was about 3,545 people in Krasnodar kray and 1,573 in Stavropol kray.

As every and each incurably ill patient needs pain therapy, the plan of activities (road map) "Improving Availability of Narcotic and Psychotropic Substances for Medical Use" was approved in 2016 in order to improve the mechanisms of state regulation of distribution of narcotic drugs and psychotropic substances and provide the citizens with modern analgesic medicinal drugs when delivering care for inpatients and outpatients. The program sets the following tasks [8]:

- to expand the nomenclature of narcotic drugs and psychotropic substances used in case of pain syndrome, including for children.
- to optimize estimation of the need for narcotic drugs and psychotropic substances.
- to improve availability and quality of pain therapy, including simplification of the procedure for administration and prescription of narcotic drugs and psychotropic substances.
- to introduce modern approaches to the pain syndrome treatment into clinical practice.
- to harmonize regulatory legal acts of Russia and Russian entities in the sphere of distribution of narcotic drugs and psychotropic substances.
- to decriminalize medical and pharmaceutical workers' actions connected with violations of the rules for distribution of narcotic drugs and psychotropic substances, that do not pose public danger, in the process of their professional activity.
- to improve the legal regulation of activities connected with dissemination of information on the use of narcotic drugs and psychotropic substances for medical purposes.
- to develop palliative care and train medical workers on the issues of palliative care provision.

The established measures are fully harmonized with the general approaches to the formation in Russia of a sustainable pharmaceutical safety system [9]. Apart from the organizational aspects of palliative care, currently there are also some other problems, connected with pain

therapy itself.

The first group of problems is connected with the pain therapy procedure. For example, even high doses of narcotic drugs are not always effective for certain patients (10-20%). Such cases require more complex approaches to pain relief and personal adjuvant therapy. It should be noted that some opioid analgesics may become less effective because of the “ceiling” effect, when the dose escalation does not lead to adequate relief but expands the range of side effects, leading to appearance of opioid-induced hyperalgesia. It was found that there are other factors, along with the dose, that can impede an effective analgesic response like different characteristics of opioids themselves, their pharmacokinetics and pharmacodynamics, disease progression, tolerance, intractable pain mechanisms, presence of toxic metabolites, multi-organ failure, complete immobility, genetic factors and so on. That is why now pain management implies an absolutely personalized approach to each patient, and that’s what the doctors should be taught [10].

The second group is connected with availability of the pain relief therapy itself. Despite the fact that Russia has recently seen some radical changes in the legal regulation of distribution of narcotic drugs and psychotropic substances, certain regions don’t always ensure quick, easy and high-quality provision of necessary medicinal drugs to cancer patients.

The third group concerns the persisting caution of medical workers in prescribing narcotic drugs and psychotropic substances because of the existing liability to prosecution for some types of violation in distribution of these substances.

There is a number of effective documents at federal and regional levels that regulate the sphere of palliative care. For example, Law № 3929-K3 “On Territorial Program of Government Guarantees of Free Medical Care for Citizens in Krasnodar kray for 2019 and for the Planning Period of 2020 and 2021” was adopted on 11.12.2018 in Krasnodar kray; its section 3 states that palliative care, provided on outpatient basis, at home, by mobile visiting teams, in day and twenty-four-hour patient departments, including palliative care beds and nursing care beds, is covered by the regional budget [11].

The Krasnodar Administration Directive № 276-p dated 30.08.2019 approved the regional program “Development of Palliative Care System” to improve availability and quality of palliative care for residents of the region. The program determines 13 target performance indicators for its implementation up to 2024 [12]. The main guideline of this program is absolute (100%) coverage of the patients that need palliative care with pain medication with the recall ratio of narcotic drugs and psychotropic substances within the stated need in accordance with the distribution plan of 95% by 2023 and 100% by 2024 and with the achievement of 100% share of the patients that receive pain therapy within the palliative care provision.

Krasnodar kray has registered 72 pharmacy organizations that have the right to sell narcotic drugs and psychotropic substances, that are on the List 2 of the Nomenclature of Narcotic Drugs and Psychotropic Substances That Are Subject to Control in Russia, to natural persons. In 2018, the regional pharmacy and healthcare organizations that render specialized palliative care were provided with the full range of the nomenclature of narcotic drugs and psychotropic

substances, registered in the country, including all dosage forms and dosages.

Analysis of the results of work carried out by the departments that provide with palliative care on an outpatient basis revealed an increase in the number of patients that received such care and of prescriptions on narcotic drugs and psychotropic substances from 1,719 forms in 2017 to 2,010 forms in 2018. The number of patients who were assigned to take opioid analgesics on a regular basis, reached 2,010 people, and the average period of their receipt by patients was within 3 weeks.

Palliative care implies such ways of analgesic administration as peroral, parenteral and transdermic.

Methods that were established by clinical guidelines are applied to assess pain syndrome and efficacy of pain management in the healthcare organizations of Krasnodar kray that provide with palliative care:

“Chronic Pain Syndrome (CPS) in Adult Patients That Need Palliative Care”, developed by the Association of Hospice Care Professionals, Interdisciplinary Medicine Association, Russian Society for Evidence Based Medicine and Russian Scientific Medical Society of Internal Medicine [13].

“Pain Syndrome (PS) in Children That Need Palliative Care”, developed by the Association of Hospice Care Professionals, Russian Society of Pediatric Oncologists, Pediatric Anesthesiologists and Reanimatologists Association, National Society of Pediatric Hematologists and Oncologists of Russia [14].

For 2020, it is planned to create and introduce a single database (registers) of patients with chronic pain syndrome who receive palliative care in order to assess the conformity of the provided care with the modern clinical guidelines.

In Krasnodar kray, the State Budgetary Healthcare Institution “Scientific Research Institute – Ochapovsky Regional Clinical Hospital № 1” of the Krasnodar Ministry of Health runs the Centre for Acute and Chronic Pain Syndrome Centre within the Anesthesiology and Reanimation Department № 6, including for patients that need palliative care. The Centre applies methods of regional anesthesia to treat chronic pain in such patients. 499 blockings were made in 2018, they also apply systems for intrathecal (endolumbar) administration of opioid analgesics. 7 spinal port systems were implanted in 2018.

Now patients of all age groups, who are recommended to take narcotic drugs and psychotropic substances, receive therapy with prefabricated drugs. However, the Krasnodar Ministry of Health is ready to consider organization of pharmaceutical compounding preparations from the specified pharmaceutical substances in the pharmacy organizations of the municipal unitary enterprise “Krasnodar Municipal Pharmaceutic Directorate” (Krasnodar), and the municipal unitary enterprise “Krasnodar Municipal Pharmaceutic Directorate” (Sochi), if necessary.

In Stavropol kray, the palliative care provision is regulated by Order №. 01-05/666 “On organization of Palliative Care to Adult Population of Stavropol kray” of the Stavropol Ministry of Health dated 09.10.2014 [15]. Besides, Stavropol kray launched a program “Region of Care” as an individual program of palliative care development in 2020-2024 in pilot regions among 25 entities of Russia. The program is financed almost in equal part with the federal and regional budgets. For example, the amount of financing in 2019 was 220 million

rubles (124 million of which were finances from the regional budget). 48 million rubles were allocated for procurement of narcotic drugs and psychotropic substances for pain treatment both for in-hospital therapy and under outpatient treatment.

Stavropol kray launched a national project "Combating Cancers", which has the following main principles: prevention, early detection, diagnostics and treatment, rehabilitation and palliative care [16]. Pain treatment is becoming far more available because common approaches to it, including 550 regimens, have been determined for financing of treatment for cancer patients. In this regard, the Stavropol Oncologic Centre received 3 billion rubles from all the sources of financing, and 100 million rubles were allocated for diagnostic testing. The regional budget allocated 125 million rubles for provision of medicines to cancer patients, 14 million of which were meant for pain treatment.

In Stavropol kray, the procurement of analgesic medicinal drugs is covered by the federal and regional budgets. Necessary stock of narcotic drugs and psychotropic substances to relieve cancer and neuropathic pain is available. Getting palliative care does not depend on the disability group, the patient only needs to be registered at a clinic.

Children under 3 years of age, registered at a healthcare organization, have the right for free palliative care (covered by the regional budget) if medically required. The drug reimbursement list is published on informational brochure stands in clinics and official websites of the regional healthcare organizations on a regular basis.

Now only the first prescription of analgesics takes place with involvement of the medical board, after which doctors prescribe the medicine themselves, which allows palliative care patients to get necessary medicinal drugs without much delay.

Pain treatment in Stavropol kray is provided in all dosage forms in accordance with the guidelines of the Eurasian Association for Palliative Care, approved for procurement by Order № 913 "On Approval of Methodological Guidelines on Identifying Need for Narcotic Drugs and Psychotropic Substances for Medical Use" (amended) of the Ministry of Health of the Russian Federation dated 16.11.2017 [17]. The relation between invasive and non-invasive dosage forms is approximately 40% and 60% respectively, and 20% of the non-invasive dosage forms fall on transdermic systems. Non-invasive dosage forms with prolonged release, which ensure therapeutic concentration of analgesics at one level during several days, include pills (capsules) of morphine sulfate with sustained release, pills of oxycodone combined with naloxone, transdermic systems with fentanyl and others. Now transdermic systems with fentanyl are permitted for use for children from 2 years of age.

However, despite the obvious success that has been achieved in the sphere of palliative care provision in both regions, there are some common problems too.

For example, a large number of patients that need palliative care are persons with disabilities who often forgo the benefits package, covered by the federal budget, in favor of cash payment (less than 1 thousand rubles) which does not allow them to buy necessary medicinal drugs. As a result, the number of complaints from the same patients is growing. In order to change the situation for the better, the regions have to allocate money from the regional budgets to buy necessary medicinal drugs.

The problems of late receipt of narcotic drugs and psychotropic substances by incurably ill patients, which is connected with difficulties in choosing an adequate regimen by doctors, especially in case of comorbid states, or the fear of criminal penalty in prescribing narcotic drugs and psychotropic substances, are still unresolved.

Some palliative care patients have to buy the necessary analgesics using their own funds, particularly because the amount of prescribed narcotic drugs and psychotropic substances is not enough to improve their "life quality". Besides, there are complaints from such patients or their relatives on the availability of care and rehabilitation means.

Another equally important problem is limited inpatient palliative care for incurably ill patients. As a rule, further therapy of seriously ill patients after their discharge from a common hospital takes place at home without qualified medical care and skills of medicinal drugs injection and professional nursing.

A global problem both for the regions under study and for the whole country is rapid growth of the number of socially vulnerable citizens. It especially affects families with an incurably ill patient whose treatment, rehabilitation and service require serious financial expenses. Free provision with expensive hygiene products and technical means for nursing are available only for people with an officially registered disability. Unfortunately, not all patients (and they are a significant number) live from diagnosing till gaining the status of a disabled person, which is connected with certain difficulties in passing sociomedical assessment for disability registration. What is more, some relatives have to quit job because it's impossible to combine such activities, which drastically affects the already small income of the family.

## Conclusion

Therefore, the results of the conducted study on the quality of palliative care provision in certain entities of Russia (Krasnodar and Stavropol krais) showed that the heads of the regional healthcare authorities actively introduce the roadmap. Despite certain common problems that exist, the availability of pain treatment in the entities is close to the maximum, and the pain therapy measures are effective; attention is paid to algorithms of patient's actions in case of palliative care with the use of the main principle of "medicinal drugs must be available as close to the patient as possible". Besides, all legislative changes, adjusted to regional peculiarities, are being implemented.

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