### POLICY ARTICLE

# Influence of unbalanced opioid policy on pain management and home-based palliative care services in Republic of Georgia

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### **ABSTRACT**

Introduction: Most patients with incurable diseases prefer to spend their treasured time in home settings. As pain is the most frequent symptom, often requiring opioid analgesics, it is essential that outpatient medical services are supported by policies that allow managing patients' conditions at home. This paper aims to show how over-restrictive regulations/policies can impact patients' ability to access pain management and hamper the development of home-based palliative care services.

Methods: To evaluate the influence of strict regulations on pain management and their impact on home-based palliative care services, on one hand the opioid legislation and policy documents were reviewed and on the other opioid consumption reports, data on mortality and provided palliative care services, and data from the patient survey were analyzed.

Results: The palliative care program states that only incurable patients who are at the end of their lives and need home-based support can benefit from the program. Additionally, the physician must be convinced that the diagnosis is correct and that the estimated life expectancy is no more than 3-6 months (duration of benefiting from the program). Consequently, fearing the penalties, physicians mostly include patients in the program, when apparent signs of death are present. Therefore, patients have to be hospitalized, to receive care. As a result, the number of provided home based services has decreased more than half and its' ratio to inpatient services is 1:4.

Simultaneously, the legislation allows prescribing opioids only to terminally ill patients, for whom no other treatment options are available. Before being prescribed morphine, about 94% of the terminal patients experienced moderate to severe pain. 75% experienced severe pain for 1 month and more. Yet, opioids were prescribed with substantial delay in most cases (61-70%). In 45%, morphine was first prescribed by palliative care physicians available only at inpatient units.

Conclusion: Strict opioid policies negatively impact pain management in palliative care patients. Even been incurable, most patients cannot receive appropriate pain treatment, until they reach the "end-of-life" stage, or receive such treatment in inpatient settings. Such an approach ignores the possibility of improving the quality of life for patients in their home setting.

### Introduction

Most patients facing life-threatening diseases prefer to avoid hospitalization and spend their treasured time in familiar home settings among family or close friends<sup>1</sup>. To achieve this goal, well-established outpatient services are essential<sup>2</sup>. As pain is the most frequent symptom among such patients<sup>3</sup>, often requiring opioid analgesics, home-based services must be supported by legislation that allows managing patients' conditions in home-based settings.

Worldwide experience has revealed that to maximize access to outpatient services, improve quality of life (QOL), and relieve suffering for most patients with life-threatening diseases, it is essential to strengthen primary health care by integrating palliative care (PC) services into the system<sup>4</sup>. Palliative care is an approach that aims to relieve suffering and improve the quality of life for patients (and their families) facing life-threatening illnesses through early identification, accurate assessment, and treatment of pain and other issues<sup>5</sup>. In 2018, World Health Organization (WHO, Declaration of Astana) stated that "palliative care must be accessible to all ... through primary health care"6. However, even many years before that, WHO noted that "a palliative care programme cannot exist unless it is based on a rational national drug policy"7. Thus, home-based palliative care services and pain treatment cannot be established without rational policy support.

The most efficient services in palliative care are mainly home care setting services<sup>8</sup>. Inpatient services are recommended only for patients who experience symptoms difficult to manage at home. This approach considers the patients' desire to spend the final stage of life in their familiar settings surrounded by loved ones and maximally avoid hospitalization. Additionally, it considers the cost-effectiveness of such services<sup>9–11</sup>. Therefore, it is especially important to develop home-based palliative care in developing countries with limited budgets and funding for medical services. However, over-restrictive regulations and opioid policies can negatively impact patients suffering from pain and hamper the development

of home-based palliative care services and their integration into the primary health care system.

Georgia's example clearly demonstrates the negative impact of legislation on adequate pain treatment in incurable patients, where the statistically defined daily dose (S-DDD) of morphine consumption ranges from 60-66 S-DDD, falling into the very low (1-100 S-DDD) consumption category according to the International Narcotic Control Board (INCB)<sup>12</sup>.

Development of palliative care services started over two decades ago in Republic of Georgia<sup>13</sup>. However, despite the good start and development, due to strict regulations and policies, home-based palliative care has almost vanished in Georgia (Table N1). The table shows data on the need for palliative care versus the services provided from 2017 to 2022. Based on mortality data<sup>14</sup> the third column indicates calculated number of patients in need of palliative care according to Worldwide Palliative Care Alliance estimation (WPCA) method; in the report it is estimated that "37.4% of all deaths from all causes need palliative care"3. Afterwards the table reflects the number of patients who actually received palliative care services in the same period and the last two columns specify proportions of the provided out and in patient services in the frame of the state health care programs - "palliative care for incurable patients"15.

**Table N1**. Estimated need for palliative care, based on mortality data and provided palliative care services in the frame of the state PC program in Georgia (2017-22)

Year	Total deaths	In need of pain	Total N % of served	N / % of	N / % of
	Georgia	relief and PC	patients by state PC	outpatients	inpatients
		(37.4%)	program	served	served
2017	47 822	17885	1891(10.5%)	894 (47%)	997 (53%)
2018	46 524	17400	2810 (16%)	957 (34%)	1853 (66%)
2019	46 659	17450	2986 (17 %)	826 (28%)	2160 (72%)
2020	50537	18900	2227 (12 %)	574 (25%)	1703 (75%)
2021	59 906	22405	1959 (8.7%)	459 (23%)	1500 (77%)
2222	49 118	18370	2365(12.8%)	465 (20%)	1900 (80%)

The above table shows that a maximum of 17% of patients in need of palliative care can receive such services. Moreover, during 2017 – 2022, not only did the number of patients who benefited from home-based services decrease significantly (twice more), but also the ratio between outpatient and inpatient services changed in favor of inpatient services (1:4).

The paper aims to discuss the main regulatory / policy barriers to opioid use that impede pain treatment in incurable patients and to evaluate their impact on accessibility of strong pain medications and the availability of home-based palliative care services.

### **Methods**

To evaluate the influence of strict regulations on patients' ability to access opioid medications for pain treatment and their impact on home-based palliative care services, the legislation and policy documents regulating opioid prescription and accessibility of palliative care services were summarized. To identify the influence of the policy on patients in need, the following data were used: statistical data on opioid consumption from INCB annual reports, data on mortality/morbidity and provided services, and data from the patient survey performed in the frame of the PhD study - Evaluating Barriers to Chronic Pain Management and their Impact on the Quality of the Health Service by Pati

Dzotsenidze, author of the current paper<sup>16</sup>. The following sources were analyzed:

• Policy: To assess the main regulatory and policy barriers, the well-established European Society for Medical Oncology's' (ESMO)\_ policy framework regarding accessibility of opioid medications was used. These indicators were applied by ESMO and the European Association for Palliative Care (EAPC) in a large-scale survey in 41 European countries<sup>17,18</sup>. The same validated indicators were used by Global Opioid Policy Initiative (GOPI) project in countries in Latin America, Africa, Asia, India, and the Middle East<sup>19</sup>.

Barriers to accessibility can be categorized as prescription-related or dispensing-related barriers (Table 2).

• To review the adequacy of pain treatment and palliative care services in Georgia, the following data were used: a. Statistical data reflecting opioid consumption from INCB annual reports<sup>12,20</sup>. One of the most objective indicators of the adequacy of pain management is the rate of opioid consumption for the same purpose in a given country<sup>21–24</sup>. b. Statistical data on provided actual palliative care services to check their compliance with the need for such services based on the WPCA recommendation<sup>24</sup> (for the period of 2017 – 2022 years). The WPCA

is "focusing exclusively on hospice and palliative care development worldwide and is in official relations with WHO"<sup>25</sup>.

Table 2. Barriers to opioid accessibility

# Prescription-related barriers Authority to prescribe opioids Special permit Prescription form availability Patient eligibility Dispensing-related barriers Pharmacy reluctance to dispense opioids Authorized pharmacies Cost-related factors

In the joint report WHO & WPCA estimate that 37.4% of all deaths from all causes need palliative care. The same report estimates the number of people in need of palliative care based on the prevalence of pain by disease c. Data from the results of the patient survey performed in the frame of the authors' PhD study to clearly describe the problems which incurable patients in pain face in Georgia. The data collected in 2017 allows for a clear observation of the effect of further changes over the following years resulting in a decreased number of home-based palliative care services.

### Results

### GEORGIA - REGULATIONS / POLICY

Opioid policy for medical use in patients suffering from pain remains an unresolved issue in Georgia. According to regulations In Georgia opioids can only be prescribed to incurable patients in terminal stages of their diseases, when no any other treatment option is left for cure. However, opioids are not always prescribed even to incurable patients to relieve pain and suffering.

To make the issue clear, it is important to review two different points of the policy:

1. Legislation - regulating rules for opioid prescription  $^{26}$  and

2. The palliative care state program through which it is possible to have access to the PC services or to opioids

(https://matsne.gov.ge/ka/document/download/6 375605/0/ge/pdf).

### **REGULATIONS**

In Georgia opioids prescription and dispensing rules are regulated by the order N32/o-N102 (joint decree 32-102 MOH and MIA 2000). Though some updates were done, due to ambiguity and inconsistence of those updates <sup>28</sup> the older version of the regulation still dominates<sup>29</sup>.

BARRIERS TO OPIOIDS ACCESSIBILITY - for better categorization of the barriers the ESMO <sup>30</sup> barriers to opioid analgesic accessibility were used.

### PRESCRIPTION-RELATED BARRIERS

- Authority to Prescribe Opioids: In Georgia, only general practitioners, family/village doctors from authorized primary health care facilities serving patients according to residence place can prescribe opioids to outpatients. However, this can be prescribed only with a special permit.
- Special Permit: The decision on assigning opioids is made by a special commission consisting of three members. After verifying the diagnoses, the commission decides

whether the patient needs opioid treatment and determines the starting dose or further escalation of the dose.

- Patient Eligibility: Prescribing is allowed only for terminally ill patients in Clinical Group IV – these are patients in the terminal stage of the incurable disease. This means that opioids can be prescribed provided no other treatment option is left.
- Prescription Form Availability: A special prescription form is required, which is available only within the National Health State Palliative Care Program and just for those physicians who serve in polyclinic-type facilities serving patients according to the place of residence registration. This special prescription form can cover a 7-day supply of morphine (the only opioid, though different formulations injectable and oral forms are available) for incurable outpatients within the same PC program.

DISPENSING RELATED BARRIERS – Only few authorized pharmacies, which have special dispensing point located in police stations, can dispense opioids once a week according to the patient's official place of residence.

# NATIONAL HEALTH STATE PALLIATIVE CARE PROGRAM FOR INCURABLE PATIENTS

The palliative care program was launched in 2004 in Georgia. The program covers: a) Outpatient palliative care for incurable patients, which includes outpatient palliative care at the homes of incurable patients in several municipalities (in 6 out of 69) - by a palliative mobile team (doctor/nurse) b) Inpatient palliative care and symptomatic treatment for incurable patients c) Provision of incurable patients with medications (opioids).

The beneficiaries of the program are defined as: a. Patients with malignant tumors of the 4th clinical group b. Patients with AIDS in the terminal stage c. Patients with non-oncological chronic progressive diseases in the terminal stage.

Though all those patients who can benefit from the program are terminal, yet in 2013, the government's annual resolution on the Health Care State Program introduced an amendment to the program "Palliative Care for Incurable Patients." The amendment further defined those eligible for home-based palliative care services as incurable patients who at the "end of life" need such services. It also added some more additional restrictive criteria that patients must meet: a) Estimated life expectancy of no more than 3-6 months b) Inexpediency of any further treatment attempts (taking into account the specialists' firm belief that the diagnosis is correct).

The other issue is financing and reimbursement rules for the components defined by the program, which have not changed since 2004 and do not take into account the severe devaluation of the national currency as well as inflation during the last decade. Reimbursement for the home-visit services per team for one visit is 11 GEL (currently up to 4 Euro).

### **RESULTS - PATIENTS**

Before morphine prescription, about 94% of the incurable patients experienced moderate to severe pain. Of those, 61% experienced severe pain (7-10) and 33% moderate pain (4-6), despite the fact that 90% of them regularly used non-opioid pain medications.

According to the patients, pain had negatively impacted their quality of life. Before morphine prescription, 97% (94/97) of them admitted that pain limited their ability to be engaged in activities with which they had no difficulties before; in 75% the activities were always/frequently limited.

About 25% of the patients experienced severe pain for less than 1 month, about 40% from 1 month to 3 months, and about 35% for 3 months or more. 31% of patients answered that it was more than 3 months between beginning to experience severe pain and being prescribed morphine. 38% of patients stated that it took more than 1 month to find a doctor with the intention of pain treatment. The cross-tabulation revealed that morphine was prescribed with delay

to 61% of the patients who had pain for 1 to 3 months and to 70% who had pain for more than 3 months.

To the question - Which type of doctor did you first see for pain treatment? most of the patients responded that they first addressed GPs (39%) or oncologists (44%) and only 9% addressed palliative care physicians (Figure N1).

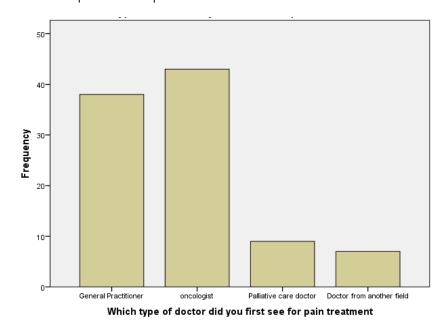


Figure N1 Type of doctor which the patients addressed first for pain treatment

After their first contact with the physician for uncontrollable pain, opioids were prescribed only to 45% of patients in total. Out of the general practitioners that were addressed for pain treatment by incurable patients, only 39% prescribed morphine; among oncologists, only 41% did so.

The responses to the question - which type of physician finally prescribed morphine to them for intensive pain relief, show that (Figure N2):

- To 8% morphine was prescribed by the general practitioner
- To 25% by the oncologist
- And to 67% by the palliative care doctor.

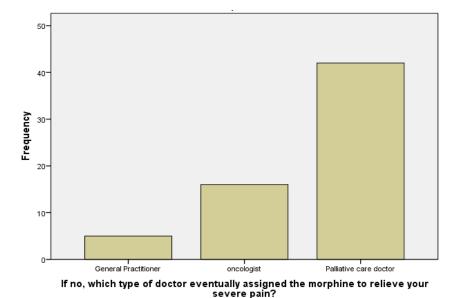


Fig.2 Type of doctor which finally assigned morphine to the patients

Finally in total, based on crosstabulation of the data, morphine was prescribed in 19% by GPs, in 31% by oncologists, and in 45% by the palliative care physicians. If we take into account that by that time palliative care physicians were only available in inpatient settings, it becomes clear that in order to receive adequate pain treatment, patients had to be placed in hospitals or palliative care units (the latter are also mostly located in hospitals).

It is noteworthy that although the Health Care State Programs' component - "Palliative care for incurable patients" - in Georgia still covers home-based services, its proportion dramatically decreases each year and in 5 years dropped from 47% to 20%. Thus, the ratio of home-based and inpatient services becomes 1:4 (Table N1).

As regards the level of consumption of morphine (the only opioid for outpatients), defined daily doses for statistical purposes per million inhabitants per day - S-DDD, in 2022 it was 66 S-DDD. This level falls in a very low consumption category (1 – 100 S-DDD) indicating that the majority of patients did not have access to pain medication at all<sup>12</sup>.

### Discussion

The most restrictive negative provision in regulations is that opioids are discussed as a treatment of last resort. In order to prescribe opioids to patients, they must be terminally ill in Clinical Group IV - the incurable stage of disease when no other treatment options are available. Pain severity and its duration, or history of previous pain treatment effectiveness, with its possible accompanying complications, aren't considered. The main requirement to start pain treatment is a verified incurable diagnosis. If we take into account the tendency of increasing deaths with unverified causes (since 2020, unverified deaths have increased from 6,471 to 10,603 in 2023, whereas in the same period the number of deaths due to cancer decreased by about 3,500)14, we can conclude that all undiagnosed and non-hospitalized patients die suffering, without receiving any relevant pain treatment.

In Georgia, only general practitioners, family/village doctors from authorized primary health care facilities such as polyclinics, which serve patients according to residence place, can prescribe opioids to outpatients. However, it should be considered that the place of residence should be an official registration of living place. So, if the patient needs to move to another district, e.g., to a family member in order to get care, they have to go through a lot of procedures to change the place of registration, which is also timeconsuming. However, that is not all that requires time. The physician (with the intention to prescribe, which is not always the case<sup>29,31</sup> as to obtain a special permit in order to prescribe opioids. The decision on assigning opioids is made by a commission consisting of three members, including the physician (GP or family doctor), oncologist or relevant field specialist, and specially authorized representative from the administration. The commission verifies the diagnosis and makes a decision whether or not to prescribe morphine, including the initial dosage and possible increase. The commission is available only one or two days a week. Once the decision is taken and opioids are prescribed to a patient, the patient or mostly the patient's caregiver (as most of the patients are unable to do so) have to rush the same day to the pharmacies with special dispensing points for opioids located in police stations. As those dispensing points are not regular pharmacies, they work and dispense opioids only once a week on a specially designated day for dispensing, when a representative from the authorized pharmacy goes to the police station to dispense opioids. Moreover, such dispensing points are few, just five in Tbilisi, the capital of Georgia, so caregivers, after obtaining prescriptions, must hurry up to reach them and take place in a long queue. The patients or caregivers have to repeat that ritual every week as the special prescription form can cover only a 7-day supply of morphine and one can't refill the supply with the same prescription.

A special prescription form is available only within the National Health State Palliative Care for Incurables' program and just for those physicians who serve in polyclinic-type facilities serving patients according to living registration place. Based on the evaluation of palliative care services in Georgia (2021), only about 50% of the home-based palliative care service providers (in total seven) have access to opioids, while only 25% prescribe them<sup>32</sup>. However, it cannot be excluded that the remaining providers just avoid prescribing opioids due to strict requirements and procedures<sup>29</sup>.

Thus, over-restrictive regulations and policy not only have a negative impact on patients suffering from severe pain, but they also impede the normal functioning of home-based palliative care services and their integration into primary health care in Georgia.

According to the requirements of the state program on palliative care for incurable patients, physicians must be convinced that patients will not live longer and will die within 6 months. Otherwise, they have to stop treatment because the program states that the treatment can be delivered for no more than six months. The physicians must be convinced of the "inexpediency of any further treatment attempts (taking into account the specialists' firm belief that the diagnosis is correct)"

(https://matsne.gov.ge/ka/document/download/63 75605/0/ge/pdf). However, most of the physicians, especially those working in outpatient facilities, lack the knowledge to make a prognosis or do not wish to take responsibility for a "firm belief that the diagnosis is correct". Under the circumstances, it is not always possible to make a clear prognosis, particularly 'in favor of' patients. Moreover, fear of sanctions can prevent the physicians from including the patient in the program or offering palliative care services timely, as they wait for apparent "end-of-life" signs to appear.

The restrictions since 2013 and lawsuits linked to patients living longer than six months resulted in stopping the functioning of professional home-based services that had operated for one decade in Georgia. Hence, it is not surprising that, though the Health Care State Program component -

"Palliative care for incurable patients" - in Georgia also covers home-based services, its proportion dramatically decreases each year (Table N 1) and the ratio of home-based services to inpatients is currently 1:4.

Thus, a physician's decision-making is based on the life prognosis of a patient and it doesn't consider severity of the symptoms or their influence on quality of life of the patients, because a physician has to wait until the patient reaches "end of life' and will have clearly verified diagnosis to be eligible for the program. Though the program's inclusion criteria – limitation of the service up to six months and reaching the end of life stage mentioned above are meant for outpatient services and do not directly apply to opioids assignment, yet in most cases the same criteria are applied to opioid prescription, because likewise, in order to prescribe opioids, a physician must be sure that no other treatment option is left and the patient is in the terminal stage of the disease<sup>28</sup>.

Therefore, considering the above, the results of the patients' survey must be no surprise. The patient survey revealed that before opioid prescription, out of the 90% of the patients who were regularly receiving non-opioid treatment, 94% were still in pain (from moderate to severe pain). Although the legislation allows assigning opioids to incurable patients, most of the patients weren't able to receive adequate pain management or receive such treatment timely from the primary health care physicians responsible for prescribing opioids. Pain duration prior to opioid prescription exceeded one month among 88% of the patients with severe pain and 76% of the patients with moderate pain. Though all the patients were at the incurable stage of the disease, it took from 1 week to 1 month in 33% and more than 1 month in 40% of them to find a physician who prescribed morphine to them. To summarize, in 59% of the patients, morphine wasn't prescribed by the physicians responsible for doing so. Finally in total, based on crosstabulation of the data, morphine was prescribed in 19% by GPs, in 31% by oncologists, and in 45% by the palliative care physicians available only at inpatient units<sup>16</sup>. In most of the cases opioids were prescribed with delay, making patients wait and suffer until they reach "end-of life" stage with apparent death signs, when most of them already needed hospitalization due to uncontrolled symptoms.

This explains why the number of patients benefitting from the home-based services as well as the share of home-based services intensively declines annually. Unsurprisingly, that morphine consumption for pain control determined as statistical – defined daily doses by INCB report is in the range of 60-66 S-DDD<sup>12</sup> and falls in a very low classification (1–100 S-DDD), very inadequate to control pain in most of the patients in need.

The table N1 reveals that a maximum of 17% of patients in need of palliative care had access to the services. Similar data is shown by The Lancet Commission on global access to palliative care and pain relief, according to which the distributed opioid morphine-equivalent (DOME) for Georgia is 17%<sup>33</sup>. Though in their report, the Lancet Commission states that "the difference between DOME and total need for pain relief medicine is a minimum measure of unmet need" as the availability of morphine is not the same as "the amount dispensed or consumed by patients"<sup>34</sup>.

Thus, based on the discussion above, the following suggestions are recommended:

Opioid Prescription and Dispensing Rules

- Opioid prescription practices should primarily be based on pain severity, previous pain treatment history, and its impact on the quality of life. Additionally, they should take into consideration the diagnosis and prognosis of the patients. They must follow WHO 3 step analgesic ladders' recommendations<sup>35,36</sup>.
- The regulation must clearly state that the decision to prescribe opioids must be made by the physician caring for the patient, based on careful and regular assessment of the patient's condition; Although a provision supporting

this approach already exists, it is often ignored by most physicians and their administration due to ambiguity and conflicting norms.<sup>29</sup> More clarity can automatically change the practice of prescribing morphine (issuing prescriptions) only once a week, on the day of dispensing opioids from the authorized 'pharmacies' located in police stations.

 The Government must seek solutions to reintegrate opioid dispensing practices back into regular pharmacies. This will eliminate the need to wait several days to obtain opioid medications for pain relief and spare valuable time for patients and caregivers, who will no longer have to travel long distances to police stations.

# NATIONAL PALLIATIVE CARE PROGRAM FOR INCURABLE PATIENTS

The program should not restrict the eligibility of outpatients to the "end of life" stage or limit service duration strictly to a 3-6-month period. In addition, it is advisable to increase funding to transition from purely medical care to a more holistic model of palliative care.

### **Conclusions**

Strict opioid regulations and restrictive policy of palliative care programs have a negative impact on pain management in palliative care patients. Even being incurable, mostly they can't receive appropriate pain treatment, if any at all, until they become the "end-of-life" patients, or receive such treatment already in inpatient settings. Such an approach totally ignores the possibility of improving the quality of life of the patients in their home setting and does not allow them to pass their last period of life in dignity and without suffering and isolation.

Thus, it is strongly recommended that all groundless limitations and impediments be removed: Opioid Prescription Rules must be based on medical indications for pain treatment and must follow WHO 3 step analgesic ladders' recommendations<sup>35,36</sup>. The regulations must use clear language to avoid

ambiguity. National Palliative Care Program for Incurable Patients should not restrict the eligibility of outpatients to the "end of life" and service duration strictly to the 3-6-month period. The focus must shift from incurable diagnosis to quality of life and functional assessment of the patients.

Amendments to regulations and elimination of needless restrictions can also increase the role of the Primary Health Care Sector to ensure maximal access to pain relief and quality palliative care for outpatients.

### Conflicts of Interest:

The author has no conflicts of interest to declare.

### Acknowledgements:

None

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