

Special Article

Romania: Changing the Regulatory Environment

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Abstract

Access to the necessary medications for palliative care, especially opioids, is an essential part in the development of a national palliative care program. In November 2005, Romania's Parliament adopted new legislation concerning the medical use of opioids and psychotropic substances to replace the old and restrictive legislation of 1969. The new law and regulations are the result of a four-year project in which governmental authorities collaborated with health care professionals and international experts. The World Health Organization "Achieving Balance in National Opioids Control Policy—Guidelines for Assessment" was used to propose balanced legislation that would facilitate modern pain management and provide adequate control of these substances with the potential for abuse. A national education program to facilitate the implementation of the new legislation has been organized. The training started in November 2006 and will continue throughout 2007. It is anticipated that at least 3,000 doctors and 500 pharmacists will attend these courses. J Pain Symptom Manage 2007;33:610–614. © 2007 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Opioids legislation, education, Romania, palliative care

Palliative Care and Pain Control in Romania

To map the development of palliative care worldwide, the International Observatory on End of Life Care developed criteria to categorize countries: no known activity, capacity building, localized provision, and approaching

integration.¹ Romania has been included in the category "approaching integration," not due to an extensive number of services, but due to the steps that have been taken in changing policies, education, and legislation. These steps include

- 1) Laws passed regarding patients' rights,² hospital legislation,³ and the contract framework for national health insurance⁴ that includes provision for palliative care.
- 2) Palliative care is recognized as a specialty for physicians, and training is required over a period of 18 months. Although there are few services at present, it is encouraging that there is

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Accepted for publication: February 14, 2007.

a constant and increasing interest in palliative care. In November 2006, 85 new candidates (physicians) enrolled in the diploma training program.

- 3) According to the data collected by a European Association for Palliative Care task force,⁵ Romania has a total of 36 services (one provider can offer more than one service), most of which are home care services. Services are mainly directed toward cancer patients and children with AIDS. This is not surprising, as most palliative care services worldwide started by caring for cancer patients, and in Romania, cancer is the second leading cause of death, with over 40,000 deaths/year.⁶⁻⁸ The data concerning HIV infection vary widely, and the number of people infected with HIV is reported to be from 5,500 to 14,000.⁹ Most infections are due to unscreened blood products and re-use of contaminated needles in the late 1980s.

Changing Opioid Laws and Regulations

The World Health Organization (WHO) views the consumption of opioids, including morphine, to be an indicator of a country's capability to relieve moderate to severe pain. WHO believes that opioid analgesics are absolutely necessary for pain relief and palliative care and should be sufficiently available to meet all legitimate medical needs.¹⁰ In Romania, with a consumption of 1.23 mg of morphine/capita,¹¹ one of the lowest in Europe, pain is a problem that is far from being addressed adequately. This low opioid consumption can be explained in several ways: 35-year-old narcotic policies imposed a complex, restrictive, and burdensome regulatory system for prescribing opioids; poor education and the bias of health care professionals regarding this class of medications; and fears and prejudice against opioids in the general public.¹²

Improving this drug availability, including access to opioid analgesics, has been one of the foundational measures for an effective national palliative care program.¹³ Opioids are seen as essential medicines and are included on the WHO essential drugs list. Essential medicines

are those that satisfy the priority health care needs of the population. They should be available at all times in adequate amounts, in the appropriate doses, with assured quality and adequate information, and at a price the individual and community can afford.¹⁴

Romania has struggled for 35 years with a very restrictive policy concerning the medical use of opioids. According to the old law, doctors were allowed to prescribe opioids for outpatients only with advanced cancer or with obliterative arteritis with necrosis.¹⁵ Even for these patients, the process was extremely complicated: authorization was required with a dry stamp prescription in triplicate, and there was just one dispensing pharmacy per district (usually serving a population of 400,000 inhabitants).

Since the 1990s, there have been attempts to amend this law and the associated regulations.^{16,17} In 2002, Romania took part in an Open Society Institute (OSI)/WHO workshop, made a preliminary assessment of the national opioid control policies using the WHO guidelines, and proposed an action plan.¹⁸ Subsequently, Romania was selected by OSI and the Pain and Policy Studies Group (PPSG) at the University of Wisconsin Comprehensive Cancer Center/WHO Collaborating Center for Policy and Communications in Cancer Care to be a pilot country for continued work.

Because regulatory barriers severely restricted access to pain relief, palliative care leaders were eager to address the problem, and the Ministry of Health of Romania recognized the problem by appointing a Palliative Care Commission to make recommendations.

A Romanian and PPSG working group reviewed the policies using the 2000 WHO guidelines and created a report with policy recommendations¹⁹ that was presented to the Minister of Health. The Ministry of Health Pharmaceutical Department began drafting legislation to replace the national narcotics law on the basis of the recommendations of the Palliative Care Commission. The process was also facilitated by the fact that the National Anti-Drug Agency was co-opted in a European Union project that highlighted the need to bring the opioid legislation in accordance with scientific evidence and international recommendations.

To focus on drafting the new regulations that would implement the law when adopted,

the PPSG sponsored a one-week study visit to Madison, Wisconsin, USA, for a team of five members from Romania to begin drafting the new opioid prescribing regulations.

The proposed law was passed by the Romanian Parliament on November 26, 2005.²⁰ In May 2006, the Ministry of Health finalized the draft regulations and approved them.²¹

Implementing the New Legislation: The National Education Program

New legislation is the first step in a cascade of events. The new regulations imply radical changes. Every doctor will be allowed to prescribe strong opioids for patients with severe pain, regardless of the underlying disease. It will be his or her sole responsibility to decide, according to his or her medical judgment, when and in what dose an opioid medication should be prescribed (Article 36 of the draft regulations).

Although this change is seen as important progress by the few doctors active in the field of palliative care and pain management, it could initially scare a large number of physicians, especially family doctors who until now had the role of just transcribing the drug and dose prescribed by the authorizing oncologist. Anxiety could also be generated by the lack of appropriate training in the field of pain management and opioid prescribing, coupled with all the common fears about strong opioids (respiratory depression, addiction, etc.).

The team that drafted the regulations felt strongly about the need to establish an education program to overcome some of these barriers. This was incorporated in Article 54 of the regulations as follows: “*Universities of medicine and pharmacy, the Ministry of Public Health, the College of Physicians from Romania, the College of Pharmacists from Romania and professional or scientific societies, as well as other suppliers of professional training shall take measures for the regular organization of training, courses for adequate therapy of pain and prescribing, use and legal status of narcotic and psychotropic plants, substances and preparations.*”

Hospice Casa Sperantei took on the lead role in this training project. A 15-month grant was obtained from the OSI to start the national education project.

A curricula committee was selected that included 13 members:

- Two U.S. experts from the PPSG
- The four coordinators of the branches of the Training and Resource Centre in Palliative Care, Hospice Casa Sperantei, from Bucharest, Cluj, Timisoara, and Constanta
- The president of the Pain Society
- The president of the National Palliative Care Association
- One representative from the National College of Physicians,
- One representative from the National College of Pharmacists
- One representative from the Ministry of Health Pharmaceutical Department
- One representative from the Postgraduate Training Centre, Ministry of Health
- One professor of pediatrics with a subspecialty in palliative care

The committee was responsible for drafting the curriculum and preparing the trainers' manual and the participants' handbook. In preparing the curriculum, the committee looked at different educational models (e.g., Wisconsin and Nigeria), as it was clearly a huge task to change attitudes. The committee chose interactive and case studies as their teaching methodology.

Table 1
Course Topics

Initial Evaluation	60 minutes
1. New regulations on distribution, rational prescribing, and dispensing of controlled medicines	90 minutes
2. Definition and pain classification	60 minutes
3. Pain evaluation	60 minutes
4. Opioid pharmacology	120 minutes
5. Chronic pain treatment in cancer. Therapeutic strategy. WHO ladder	120 minutes
6. Morphine myths	60 minutes
7. Routes of dosing	30 minutes
8. Opioid conversion	60 minutes
9. Opioid side effects	60 minutes
10. Co-analgesics	120 minutes
11. Particularities in pediatric evaluations and pain treatment	60 minutes
12. Pain treatment for the elderly	30 minutes
13. Particularities of patient-physician relations in the opioid treatment	30 minutes
14. Practical aspects in opioid prescribing	120 minutes
15. Opioid use for patients with renal and liver impairment	30 minutes
16. Educational resources	30 minutes
Final evaluation	60 minutes
Total no. of hours: 26 (Theory 20, Practice 6)	

The final curriculum for the training of physicians comprises 20 hours of classroom teaching on two consecutive weekends and six hours of clinical practice in each participant's own setting. The topics and time allocated to each subject are presented in Table 1. The courses are recognized by the Ministry of Health, which will issue a certificate, and are nationally accredited for continuing medical education credits by the College of Physicians and Pharmacists.

Forty trainers have been selected from the doctors who have completed the palliative care diploma course and who are also either accredited as trainers in palliative care or are academicians. Physicians with hands-on experience using opioids will serve as teachers for the courses. The course produced by the curricula committee was piloted on this group and adjusted accordingly.

In September 2006, 166 regulators and doctors from each district participated in

a national three-day strategic meeting. Following this meeting, representatives from the College of Physicians and Pharmacists and the Anti-Drug Agencies offered to contribute the locations, advertising, and administrative support for these courses. In June 2007, courses for physicians will be organized in 27 districts (shaded on the map) and in 30 districts for pharmacists (Fig. 1). The results of the education program will be monitored with pre- and post-tests and again six months after the training.

Conclusions

Changes to national drug policy in Romania were possible because of the cooperative efforts of local professionals, international experts, and national authorities. Any country facing the same problem of limited access due to restrictive legislation can use the WHO guidelines to change national opioid



Fig. 1. Districts where training programs will start with local support are indicated by dark gray and medium gray shading. Months indicate proposed start dates in 2007–2008. After publ-dates only available post publication of this article.

policy. Implementation of the new law is a critical step that cannot be overlooked to effectively improve patient access to opioid medication. The success of the educational program will be reflected in the increased medical use of opioids to relieve pain.

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