Original Article

A Systematic Content Analysis of Policy Barriers Impeding Access to Opioid Medication in Central and Eastern Europe: Results of ATOME

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Abstract

Context. Reliable access to opioid medication is critical to delivering effective pain management, adequate treatment of opioid dependence, and quality palliative care. However, more than 80% of the world population is estimated to be inadequately treated for pain because of difficulties in accessing opioids. Although barriers to opioid access are primarily associated with restrictive laws, regulations, and licensing requirements, a key problem that significantly limits opioid access relates to policy constraints.

Objectives. To identify and explore policy barriers to opioid access in 12 Eastern and Central European countries involved in the Access to Opioid Medication in Europe project, funded by the European Community's Seventh Framework (FP7/2007–2013, no. 222994) Programme.

Methods. A systematic content analysis of texts retrieved from documents (e.g., protocols of national problem analyses, strategic planning worksheets, and executive summaries) compiled, reviewed, approved, and submitted by either the Access to Opioid Medication in Europe consortium or the national country teams (comprising experts in pain management, harm reduction, and palliative care) between September 2011 and April 2014 was performed.

Results. Twenty-five policy barriers were identified (e.g., economic crisis, bureaucratic issues, lack of training initiatives, stigma, and discrimination), classified under four predetermined categories (financial/economic aspects and governmental support, formularies, education and training, and societal attitudes). Key barriers related to issues of funding allocation, affordability, knowledge, and fears associated with opioids.

Conclusion. Reducing barriers and improving access to opioids require policy reform at the governmental level with a set of action plans being formulated and concurrently implemented and aimed at different levels of social, education, and economic policy change. J Pain Symptom Manage 2016;51:99–107. © *2016 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.*

Key Words

Opioids, policy barriers, pain management, harm reduction, palliative care

Introduction

Opioid analgesics (opioids) are indispensable medicines for the management of moderate and acute severe pain related to advanced medical illness, and their use being considered as the standard of care in most of the world.[1,2] Reliable access to opioids is, therefore, critical to delivering effective pain management, adequate treatment of opioid dependence, and quality palliative care.[3,4]

However, it has been demonstrated that most patients in the developing world do not have access to opioids,[5–7] whereas, at country and regional levels,

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Accepted for publication: August 20, 2015.

0885-3924/$ - see front matter
http://dx.doi.org/10.1016/j.jpainsymman.2015.08.012

great disparities in the amount of morphine consumed between high-income and low- and middle-income countries are observed.[8,9] More than 80% of the world population has been estimated to be inadequately treated for pain, at least in part, because of difficulties in accessing opioid medication,[10] resulting in unnecessary suffering of patients and their families.[11] It also is estimated that improved access to pharmacological treatment of opioid dependence could prevent up to 130,000 new HIV infections as well as other blood-borne diseases, improve quality of life for people with substance use disorder, and have cost-effective benefits for the health care system.[12]

In 2010, an Opioid Policy Initiative, developed by the European Society for Medical Oncology and the European Association for Palliative Care to evaluate opioid accessibility for the management of cancer pain in Europe, reported on formulary deficiencies and excessive regulatory barriers that interfere with adequate pain relief and appropriate patient care.[13] Similarly, the Global Opioid Policy Initiative addressing the same issue in Africa, Asia, Latin America and the Caribbean, and the Middle East reported that opioid access is significantly impaired by severely restricted formularies and widespread overregulation.[14]

This evidence indicates that barriers to opioid access appear to be pandemic, multifaceted, and primarily associated with overly restrictive laws, regulations, and licensing requirements.[15] However, a key problem that considerably limits availability (level of distribution among populations and areas in need) and access (level of obtainment with the least possible regulatory, social, or psychological obstacles) to opioid medication worldwide relates to policy-related strategies aiming to implement new or to maintain existing provisions that are defined in laws and legally binding documents.[16–18] At the same time, information about aspects characterizing policy-related issues that might impede successful implementation of balanced legislation is underrepresented. This study addresses the issue of policy deficiencies, aiming to identify, explore, and report on policy-related barriers impeding opioid access in Central and Eastern Europe.

Methods

Study Design

This exploratory study is part of a project under the European Community's Seventh Framework Programme (FP7/2007–2013; under grant agreement no. 222994) aimed at improving access to opioid medication across Europe. Launched in December 2009, Access to Opioid Medication in Europe (ATOME) project aimed to address and explore the legal, regulatory, and policy barriers that impede access to morphine and other opioids for pain management, palliative care, and harm reduction in 12 Central and Eastern European countries (Bulgaria, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Serbia, Slovakia, Slovenia, and Turkey). During ATOME, several multicountry workshops (two six-country workshops held in Bucharest, Romania in 2011) and national events (ATOME national conferences hosted by each participating country) were implemented to ensure a sharing of experience and to undertake national situational analyses in the 12 participating countries. The design of these events was guided by the revised World Health Organization (WHO) policy guidelines as an important assessment and analysis tool.[16] Based on this framework, national policies and legislation affecting controlled medicines were reviewed, and strategies have been developed to overcome barriers and to achieve a balanced approach.[19] The main focus of this article is placed on the analysis of policy barriers.

Data Sources

Data comprised texts retrieved from documents compiled and submitted over the life span of ATOME (between September 2011 and April 2014). To ensure accurate and comprehensive reporting, five documents, reflecting the national situation with respect to opioid access, were set as the minimum requirement for a country to be included in this study as follows:

1. protocols of national problem analyses,
2. strategic planning worksheets,
3. minutes of ATOME six-country workshops,
4. minutes of ATOME national conferences,
5. executive summaries of country profiles.

These documents were drafted and submitted by either the research team, that is, ATOME delegates (reviewed and approved by the ATOME consortium) or by representatives of the national administration (reviewed and approved by the national country teams involved in ATOME comprising experts in pain management, harm reduction, and palliative care). Executive summaries containing information about opioid availability, pain management, palliative care, harm reduction, and highlights of challenges faced by each country in relation to opioid access are openly accessible reports on the ATOME Web site.[20] To maximize input, when possible, additional information also was retrieved from other documents compiled and submitted during ATOME such as press releases, e-mails, PowerPoint presentations, and blog posts.

Of the 12 countries involved in ATOME, 11 met the number of documents set as the minimum

requirement for inclusion in this study. Bulgaria was excluded from the current analysis.

Analysis and Interpretation

Texts were analyzed using thematic content analysis.[21,22] This approach involves a rigorous and systematic classification process of coding and identifying themes or patterns that emphasize the reliability and replicability of observations and subsequent interpretations and is particularly useful to classify, summarize, quantify, and tabulate qualitative data.[22]

An initial coding framework was developed comprising four main themes (financial/economic aspects and governmental support, formularies, education and training, and societal attitudes), adapted from the four main categories of barriers to opioid access identified in the literature (legislative and policy barriers, economic barriers, knowledge barriers, and attitude barriers).[23] This adaptation occurred in an attempt to 1) exclude legislative barriers that were already addressed and reported in previous ATOME research[24]; and 2) explore reported barriers under the scope of challenges necessitating economic, education, and social policy reform. *Formularies* were added as an extra coding theme to reflect barriers associated with formulas or methods adopted by individual countries based on established models/systems or approaches because the focus of ATOME was on all aspects of opioid medication supply and distribution.

The initial coding framework was independently applied to a sample of texts by E. P. and an independent expert in qualitative analyses. Results were compared, and this framework was refined into its final version through discussion and consensus. The final coding framework comprising 25 subthemes falling under the four main themes of the initial framework (for instance, insufficient funding for palliative care, economic crisis, bureaucratic issues, low adequacy, lack of training initiatives, fears, inadequate social dialogue, and dissemination) was submitted and approved by S. P. and L. R. This final framework was applied to all data, and the contents of each text were coded under the appropriate subtheme.

Data were inserted into a spreadsheet, providing a visual summary of the data set that allowed for explanations and patterns to be identified. This was a means of connecting the data with the primary research aim to identify and explore the policy barriers impeding access to opioids. To ensure explicit and comprehensive reporting, the COREQ (consolidated criteria for reporting qualitative research) checklist was used.[25]

Results

Financial/Economic Aspects and Governmental Support

The major barriers related to financial/economic aspects and governmental support considered to impede opioid access in most countries were associated with insufficient funding for palliative care ($n = 9$) and harm reduction initiatives ($n = 8$; Fig. 1). The impact of economic recession as well as the lack of governmental support (of noneconomic nature) also were identified as barriers to opioid access in almost half of the countries ($n = 5$) involved in ATOME. Finally, in some countries ($n = 3$) the governmental commitment/endorsement appeared to be more focused on diverse economic priorities rather than on the development, extension, or promotion of effective standards for opioid treatment.

Formularies

Related to formularies (Fig. 2), issues of affordability (high cost and/or inadequate reimbursement)

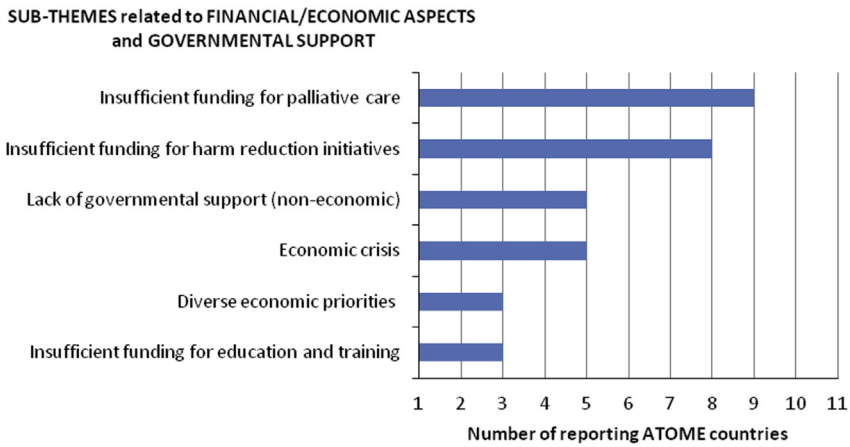

Fig. 1. Barriers identified related to financial/economic aspects and governmental support. ATOME = Access to Opioid Medication in Europe.

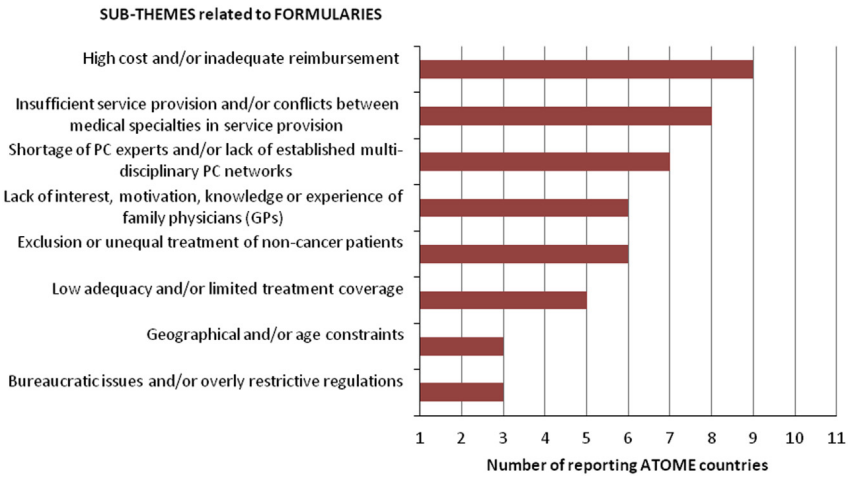

Fig. 2. Barriers identified related to formularies. PC = palliative care; GPs = general practitioners; ATOME = Access to Opioid Medication in Europe.

were reported as major impediments to opioid access in most countries ($n = 9$), followed by issues of service provision (insufficient service provision and/or conflicts between medical specialties in service provision; $n = 8$). The shortage of palliative care experts and the lack of established multidisciplinary palliative care networks also were identified as key barriers to opioid access in more than half of the countries ($n = 7$) involved in ATOME. Finally, barriers such as bureaucracy or overly restrictive regulations as well as geographical or age constraints were observed in a minority of countries ($n = 3$).

Education and Training

In relation to education and training (Fig. 3), barriers related to lack of training initiatives and absent, limited, or fragmented postgraduate education were identified in all countries ($n = 11$), followed by countries in which similar issues were observed in undergraduate education ($n = 10$). Absent or inadequate continuing medical education was reported as a barrier to opioid access in more than half of the countries ($n = 6$) involved in ATOME, whereas in some countries ($n = 4$), the lack of a multidisciplinary (network) approach to education also was identified as a major impediment to opioid access.

Societal Attitudes

Related to societal attitudes (Fig. 4), fears associated with opioids (fear of dependence, tolerance, diversion, and death), inadequate social dialogue and dissemination (of information and advice), and lack of awareness (misinformation and misconceptions) about the use of opioids in pain management, palliative care, and harm reduction were identified as major impediments to opioid access in all countries ($n = 11$). Stigma and discrimination (prejudice, cultural stereotypes, and skepticism) also were reported as key barriers to opioid access in most countries ($n = 10$), followed by lack of knowledge

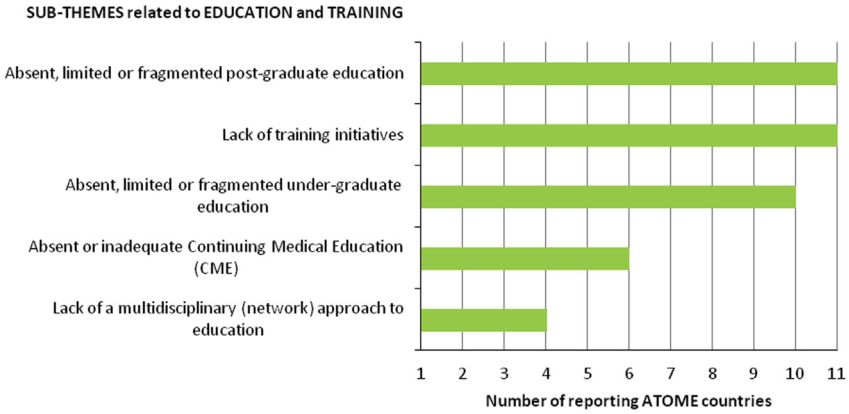

Fig. 3. Barriers identified related to education and training. ATOME = Access to Opioid Medication in Europe.

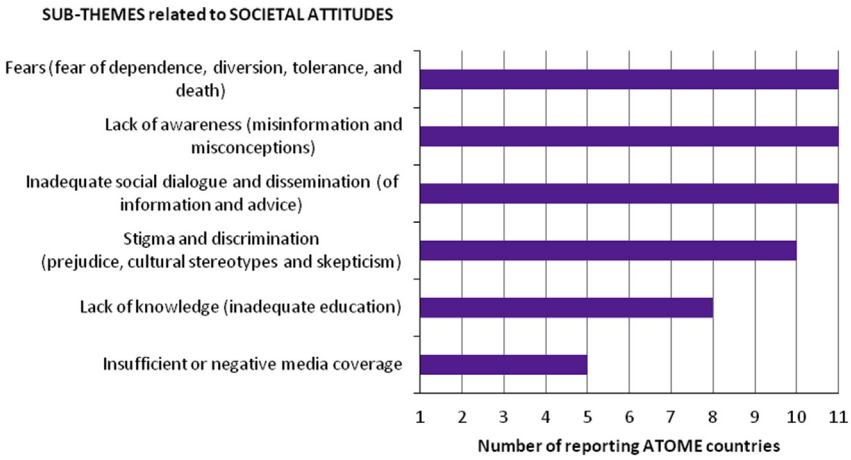

Fig. 4. Barriers identified related to societal attitudes. ATOME = Access to Opioid Medication in Europe.

(as a result of inadequate education; $n = 8$) and insufficient or negative media coverage observed in almost half of the countries ($n = 5$) involved in ATOME.

Overall, the most dominant policy barriers to opioid access in the countries of Central and Eastern Europe involved in ATOME appeared to be those relating to societal attitudes (40%), followed by barriers associated with education and training (27%) and formularies (19%). Policy barriers related to financial and economic aspects, contrary to what one might expect given the conditions of economic instability currently prevailing in Europe, ranked last in the list of identified barriers impeding opioid access (14%; Fig. 5).

Discussion

This study aimed to identify and explore policy barriers that impede access to opioid medication in Central and Eastern Europe. Evidence reveals that critical barriers requiring policy reform at the governmental level relate to issues of funding allocation, affordability, knowledge, and fears of opioids. Additionally, in line with what the literature suggests, most barriers appear to exist simultaneously and be interrelated, that is, they interact and maintain each other.[23]

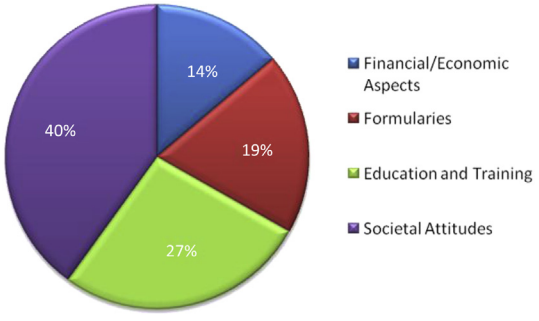

Fig. 5. Rate (%) of policy barriers identified per main theme.

Funding Allocation

Allocation of funding was reported as the key economic barrier to opioid access for most countries in our study. This might be causally associated with the economic crisis that was concurrently experienced by a number of European countries or the decision of some countries to financially invest in other focus areas of health care and well-being, although such barriers were not as frequently reported as major impediments to opioid access. Still, this finding could be perceived as an indication that pain management, both within and outside the context of palliative care, and treatment of opioid dependence do not seem to attract adequate attention. A recently updated systematic review indicated that economic level was a major determinant of quality of cancer pain management.[26] Although access to pain medicines and palliative care is an element of the right to the highest attainable standard of physical and mental health, a human right as laid down in United Nations conventions;[27–30] our evidence indicates low prioritization of pain management and palliation on national health care agendas. This situation applies even to countries where pain education features in the core curriculum in medical schools, and palliative care has been granted official specialty or subspecialty status.[31] Similarly, although several developments occurred acknowledging harm reduction as an important factor for public health (e.g., finalized HIV strategies and national programs that include harm

reduction activities), there is, at least in part, stagnation of governmental attention to harm reduction initiatives represented by insufficient allocation of new funds for strengthening and extending available programs.[18,32] Despite the fact that opioid agonist therapy in combination with psychosocial support is known as the most effective currently available treatment of opioid dependence, and despite evidence that expenditures on treatment of opioid dependence result in saving costs associated with crime, health, and social productivity (between 3:1 and 13:1),[33] our study confirms what the literature indicates, that people with substance use disorder (especially those in prisons or rural areas) are still not able to adequately access their right to the highest attainable standard of physical and mental health because of governmental financial neglect.[18]

Affordability

Although the lack of attention to pain management and palliation could be used to explain the shortage of palliative care experts or the lack of established multidisciplinary palliative care networks reported as critical barriers to opioid access in more than half of the participating countries, issues of affordability (high cost and inadequate reimbursement) were the ones persisting in terms of formularies. Affordability refers to the degree to which a medicine is obtainable for those who need it at the time of need at a cost that does not expose them to the risk of serious negative consequences such as not being able to satisfy other basic human needs.[16,23] In this respect, overly high prices and failure to adequately reimburse opioid treatment are common issues that can hamper access to opioid medication. These issues can result in fewer people being able to afford opioid treatment, leading to exclusion or unequal treatment and insufficient service provision, both reported as major impediments to opioid access in more than half of the countries in our study. Affected groups could be patients with a low income or those with noncancer pain for whom opioid treatment is either not acknowledged in the regulatory framework or not reimbursed. For people with substance use disorder, insufficient provision of free-of-charge treatment results in long waiting lists and dropouts.[18] A recent cross-sectional pilot study to monitor availability, dispensed prices, and affordability of opioids around the globe points to the need to continue efforts at improving availability and affordability of opioid medication especially for patients in low- and middle-income countries for whom opioid access is fairly limited.[34] Still, affordability remains one of the main barriers to accessibility and, as a result, any issues related to affordability need to be further explored.

Knowledge of Opioids

Health care professional knowledge is perhaps the most critical barrier to opioid access in terms of education and training described by all countries in our study. In accordance with this, insufficient understanding of how to use opioid analgesics adequately has been widely reported as a barrier to opioid access.[35–37] Health care professional knowledge about opioids frequently appears to be quite problematic, as many schools of medicine and pharmacy have either no time or very limited time included in their curricula for pain management and palliative medicine.[38] Evidence from APPEAL (Advancing the Provision of Pain Education and Learning), the first ever Europewide review of pain education, confirmed that pain topics are poorly documented in undergraduate medical curricula, with pain teaching being inconsistent and variable and only a peripheral part of undergraduate medical teaching.[39] Hence, absent, limited, or fragmented education and lack of training initiatives can result in professionals being reluctant, uncertain, or disinclined to prescribe opioids.[40,41] In addition, literature suggests that inadequate knowledge can allow space for false beliefs and misconceptions among health care workers—for instance, with regard to the development of dependence syndrome or imminent death associated with opioid treatment.[42] However, a systematic review could not produce convincing evidence for dependence syndrome resulting from opioid prescription and concluded that it is not justified to withhold treatment from patients because of this fear.[43] In addition, empirical evidence suggests that opioids do not hasten death in palliative care patients and that adequate relief from pain improves quality of life and may even prolong survival.[44–46]

Fear of Opioids

The previously mentioned misconceptions and misinformation surrounding opioid treatment and other types of fears (fear of diversion, tolerance, and death) persevered in the identified barriers related to societal attitudes. Literature suggests that attitudes that prevent adequate use of opioid medication among health care professionals also can be observed among patients and their families.[47,48] Fear of opioids can be directly associated with lack of awareness in the sense that these barriers interact and maintain each other. It also can be perceived as the source of stigma and discrimination (prejudice, cultural stereotypes, and skepticism) against patients receiving opioid treatment, especially those participating in harm reduction initiatives.[32,49,50] Although fear of opioids has been frequently studied and reported as a major impediment to opioid access,[51–53]

inadequate social dialogue and insufficient dissemination of information and advice about the benefits as well as the potential risks/harms of opioid use were still reported as a barrier by all countries in our study. Hence, further research is necessary to develop feasible solutions for patient and public access to unprejudiced information about the use of opioids for medical treatment and their consequences for public health outcomes.

Study Limitations

This study has a number of limitations. First, the policy barriers identified to have an impact on access to opioid medication were reported for individual countries strictly on the basis of the data developed and collected during the project lifetime. However, the amount of available data varied between countries. Some country teams may have more intensively tried to identify policy barriers than other teams. In this respect, if a particular barrier was not identified or directly reported in some countries, this does not necessarily mean that it is nonexistent. Lack of reporting of any barrier might even mean that there is a lack of awareness or unwillingness to acknowledge barriers by the country team. Second, given the different dates that documents were compiled and submitted by each individual country team, some of the information might not be directly comparable. An attempt to counterbalance this was made by asking the country teams to review, update, and approve the findings from the analysis of policy barriers derived from the documents that were used in this study. Third, there may be inaccuracies in the minutes of the ATOME national conferences and the six-country workshops (two of the documents set as the minimum requirement for inclusion). However, to counterbalance this, minutes were recorded by two ATOME delegates when possible and were reviewed and approved by the ATOME consortium.

Conclusion

This study showed that the most critical policy barriers impeding opioid access in Central and Eastern Europe relate to issues of funding allocation, affordability, knowledge, and fear of opioids. Reducing barriers and improving access to opioids require policy reform at the governmental level. Given the interdependent nature of policy barriers, interacting and maintaining each other, a series of action plans needs to be formulated and concurrently implemented and aimed at different levels of social, education, and economic policy.

To start with, policies to promote social reform (societal attitudes being the most dominant policy barrier observed in this study) should include open societal dialogue, better dissemination of information, and advice concerning the benefits from the use of opioids for pain relief, opioid dependence, and palliative care, and wider and more positive media coverage. This could assist to break down stereotypes and misconceptions, increase awareness, and minimize fears, stigma, and discrimination against opioid use that are seen to currently persist among patients, families, and the public as well as health care professionals.

Better education and more training initiatives aimed at enhancing knowledge and expertise of health care professionals and other stakeholders (e.g., managers of health care services, health information technicians, and assistive personnel) could further contribute to reducing fears, prejudice, and skepticism associated with the use of opioid medicines for pain relief and drug dependence treatment. National strategies are needed to improve the communication and dissemination of up-to-date information between health care professionals, decision makers, and lay people. This could be achieved by introducing pain education, substance misuse, and palliative care as core modules in undergraduate medical curricula as well as part of continuing medical education and training to support professional development of health care providers.

Finally, the action plans necessary to bring about policy reform to reduce barriers and improve opioid access could be more easily launched if pain management and palliative care were strengthened as components of integrated treatment throughout the life course, and opioid agonist therapy service provision was considered as appropriate to improve public health outcomes.

Although critical revision of legislation is considered to be the first step toward a balance between ensuring access to opioid medication and preventing abuse in national policies, our study shows that supportive policy frameworks are important for successful implementation of adequate legislation. The purpose of our study was to describe various manifestations of the main policy-related barriers including economic, educational, and sociocultural elements from the perspective of national representatives of the ATOME countries. Allocation of main barriers into smaller subthemes might enable the development of more goal-orientated and effective solutions. In addition, our findings show that the subthemes pertaining to societal attitudes have a central role within the interdependent barriers to opioid access. This indicates the priority for further research in this area to provide guidance on how to achieve a balanced approach in national policies on controlled substances.

Disclosures and Acknowledgments

The research leading to these results received funding from the European Community's Seventh Framework Programme (FP7/2007–2013) under grant agreement no. 222994 with the overall aim to improve the access to opioid medication in Europe. The authors declare no conflicts of interest.

The authors thank all national authorities, speakers, and experts who contributed to the ATOME workshops and national follow-up conferences and to the representatives of all country teams for their commitment, support, and fruitful collaboration throughout the ATOME project. Without their contribution, this study would not have been possible.

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