

## Original Article

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

Eugenia Larjow, MA, Evangelia Papavasiliou, PhD, Sheila Payne, PhD, Willem Scholten, PharmD, MPA, and Lukas Radbruch, MD

Department of Palliative Medicine (E.L., L.R.), University Hospital Bonn, Bonn, Germany; International Observatory on End of Life Care (E.P., S.P.), Lancaster University, Lancaster, United Kingdom; Willem Scholten Consultancy (W.S.), Lopik, The Netherlands; and Palliative Care Centre (L.R.), Malteser Hospital Bonn/Rhein-Sieg, Bonn, Germany

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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

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## 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.<sup>1,2</sup> Reliable access to opioids is,

therefore, critical to delivering effective pain management, adequate treatment of opioid dependence, and quality palliative care.<sup>3,4</sup>

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

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Address correspondence to: Sheila Payne, PhD, International Observatory on End-of-Life Care, Division of Health Research, Faculty of Health and Medicine, Lancaster

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University, Lancaster LA1 4YG, United Kingdom. E-mail: [s.a.payne@lancaster.ac.uk](mailto:s.a.payne@lancaster.ac.uk)

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great disparities in the amount of morphine consumed between high-income and low- and middle-income countries are observed.<sup>8,9</sup> 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,<sup>10</sup> resulting in unnecessary suffering of patients and their families.<sup>11</sup> 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.<sup>12</sup>

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.<sup>13</sup> 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.<sup>14</sup>

This evidence indicates that barriers to opioid access appear to be pandemic, multifaceted, and primarily associated with overly restrictive laws, regulations, and licensing requirements.<sup>15</sup> 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.<sup>16–18</sup> 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.<sup>16</sup> 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.<sup>19</sup> 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.<sup>20</sup> 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

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