

# **How to Overcome Barriers to Adequate Pain Management in Ukraine**

*by Olena Stetskevych*

Thesis submitted to  
The University of Ottawa, Faculty of Graduate and Postdoctoral Studies  
in partial fulfillment of the requirements for the degree of

**Master of Laws**

Faculty of Law, University of Ottawa  
Ottawa, Ontario, Canada  
January 2015

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## **Acknowledgements**

This interdisciplinary study could not have been accomplished without perfect guidance of my supervisor Professor Amir Attaran. I deeply appreciate his immense investment of time, effort and care to provide advice and comments. I am grateful for his teaching me a lot of things and for his belief in my ability to undertake this research project. I am also appreciative to Professor Attaran for supporting my travels to Ukraine to collect the necessary evidence and to attend scientific conferences on the research issues. I am very thankful to other professors and staff members, particularly to the Faculty of Graduate Studies in Law and the University of Ottawa Ethics Board for their great support with this research project.

I am deeply grateful to my family for their continued support in my endeavour to write this paper. Particularly, to my husband Viktor, who put aside his professional interests and continuing education for the period of this study. He created the conditions for which I could accomplish this thesis. I want to say most special words of gratitude to my little son Misha, who has been my inspiration, and who as a baby had to travel with me overseas to collect data for the research.

I am also very thankful to the Ukrainian doctors who participated in this study. I particularly appreciate the efforts of Vladimir Romanenko (Ukrainian doctor-neurologist, member of the Ukrainian Chapter of the International Association of the Study of Pain) and Yurii Kuchin (Ukrainian doctor-anaesthesiologist, Head of the Association of the Anaesthesiologists of Ukraine), who helped me collect data by distributing the Questionnaire on Barriers to Pain Control to the health professionals.

I want to thank everyone who contributed to this research, who supported me and who wished good things.

Thank you!

Olena Stetskevych

## **Abstract**

There is a large gap between contemporary evidence-based remedies for pain control and what is offered to Ukrainian patients with pain. Having thousands of people needlessly suffer from avoidable pain forces a consideration of 1) what prevents from their access to pain relief, 2) are their human rights being violated and 3) how can the situation be improved.

In order to identify the obstacles to adequate pain management in Ukraine I collected evidence using two methods. First, I designed a questionnaire for the Ukrainian doctors, received approval from the University of Ottawa Ethics Board, distributed the questionnaire among potential responders and then organized the obtained results. Second, I did an extensive literature review to provide evidence from the patients. Then I analysed the provisions of Ukrainian domestic and international legislation as well as the available case law to find out if the human rights of Ukrainian patients and doctors are being violated by denial of adequate pain relief.

According to my findings, the barriers to pain control in Ukraine are multidimensional and interdependent. They cause violations of human rights, which are not being effectively defended through the courts of Ukraine. These findings call for a more constructive approach to the development of the Ukrainian health law and policy, which I offer in this thesis.

## **List of Acronyms**

CAT – Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment

ECAT – European Convention on Prevention of Torture and Inhuman or Degrading Treatment or Punishment

ECPHRFF - European Convention for the Protection of Human Rights and Fundamental Freedoms

GDP – Gross Domestic Product

HRW – Human Rights Watch

IASP – International Association for the Study of Pain

ICCPR – International Covenant on Civil and Political Rights

ICESCR – International Covenant on Economic, Social and Cultural Rights

INCB – International Narcotics Control Board

IRF – International Renaissance Foundation

UDHR – Universal Declaration of Human Rights

WHO – World Health Organization

## **A Note on Sources**

1. In the present paper many sources in Russian and Ukrainian languages were used, with no official translation available. Where this was the case, the translation into English was provided by the author. The present note is made in order to avoid multiple notes throughout the Thesis, indicating that the quote was translated by the author, as required by the McGill protocol.
  
2. The author created footnotes and bibliography with a view to follow the rules of McGill Guide. At the same time, citing particularly foreign sources in Russian and Ukrainian languages, as well as many international sources, did not always fit the McGill protocol. Specifically, the McGill Guide requires the name of the source in the original language. However, using the name in Russian or Ukrainian would disable the English-speaking readers from finding the sources and understanding their origin. This relates particularly to the acts in Ukrainian legislation and jurisprudence, which have characteristics different to North-American legislative acts. Also, foreign and international sources do not always provide pieces of information, necessary to create references in adherence to the McGill protocol. Therefore, I tried to keep the format of the citations close to the requirement of the McGill Guide, providing the necessary information for readers to access the sources cited.

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**Appendix # 1. Answers to the Questionnaire on Barriers to Pain Management in Ukraine**

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## Introduction

### *Background*

In Ukraine, with a population of nearly 45 million,<sup>1</sup> almost five hundred thousand people need palliative care each year,<sup>2</sup> but only about 5% of them receive adequate pain treatment and professional care.<sup>3</sup> Although modern medicine offers different remedies to treat pain,<sup>4</sup> many patients require opioid analgesics as essential medication to relieve the pain.<sup>5</sup> While contemporary advancement in medical knowledge and care offers adequate treatment for pain<sup>6</sup> by rather inexpensive medicine,<sup>7</sup> Ukrainian patients continue to suffer needlessly from untreated or ineffectively treated pain.<sup>8</sup>

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<sup>1</sup> See World Population by Country, Ukraine, online: Worldometers <<http://www.worldometers.info/world-population/>>.

<sup>2</sup> See Human Rights Watch (HRW), “Uncontrolled Pain: Ukraine’s Obligation to Ensure Evidence-Based Palliative Care” Report (May 2011) at 8, online: <<http://www.hrw.org/sites/default/files/reports/ukraine0511WebRevised.pdf>> [HRW Uncontrolled Pain]; see also Open Society Foundations Public Health Program, “Access to Palliative Care: A Neglected Component of The Right to Health”, a Report on the Human Rights Council Side Event, (Geneva, 6 June 2011) at 12, online: <<http://www.opensocietyfoundations.org/sites/default/files/access-palliative-care-20130311.pdf>>.

<sup>3</sup> See “In Lviv region the quantity of hospice beds is ten times less than needed” (“На Львівщині кількість хоспісних ліжок вдсятеро нижча від потреби”) (12 October 2012), online: Galinfo <<http://www.galinfo.com.ua/news/119530.html>>; for more general information see also Tahla Khan Burki, “Ukraine Failing to Provide Evidence-Based Palliative Care” (24 September 2011) 378:9797 the Lancet 1130, online: The Lancet <[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(11\)61493-1/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)61493-1/fulltext)>.

<sup>4</sup> World Health Organization (WHO), Normative Guidelines on Pain Management (Geneva, June 2007), online: WHO <[http://www.who.int/medicines/areas/quality\\_safety/delphi\\_study\\_pain\\_guidelines.pdf](http://www.who.int/medicines/areas/quality_safety/delphi_study_pain_guidelines.pdf)>; see also Nicholas B. King and Veronique Fraser, “Untreated Pain, Narcotics Regulation, and Global Health Ideologies” (April 2013) 10: 4 PLoS Medicine, online: PLoS Medicine. <<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3614505/>>; see also The Free Dictionary, Pain Management Definition, online: <<http://medical-dictionary.thefreedictionary.com/pain+management>>.

<sup>5</sup> HRW Uncontrolled Pain, *supra* note 2 at 8; see also N.I. Cherny et al., “Formulary Availability and Regulatory Barriers to Accessibility of Opioids for Cancer Pain in Europe: a Report from the ESMO/EAPC Opioid Policy Initiative”, online: (2010) 21:3 Annals of Oncology 615, <<http://annonc.oxfordjournals.org/content/21/3/615.full>>.

<sup>6</sup> See International Narcotics Control Board (INCB), “Availability of Opiates for Medical Needs” in Report of the International Narcotics Control Board for 1995, United Nations (1996); see also WHO, “Achieving Balance in National Opioids Control Policy: Guidelines for Assessment” (2000); see also Canadian Pain Society, “Position Statement on Pain Treatment as a Human Right” of the Canadian Chapter of International Association of the Study of Pain, online: The Canadian Pain Society <[http://www.canadianpainsociety.ca/en/about\\_policy.html](http://www.canadianpainsociety.ca/en/about_policy.html)>.

<sup>7</sup> See, e.g., Open Society Foundations, “Palliative Care as a Human Right” Public Health Fact Sheet (May 2011), online: <<http://www.opensocietyfoundations.org/sites/default/files/palliative-care-human-right-20110524.pdf>> (“[s]evere pain can be effectively managed with inexpensive oral morphine.”)

<sup>8</sup> Andrew Rokhansky et al., *We have the right to live without pain and suffering (Мы имеем право жить без боли и страданий)*. The Report of the human rights organizations on observance of the rights of palliative patients in Ukraine, by Olga Lubyana (Kyiv, Publishing House “Kalyta”, 2012) at 83, online: <<http://library.khpg.org/files/docs/1352804089.pdf>>.

Besides terminal patients, pain management is paramount for patients with curable diseases and conditions like pre- and post-operative cases, traumas, injuries, exacerbation of chronic conditions, labour-related conditions, etc. However, there is currently no reliable data or estimate of the number of curable patients in need of pain medication in Ukraine. Research attention is mainly given to the problems of pain relief for terminal patients, mainly those who suffer from cancer. This indicates that the Ukrainian pain relief problem is definitely large, but the scale of it has not yet been accurately defined or recorded.

### ***Problematic and the Initiatives for Solving the Issue***

There is the social aspect of the use of narcotic medicines, which can be also used as illegal recreational drugs and for non-medical purposes, causing drug addiction and leading to personal degradation and social disruption.<sup>9</sup> Although this is an issue of grave concern for governments and agencies, the threat of addiction can neither excuse nor justify leaving patients suffering without necessary analgesia. That is why both prevention of drug abuse and ensuring adequate pain control are recognized in the Single Convention on Narcotic Drugs (*hereafter referred to as “Single Convention”*) as equally important matters.<sup>10</sup> However, arguably current Ukrainian legislation provides far more coverage to prohibit illegal use of drugs than to ensure legitimate access to them for medical purposes. This imbalance transpired even in the recent adoption by the Ukrainian government of the “Strategy of state policy regarding drugs for the period till 2020”,<sup>11</sup> where there is no initiative to work out a policy on pain management.

Although pain is the most common problem leading people to seek medical care,<sup>12</sup> for decades the problem has been seriously underestimated in Ukraine. Only recently was the issue of adequate medical response to people suffering from pain in Ukraine brought up for public scrutiny. Human Rights Watch played a significant role in recognizing the

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<sup>9</sup> Single Convention on Narcotic Drugs, 30 March 1961, 520 UNTS 204;18 UST 1407;14 ILM 302 (1975) at Resolution III, “Social Conditions and Protection Against Drug Addiction”, online: United Nations <[http://www.unodc.org/pdf/convention\\_1961\\_en.pdf](http://www.unodc.org/pdf/convention_1961_en.pdf)>.

<sup>10</sup> *Ibid* at Preamble.

<sup>11</sup> Order of the Cabinet of Ministers of Ukraine “On approval of the Strategy of state policy regarding narcotics for the period till year 2020” (“Про схвалення Стратегії державної політики щодо наркотиків на період до 2020 року”) 735-р, 28 August 2013, online: Rada <<http://zakon2.rada.gov.ua/laws/show/735-2013-%D1%80>> [Order 735-p].

<sup>12</sup> See Scott M. Fishman, “Recognizing Pain Management as a Human Right: a First Step” (2007) 105:1 *Anesthesia & Analgesia* 8 at 8; see also Kathleen M. Foley et al., “Pain Control for People with Cancer and AIDS” in *Disease Control Priorities in Developing Countries*, 2nd ed. (Washington, 2006) at 981-993, online: NCBI <<http://www.ncbi.nlm.nih.gov/books/NBK11800/pdf/ch52.pdf>>.

problem with its report, “Uncontrolled Pain: Ukraine’s Obligation to Ensure Evidence-Based Palliative Care” (*hereafter referred to as HRW Report or HRW Report “Uncontrolled Pain”*),<sup>13</sup> which revealed a systematic failure of the Ukrainian healthcare system to ensure pain relief for terminally ill patients. Additionally, the All-Ukrainian Council for Patients’ Rights and Safety<sup>14</sup> was among the pioneers that raised awareness on the importance of pain control in Ukraine, by bringing the issue into open debate and encouraging a new approach for consideration, the perspective of human rights. In December 2010 the Ukrainian League of Contribution to the Development of Palliative and Hospice Care<sup>15</sup> was created to promote the right to palliative care as part of the right to health and to advocate the need to ease the access of terminal patients to opioid analgesics in order to control their pain and to allow them to die with dignity. Public attention is now being professionally fostered by the International Renaissance Foundation’s<sup>16</sup> special campaign named “StopPain”.<sup>17</sup> The program aims at promoting the concept of pain relief as a human right and improving access to pain management in palliative care, mainly by ensuring reasonable access to opioid pain relievers. In addition, in order to advocate the right to pain control and to promote this concept among Ukrainian healthcare providers, earlier in 2013 a Committee on Legal Issues was created within the Ukrainian Chapter of the International Association of the Study of Pain (*hereafter referred to as IASP*).<sup>18</sup> This is an advisory body, created to coordinate a dialogue between Ukrainian healthcare practitioners and lawyers in order to address the challenge of adequate pain control for all patients, without unnecessary and unreasonable hardships.

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<sup>13</sup> HRW Uncontrolled Pain, *supra* note 2.

<sup>14</sup> All-Ukrainian Council for Patients’ Rights and Safety (Рада захисту прав та безпеки пацієнтів), online: Medrada <<http://www.medrada.org>>.

<sup>15</sup> Ukrainian League of Contribution to the Development of Palliative and Hospice Care (Українська ліга сприяння паліативної та хоспісної допомоги), online: Ligalife <<http://www.ligalife.com.ua>>.

<sup>16</sup> The International Renaissance Fund (IRF) is one of the Open Society Foundations, established for the promotion of the values of democracy through the issues of education, governance and accountability, healthcare, human rights and justice, etc. More information may be found at the IRF official web-site, online: Open Society Foundation <<http://www.opensocietyfoundations.org/about/offices-foundations/international-renaissance-foundation>>.

<sup>17</sup> “StopPain” (“StopБіль”) Initiative of Caring People, funded by the IRF (See *supra* note 16), online: StopBil <<http://www.stopbil.in.ua>>.

<sup>18</sup> International Association for the Study of Pain (IASP), Ukrainian Chapter, online: IASP <<http://www.iasp-pain.org/AM/Template.cfm?Section=Chapters&Template=/CM/HTMLDisplay.cfm&ContentID=11716>>; see more specifically about the Committee on Legal Issues, IASP, Ukrainian Chapter, online: <<http://www.pain.in.ua/uasp/committees/law-committee>>.

### ***Achievements in Solving the Problem***

In July 2011 the term “*palliative care*” as a component to medical care guaranteed to every Ukrainian has been incorporated into the Ukrainian legislation.<sup>19</sup> In February 2013 the Ministry of Healthcare of Ukraine issued Order 77,<sup>20</sup> which included oral morphine in the list of essential medicines in Ukraine. Moreover, in May 2013, Decree 333<sup>21</sup> has been adopted, which offers less restrictive rules for the use of opioids in medical practices in Ukraine. Arguably, these achievements were reached with significant efforts by the NGOs, together with patients, social activists and human rights defenders, who advocated improved access to pain relief at the government level.

### ***Research Questions and the Purpose of the Research***

However, while important steps forward have recently been made, thousands of Ukrainian patients continue to remain deprived of medication for the treatment of pain. First of all, if people are suffering needlessly from pain that could be treated by relatively inexpensive, evidence-based medical remedies, then there is a need to explore certain barriers to patients’ reasonable access to these remedies. Second, the idea that denial of pain treatment violates human rights has been brought up in several studies.<sup>22</sup> If so, there is a need to learn if the rights of Ukrainian patients are being violated by the denial of pain control and if so, then close attention must be paid to how the courts of Ukraine are

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<sup>19</sup> Law of Ukraine, “Basics of the legislation of Ukraine on health care” (“Основи законодавства України про охорону здоров’я”) 2801-XII, 19 November 1992, online: Rada <<http://zakon4.rada.gov.ua/laws/show/2801-12>> [Law 2801-XII].

<sup>20</sup> Order of the Ministry of Healthcare of Ukraine, “On state registration (reregistration) of medicinal products and introduction of amendments to the registration materials” (“Про державну реєстрацію (перереєстрацію) лікарських засобів та внесення змін до реєстраційних матеріалів”) 77, 1 February 2013, online: <[http://www.moz.gov.ua/ua/portal/dn\\_20130201\\_0077.html](http://www.moz.gov.ua/ua/portal/dn_20130201_0077.html)>.

<sup>21</sup> Decree of the Cabinet of Ministers of Ukraine, “On the adoption of the Regulation on purchase, transportation, storage, dispensation, and utilisation of narcotic drugs, psychotropic substances and precursors in the healthcare system” (“Про затвердження Порядку придбання, перевезення, зберігання, відпуску, використання та знищення наркотичних засобів, психотропних речовин і прекурсорів у закладах охорони здоров’я”) 333, 13 May 2013, online: Rada <<http://zakon2.rada.gov.ua/laws/show/333-2013-п>> [Decree 333].

<sup>22</sup> See International Association of the Study of Pain (IASP), “Pain Relief as a Human Right” (September 2004) 7:5 Pain: Clinical Updates, available online: <http://www.iasp-pain.org/AM/AMTemplate.cfm?Section=HOME&CONTENTID=7636&TEMPLATE=/CM/ContentDisplay.cfm&SECTION=HOME>; see also e.g. Frank Brennan, Daniel B. Carr and Michael Cousins, “Pain Management: A Fundamental Human Right” (2007) 105:1 Anesthesia and Analgesia 205; see also Frank Brennan, “Palliative Care as a Human Right” (2007) 33:5 Journal of Pain and Symptom Management 494; see also e.g. Fishman, *supra* note 12; consider also “Please Do Not Make Us Suffer Any More...”: Access to Pain Treatment as a Human Right”; see also HRW Uncontrolled Pain, *supra* note 2 ; see also Diederik Lohman, Rebecca Shleifer and Joseph J. Amon “Access to Pain Treatment as a Human Right” (2010) 8:8 BMC Medicine, online: <<http://www.biomedcentral.com/1741-7015/8/8>>.

responding to the violations with their rulings. Last, it is important to consider how the situation with pain management in Ukraine can be improved and what role the law can play in settling the issue of inadequate patient pain control in Ukraine. The present research aims at identifying and organizing the main arguments from theoretical standpoints and practical examples that constitute barriers to adequate access to reasonable and evidence-based pain management in Ukraine and offering ways to overcome them, mainly through changing the Ukrainian legislation and by using already available legislative remedies.

### ***Methodology***

To identify the barriers to adequate pain control in Ukraine it was necessary to gather evidence from Ukrainian patients and doctors and to study the current regulations of the use of controlled substances, as well as the matters of access to other medicines for the relief of pain. The extensive literature review provided much evidence about how inadequate access to pain control affects the lives and well-being of the Ukrainian patients and their families. At the same time the available sources only randomly elucidated the practical hardships faced by Ukrainian doctors in introducing analgesia to their patients. Therefore, I designed a Questionnaire for Ukrainian healthcare providers on the challenges of providing pain control from their professional perspectives. The Questionnaire was approved by the Ethics Board of the University of Ottawa.<sup>23</sup> With the help of the Ukrainian Chapter of the International Association of the Study of Pain (IASP)<sup>24</sup> and the Association of Anaesthesiologists of Kyiv,<sup>25</sup> I distributed the Questionnaire among Ukrainian doctors of different specializations through e-mail lists of these organizations as well as during my participation at the scientific conferences on matters of pain control conducted by these organizations in Ukraine.<sup>26</sup> My goal was not just to recruit as many doctors as possible, but rather to gather evidence from health professionals of various specializations and from different regions of the country. There

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<sup>23</sup> University of Ottawa Ethics Board Approval Notice, April 4<sup>th</sup>, 2013, file # 02-13-14.

<sup>24</sup> Ukrainian Chapter of the International Association of the Study of Pain (IASP), online: [IASP <http://www.iasp-pain.org/am/template.cfm?Section=Home>](http://www.iasp-pain.org/am/template.cfm?Section=Home).

<sup>25</sup> Association of Anaesthesiologists of Kyiv, online: [<http://criticalcare.kiev.ua/>](http://criticalcare.kiev.ua/).

<sup>26</sup> All-Ukrainian research-to-practice conference with international participation on “Implementation of standards of palliative care” (Kyiv, Ukraine, Sept. 26-28, 2012), information available at official website of the Ministry of Healthcare of Ukraine, online: [http://www.moz.gov.ua/ua/portal/pre\\_20130930\\_e.html](http://www.moz.gov.ua/ua/portal/pre_20130930_e.html) [Conference on Palliative Care]; also East-European Congress on Pain (Yalta, Ukraine, Sept. 18-21, 2013), online information: <http://www.paincongress.com.ua/en/general-info/how-it-was> [East-European Congress on Pain].

are published research papers based on surveys with relatively small number of participants,<sup>27</sup> which support my position. Such an approach allowed me to obtain confirmation of the evidence from other sources (books, journals and newspaper articles, press releases, etc.) and to verify that the difficulties described in those sources relate to all Ukrainian regions and fields of medicine.

Basically, inadequacy of pain control derives from the analysis of legislative regulations of related issues, which I provide in this thesis. Doctors' answers support concerns related to the legislative norms and illuminate their unfortunate influence on medical practice.

Although the questionnaire was sent to over two hundred doctors, only twenty-nine participated in my data collection. However, they represent various specializations and all parts of Ukraine so that their answers provide an overview of Ukrainian pain control problems. The results are presented summarily in a single document, Appendix 1 of the present thesis. Importantly, I use the doctors' answers in support of my arguments in this thesis, mostly when a certain position is supported by a large majority of respondents. I randomly use separate quotes in order to provide important details.

Overall, respecting relatively small number of participants, the survey is sufficient to be indicative, but not to make quantitative statements. I adhere to this position in the relation to the survey in creating arguments in the present thesis.

Apart from the doctors' questionnaire, some evidence presented is my personal interpretation of what I learned when participating in the scientific conferences<sup>28</sup> on the issues of pain management in Ukraine.

In order to learn which specific human rights of the Ukrainians are being violated by inadequate access to pain management, I analysed the provisions of international laws ratified by Ukraine, as well as the norms of the Ukrainian domestic legislation related to the issues of pain control, particularly in relation to the use of controlled substances. I also did extensive research on the Ukrainian court cases regarding the discussed issue to learn how the rights that encompass pain management are being defended in Ukraine.

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<sup>27</sup> D. Husereau et al, "Health technology assessment and personalized medicine: are economic evaluation guidelines sufficient to support decision making?" (2014) 30:2 International Journal of Technology Access to Healthcare 197; see also Scott Berry et al, "The effect of priority setting decisions for new cancer drugs on medical oncologists' practice in Ontario: a qualitative study" (2007) 7:193 BMC Health Services Research.

<sup>28</sup> *Supra* note 26.

Then, on the basis of my findings I developed my vision on how reasonable access to adequate analgesia can be improved in Ukraine, both from legislative and health policy points of view.

### ***Structure of the Thesis***

In the first chapter I define the problem of pain management and identify barriers to pain control in Ukraine according to my findings, based on the collected data. I organize the defined barriers by dividing them into three groups, as offered by the World Health Organisation (*hereafter referred to as WHO*); then I analyse and discuss them. In the second chapter I consider how the barriers to pain management in Ukraine affect the lives, behaviour and choices of the patients and doctors. My considerations are based primarily on the evidence available in multiple secondary sources from Ukraine that I cite in this paper. I also analyse certain statistical data, particularly the use of opioid pain medication in Ukraine, compared to other countries. In the third chapter I consider the application of the provisions of international legislation and the Ukrainian national law to the issues of pain control. I discuss the Ukrainian State's obligations to the Ukrainian people as well as their international commitments and how these duties apply to the matters of ensuring adequate pain control. In conjunction with the analysis of the legislative provisions, I review the Ukrainian court cases in view of the application of the human rights that pertain to the issues of pain relief. In the last chapter I suggest avenues to decrease the gap between contemporary medical knowledge on evidence-based care and the current approaches to the matters of pain management in Ukraine through the instruments of law and policy. Aiming at finding ways to remove certain barriers to pain control, where reasonable, I borrow examples on regulations regarding the same issues from other countries. My propositions are considered through the concept of human rights of the Ukrainian patients and through discussion of the role of law in ensuring better pain relief.

## Chapter 1. Identifying Barriers to Adequate Pain Management in Ukraine

### 1.1. General Identification of the Issue of Pain Management

The challenge of ensuring adequate pain management for palliative patients in Ukraine has recently received public attention<sup>29</sup> and a reaction from the government.<sup>30</sup> While many discussions have recently arisen regarding the necessity of pain management for terminal patients, other cases requiring pain treatment are barely mentioned or recognized. According to Olga Skoryna, Head of the Legal Department of the All-Ukrainian Council for Patients' Rights and Safety, "Pain relief in cases except palliative care is not identified in Ukraine as a problem at all".<sup>31</sup> She emphasizes that the Council has not received any complaints from patients about the response to pain in cases other than in palliative care. She presumes that pain management is not supported adequately in Ukraine.

Although *pain management* and *palliative care* are fields that overlap in many areas, they form different aspects of healthcare and refer to different fields of human rights. Pain management is undoubtedly a huge part of palliative care, and palliative care is a large field where pain management is needed, although definitely not the only one. Indeed, the HRW Report stressed that

[r]elieving pain is a critical part of palliative care. About 80 percent of patients with advanced cancer develop moderate to severe pain, and a significant number of patients with HIV and other life-limiting illnesses as well.<sup>32</sup>

One Ukrainian healthcare provider and a manager of a medical department in Ukraine emphasized in his interview with the Institute of Human Rights Research in Ukraine<sup>33</sup> that "with any pathology, the patient shouldn't suffer from pain".<sup>34</sup> The authors of the

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<sup>29</sup> E.g., IRF, "StopPain" Campaign in Ukraine, online: [http://www.irf.ua/index.php?option=com\\_content&view=article&id=35681:qstoppainq-campaign-launched-in-ukraine&catid=75:news-health-en&Itemid=71](http://www.irf.ua/index.php?option=com_content&view=article&id=35681:qstoppainq-campaign-launched-in-ukraine&catid=75:news-health-en&Itemid=71).

<sup>30</sup> E.g., Decree 333, *supra* note 21.

<sup>31</sup> Head of the Legal Department of the All-Ukrainian Council for Patients' Rights and Safety (see *supra* note 14) Olga Skoryna issued a note that although Council receive complaints from cancer patients regarding inadequate pain relief, complaints from non-cancer patients are exceptionally rare. However, they have information that in non-cancer departments, introducing pain relief is also problematic. According to Ms. Skoryna, this means that people do not identify pain relief as a problem.

<sup>32</sup> HRW Uncontrolled Pain, *supra* note 2 at 8.

<sup>33</sup> Non-Government Organization "Institute of Human Rights Research and Strategies", online: <http://helsinki.org.ua/index.php?id=1275483011>.

<sup>34</sup> Andrew Rokhansky et al., *supra* note 8 at 83.

HRW Report “Uncontrolled Pain” also recognized that “all patients facing severe pain have an equal right to pain treatment, irrespective of the type of underlying illness or condition.”<sup>35</sup>

To clarify the problem of pain management, it is important to distinguish between the meanings of *pain management* and *palliative care*. According to the WHO,

Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and *treatment of pain and other problems*, physical, psychosocial and spiritual.<sup>36</sup>

Considering Health Canada as an example of a country which fully integrated and developed the concept, palliative care includes:

- managing pain and other symptoms;
- providing social, psychological, cultural, emotional, spiritual and practical support;
- supporting caregivers;
- providing support for bereavement.<sup>37</sup>

Non-palliative patients experience pain as well. Pre- and post-operative cases, traumas, injuries, exacerbation of chronic conditions, labour-related illnesses and other health conditions are known to be accompanied by pain, which undoubtedly requires an adequate treatment. Table 1 illustrates the intersection between the issues of pain management and palliative care and demonstrates other aspects of pain management and palliative care that do not intersect.

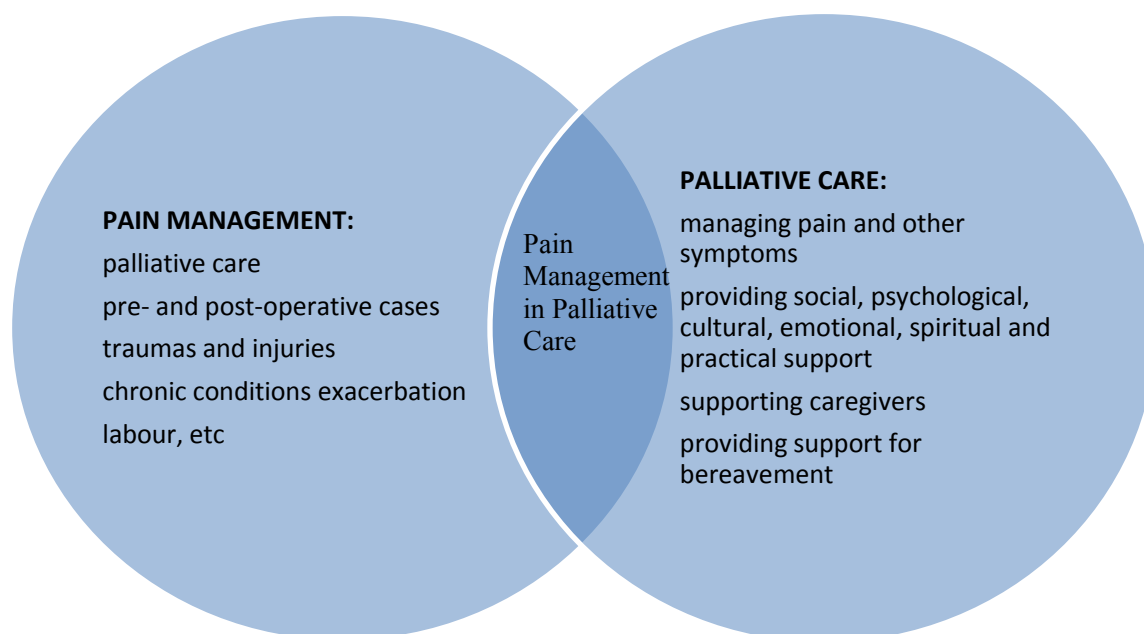
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<sup>35</sup> HRW Uncontrolled Pain, *supra* note 2 at 51.

<sup>36</sup> WHO Definition of Palliative Care, online: WHO <<http://www.who.int/cancer/palliative/definition/en/>>.

<sup>37</sup> Palliative and End-of-Life Care, online: Health Canada <<http://www.hc-sc.gc.ca/hcs-sss/palliat/index-eng.php>>.

**Table 1. Pain Management and Palliative Care Intersection**

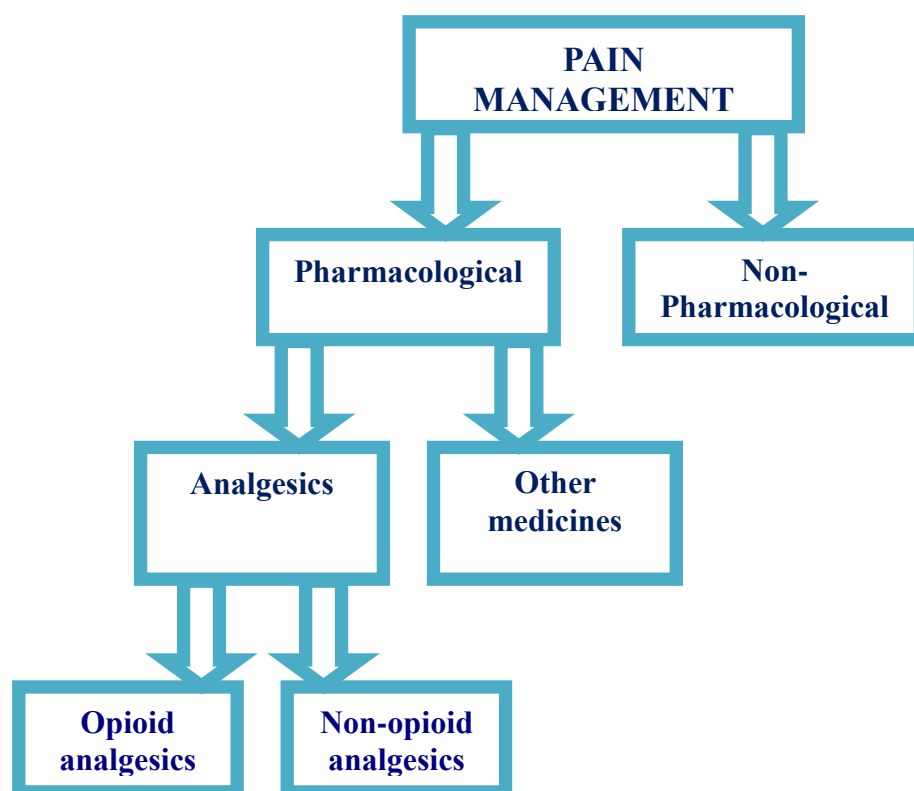


It appears, however, that in Ukraine connotation of pain control does not go beyond the intersection of the two spheres, as shown in Table 1 above. This provides a very limited approach to solving the problem, while both areas of pain relief and palliative care are important and necessary to adequately respond to the problems within these spheres. Pain management refers not only to different cases and conditions, but also presents a rather complex issue in itself. *Pain management* is defined in medical literature basically as encompassing the “pharmacological, non-pharmacological, and other approaches to prevent, reduce, or stop pain sensations”.<sup>38</sup> Using medicines is considered the main method to deal with the pain syndrome, followed by physical (e.g., ice application, physical therapy), psychological or other techniques meant to remove pain temporarily. The pharmacological approach, as the main component of pain management, involves several options such as analgesics, spasmolytics, muscle relaxants, antidepressants and other options, more common to healthcare practitioners. Analgesics, being the largest category of medication for pain relief, can also be divided in two categories, opioid and non-opioid analgesics.

<sup>38</sup> Medical Dictionary, definition of “Pain Management”, online: Free Dictionary <<http://medical-dictionary.thefreedictionary.com/pain+management>>.

For the purpose of the present research, which is focused on law and policy rather than on pharmaceutical or medical issues, analgesics are considered as being basically of two types: opioid and non-opioid analgesics. The present paper covers mainly the issues of accessibility to opioid analgesics, as well as the availability of and accessibility to non-opioid medicines. Patients' accessibility to other possible remedies for pain relief is not the focus of the present paper, because considering these issues would require specific medical knowledge and background. However, this paper considers the overall societal attitude toward the necessity of relief pain that involves non-pharmacological remedies as well. Table 2 illustrates the distinction between the types of pain management for the purpose of the present research and highlights the areas of focus in the present paper.

*Table 2. Types of Pain Management as Discussed in the Present Thesis*



As mentioned in the introduction, no statistical research on Ukraine has been found that provides data on how many people may need pain management daily or annually, neither sorted by dosage nor differentiated by diagnosis. However, pain is a common symptom of many illnesses and conditions, as well as of traumas, from the most severe to the most common, such as burns, pre- and post-surgery periods, childbirth, back pain and

headaches.<sup>39</sup> This list of conditions usually accompanied by pain is not full, as it would probably be supplemented by many other conditions and diagnoses if research on the issue is conducted. The important thing, however, is that pain is generally recognized as the most common symptom that brings people to doctors.<sup>40</sup>

## **1.2. Synopsis of the Content and Hierarchy of the Current Ukrainian Legislation Regulating Circulation of Pain Control Medication**

The use of medicines in Ukrainian healthcare, including in particular strong analgesics, is regulated mainly by several Laws of Ukraine, Government Decrees and Orders of the Ministry of Healthcare of Ukraine. Laws of Ukraine are legislative acts of ultimate legal force, as they are adopted by the Parliament of Ukraine – the highest representative body of legislative power in the State, which is called “Verhovna Rada”. Laws of Ukraine are referred to in the Theory of Law as acts of ultimate force, which regulate most important social matters and set basic principles, so that other acts of legislation are adopted for the implementation of the laws and in strict compliance with their norms and principles.<sup>41</sup>

Law of Ukraine “On Medicines”<sup>42</sup> and Law of Ukraine “On narcotic medicines, psychotropic substances and precursors”<sup>43</sup> set most basic frameworks and conditions of the circulation of medicines and their use.

Decrees of the Ukrainian Government (Cabinet of Ministers of Ukraine), being the highest body of executive power in the State,<sup>44</sup> are adopted for the purpose of fulfilment of the Laws of Ukraine. Thus, the Order of licensing of the activity related to circulation

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<sup>39</sup> Edward Paul, Associate Professor of Family and Community Medicine, University of Arizona College of Medicine, interview for ABC News, answer to question: “What Are The Most Common Types Of Chronic Pain?” (12 November 2008), online: ABC News <<http://abcnews.go.com/Health/PainOverview/story?id=4034145>>.

<sup>40</sup> See *supra* note 12 with all provided references.

<sup>41</sup> See O.F. Skakun, “The Theory of the State and Law” (“Теорія права і держави”): Textbook, 2nd ed. (Kyiv, Publishing House “Alerta”, 2011); see also the project of the Law of Ukraine, “On the legislative acts” (“Про нормативно-правові акти”) 7409, registered on 01 December 2010, particularly article 71, together with the Decree of the Verkhovna Rada of Ukraine (Parliament of Ukraine), “About the bills on the legislative acts” (“Про законопроекти про нормативно-правові акти”) 3428-VI, 20 May 2011, online: Rada <<http://zakon2.rada.gov.ua/laws/show/3428-17>> [Law Project 7409].

<sup>42</sup> Law of Ukraine, “On medicines” (“Про лікарські засоби”) 123/96-ВР, 04 April 1996, online: Rada <<http://zakon4.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80>> [Law on Medicines].

<sup>43</sup> Law of Ukraine, “On narcotic medicines, psychotropic substances and precursors” (“Про наркотичні засоби, психотропні речовини і прекурсори”) 60/95-ВР, 15 February 1995, online: Rada <<http://zakon4.rada.gov.ua/laws/show/60/95-%D0%B2%D1%80>> [Law on Narcotic Medicines].

<sup>44</sup> *The Constitution of Ukraine*, Law of Ukraine 254к/96-ВР, 28 June 1996, at article 9, available in English online: Rada <[http://static.rada.gov.ua/site/const\\_eng/constitution\\_eng.htm](http://static.rada.gov.ua/site/const_eng/constitution_eng.htm)> [Constitution of Ukraine]. It is important to mention that certain norms of the Constitution of Ukraine were changed on 22 February 2014 according to the Decree of Verkhovna Rada of Ukraine (Parliament of Ukraine) 750-18, online: Rada <<http://zakon4.rada.gov.ua/laws/show/750-18>>. These changes do not influence the legal analysis, provided in the present thesis.

of narcotic drugs, psychotropic substances and precursors<sup>45</sup> and the Regulation on Purchase, Transportation, Storage, Dispensation, and Utilisation of Narcotic Drugs, Psychotropic Substances and Precursors in the Healthcare System<sup>46</sup> are enforced by relevant Decrees of the Ukrainian Government.

Ministries of Ukraine, being accountable to the Government, elaborate on and adopt regulatory acts on concrete matters, which provide specific regulations of issues in compliance with the principles and norms of the Government Decrees and Laws of Ukraine. Regarding the use of pain control medication, the most basic Orders of the Ministry of Healthcare of Ukraine are # 11<sup>47</sup> and #360.<sup>48</sup> Order 11 affirms the Rules of circulation of narcotic medicines, psychotropic substances and precursors in healthcare settings of Ukraine, and Order # 360 enforces the following Rules: 1) for making prescriptions and orders for medicines and medical appliances, 2) for dispensing of medicines and medical appliances from pharmacies and their subdivisions and 3) instruction on the rules for storing, recording and utilization of the forms.

These legislative acts present the regulatory basis of circulation and use of pain-control medication in Ukraine and will be discussed in detail in following chapters of the present thesis.

### **1.3. Evidence on Barriers to Pain Control in Ukraine, Provided by the Doctors**

In 1996 the WHO recommended the Foundation Measures for implementing cancer pain relief programs. Their official publication for Cancer Pain Relief with a Guide to Opioid

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<sup>45</sup> Decree of the Cabinet of Ministers of Ukraine, “On adoption of the Order of licensing of the activity related to circulation of narcotic drugs, psychotropic substances and precursors and on putting amendments to the decrees of the Cabinet of Ministers of Ukraine dated 14 November 2000 #1698 and dated 4 July 2001” (“Про затвердження порядку ліцензування діяльності, пов’язаної з обігом наркотичних засобів, психотропних речовин і прекурсорів, та внесення змін до постанов Кабінету Міністрів України від 14 листопада 200р. № 1698 і від 4 липня 2001р. № 756”) 1387, 5 December 2007, online: Rada <<http://zakon2.rada.gov.ua/laws/show/1387-2007-п>>.

<sup>46</sup> Decree 333, *supra* note 21.

<sup>47</sup> Order of Ministry of Healthcare of Ukraine, “On affirming the Rules of circulation of narcotic medicines, psychotropic substances and precursors in healthcare settings of Ukraine” (“Про затвердження Порядку обігу наркотичних засобів, психотропних речовин та прекурсорів у закладах охорони здоров’я України”) 11, 21 January 2010 [Order 11].

<sup>48</sup> Order of the Ministry of Healthcare of Ukraine, “On adoption of the Rules for making prescriptions and orders for medicines and medical appliances, the Rules for dispensing of medicines and medical appliances from pharmacies and their subdivisions, Instruction on the rules for storage, recording and utilization of the forms and orders” (“Про затвердження Правил виписування рецептів та вимог-замовлень на лікарські засоби і виробу медичного призначення, Порядку відпуску лікарських засобів і виробів медичного призначення з аптек та їх структурних підрозділів, Інструкції про порядок зберігання, обліку та знищення рецептурних бланків та вимог-замовлень”) 360, 19 July 2005, online: Rada <<http://zakon2.rada.gov.ua/laws/show/z0782-05>> [Order 360].

Availability<sup>49</sup> offered three universal reference points every country should relate to. The suggested Foundation Measures are set standards that involve three areas of reference:

- Education
- Government Policy and
- Drug Availability.

The existing Foundation Measures standards can also function as reference guides by extrapolation to other health related areas where pain relief is a necessity and as a reference in identifying the barriers to the practical application of adequate analgesic therapies at a local level within a country or state. Therefore I present my findings regarding the barriers to pain control in Ukraine from the perspective of the above-mentioned three reference points, having narrowed the “Government Policy” category to the issues of “Health System Policy”.

According to the doctors’ answers to the Questionnaire on barriers to pain management, which I provide in Appendix 1 to this thesis,<sup>50</sup> the problems relate to all spheres: medical education, healthcare policy and drug availability. Only one of the twenty-nine respondents evaluated the general conditions for pain control in Ukraine as “excellent”. Eleven doctors said the conditions are “good”, and twelve responders suggested that the improvements are necessary.

Education. The Ukrainian healthcare practitioners who completed the Questionnaire identified *a lack of adequate training in the treatment of pain* as one of the main barriers to adequate pain management in Ukraine.<sup>51</sup> They pointed out that due to lack of certain knowledge, many of them are afraid of the side effects of narcotic analgesics, so only a few of them prescribe certain medicines.<sup>52</sup> In addition to lack of training, the problem highlighted by the responders is an *absence of standards and protocols in treatment of pain*, coupled with the “uncertainty of the necessity to treat pain in every particular case.”<sup>53</sup> In addition, the answers to the Questionnaire highlighted the absence of a system to notify the healthcare providers of new medicines available in Ukraine<sup>54</sup> as well as lack

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<sup>49</sup> WHO, *Cancer Pain Relief with a Guide to Opioid Availability*, 2nd ed. (Zheneva, 1996) at 43, online: WHO <<http://whqlibdoc.who.int/publications/9241544821.pdf>>.

<sup>50</sup> Appendix 1, Answers to the Questionnaire on Barriers to Pain Control in Ukraine.

<sup>51</sup> *Ibid* at 5,7 and 15.

<sup>52</sup> *Ibid* at 7.

<sup>53</sup> *Ibid* at 7.

<sup>54</sup> *Ibid* at 13.

of access to information about changes in regulations regarding the use of opioid medicines.<sup>55</sup>

*Health System Policy.* At this level, most complications in the treatment of pain relate to overwhelmingly restrictive regulations of the use of narcotic analgesics. The pain medicines of this category are referred to by several doctors as “*impossible to prescribe*” or as “*easier to not prescribe.*”<sup>56</sup> They fear being unfairly penalized for using narcotic painkillers.<sup>57</sup> Seventeen respondents recognized that the relation of an analgesic to the category of opioids affects their decisions regarding prescription.<sup>58</sup> Six doctors wrote that they frequently deliberately avoid prescriptions of narcotic analgesics even though they consider such prescriptions necessary.<sup>59</sup> Five doctors reported they sometimes prescribe weaker medicines than they should.<sup>60</sup> Overall, twenty healthcare providers answered they believe that *the barriers to narcotics cause their patients suffering.*<sup>61</sup> Many doctors referred to the complicated and time-consuming procedures for prescribing opioids as barriers to pain control.<sup>62</sup> Some respondents also brought up the problem of the imposed maximum 50 mg. daily dose of morphine, which may be too low to permit adequate pain control and which is established contrary to the WHO recommendations<sup>63</sup> suggesting that no “ceiling” dose may be established for pain medication.

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<sup>55</sup> *Ibid* at 13-14.

<sup>56</sup> *Ibid* at 2, 11, 13 and 15.

<sup>57</sup> *Ibid* at 3 and 12.

<sup>58</sup> *Ibid* at 3.

<sup>59</sup> *Ibid* at 3.

<sup>60</sup> *Ibid* at 3.

<sup>61</sup> *Ibid* at 4.

<sup>62</sup> *Ibid* at 2, 8, 10-16.

<sup>63</sup> *Ibid* at 8 and 15.

Availability and Accessibility to Pain Medication. The main problem of availability of painkillers in Ukraine, as specified by the doctors, is *the limited assortment of pain medication*. Another issue raised by the doctors is *the price of painkillers*. Twenty-seven of twenty-nine respondents answered “*sometimes*” and “*often*” to the question whether they heard their patients complain about the high prices for pain medication. And finally,

*The System of Education of Medical Doctors in Ukraine - necessary explanations*

1) Unlike Canada, but like some other countries, in Ukraine medical schools are open to those who have just finished high school. A bachelor’s degree is not a pre-requisite for applying to a medical school in Ukraine.

2) The future specialization is chosen almost from the beginning (usually during the second or third year of studies), so the medical students pursue their studies in the particular sphere without mandatory completion of a general therapist program. The duration of studies is usually about 7 years. This includes residency training in hospitals. Upon successful completion of medical school studies, one receives a Diploma of Medical Doctor, which allows him (or her) to practice without obtaining a licence.

3) The system and practices of licensing healthcare providers in Ukraine are also different from the Canadian system. Although medical graduate is entitled to work as a doctor right after graduation from a medical school, a hospital or a clinic may be established only under the condition of obtaining a licence for medical activity. This means that a licence is a document issued by a permitting state body to a hospital or a medical clinic, not to a particular practitioner. The clinic is responsible for hiring a certain number of qualified medical doctors and other practitioners. A mandatory pre-condition to apply for a licence for medical activity is usually a staff of hired specialists with relevant qualifications, which means both adequate education and professional experience.

4) All medical doctors are obliged to upgrade their skills. Advanced training is mandatory at least once every 5 years for every medical doctor in Ukraine. The advanced training is provided in compliance with the doctor's specialization.

the physicians’ answers regarding supplies of medicines to hospitals and units differ greatly. While some emphasize the shortages of painkillers in medical units, others state they have no shortages.

#### **1.4. Discussion of the Barriers to Pain management, Related to Education**

##### 1.4.1. Lack of Adequate Training for Healthcare Providers as a Barrier to Adequate Pain Control

To better understand how *the system of education of medical doctors in Ukraine* is set up, please refer to the box on this page.

According to the discussion of the issues of education of the Ukrainian healthcare providers in matters of pain control during the

East-European Congress on Pain in Yalta (Ukraine) in September 2013,<sup>64</sup> Ukrainian medical school students do not receive any training in the treatment of pain, because Ukrainian medical schools do not provide courses on the principles of pain management. The issue of general principles of pain control is only highlighted during advanced training for practicing medical doctors. However, not all practicing healthcare providers are adequately trained in pain management, because advanced training is usually

<sup>64</sup> East-European Congress on Pain, *supra* note 26.

provided separately, as a complement to the doctors' specializations and professional interests, which are often determined by the Chief Therapists of the healthcare settings. Training in the general principles of pain management is not necessarily considered essential for every doctor in Ukraine. There are no rules or legal provisions that would require mandatory training in pain management even for clinic staff therapists responsible for prescribing narcotic analgesics to in-home palliative and non-palliative patients. Also, training in this area is not available in every Ukrainian region. As was emphasized in the HRW Report "Uncontrolled Pain",

[...] just two medical institutions in Ukraine offer continuing medical education courses in palliative care: the Shchupik National Medical Academy for Post-Graduate Education and the Post-Graduate Department of the Faculty of Ivano-Frankivsk Medical University. Two departments of the National Academy offer such courses.<sup>65</sup>

These circumstances explain why the health practitioners' chances to receive adequate training in pain management are extremely low. According to one Ukrainian doctor in his answers to our Questionnaire, **"We do not have educational programs and specialists on the treatment of pain"**.<sup>66</sup> In addition to the recognized lack of training programs, future oncologists have also little chance to participate in residency programs in hospitals because only two teaching facilities offer palliative services.<sup>67</sup> As also revealed by the HRW in their Report:

[...] so most doctors specializing in oncology or anesthesiology receive no practical exposure to palliative care and pain management. Even doctors specializing in oncology do not currently do rotations in hospices. As a result, the next generation of Ukrainian doctors is educated with very limited exposure to palliative care services.<sup>68</sup>

It appears that in Ukraine even healthcare providers with specialization in oncology or in other medical fields where they are most likely to have to treat a lot of incurable patients, actually have very little chance to receive adequate training or accumulate practical experience in the treatment of pain. The doctors in other specializations have even fewer chances to receive adequate professional knowledge in dealing with such a common problem as pain.

It must be recognized that there are few sources of evidence about the lack of training of Ukrainian doctors in pain control issues. The HRW Report was the first and remains

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<sup>65</sup> HRW Uncontrolled Pain, *supra* note 2 at 59.

<sup>66</sup> Appendix 1, *supra* note 50 at 8.

<sup>67</sup> HRW Uncontrolled Pain, *supra* note 2 at 58.

<sup>68</sup> *Ibid* at 58.

among only a few sources, bearing witness to the inadequacy of doctors' training in the treatment of pain. The present research relies on the findings of the HRW concerning doctors' education,<sup>69</sup> because they are also supported by the answers of the Ukrainian health professionals to the results of the abovementioned survey;<sup>70</sup> additionally, similar findings were presented in the abovementioned report of the human rights organizations on observance of the rights of palliative patients in Ukraine "We have the right to live without pain and suffering".<sup>71</sup> Naturally, when doctors are not familiar with the world's best practices of pain control, they cannot recognize the gap between the best practices and their practices. Therefore, there is a possibility that many doctors may not identify the problem of their inadequate training in this field. Such a situation does not create favourable conditions for bringing evidence about this problem in Ukraine and for this reason, it is not surprising that international organizations like HRW (not a Ukrainian-based agency) were the first to identify the problem and provide evidence of shortcomings in doctors' education in Ukraine.

#### 1.4.2. "Fear of Addiction" and Other Myths about Opioid Analgesics as a Result of Lack of Education

According to the official WHO findings,

Fear of abuse and dependence is a major factor limiting access to opioid analgesics. In practice, most patients do not become dependent from rational medical use of opioid medicines to relieve pain.<sup>72</sup>

While these WHO recommendations are publicly available and easily accessible, many of the Ukrainian healthcare providers, as well as doctors in other countries of the industrialized and developing world,<sup>73</sup> continue to accept several myths about the negative consequences of opioid analgesics use, particularly the myths connected with drug addiction. Not many Ukrainian doctors are aware that the term "addiction" in its

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<sup>69</sup> HRW Uncontrolled Pain, *supra* note 2 at 8, 13, 40, 55, 58-59, 64 and 86.

<sup>70</sup> Appendix 1, *supra* note 50 at 7 and 16.

<sup>71</sup> Andrew Rokhansky et al., *supra* note 8.

<sup>72</sup> WHO Fact sheet #336, "Medicines: Access to Controlled Medicines (narcotic and psychotropic substances)" (June 2010), online: WHO <<http://www.who.int/mediacentre/factsheets/fs336/en/>>.

<sup>73</sup> R. Webster, J. Lacey & S. Quine, "Palliative Care: A Public Health Priority in Developing Countries" (2007) 28:1 Journal of Public Health Policy 28.

proper connotation (see Table 3 below)<sup>74</sup> is rather “uncommon to the pain-relieving effect of opioids”.<sup>75</sup>

**Table 3. Definitions of addiction-related terms<sup>76</sup>**

<p><i>Analgesic Tolerance</i></p> <p>Analgesic tolerance refers to the diminishing analgesic effect of an opioid because of physiological adaptation to the opioid. Analgesic tolerance is not inevitable, but it does occur. The dose of an opioid such as morphine typically can be increased to overcome any tolerance that may develop, as long as side effects are tolerated. Analgesic tolerance should not be confused with the need to increase the dose because of an increase in pain.</p> <p>(Miaskowski C, Cleary J, Burney R, et al. <i>Guideline for the Management of Cancer Pain in Adults and Children. APS Clinical Practice Guidelines Series, No. 3.</i> Glenview, IL: American Pain Society; 2005.)</p>
<p><i>Physical Dependence</i></p> <p>Physical dependence (also referred to as withdrawal syndrome) refers to the consequences of repeated administration of certain drugs, abstinence from which can increase the intensity of drug-seeking behavior because of the need to avoid or relieve withdrawal discomfort and/or produce physiological changes of sufficient severity to require medical treatment (World Health Organization. <i>Achieving Balance in National Opioids Control Policy: Guidelines for Assessment.</i> Geneva, Switzerland: World Health Organization; 2000. Available at <a href="http://www.painpolicy.wisc.edu/publicat/00whoabi/00whoabi.htm">http://www.painpolicy.wisc.edu/publicat/00whoabi/00whoabi.htm</a>). Patients who use opioids for pain relief on a long-term basis will likely develop a withdrawal syndrome when therapy is stopped abruptly, the dose is reduced sharply, or an antagonist is administered. However, this can be avoided if opioids are tapered gradually over a period of time.</p>
<p><i>Addiction</i></p> <p>Addiction (also referred to as <i>dependence syndrome, drug dependence, psychological dependence, or substance dependence</i>) refers to a maladaptive pattern of behaviors and compulsive use of drugs despite harm. Addiction is distinct from analgesic tolerance or physical dependence, although the phenomena may co-occur (e.g., in heroin addicts). Neither analgesic tolerance nor physical dependence is sufficient to characterize addiction. Addiction is a biopsychosocial condition and evidence shows that it is not more common in patients with chronic pain from cancer than in the general population. <u>Addiction is not a side effect, or an expected consequence, of opioid use.</u></p>

As stated by Chris Stern Hyman in his article “Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment”.<sup>77</sup>

<sup>74</sup> See Pain & Policy Studies Group, University of Wisconsin, Paul P. Carbone Comprehensive Cancer Center, Definitions of addiction-related terms in Lesson 3, “Barriers to Opioid Availability and Access”, course “Increasing Patient Access to Pain Medicines around the World: A Framework to Improve National Policies that Govern Drug Distribution” (Madison, Wisconsin, 2008) at 4, online: Pain & Policy Studies Group <[https://uwmadison.qualtrics.com/CP/File.php?F=F\\_3rDzsnXt93YboYQ](https://uwmadison.qualtrics.com/CP/File.php?F=F_3rDzsnXt93YboYQ)> [Definitions of addiction-related terms].

<sup>75</sup> Jennifer P. Schneider, “Opioids, Pain Management, and Addiction” (Winter 2006-2007) 16 Pain Practitioner, online: Pain Practitioner <[http://www.jenniferschneider.com/articles/PainPractitioner\\_10\\_06.html](http://www.jenniferschneider.com/articles/PainPractitioner_10_06.html)> ; See also Pain & Policy Studies Group, “Achieving Balance in State Pain Policy”, A progress Report Card (CY 2012) for further references. (“Physical dependence or tolerance is not synonymous with addiction.”)[ Pain & Policy Studies Group]; for more information see also Sophie M. Colleau & David Joranson, “Tolerance, Physical Dependence and Addiction: Definitions, Clinical Relevance and Misconceptions” (1998) 11 Cancer Pain Release 3, online: <<http://www.whocancerpain.wisc.edu/index?q=node/245>>.

<sup>76</sup> See Definitions of Addiction-Related Terms, *supra* note 74; for more information see also *ibid*.

[...] many [physicians] do not understand the distinction between drug abusers who are psychologically dependant on and compulsive users of a drug and pain patients who are physically, but not psychologically, dependent on a drug.

All these appear to be true in Ukraine, where the *fear of addiction* constitutes a significant barrier to adequate pain control and that is, arguably, a direct result of a lack of adequate training in the basics of pain management drug use.

The Report of Human Rights Organizations on the Observance of Rights of Palliative Patients in Ukraine<sup>78</sup> named five basic reasons for the increased suffering from pain and the lack of adequate pain treatments. The *fear of addiction* was mentioned as the first and main reason, along with other four barriers: resource limitation, bureaucratic absolutism, and total control and access limitations.<sup>79</sup> Due to the generally accepted misconception or myth of potential drug addiction as a result of the treatment of pain with opioids, many Ukrainian patients are prescribed inadequate doses of narcotic painkillers and in many cases only several days before death.<sup>80</sup> As emphasized in the Human Rights Watch Report “Uncontrolled Pain”:

Most healthcare workers interviewed [in Ukraine] were unaware or only partially aware of international best practices for pain treatment.<sup>81</sup>

Most common healthcare providers' misunderstandings were summarized in the HRW Report, stating that in Ukraine:

Many doctors and nurses expressed the erroneous belief that giving patients morphine would turn them into “drug addicts”; they confused physical dependence and tolerance with dependence syndrome (addiction); they interpreted patient requests for more morphine as a sign of “addiction” rather than as a sign that the current dose was insufficient; they believed that one dose of morphine could provide relief far beyond the four to six hours it is active; and that a maximum daily dose was appropriate.<sup>82</sup>

This lack of knowledge causing “irrational fears about using opioid analgesics” is identified as *the primary reason for inadequate pain relief* and unnecessary suffering for

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<sup>77</sup> Chris Stern Hyman, “Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment” (1996) 24:43 *Journal of Law, Medicine and Ethics* 338 at 338; see also R.K. Portenoy, “Opioid Therapy for Chronic Non-Malignant Pain: A Review of the Critical Issues”, online: (1996) 24:4 *Journal of Pain and Symptom Management* 296 at 331 <<http://www.aslme.org/pdfs/jlme1996244.pdf>>.

<sup>78</sup> Andrew Rokhansky et al, *supra* note 8.

<sup>79</sup> *Ibid* at 100.

<sup>80</sup> *Ibid* at 100; see also HRW Uncontrolled Pain, *supra* note 2 at 43.

<sup>81</sup> *Ibid* at 58.

<sup>82</sup> *Ibid* at 58.

hundreds of thousands of patients throughout the world,<sup>83</sup> and Ukraine is not an exception.

The problem of irrational fear of prosecution because of prescribing opioids in Ukraine has been brought up by HRW research findings<sup>84</sup> and the data collected by the human rights organizations on observance of the rights of palliative patients in Ukraine. At the same time, the survey does not prove that this problem prevents all Ukrainian doctors from prescription of strong analgesia.<sup>85</sup> Among twenty-five respondents who chose to answer the question related to their fear of being prosecuted for the use of opioids, nine said that they often avoid prescription of narcotic analgesics due to fear of criminal prosecution, or that they used to be scared to prescribe opioids for this reason. However, seventeen respondents stated that they had never replaced narcotic medicines with non-narcotic prescriptions due to fear of being unfairly made responsible for using narcotic painkillers.

#### 1.4.3. Absence of a Standard of Care in the Treatment of Pain

In fact, problems with adequate analgesia in Ukraine begin even at the stage of *diagnosing pain* and only “grow” along with the stage of treatment, because there is neither a standard nor any accepted general practice for pain evaluation in Ukraine. During the abovementioned East European Congress on Pain, which was held in Yalta (Ukraine) on 18-21 September 2013, health practitioners expressed concerns about the absence of guidelines to assess the pain levels of their patients. The discussion arose as to whether they *should or should not believe* to their patients’ description of the level of their pain. Absence of comprehensive instructions on pain evaluation practically leaves pain assessment to the rather subjective judgement of each individual Ukrainian medical doctor.

In addition to the lack of training, there are no universally binding guidelines for pain management for any health conditions available to Ukrainian healthcare providers. “[*The absence of*] *clinical guidelines for palliative care or pain treatment in patients with cancer and other conditions*” in Ukraine has been presented as a barrier to adequate pain

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<sup>83</sup> Sophie M. Colleau and David Joranson, “Fear of Addiction: Confronting a Barrier to Cancer Pain Relief”, online: (1998) 11 Cancer Pain Release 3 <<http://www.whocancerpain.wisc.edu/?q=node/244>>.

<sup>84</sup> HRW Uncontrolled Pain, *supra* note 2 at 14, 73-75.

<sup>85</sup> Appendix 1, *supra* note 50 at 3.

control by the HRW in their report “Uncontrolled Pain.”<sup>86</sup> It appears that when dealing with a patient’s pain, health practitioners in Ukraine exclusively follow their own knowledge received from their undergraduate programs, with rather limited awareness about recommendations on this matter. In addition, the HRW found “a conspicuous absence of evidence-based resource materials on palliative care in Ukraine”.<sup>87</sup>

Doctors’ education and universal instructions on how to treat pain in different cases, so-called guidelines, are closely associated with a wider definition of a “standard of care”. This definition is rather complicated and has been developing for many decades.

According to Peter Moffet and Gregory Moore in their article “The Standard of Care: Legal History and Definitions: the Bad and the Good News”,<sup>88</sup> the most updated and most general definition of the standard of care, upheld by recent court cases, is “what a minimally competent physician in the same field would do in the same situation, with the same resources.” The definition of the standard of care is of primary importance for understanding the duty of care, as it serves a test of whether or not the duty was fulfilled. Most generally, the duty of care corresponds with medical service in compliance with the standard of care. Breach of the duty of care means acting below the standard.

As medicine is not a precise science, clinical guidelines “*may or may not represent the standard of care*”.<sup>89</sup> This issue is considered in courts on a case-to-case basis. At the same time, the court practice appears to recognize clinical guidelines as an important element of the standard of care and, moreover, to rely on them increasingly.<sup>90</sup> This, however, does not mean ignoring medical expert witness, recognizing the uniqueness of every patient, condition and case. The issues of standard of care, medical guidelines and their interaction will be discussed in more detail later in this thesis.<sup>91</sup>

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<sup>86</sup> HRW Uncontrolled Pain, *supra* note 2 at 59.

<sup>87</sup> *Ibid* at 59.

<sup>88</sup> Peter Moffett & Gregory Moore, “The Standard of Care: Legal History and Definitions: the Bad and the Good News” (Feb 2011) 12:1 Western Journal of Emergency Medicine 109.

<sup>89</sup> *Ibid*.

<sup>90</sup> Clay Kelly & Gina Manguno-Mire, “Commentary: Helling v. Carey, Caveat Medicus” (2008) 36, Number 3, The Journal of the American Academy of Psychiatry and the Law 306, online: JAAPL <<http://www.jaapl.org/content/36/3/306.long>> (“[...] medical practice guidelines serve to standardize care in a way that helps to shield clinicians from legal action”).

<sup>91</sup> Peter Moffett & Gregory Moore, *supra* note 88; see also *ibid* ; see also P. Recupero, “Clinical practice guidelines as learned treatises: Understanding their use as evidence in the courtroom” (2008) 36 Journal of American Academic Psychiatry and the Law 290; see also A. Napoli & A. Jagoda, “Clinical policies: Their history, future, medical legal implications, and growing importance to physicians” (2007) 33 Journal of Emerging Medicine 425; R. Moses & A. Feld, “Legal risks of clinical practice guidelines” (2008) 103 American Journal of Gastroenterology 7.

It appears from the present findings that pain management in Ukraine is generally performed by often undereducated doctors (in terms of pain control) without the availability of information or mandatory supervision of colleagues with advanced training. There is no standard of care for patients with pain and no instructions that would guide physicians in their treatment of patients' pain syndrome.

#### 1.4.4. Absence of a System of Notification of Healthcare Providers about New Medicines

Besides inadequate training in the basics of analgesia and the absence of accepted guidelines, Ukrainian doctors are not even sufficiently informed about the new medicines available in Ukraine. There is practically no coordinated system that informs healthcare providers about the new pharmaceuticals registered and launched by the pharmaceutical market. According to my findings from the doctors' answers to the Questionnaire, the medical representatives of pharmaceutical companies are usually the first to tell the doctors about the new drugs available within their medical specialization.<sup>92</sup> As a result, in personal communication with a Ukrainian anaesthesiologist in November 2012, I learned that he was not aware of the fact that oral codeine was registered and available in Ukraine. This is, however, not at all unusual; in another example, in April 2013, the first batch of oral morphine,<sup>93</sup> previously available exclusively in injectable form, was released by the Ukrainian pharmaceutical plant "InterKhim". This first batch of painkillers in oral form was donated by this enterprise to the Ukrainian Ministry of Healthcare. For several months, this first batch of medicines was not distributed among healthcare providers or among licenced pharmacies due to the waiting process for legal measures and procedures from the Ministry of Healthcare of Ukraine. No notifications at all were sent to Ukrainian healthcare providers.

While the practice of medical representatives promoting medicines is not prohibited in Ukraine, or in other countries, the absence of a state-coordinated system of notification about new drugs and their characteristics is first of all a state's failure to provide every Ukrainian healthcare practitioner with important, objective information to treat their patients.

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<sup>92</sup> Appendix 1, *supra* note 50 at 13.

<sup>93</sup> "First batch of tablet morphine for incurable patients was transferred to the Deputy Prime-Minister in Odessa" ("В Одессе вице-премьеру передали первую партию таблетированного морфина для неизлечимо больных") (12 July, 2013) Dumskaya News, online: Net.News <<http://dumskaya.net/news/v-odesse-vice-premeru-peredali-pervuyu-partiyu-t-027994/>>.

#### 1.4.5. “Wrong” Diagnosis or Absence of “Necessary” Diagnosis as a Barrier to Pain Relief

Due to the efforts of public activists and coordinated programs<sup>94</sup> in raising public awareness on the issue in Ukraine, gradually more doctors are becoming aware of the imperative to treat pain. Also, due to many conferences and seminars on the issue,<sup>95</sup> oncologists and other caregivers for palliative patients tend to recognize the need to use opioid analgesics with minimal limitations (certainly while side effects are tolerated), as such patients are likely to require analgesic treatment for a short time before death. This assumption, of course, does not solve the issues of proper maintenance of numerous documents, observing excessive procedures and reporting to the controlling bodies, but at least it ensures doctors’ personal satisfaction with their prescriptions of opioids for pain control to help their affected patients. Arguably, the need for non-cancer and non-palliative pain control hardly receives the same recognition. Pain management for chronic conditions which are not associated with cancer are rather underestimated and have become a common concern in Ukraine.

In support of the above statements, below are some documented examples.

##### Example 1. Non-cancer pain

The story of Oleg Malinovsky<sup>96</sup> was recorded in the HRW Report. He was a 35-year old man diagnosed with chronic hepatitis C and other medical problems that caused degeneration in his joints and severe pain as a result. He was prescribed small doses of morphine before planned surgeries, which brought some relief. Having undergone those surgeries, which made some positive changes, in several months, the pain returned, and became even worse, affecting many parts of Oleg’s body. In response to Oleg and his wife’s complaints, the doctors failed to provide any pain relief. Instead, additional assessments were required. In addition to examinations related to Oleg’s diagnosis, he had to be seen by psychologists regarding his mental state and by drug treatment doctors to determine whether or not he was addicted to morphine. In spite of the results, which assured his adequacy and lack of addiction to drugs, Oleg never received adequate pain control. Somehow his state improved on his own after several months of tremendous suffering of unbearable pain that led him to express to his family his wish to die.

Example 2. A story of a woman with **chronic back pain** and a diagnosis of scoliosis and osteoporosis from Dnipropetrovska oblast (central Ukraine) was shared by a Ukrainian doctor during the scientific conference on the issues of pain control.<sup>97</sup> The patient complained that exacerbations of her condition occurred about two or three times a year. She felt severe pain that made it very difficult to move around and that prevented her from living a normal life. In spite of her constant complaints to many doctors in different clinics, hospitals and even in different

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<sup>94</sup> E.g., IRF “StopPain” Campaign, *supra* note 17.

<sup>95</sup> E.g., Conference on Palliative Care, *supra* note 26.

<sup>96</sup> HRW Uncontrolled Pain, *supra* note 2 at 52; see also J. Amon & D. Lohman, “Denial of Pain Treatment and the Prohibition of Torture, Cruel, Inhuman or Degrading Treatment or Punishment” (2011) 16:4 Interights Bulletin 172 at 174.

<sup>97</sup> East-European Congress on Pain, *supra* note 26.

regions of Ukraine, she has never been prescribed any opioid analgesics, even for the most severe exacerbations of her chronic condition. Indeed, as was confirmed by the doctor, although “*back pain ranked highest among the diagnoses for which patients received narcotics, [...]*”<sup>98</sup> there is absolutely no practice of prescribing narcotic analgesics to patients with chronic back pain in Ukraine.

### **Example 3. Undiagnosed pain**

One HIV positive man died from Kaposi’s sarcoma<sup>99</sup> in extreme pain with absolutely no pain treatment, because he was not diagnosed for the condition before he died. After this man’s death, his relative named Anna told his story to the Human Rights Research Institute,<sup>100</sup> stating that all that was done to relieve the patient’s terrible pain was “[...] wet towel on [his] head and some Analgin.” According to Anna, the absence of a diagnosis prevented the treatment of pain.

**Example 4. Pain management in childbirth** is another controversial area of pain management administration. There are no official standards for pain management during labour in Ukraine. Anaesthesia in childbirth differs from city to city and even from hospital to hospital. One young lady, who gave birth in Kyiv in early 2012, shared her positive opinion on how her pain was treated, because epidural anaesthesia was offered and performed successfully. Another lady, however, who gave birth in Kryvyj Rih, Dnipropetrovska oblast (central Ukraine) in the beginning of 2013 said that during her labour she was offered nothing but an injection of No-spa,<sup>101</sup> and only when pain was reaching its peak.

There is currently no universal practice for pain management during labour in Ukraine, no unified standard. No mandatory special training in pain management is provided for anaesthesiologists in maternity clinics.<sup>102</sup> Under such circumstances, the way anaesthesia is performed depends on the particular maternity clinic, the resources available and the training received by the clinic staff. There is only one case when anaesthesia is mandatory<sup>103</sup> in “normal labour” according to the Ukrainian legislation and this is episiotomy, even though the method of anaesthesia is not specified. Certainly in case of serious complications the need for *adequate anaesthesia* is mentioned in clinical midwife protocol,<sup>104</sup> although this term is not clarified. This means that the *comfort* of childbirth in Ukraine is based on the personal and professional qualifications of the staff of the particular maternity clinic and the resources available there, rather than on “*contemporary standards of medical care*”, as it is declared in Ukrainian Law.<sup>105</sup>

In fact, the *diversity* in the Ukrainian doctors’ professional approaches to the treatment of non-cancer pain has been demonstrated in the results of the Questionnaire. The respondents provided diametrically opposed opinions on the appropriateness of the use of

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<sup>98</sup> Yngvid Olsen & Gail L. Daumit, “Chronic Pain and Narcotics, A Dilemma for Primary Care” (March 2002) 17:3 Journal of General Internal Medicine 238, online: NCBI <<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1495025/>>.

<sup>99</sup> Kaposi sarcoma (KS) is a cancer that develops from the cells that line lymph or blood vessels. Dermal syndrome is common in HIV positive people, online: <http://www.cancer.org/cancer/kaposisarcoma/detailedguide/kaposi-sarcoma-what-is-kaposi-sarcoma>.

<sup>100</sup> Andrew Rokhansky et al., *supra* note 8 at 63-65.

<sup>101</sup> Brand name of Drotaverine - antispasmodic drug. Information available online: DrugBank <<http://www.drugbank.ca/drugs/DB06751>>.

<sup>102</sup> Commonly, in Ukraine women give birth in specialized maternity clinics. Usually, these are separate clinics, sometimes departments in big hospitals.

<sup>103</sup> Order of Ministry of Healthcare of Ukraine, “On adoption of Clinical Protocol on childbirth “Normal labour” (“Клінічний протокол з акушерської допомоги “Нормальні пологи”) 624, 3 November 2008.

<sup>104</sup> *Ibid.*

<sup>105</sup> Law 2801-XII, *supra* note 19 at article 4.

opioid analgesics in different diagnosis and cases,<sup>106</sup> which arguably demonstrates lack of a standard of training for the health professionals in the state.

Regarding this controversial topic, and as a comparison, even in the USA, as evaluated by Jennifer P. Schneider in her article “Opioids, Pain Management, and Addiction ” in 2006, “[...] most prescribers [were] still reluctant to adequately treat chronic pain, especially pain that is not caused by cancer.”<sup>107</sup> As demonstrated in the given examples, the Ukrainian reality appears much more concerning. The fear of addiction prevents the prescription of adequate amounts of opioid analgesics, even for terminal cancer patients. Curable patients or those with chronic pain syndrome have even less chance to receive adequate pain control. In most cases, these patients are not only deprived of an opportunity to obtain opioid analgesics, but are not even advised adequately on the use of non-opioid painkillers due to the lack of doctors’ awareness of contemporary methods of pain control, as customary in developed countries. Although these examples do not bring to light the complete list of challenges in pain management for non-palliative and non-cancer patients in Ukraine, they illustrate substantial problems in the response aside from palliative care.

The present findings confirm and demonstrate how the unsatisfactory overall qualification of healthcare providers in treatment of pain, coupled with the absence of a standard of care, constitutes a serious barrier to pain relief for Ukrainian patients with various diseases and conditions.

### **1.5. Discussion on the Barriers Related to Health System Policy**

Opioid substances, although fairly called “indispensable for the relief of pain and suffering”<sup>108</sup> and “essential for the treatment of moderate to severe acute and chronic pain,”<sup>109</sup> at the same time carry the social stigma of drug abuse. That is why, without a doubt, the use of these necessary medicines requires carefully considered and clearly stated policies and regulations. There is a fine line between ensuring access to opioid analgesics for medical purposes and protection from drug abuse. Simultaneously, a policy in favour of either task in the prejudice of another cannot be accepted. However, as I will further discuss in detail in the present chapter, currently the Ukrainian Government Policy

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<sup>106</sup> Appendix 1, *supra* note 50 at 4-5.

<sup>107</sup> Schneider, *supra* note 75.

<sup>108</sup> Single Convention, *supra* note 9 at Preamble.

<sup>109</sup> WHO Fact sheet #336, *supra* note 72.

regarding the use and circulation of narcotic substances has been chosen to fight drug abuse rather than to relieve patients' suffering from pain. Narcotic pain medication remains overwhelmingly inadequately accessible to Ukrainian patients.

#### 1.5.1. News on the Ukrainian Rules of Opioids Use in Healthcare

While discussing the sad reality of the Ukrainian pain management policies, it would be fair to start a dialog about the state policy on the use of narcotics from what appears to be a very important positive perspective. In May 2013 the Ukrainian Government adopted a new regulatory Decree 333<sup>110</sup> on the circulation of opioid medicines in Ukrainian healthcare settings. The most important progressive changes introduced in the new Decree touch mainly upon the following issues:

- introducing opioid injections without the mandatory presence of a licenced healthcare provider in patients' homes (the "old" rules required injections to be made exclusively by a licenced healthcare professional);
- less complicated procedures for opioid prescriptions (one doctor instead of a commission of three doctors, as the "old" ruled required);
- increased (15-days) supply of opioid painkillers at patients' homes; and
- increased stock of opioid analgesics in healthcare settings.

A more detailed comparison of the provisions of the new Decree 333 with the "old" rules is provided in Table 4 in Appendix 2 of the present paper. The provisions of Decree 333, if implemented adequately, could significantly ease the process of prescribing narcotic analgesics and access to them. However, the Ukrainian Government, having adopted the new Decree 333 on opioids circulation, "forgot" to repeal the "old" regulations formalised in Order 11<sup>111</sup> of the Ministry of Healthcare of Ukraine, regulating the same issue. As a result, to date nothing has really changed in opioids use in Ukrainian healthcare. Most Ukrainian healthcare providers have not even heard about the new regulations on opioids. Ten of the twenty-nine respondents to our Questionnaire on barriers to pain management in Ukraine provided answers on the questions regarding the new Decree and changes in rules for opioids prescriptions, and only seven said they at least knew something about the new Decree. All ten acknowledged that nothing really changed in their practice regarding controlled substances even though the new regulations

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<sup>110</sup> Decree 333, *supra* note 21.

<sup>111</sup> Order 11, *supra* note 47 at para 3.11.

were adopted.<sup>112</sup> Furthermore, no information about easier access to opioid analgesics has been mentioned so far on the official web page of the Ministry of Healthcare of Ukraine. Thus, the appropriate realization and further implementation of these progressive new regulations remains questionable.<sup>113</sup> The existing policy regarding opioid medicines in Ukraine continues to overwhelmingly limit access to narcotic painkillers.

### 1.5.2. Unfeasible Licence Requirements for Healthcare Settings to Use Opioids

#### a) Licensing of Healthcare Settings

To begin with, every healthcare institution in Ukraine requires a licence for medical practice.<sup>114</sup> This special permit plays the role of an acknowledgement that all necessary conditions, equipment and adequately trained professionals are available in the institution to provide due medical care.

Although it would be rather difficult to imagine the functioning of a contemporary healthcare setting without opioid medicines, in Ukraine, in addition to a regular licence for medical practice, a separate licence for the use of opioid medicines is required.<sup>115</sup> This requirement is established even though most such medical institutions are *community property*,<sup>116</sup> so that the local government can directly regulate and control their work in such a way that the Single Convention requirement for licensing, as discussed above, may not necessarily apply to these healthcare institutions. As a result, all narcotic analgesics like morphine, codeine and others can be used only within healthcare institutions that are specially licenced for keeping narcotics.

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<sup>112</sup> Appendix 1, *supra* note 50 at 13-14.

<sup>113</sup> Further discussion of the legal matter of two laws simultaneously in force will be found at 68-69, below.

<sup>114</sup> Law of Ukraine, "On licensing of certain types of economic activities" ("Про ліцензування певних видів господарської діяльності"), 1775-III, 1 June 2000 at article 9 para 20, online: Rada <<http://zakon4.rada.gov.ua/laws/show/1775-14?test=XX7MfyrCSgkyZr7IZi0ShHU0HI4rMs80msh8Ie6>> [Law on Licensing].

<sup>115</sup> Decree 1387, *supra* note 45.

<sup>116</sup> According to the Ukrainian *Constitution* (see *supra* note 44), Community property is a form of public property that appeared in Ukraine at the time of the institution of local governance. When in 1990 Ukraine became an independent state, being separated from the former Union of Soviet Socialist Republics, its administrative-territorial system stipulated division into 24 regions (oblasts), an Autonomous Republic of Crimea and two cities (Kyiv and Sevastopol) with a special status. The regions (oblasts) are also divided into parts, with their local governing authorities to regulate certain territorial communities. The objects of community property are those estates allocated from state property to territorial communities. Thus community property is a property of the territorial community. Local governments are subject to the right to community property.

## b) Special Permit for Healthcare Providers

Although healthcare providers are not licenced in Ukraine, and are allowed to conduct medical practice within licenced healthcare settings on the basis of having earned the appropriate degree from a University, those who need to use opioids in performing their professional duties or just to prescribe them must obtain a special permit for this

### ***Licence for medical practice***

According to the Ukrainian Law<sup>1</sup> the market participant intending to conduct medical practice shall apply to the appropriate authority of the Ministry of Healthcare of Ukraine for a special permit - a licence for medical practice. The licence requirements and process for obtaining this permit are identified in the Ukrainian legislation<sup>2</sup>, formalizing Licence Provisions for Medical Practice and Standard of administrative service of the Ministry of Healthcare of Ukraine on licensing economic activity of medical practice.

<sup>1</sup> Law on Licensing, *supra* note 114.

<sup>2</sup> On adoption of the Standard of administrative service of the Ministry of Healthcare of Ukraine on licensing of economic activity of medical practice (Стандарт надання адміністративної послуги Міністерством охорони здоров'я України з ліцензування господарської діяльності з медичної практики), Order of the Ministry of Healthcare of Ukraine 405/20718, 28 December 2011.

purpose.<sup>117</sup> Even oncologists are required to obtain such a special permit for the prescription of opioids, given that they are not considered an exception from the general rules. The same situation exists in some other European countries like Belarus, Georgia, Russia and Greece. In several other countries of Europe and Asia like Bosnia and Herzegovina, Bulgaria, and Tajikistan an exception is made for oncologists, who do not have to apply for and receive licence to prescribe and

use opioids, but other medical doctors still have to.<sup>118</sup> Some European countries require that such permits for the use of opioids are mandatory only for Family Medical Doctors.<sup>119</sup> In other countries healthcare providers do not need a licence to administer opioids to their patients.<sup>120</sup> Ukraine is among a few European states with the strictest requirements for medical doctors in terms of the prescription of opioids.

<sup>117</sup> Order of the Ministry of Healthcare of Ukraine, "On adoption of the licence conditions of conducting economic activity of cultivating of plants, included to table 1 of the List of narcotic medicines, psychotropic substances and precursors, affirmed by the Cabinet of Ministers of Ukraine, working out, production, preparation, storage, purchase, dispense, transportation to the territory of Ukraine, transportation from the territory of Ukraine, use, utilisation of narcotic medicines, psychotropic substances and precursors, included in the abovementioned List" ("Про затвердження Ліцензійних умов провадження господарської діяльності з культивування рослин, включених до таблиці I Переліку наркотичних засобів, психотропних речовин і прекурсорів, затвердженого Кабінетом Міністрів України, розроблення, виробництва, виготовлення, зберігання, перевезення, придбання, реалізації (відпуску), ввезення на територію України, вивезення з території України, використання, знищення наркотичних засобів, психотропних речовин і прекурсорів, включених до зазначеного Переліку") 66, 2 February 2010, at para 3.3., online: Rada <<http://zakon2.rada.gov.ua/laws/show/z0213-10>> [Order 66].

<sup>118</sup> Cherny et al., *supra* note 5 at 619.

<sup>119</sup> *Ibid.*

<sup>120</sup> *Ibid.*

The Ukrainian permit for the use of narcotic medicines in medical practices consists of two documents: “*Certificate of no mental disorders, related to alcohol, narcotic drugs or psychotropic substances abuse*”<sup>121</sup> from either a state or a community healthcare setting (private healthcare settings are prohibited from issuing this document) and “*Certificate of no criminal record*”<sup>122</sup> from the authorized local subdivisions of the Ministry of Internal Affairs of Ukraine. These certificates are needed not only by the doctors to use opioids in their practice; together with the proof of relevant medical degrees of the medical employees, these documents are also mandatory “*staff requirements*” for the healthcare setting to obtain a permit to use narcotics on the premises.<sup>123</sup>

It follows from the above that healthcare institutions require two separate licences: one regular licence for medical practice and another licence for the use of opioid medicines. In addition, a “personal” permit is required for each healthcare provider in the medical institution to prescribe opioid medicines while performing their professional duties. In summary, three permits are necessary to use opioids in medical practice in Ukraine.

#### c) Licence Requirements for Premises to Store Controlled Substances

In addition to the large number of permits required, the licence conditions for the Ukrainian healthcare settings in terms of technical matters are rather burdensome. For example, according to the rules,<sup>124</sup> the walls of the premises where opioids are stored shall be no less than 500mm thick and as firm as a brick wall; the floor and the ceiling shall be as firm as a reinforced concrete slab and no less than 180mm thick. Otherwise, the walls, floor and ceiling shall be consolidated by metal grating with section bars no less than 10mm in diameter with a crossover bar no more than 150x150mm. Metal grates shall be installed at the windows and bolted into the walls. Doors shall be thick and as firm as required. The metal cabinets for narcotics shall be securely fixed either to the floor or to the wall. After all these specifics, the premises must be equipped with an alarm, securing all the space of the premises and safes, with either an alarm-trigger

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<sup>121</sup> Order 66, *supra* note 117 at para 3.3.

<sup>122</sup> *Ibid.*

<sup>123</sup> *Ibid.*

<sup>124</sup> Order of the Ministry of Internal Affairs, “On adoption of the requirements to objects and premises for conducting activity related to circulation of narcotic medicines, psychotropic substances and precursors and to storage of such medicines and substances withdrawn from illegal circulation” (“Вимоги до об’єктів і приміщень, призначених для здійснення діяльності з обігу наркотичних засобів, психотропних речовин, прекурсорів та зберігання вилучених з незаконного обігу таких засобів і речовин”) 216, 15 May 2009, online: Rada <<http://zakon2.rada.gov.ua/laws/show/z0759-09>> [Order 216].

**Feldsher station (or Feldshersko-akusherski punkt (FAP))** is a common healthcare station for non-urban areas of Ukraine, established to provide pre-hospital care in areas distant from healthcare settings with physicians available. Feldshers are usually health care providers with a secondary-level medical education. When working in a team with a physician, Feldsher acts under the supervision of a physician. FAPs provide mainly emergency first-aid services, general checkups and midwifery care.

See more in the Order of the Ministry of Healthcare, “On adoption of the Approximate Provisions on Feldsher-midwifery station” 131 (23 February 2012), online: Rada <[http://moz.gov.ua/ua/portal/dn\\_20120223\\_131.html](http://moz.gov.ua/ua/portal/dn_20120223_131.html)>.

connected to the Central Security Console or local sound and light signals. These specific requirements are rather costly and rarely affordable by most of Ukrainian healthcare institutions,<sup>125</sup> which are funded exclusively from state and local budgets.

All these factors, combined with the difficulty of proper licensing and the

excessively strict standards imposed on the facilities, result in only central regional healthcare settings being able to afford the expenses and thus have narcotics at hand. Smaller hospitals, clinics and particularly “feldsher stations”<sup>126</sup> do not have necessary premises and staff to satisfy licensing conditions and obtain the permit to use narcotic analgesics. Given that about one third of the 45 million population of Ukraine live in non-urban areas,<sup>127</sup> the distance from their homes to the nearest hospitals where narcotic treatments are available can sometimes be measured in many tens or even hundreds of kilometres.

Again, not only palliative patients find themselves separated by distance from medical facilities, where narcotic analgesics for pain control can be legally obtained. Even the patients of small emergency units do not always have access to pain relief in a timely fashion. Shocking examples are the Emergency First-Aid Units in Boryslav and Skhydnytsya (small cities in Lvivska oblast in the West of Ukraine), where the facilities are not licenced for the storage and dispensation of opioid painkillers, therefore they are not available to patients. As indicated in a Lviv newspaper, released on January 2013:

Obtaining a licence is a long process. Besides, there are tough terms of storage of narcotics, while the “Emergency Medicine” [the name of the

<sup>125</sup> Rokhansky et al., *supra* note 8 at 47; See also “Emergency Medicine Sub-Station of Boryslav and Shydnytsya have no licence for narcotic medicines” (“Підстанції медицини катастроф Борислава та Східниці не мають ліцензій на наркотичні засоби”) (January 2013), online: Western Information Corporation <<http://zik.ua/ua/news/2013/01/23/389908>>.

<sup>126</sup> Order of the Ministry of Healthcare of Ukraine, “On adoption of the approximate provisions on feldsher-midwifery station” (“Про затвердження Примірного положення про центр первинної медичної (медико-санітарної) допомоги та примірних положень про його підрозділи”) 131, 23 February 2012, online: MOZ <[http://moz.gov.ua/ua/portal/dn\\_20120223\\_131.html](http://moz.gov.ua/ua/portal/dn_20120223_131.html)>.

<sup>127</sup> P.O. Maslyak and P.H. Shyshchenko, “Geography of Ukraine: Population” (Географія України - Населення України. Висновки) (Kyiv, Zodiak-ECO, 1996).

emergency units in Boryslav and Skhydnytsya] just physically cannot comply with the demands.<sup>128</sup>

In these conditions, when narcotics are needed, they have to be ordered from other emergency units. The patients just “hope” that they access the medicines “in time”. Otherwise, as indicated in the above referenced article, there is a real risk that patients may “die of pain shock”.<sup>129</sup>

It appears that in Ukraine, the excessive licensing requirements for the use of opioids for medical purposes significantly limit access of Ukrainian patients to pain relief.

### 1.5.3. Ambiguous and Often Unfeasible Requirements for the Use of Opioids and Violation of the Official WHO Recommendations

WHO issued the official recommendations<sup>130</sup> to the treatment of pain, which stipulated 5 main principles of analgesia by opioids:

- 1) Pain relief should be introduced orally** (“By mouth” principle).
- 2) Painkillers should be given every four hours to satisfy permanent pain control** (“By clock” principle).
- 3) The type of pain medication administered to a patient should depend on the severity of pain** (“By ladder” principle)
- 4) The dose of medication should be determined individually.** There is no maximum dose for strong opioid pain medications (“For the individual” principle).
- 5) The treatment of pain syndrome should be performed as needed by the particular patient** (“Attention to detail” principle).

Arguably, the Ukrainian rules regarding the use of narcotic analgesics make these recommendations practically unfeasible. According to the current Ukrainian regulations<sup>131</sup> every injection of morphine has to be administered to a patient exclusively by a licenced healthcare provider. No single dose of the medicine may be left (or stored) in a patient’s home to be used when needed. Considering the WHO “Attention to detail” principle and morphine dosage recommendations, which advise that in many cases the injection should be introduced as often as every four hours, for Ukrainian out-care patients it means that a nurse should come to their homes every four hours to give this

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<sup>128</sup> See “Emergency Medicine Sub-Station of Boryslav and Shydnytsya have no licence for narcotic medicines”, *supra* note 125.

<sup>129</sup> *Ibid.*

<sup>130</sup> WHO, Cancer Pain Relief Guide, *supra* note 49.

<sup>131</sup> Order 11, *supra* note 47 at para 3.11.

injection. Certainly, this requirement cannot be realistically achieved, and therefore, comparing with WHO's "By clock" and "Attention to detail" principles not feasible in pain management with regards to injectable morphine in out-patient care. This hardship is particularly tragic for patients in rural areas, where they are geographically separated by several dozens of kilometres from hospitals with opioids available.<sup>132</sup>

According to the "By ladder" principle, if a pain medication no longer provides pain relief, a stronger painkiller should be used. A serious violation of this principle in Ukraine was revealed by the HRW, as reflected in their Report "Uncontrolled Pain": while about 80 percent of the terminal cancer patients develop moderate to severe pain and thus need an opioid for pain relief for an average period of 90 days before death,<sup>133</sup> in Ukraine "in the best of cases", only about one third of terminal cancer patients receive strong opioid analgesics and in most cases, for a much shorter period than 90 days.<sup>134</sup> Sadly, there are many cases when no strong painkillers are introduced at all, as shown in the numerous interviews of Ukrainian patients.<sup>135</sup>

The principle "For the individual" implies that "the dose of medication should be determined on an individual basis". There is "no maximum dose for strong opioid pain medications".<sup>136</sup> Contrary to this, according to the guidelines for injectable morphine, produced by the monopolist manufacturer of this medicine in the Ukraine Pharmaceutical Plant "Zdorovja Narodu", the maximum daily dose of morphine should not exceed 50 milligrams. At the same time the HRW Report<sup>137</sup> indicated that "this dose is far below the levels of morphine used safely and effectively for the treatment of severe pain in other countries". In April 2013 I officially applied to "Zdorovja Narodu" for clarifications regarding the maximum dose of morphine they established in the instruction to this medicine, and suggested they amend the medicine guidelines so that they comply with the official WHO recommendations. At this moment my application still remains unanswered in spite of the requirement of the Ukrainian law<sup>138</sup> that Ukrainian enterprises must respond to applications and inquiries within a 30-day timeframe. Simultaneously, no law

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<sup>132</sup> This issue will be discussed more thoroughly further in the present chapter at 39-40, below.

<sup>133</sup> HRW Uncontrolled Pain, *supra* note 2 at 42; see also Foley et al, *supra* note 12 at 982.

<sup>134</sup> HRW Uncontrolled Pain, *supra* note 2 at 42.

<sup>135</sup> E.g., Andrey Rokhansky et al., *supra* note 8.

<sup>136</sup> WHO Cancer Pain Relief Guide, *supra* note 49 at 16; see also HRW Uncontrolled Pain, *supra* note 2 at 12.

<sup>137</sup> HRW Uncontrolled Pain, *supra* note 2 at 12.

<sup>138</sup> Law of Ukraine, "On applications of the citizens" ("Про звернення громадян") 393/96-ВР, 2 October 1996 at article 30, online: Rada <<http://zakon2.rada.gov.ua/laws/show/393/96-%D0%B2%D1%80>>.

imposes accountability for the violation of the present legal provision, and there is no mechanism of law enforcement of this norm of law. So my enquiry will presumably remain unanswered.

Overall, although in most cases 50mg of morphine is enough to comfort a patient,<sup>139</sup> in many cases pain still persists and/or increases, and more medicine is needed.<sup>140</sup>

According to the WHO recommendations:

There are no standard doses for opioid drugs. The “right” dose is the dose that relieves a patient’s pain. The range of oral morphine, for example, is from as little as 5mg to more than 1000mg every four hours.<sup>141</sup>

In Ukraine some doctors follow this recommendation and give their patients the necessary amount of the painkiller, while others chose to strictly follow the manufacturer’s guideline and do not prescribe more morphine even though their patients continue to suffer from pain.<sup>142</sup>

The legal analysis of this ambiguity in Ukrainian law regarding “off-label” use of medicines will be provided in the following chapters.<sup>143</sup> But it should be admitted in advance that whatever legal casuistry may arise from this ambiguity, one thing will remain certain, that the doctors are not lawyers. They cannot and certainly should not interpret laws, particularly in the absence of a clear provision. Above all, naturally, most of them just don't want additional questions and potential problems with regulatory authorities. That is why many prefer to secure their position by strictly following the guideline and do not prescribe more than 50 milligrams of morphine daily, leaving people in unnecessary and avoidable suffering.

#### 1.5.4. Fear of Criminal Prosecution

Chris Stern in his article “Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment”<sup>144</sup> states that “[...] the woeful lack of knowledge of some physicians about how to treat intractable pain and their **inaccurate**

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<sup>139</sup> This information was confirmed by a Ukrainian Neurologist during the scientific conference on pain relief. But he recognized the unacceptability of limiting the daily dose of morphine, given that it contradicts the WHO recommendations.

<sup>140</sup> E.g., story of Vlad Zhukovsky in documentary video “Fifty Milligrams Is Not Enough”, available online: Open Society Foundations <<http://www.opensocietyfoundations.org/multimedia/fifty-milligrams-not-enough>>.

<sup>141</sup> WHO Cancer Pain Relief Guidelines, *supra* note 49 at 16.

<sup>142</sup> HRW Uncontrolled Pain, *supra* note 2 at 46.

<sup>143</sup> See subchapter 3.4.9. at 103-104 and subchapter 4.2.8.1. at 127-128, below.

<sup>144</sup> Stern, *supra* note 77 at 338.

**perception about what is and is not legal”** forms a significant barrier to prescribing due analgesics in reasonable doses and thus precludes patients from adequate pain control. This view applies perfectly to the Ukrainian realities of pain management. The uncertainty concerning the maximum allowed daily dose of morphine is a clear example of this fear of repercussions to the extent of the law, among other examples. A study on the availability and regulatory barriers to opioid access in Europe revealed the following barrier to adequate pain management:

In some countries, the degree of legal intimidations is such that the fear of criminal prosecution contributes to deliberate under-treatment by clinicians to avoid the risk of persecution or prosecution.<sup>145</sup>

In Ukraine, besides the situation regarding the maximum dose of morphine, other ambiguities in legislation confuse healthcare providers. Surprisingly, many Ukrainian medical doctors are uncertain about the prescription of oral forms of opioids because of legislative requirements to strictly follow certain special procedures to utilize ampoules of injectable opioids in healthcare settings.<sup>146</sup> In fear of unfair prosecution, they wonder whether or not this rule applies to blisters from tablet forms of opioids as well. Kseniia Shapoval, the Coordinator of the Initiative on Palliative Care within the Public Health Program of The International Renaissance Fund (IRF)<sup>147</sup>, commented that:

[...] the doctors are challenged with deciding which requirements of MHU [Ministry of Healthcare of Ukraine] and SADC [State Agency for Drugs Control] will apply to blisters.<sup>148</sup>

The popular Ukrainian saying, “better ‘over-vigilant’ than less vigilant” (possibly similar to the English “better safe than sorry”) is practiced by healthcare providers, as they are intimidated by fear of prosecutions for the violation of rules on the use of narcotic medicines.

The IRF Campaign “StopPain”<sup>149</sup> applied for official clarifications for Ukrainian doctors on the issue of blisters of opioids in medical use, and in late April 2013 the response letters were obtained from three state agencies and were shared with the public. The more or less definitive answer came from the Drugs and Medical Products Agency of

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<sup>145</sup> Cherny et al., *supra* note 5 at 615.

<sup>146</sup> Order 11, *supra* note 47 at para 1.10 and 1.11.

<sup>147</sup> See *supra* note 16.

<sup>148</sup> “StopPain” Campaign publication on their web page on Facebook, dated April 10th, 2013, online: Facebook <<https://www.facebook.com/stopbil>>.

<sup>149</sup> See *supra* note 17.

Ukraine,<sup>150</sup> which replied that “on the current date requirements regarding utilization of used blisters of medicine, ‘Morphine Sulfate’ is not defined by the current legislation.” Two other agencies,<sup>151</sup> authorized to perform inspections regarding the use of controlled substances in healthcare, replied that the matter of the application was beyond their authority. The State Agency for Narcotics Control advised to apply to the manufacturer of the medicine and to the Ministry of Ecology and Natural Resources of Ukraine for clarifications on the request. The Department of Control over Illicit Circulation of Narcotics of The Ministry of Internal Affairs of Ukraine answered that clarifications on current legislation are not their responsibility.

It is clear from the provided particularly cautious and redirecting responses from the authorized government authorities that nobody wants to appear even peripherally responsible for anything related to the issue of the use of opioid substances. Under such conditions Ukrainian doctors’ extra-cautious behaviour in relation to opioid substances appears rather understandable.

#### 1.5.5. Practical Hardships Faced by the Physicians as a Result of Excessive Restrictions in the Use of Opioid Analgesics

On the whole, the rules of using narcotics in medical practice are rather stringent in terms of complexity and time- and effort-consuming demands for prescription and use of these substances. In addition to burdensome licensing requirements and procedures, there are numerous organizational and administrative requirements within every healthcare setting to enable the use of narcotic medicines. First of all, the current regulations<sup>152</sup> demand a number of specific and very detailed steps and procedures that a Chief Physician must follow regarding the use of opioids within the institution, as follows:

- 1) A Chief Physician shall appoint the individuals responsible for keys and security seals to the premises, safes and/or metal cabinets with narcotics.<sup>153</sup>
- 2) The rules of keys and/or security seals passing must be confirmed by the Chief Physician’s special order.<sup>154</sup>

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<sup>150</sup> Official Letter of the Department of the Drugs and Medicinal Products, Ministry of Healthcare of Ukraine # 18.2385/11-05/12646, dated 30 April 2013.

<sup>151</sup> The Official Letter of the Department of Control over Illicit Circulation of Narcotics of The Ministry of Internal Affairs of Ukraine # 40/2/-671, dated 18 April 2013 and the Official Letter of the State Agency for Narcotics Control # 09/02-2178, dated 15 April 2013.

<sup>152</sup> Order 11, *supra* note 47.

<sup>153</sup> *Ibid* at para 1.7.

3) An order must be issued to entitle specific healthcare providers to access the rooms and safes or cabinets with narcotics. All persons who receive access to narcotic medicines according to manager's order shall acknowledge being familiarized with the document by writing "read and understood" and putting their personal signatures.<sup>155</sup>

4) The Commission in charge of overseeing the "reasonability" of prescriptions of narcotic medicines shall be appointed through a Chief Physician's special order.<sup>156</sup>

5) A special order must be also issued by a Chief Physician to appoint a Commission that supervises the dispensing rules for empty ampoules of narcotic medicines and the order of gathering empty ampoules after injections are administered.<sup>157</sup>

According to the rules,<sup>158</sup> narcotic medicines shall be stored in special rooms and in safes or metal cabinets that satisfy licence conditions. The amount of narcotic medicines in a hospital shall not exceed the estimated two-week supply of such medicines (increased to one-month supply per the new regulations).<sup>159</sup> No more than three-days' supply may be stored in a medical unit (seven-days supply, as per the new regulations),<sup>160</sup> and no more than a one-day supply is allowed to be kept at a nurse's station or doctor's office (seven-days' supply according to the new regulations).<sup>161</sup> The estimates of need for narcotics must be also defined and established by the manager's order.

At every place where opioids are stored, special journals of narcotics use must be kept. Healthcare providers must keep these journals exceptionally up to date.<sup>162</sup> Notes to these journals are required every time ampoules are taken out or put in the safe or cabinet.<sup>163</sup>

All premises, safes and metal cabinets with narcotics shall be securely closed after each operation, and at the end of the working day they must be sealed for safekeeping.<sup>164</sup>

As a result, obtaining medicines for patients in many cases becomes a tedious, rather time-consuming task, considering the lengthy process of practically implementing the protocol imposed by the law. It should be noted that all this paperwork is still written manually in most Ukrainian hospitals, almost without the use of computers.

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<sup>154</sup> *Ibid.*

<sup>155</sup> *Ibid* at para 1.8.

<sup>156</sup> *Ibid* at para 3.8. part 2.

<sup>157</sup> *Ibid* at para 1.10.

<sup>158</sup> Order 216, *supra* note 124.

<sup>159</sup> Decree 333, *supra* note 21 at para 27.

<sup>160</sup> *Ibid* at para 23.

<sup>161</sup> *Ibid* at para 24.

<sup>162</sup> Order 11, *supra* note 47 at Addenda #5, 6 and 7.

<sup>163</sup> *Ibid* at para 3.14.

<sup>164</sup> *Ibid* at para 1.6.

In addition to this detailed and strict organizational protocol, resulting in too much paperwork, the Chief Physician or another authorized appointed doctor must, at least once a week, check the inventory of available narcotic medicines and compare it against the narcotics used according to the data entries in the journals.<sup>165</sup> Apart from these inventory control measures, the Commission on the reasonability of prescriptions of narcotic medicines must at least once a month inspect the storage situation of narcotics, their prescriptions, and the use and discarding of empty ampoules.<sup>166</sup> As a last step in the tight control, a Commission for the utilization of empty ampoules of narcotic medicines is in charge of gathering the empty ampoules and doing regular inspections on the issue.<sup>167</sup> Strict observance of all these time-consuming procedures is the minimum set standard for healthcare providers to obtain, store and prescribe narcotic analgesics in Ukrainian hospitals. However, even compliance with these strict rules does not guarantee that there will be enough medicine available and that it will be adequately prescribed and provided to the patients.

The prescription of opioid medicines is another rather complex issue that provides a further barrier to adequate pain control. According to the regulations,<sup>168</sup> Ukrainian healthcare providers with a permit (a licence) can issue prescriptions of opioid medicines exclusively by using special prescription forms or prescription blanks (*so called "form #3"*<sup>169</sup>). These blanks are printed out only by a certain state enterprise on paper with a certain protection layer and are considered strictly accountable documents with rather strict and burdensome rules for their use, accounting, and keeping.<sup>170</sup>

In general, the span of narcotic medicine prescriptions in Ukraine - according to the rules<sup>171</sup> - is limited to three-day doses. In the case where narcotic analgesics are needed for a longer period of time, the prescription must be validated by findings of a *commission* of no less than three doctors, in charge of the issue of reasonability of prescriptions of narcotic medicines. The new rules,<sup>172</sup> however, still not implemented, do not contain requirements for a commission to prescribe opioid medicines.

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<sup>165</sup> *Ibid* at para 3.15.

<sup>166</sup> *Ibid* at para 3.16.

<sup>167</sup> *Ibid* at para 1.11.

<sup>168</sup> Order 360, *supra* note 48.

<sup>169</sup> Order 11, *supra* note 47 at Addendum 8.

<sup>170</sup> Order 360, *supra* note 48.

<sup>171</sup> Order 11, *supra* note 47.

<sup>172</sup> Decree 333, *supra* note 21 at para 26.

When all the requirements for a prescription to be issued are met, in addition to the above, the prescription of narcotic medicines must be authorized by a Chief Physician or the Chief's Deputy of the healthcare setting, whose signature on the prescription is mandatory.<sup>173</sup>

It is to be noted that these procedures of prescribing and dispensing narcotics differ depending on whether it refers to in-patient or out-patient care.

In-patient care regulations allow an attending licenced medical doctor to prescribe necessary medicines for pain relief, including those containing narcotics.<sup>174</sup> This opportunity, however, not only demands a lot of paperwork but also comes with a potential requirement to rationalize all prescriptions to regulatory bodies during their inspections, which in some regions happen rather often.<sup>175</sup> Despite all the organizational difficulties Ukrainian doctors<sup>176</sup> recognize that in a hospital they usually have at least the most basic conditions to offer pain relief, despite having to follow burdensome, time-consuming procedures and requirements.

In out-patient care, the situation is much worse, particularly for patients in rural areas with long distances separating them from healthcare settings that have opioids. The most serious hardship is that according to the rules<sup>177</sup> a healthcare practitioner from the healthcare setting with opioids available has to physically come to patients' homes to introduce every injection. Besides, as these rules require, at-home patients shall be supplied with narcotic medicines directly by the healthcare settings in their area of residence. It is important to note that most of these territorial healthcare settings, organized "according to the place of residence", are polyclinics, where the doctors are only general practitioners. For example, there are no oncologists in polyclinics. Instead, the prescription of analgesics for a cancer patient (including prescription of narcotic medicines) shall be made by a therapist (a healthcare provider of general specialization, the equivalent of a family medical doctor in Canada); however, with mandatory recommendation from an oncologist from a cancer clinic. Considering that in Ukraine therapists, as well as almost all other doctors in polyclinics, are not trained in pain

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<sup>173</sup> Order 11, *supra* note 47 at para 3.8.

<sup>174</sup> *Ibid.*

<sup>175</sup> See Andrew Rokhansky et al., *supra* note 8 at 88. (Evidence of health professionals about frequent inspections in their healthcare settings); but see same source at 85 and 93 (Evidence of health professionals about a very few inspections in their healthcare settings).

<sup>176</sup> Appendix 1, *supra* note 50, especially at 12 and 14; see also Andrew Rokhansky et al., *supra* note 8 at 75-96.

<sup>177</sup> Order 11, *supra* note 47 at para 3.10.

management, this system becomes questionable in principle. For out-patient treatment of pain for people without cancer, opioid analgesics are hardly accessible even with application of burdensome protocols. Several Ukrainian doctors in answering the Questionnaire replied that *narcotic medicines are practically impossible to prescribe in out-patient care*.<sup>178</sup> With regard to both in- and out-patient health services it was commented that “the scheme of recording and prescribing controlled drugs is complicated to the greatest possible extent; it is easier to not prescribe than to fulfill recording and to keep a journal”.<sup>179</sup>

The procedural complications, however, do not completely prevent the provision of pain relief, but obviously result in delays and require much effort both from the healthcare providers, patients, and their relatives, which eventually form a significant barrier to adequate pain relief that needs to be addressed on a daily basis.

Drug abuse brings very serious harm to society, which has been recognized in the Preamble of the Single Convention on Narcotic Drugs: “addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind”.<sup>180</sup> According to the official statistics regarding Ukraine, drug-related harm to people’s health is very considerable, and the number of deaths due to drug dependence and other exposure to drugs tends to increase year by year.<sup>181</sup> It is within a Ukrainian state’s undertakings to ensure that that opioids use is limited to medical and scientific purposes, and the state is allowed and even required to “take such legislative and administrative measures as may be necessary” to fulfil this obligation.<sup>182</sup> Therefore, rules and requirements pertaining to the use of narcotic medicines are necessary and legitimate measures of protecting public health and welfare, as required by the international legislation.<sup>183</sup>

That said, the analysis of the opioid medicines regulations presented in the present chapter does not aim at questioning the reasonability and necessity of regulations *per se*. It rather calls for consideration of reasonability of the present level of strictness of the

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<sup>178</sup> Appendix 1, *supra* note 50 at 11, 12, 13 and 14.

<sup>179</sup> *Ibid* at 2 and 14.

<sup>180</sup> Single Convention, *supra* note 9.

<sup>181</sup> European Monitoring Center of Drugs and Drug Addiction, Country overview: Ukraine: Drug-related deaths, online: EMCDDA Europe <<http://www.emcdda.europa.eu/publications/country-overviews/ua#nlaws>>; see also BBC Ukraine (September 1, 2011), online: BBC Ukraine <[http://www.bbc.co.uk/ukrainian/health/2013/07/130729\\_un\\_ukraine\\_drugs\\_aids\\_az.shtml](http://www.bbc.co.uk/ukrainian/health/2013/07/130729_un_ukraine_drugs_aids_az.shtml)>.

<sup>182</sup> Single Convention, *supra* note 9 at article 4.

<sup>183</sup> Single Convention, *supra* note 9 at Preamble.

Ukrainian regulations, requirements and limitations of opioids use in healthcare for the purpose of Ukrainian public safety and welfare. Moreover, the results of this analysis push to initiate more substantial research of a social nature, aiming at finding a more adequate balance between permits and restrictions related to opioids use to ensure fulfilment of the requirements of international law in terms of limiting opioids use to medical and scientific purposes and ensuring their adequate access within these purposes.

## **1.6. Discussion of the Barriers related to Drugs Availability**

### 1.6.1. Formulary Deficit of Opioid Analgesics

The very first WHO recommendation states that if possible, *pain relief should be introduced orally* (“By mouth” principle).<sup>184</sup> This principle was almost not feasible until recently, when the production of oral morphine started. Oral morphine was not available in Ukraine until only about a year ago. The oral form of this medicine was registered in Ukraine in February 2013.<sup>185</sup> The unavailability of the oral form of morphine, considered the “gold standard” of analgesics for moderate to severe pain,<sup>186</sup> caused tremendous suffering to patients in need of it. The first batch of this oral morphine was produced in March 2013. However, it is still not widely accessible by Ukrainian patients.<sup>187</sup>

In regard to alternative painkillers (although of less effectiveness in similar dosages), oral codeine, for example, is available in Ukraine, but is not widely prescribed. Contrary to the WHO Essential Medicines List,<sup>188</sup> the Ukrainian Essential Medicines List<sup>189</sup> does not even include codeine as an essential drug. In addition, codeine is not considered a “gold standard” for pain relief. Not all Ukrainian healthcare providers know about the availability of oral codeine in Ukraine due to the lack of information on drug availability

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<sup>184</sup> WHO Cancer Pain Relief Guide, *supra* note 49 at 14.

<sup>185</sup> “Morphine in tablets - a first in Ukraine” (“Морфин в таблетках - впервые в Украине”), Press release of the Institute of Palliative and Hospice Care of the Ministry of Healthcare of Ukraine” (2 January 2013) , online: <<http://palliativecare.gov.ua/node/171>>.

<sup>186</sup> Access to buprenorphine, methadone and oral morphine, online: WHO <<http://www.who.int/hiv/amds/controlmedicine/en/>>; see also “Morphine Remains Gold Standard in Breakthrough Cancer Pain”, online: (24 December 2008) 337:a3104 BMJ.

<sup>187</sup> See information about oral morphine in Ukraine at 4 and 23, above.

<sup>188</sup> WHO Model List of Essential Medicines, 15th edition (Geneva: WHO, 2007), online: WHO <[http://www.who.int/medicines/publications/08\\_ENGLISH\\_indexFINAL\\_EML15.pdf](http://www.who.int/medicines/publications/08_ENGLISH_indexFINAL_EML15.pdf)>.

<sup>189</sup> See “National list of essential medicines and medicinal products” (“Національний перелік основних лікарських засобів і виробів медичного призначення”), Decree of the Cabinet of Ministers of Ukraine, “On certain matters of state regulation of prices for medicines and medical products” (“Про деякі питання державного регулювання цвн на лікарські засоби та вироби медичного призначення”), 333, 25 March 2009, online: Rada <<http://zakon2.rada.gov.ua/laws/show/333-2009-%D0%BF>>.

for healthcare providers, especially the newly registered medicines in the country.<sup>190</sup> This means that even though the Ukrainian law has always allowed the use of oral forms of opioids<sup>191</sup> under a doctor's prescription, in fact these medicines either were not available for the Ukrainian patients, or not widely prescribed and hardly accessible as a result.

### 1.6.2. Prices for Analgesics as a Barrier to Pain Control

The matter of prices for analgesics is discussed in this thesis for two reasons. First, affordability of medicines is an important component of access to medical care, which is declared to be a human right of Ukrainian citizens, both under domestic<sup>192</sup> and international legislation.<sup>193</sup> Second, this research aims at identifying all kinds of barriers to adequate pain control and analysing ways to overcome them through law. Therefore, to make this project integral the issue of prices for analgesics cannot be omitted.

At the same time, as it will be considered in more detail in the following chapters, the legal analysis does not appear to be most appropriate tool to find a way to settle the affordability-related problems of pain control. However, it provides human rights-based approach for solving this matter.

In addition to the restrictive regulations, actual affordability of analgesics in Ukraine is rather uncertain. In 2007 a study was conducted by the Human Awareness Institute<sup>194</sup> to

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<sup>190</sup> See discussion of the system of notification of health professionals about the new drugs registered within the state at 23, above.

<sup>191</sup> Order 11, *supra* note 47 at para 3.11.

<sup>192</sup> *Constitution of Ukraine*, *supra* note 44 at article 49; see also Law 2801-XII, *supra* note 19 at articles 6, 7 and 8.

<sup>193</sup> International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966) 993 UNTS 3/[1976] ATS 5/6 ILM 360 (1967). The ICESCR was ratified by the Decree of the Presidium of the Verkhovna Rada of the Ukrainian SSR (Parliament of the Ukrainian SSR) "On ratification of the International Covenant on Economic, Social and Cultural Rights and International Covenant on Civil and Political Rights" ("Про ратифікацію Міжнародного пакту про економічні, соціальні і культурні права та Міжнародного пакту про громадянські і політичні права") 2148-VIII, 19 October, 1973, online: Rada <<http://zakon4.rada.gov.ua/laws/show/2148-08> article 12> [ICESCR]; see also The Universal Declaration of Human Rights (UDHR), 10 December 1948, UN General Assembly, available online: The United Nations Organization <<http://www.un.org/en/documents/udhr/index.shtml>>. The UDHR was validated by the former Union of Social Socialist Republics (the USSR) and became binding in 1948. For Ukraine, as for the USSR legal successor, this International document became a part of the Ukrainian national legislation. The document in Ukrainian language can be found in Ukrainian legislation under #995-015, and is available through official Ukrainian Parliament web-site at: Rada <[http://zakon2.rada.gov.ua/laws/show/995\\_015](http://zakon2.rada.gov.ua/laws/show/995_015)> at article 25 [UDHR]; European Social Charter (Revised), 1996, Council of Europe, ETS 163 at article 13, online: Council of Europe <<http://conventions.coe.int/Treaty/en/Treaties/Html/035.htm>> [European Social Charter].

<sup>194</sup> Denis Poltavets & Larisa Konovalova, "Medicine prices, availability, affordability and price components" (2007) HAI Global, Ukraine Palliative care, available online: <[http://www.haiweb.org/medicineprices/surveys/200709UAE/sdocs/EMP\\_Ukraine%20Essential%20Final.pdf](http://www.haiweb.org/medicineprices/surveys/200709UAE/sdocs/EMP_Ukraine%20Essential%20Final.pdf)>; see also Alexandra Cameron et al., *The World Medicine Situation 2011: Medicine prices, availability*

evaluate medicine prices, availability, and affordability and price components for the medicines used in palliative care in different countries in the world. The study revealed unreasonably high prices for analgesics in Ukraine, particularly for the brand name drugs and especially in the public sector. Basic palliative care medicine needs were found to be unaffordable for low income families.

The concerns about the prices for analgesics have been confirmed by Ukrainian doctors.<sup>195</sup> In Ukraine, where healthcare insurance is not yet very popular, and where prescription drugs are usually purchased at patients' own cost, the price for the medicine is very important. Because the medical system in Ukraine is declared as offering free medical care, hospitalization and medication, injectable opioid analgesics are supposed to be provided by the healthcare settings in Ukraine free of charge. Thus opioid painkillers do not directly require patients' additional expenses. However, the unreasonably high prices for these medicines may limit their centralized procurement for the healthcare institutions, funded by state and local sources. As a result, patients' access to the analgesics may be in fact limited by their high prices. Non-narcotic analgesics are also supposed to be provided by hospitals for in-patient care, although because hospitals are usually so under-supplied, in most cases patients have to buy medicines from pharmacies on their own. Therefore, the prices for non-narcotic analgesics cause even more concern to the Ukrainian patients. Unfortunately, all attempts to find data on patients' not following doctor's prescriptions throughout Ukraine due to high prices of analgesics were unsuccessful. However, statistics of one of the Ukrainian regions, Zakarpattya – west of Ukraine – appeared striking. According to the findings of statistical authority of that region,<sup>196</sup> 93.7 per cent of households who reported their members in need of medical care over the calendar year refused all or part of the treatment because of high prices for medication. This data, however, relates only to a particular region and does not elucidate the matter of affordability of analgesics specifically. Therefore, these findings cannot be extrapolated to the matter of affordability of analgesics throughout Ukraine.

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*and affordability*, 3<sup>rd</sup> ed., (WHO, Geneva, 2011), online: WHO  
<[http://www.who.int/medicines/areas/policy/world\\_medicines\\_situation/WMS\\_ch6\\_wPricing\\_v6.pdf](http://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf)>.

<sup>195</sup> See Appendix 1, *supra* note 50 at 2 and 5-6.

<sup>196</sup> “Due to high price for medicines people of Zakarpattya give up treatment” (“Через високу ціну на медикаменти, закарпатці відмовляються від лікування”), Interview with Hanna Luchkivska, Head of the Department of Observations of the Department of Internal Affairs of Zakarpatsky Region (Ганна Лучківська начальник відділу обстежень УЖД ГУС), 21 May 2010, online:  
<[http://www.mukachevo.net/\(A\(ev1tRXz0zAEkAAAAM2RiMjk4ZjQtOTk3Zi00MTlmLWI0MjEtYTNkZmRmZDI0Mjk0S9KEhUhZ2OIqKYB7JcFmfQf39b41\)\)/ua/News/view/28114-Через-високу-ціну-на-медикаменти-закарпатці-відмовляються-від-лікування](http://www.mukachevo.net/(A(ev1tRXz0zAEkAAAAM2RiMjk4ZjQtOTk3Zi00MTlmLWI0MjEtYTNkZmRmZDI0Mjk0S9KEhUhZ2OIqKYB7JcFmfQf39b41))/ua/News/view/28114-Через-високу-ціну-на-медикаменти-закарпатці-відмовляються-від-лікування)>.

Simultaneously, this striking finding forces us to consider the problem in further detail and in other regions of the country. It flags the necessity of research on this issue with specific regard to analgesics.

In fact, the affordability of analgesics in Ukraine is part of a greater problem that has been highlighted in the media and many public sources.<sup>197</sup> The problem refers to a mechanism of pricing for all medicines in Ukraine, particularly those imported from abroad, and questionable procedures of centralized procurement of medicines for state hospitals to meet their budget costs.<sup>198</sup> These factors of concern and their effect on prices for analgesics in Ukraine probably require extensive separate research, not conducted in the present paper. However, this discussion raises serious doubts and provides grounds to identify the price of analgesics as an obvious barrier to adequate pain management in Ukraine.

A surprising finding was revealed by one study on the availability and affordability of opioids in Ukraine.<sup>199</sup> The affordability of morphine (considered relation of the price to average income) to Ukrainians is six times higher than affordability of this medicine in the United Kingdom. In general, the price for narcotic medicines is not considered a primary barrier to adequate analgesia in developed countries,<sup>200</sup> considering that the price of morphine tablets is rather low.<sup>201</sup> However, as stated in the abovementioned

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<sup>197</sup> N. Datsyuk, D. Volokh & N. Sholoyko, "Analysis of price policy for injectable narcotic medicines in Ukraine" ("Аналіз цінової політики на ін'єкційні наркотичні лікарські засоби в Україні") (2013) 3 *Pharmaceutical Journal* 29.

<sup>198</sup> "Prices for imported medicines are for some reason higher than abroad" ("Ціни на імпортовані ліки в Україні чомусь набагато вищі за ціни в країнах ЄС") (2 February 2013), online: Information Agency ZIK <<http://zik.ua/ua/news/2013/02/13/393669>>

<sup>199</sup> S. E. Prokip, B.P. Hromovnyk, E.J. Moskvayak, "The study of the assortment of narcotic analgesics and painkillers in formulary of Great Britain and Ukraine" (2012), Research Paper on Palliative Care, Lviv National Medical University, presented during the First National Congress on Palliative Care (Sept. 26-27, 2012, Irpin, Ukraine), online information: LIGA <<http://ligalife.com.ua/p.pdf>>.

<sup>200</sup> Barbara Milani, Willem Scholten, *The World Medicines Situation 2011. Access to Controlled Medicines*, 3rd ed (WHO, Geneva, 2011) online: WHO <[http://www.who.int/medicines/areas/policy/world\\_medicines\\_situation/WMS\\_ch19\\_wAccess.pdf](http://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch19_wAccess.pdf)>.

<sup>201</sup> According to the MSH database the median price for injectable morphine (data of year 2012) is approximately **30 (thirty) US cents per 10mg**. (see online: [http://erc.msh.org/dmpguide/resultsdetail.cfm?language=english&code=MOR10A&s\\_year=2012&year=2012&str=10%20mg%2Fml&desc=Morphine%20Sulfate&pack=new&frm=AMPOULE&rte=INJ&class\\_code2=08%2E4%2E&supplement=&class\\_name=%2801%2E3%2E%29Preoperative%20medication%3Cbr%3E%2802%2E2%2E%29Opioid%20analgesics%3Cbr%3E%2808%2E4%2E%29Medicines%20used%20in%20palliative%20care%3Cbr%3E](http://erc.msh.org/dmpguide/resultsdetail.cfm?language=english&code=MOR10A&s_year=2012&year=2012&str=10%20mg%2Fml&desc=Morphine%20Sulfate&pack=new&frm=AMPOULE&rte=INJ&class_code2=08%2E4%2E&supplement=&class_name=%2801%2E3%2E%29Preoperative%20medication%3Cbr%3E%2802%2E2%2E%29Opioid%20analgesics%3Cbr%3E%2808%2E4%2E%29Medicines%20used%20in%20palliative%20care%3Cbr%3E)), and the median price for oral morphine (data of year 2012) is approximately **37 (thirty-seven) US cents for a 10mg tablet or capsule** (see online: [http://erc.msh.org/dmpguide/resultsdetail.cfm?language=english&code=MOR10ST&s\\_year=2012&year=2012&str=10%20mg&desc=Morphine&pack=new&frm=TAB%2DCAP&rte=PO&class\\_code2=02%2E2%2E&supplement=&class\\_name=%2802%2E2%2E%29Opioid%20analgesics%3Cbr%3E](http://erc.msh.org/dmpguide/resultsdetail.cfm?language=english&code=MOR10ST&s_year=2012&year=2012&str=10%20mg&desc=Morphine&pack=new&frm=TAB%2DCAP&rte=PO&class_code2=02%2E2%2E&supplement=&class_name=%2802%2E2%2E%29Opioid%20analgesics%3Cbr%3E))

comparative study of morphine affordability, “analgesic retail prices are a barrier in Ukraine” and “they are priced higher than in developed countries.”<sup>202</sup>

Striking evidence comes from “Analysis of Price Policy for Injectable Narcotic Medicines in Ukraine”,<sup>203</sup> conducted by Natalia Datsiuk. The monopolist manufacturer of injectable analgesics in Ukraine, “Zdorovya Narodu”, has increased their prices for narcotic analgesics more than twice without any reasonable justification. Beyond that, purchase prices for the same medicine differ tremendously in the country, and even within the administrative districts. The range of purchase prices for one ampoule of morphine in 2010 was from as low as 2.5UAH to as high as 6.02UAH. Besides, the prices for the same medicine within the same districts vary during just one year period. Thus, according to the study, in some Ukrainian administrative districts (Volynska, Dnipropetrovska regions) the price for an ampoule of morphine increased by 32% to 59% within one year, and in some other regions the prices jumped over 100%. For example, in Sumska region the price increased by 139%, in Khmelnytska region by 145%, in Kyivska region by 166% and in Zaporyzka region by 181%, respectively.

Certainly, this evidence may justify substantial further research on pharmaceuticals pricing in Ukraine. Possibly, certain hidden factors influence the price of medicines in Ukraine, including narcotic analgesics, eventually making them less accessible to Ukrainian patients. For the purpose of the present research these findings provide evidence of challenges in Ukrainian policy regarding pricing of analgesics which constitute barriers to patients’ access to adequate pain control.

### 1.7. Concluding Remarks

In view of the above research and documentation, I am finalizing the identification of main obstacles to introducing adequate pain control to the Ukrainian patients by summarizing them in the following Table.

**Table 5. Summary and Systematization of Barriers to Adequate Pain Management in Ukraine and Practical Hardships Created by these Barriers.**

<i>Sphere</i>	<i>Barrier</i>	<i>Outcome</i>
<b>Education</b>	Poor identification of the problem by the Government, healthcare	Lack of motivation to adequately respond to patients’ complaints on

<sup>202</sup> *Supra* note 198.

<sup>203</sup> Datsyuk, Volokh & Sholyko, *supra* note 197.

	providers and the public.	pain.
	Lack of adequate training for healthcare providers (both in medical schools and continued education of healthcare practitioners) and  Lack of comprehensive instructions regarding professional rights.	“Fear of addiction” and other myths about opioid analgesics, resulted in unreasonable precautions and inadequate prescriptions of painkillers and their doses; Intimidation through possible legal persecution or prosecution.
	Absence of a system of notification of healthcare providers about new medicines.	Many doctors are not informed in a timely manner about new remedies to better treat pain, which may result in less than ideal choices of medicines.
	Absence of a standard of care for patients with pain and absence of guidelines for the treatment of pain.	Different approach in responding to patients’ suffering in different healthcare settings and/or different healthcare providers. Not guaranteed orientation on world best practices.
<b>Health System Policy</b>	Excessive and hardly feasible licence requirements for the use of opioid medicines.	Only central hospitals can meet the requirements to obtain licences to keep and use narcotic medicines. Opioid painkillers are unavailable in many healthcare settings in Ukraine.
	Overwhelming documentation and procedures to prescribe opioid medicines.	Doctors are discouraged from prescribing controlled substances.
	Ambiguity and confusion in legislation regarding opioids in healthcare, combined with censoriousness of controlling bodies in order to prevent or detect and strangle drug abuse.	Doctors may prefer to avoid adequate prescriptions of opioids in order to avoid persecution or prosecution.
	Practical hardships in delivering opioid analgesics to patients in out-patient care (especially in non-urban areas) due to the requirement that injection shall be made by licenced healthcare providers only.	Healthcare providers, separated from their patients by distances, are unable to come to each patient’s home several times every day, thus adequate pain control is not being provided.
<b>Medicine Availability</b>	Unavailability and/or inaccessibility of oral forms of opioid analgesics.	E.g., forced necessity to take injections instead of oral forms of morphine.
	Formulary deficiency of forms and types of painkillers in Ukraine.	
	Unaffordability of effective painkillers for most Ukrainian patients.	Patients not accepting necessary painkillers and suffering from pain that could be treated.

	Inadequate supply of medicines to healthcare settings.	Unavailability of necessary painkillers in some hospitals and/or units.
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Serious and interdependent problems of a rather complex nature prevent treating physicians from providing adequate pain control to Ukrainian patients as required by the contemporary practice. Even if the most effective painkillers were widely available, one can hardly access them without a prescription from a professional doctor adequately trained in pain control. In addition, a prescription for the best and most relevant analgesic will not help if the medicine is not available or available at the wrong times or in insufficient amounts. Even the most professional healthcare providers, highly qualified in pain relief, would be unable to help if the restrictive regulations for the use of appropriate analgesics are not workable in practice or if the medicines are not affordable for patients. Ukraine exhibits practically all deficiencies for adequate pain control.

These problems are chain reactions and as such, when one link in the chain breaks, the entire system becomes ineffective. Unfortunately, in Ukraine practically all parts of the pain management chain are damaged or non-existent, and current initiatives to improve the situation have not yet proven effective. The patient at the receiving end of the true consequences of this malfunctioning system remains in pain and suffering. In Ukraine, where healthcare providers are not adequately trained in the basics of pain management, where access to narcotic analgesics is extremely and unreasonably over-regulated with rules creating a lot of ambiguity, where a variety of forms of necessary medicines are not available in medical practice and where prices for non-narcotic painkillers are high, tens of thousands of people needlessly suffer pain, sometimes even without realizing they might have remedies and might live much better lives.

## **Chapter 2. Practical Outcome of Strict Prohibitions of Opioids Use in Medical Practice in Ukraine**

### **2.1. Peculiarities of the Ukrainian Use of Opioids as Opposed to Other Countries**

#### **2.1.1. The Use of Opioids in Ukraine in Comparison with other Countries and Regions**

According to the data provided by the Pain and Policy Studies Group in 2010, the so-called Morphine Equivalence Metric (ME)<sup>204</sup> was 9.0964 mg per person in Ukraine,<sup>205</sup> while in Europe, this index reached an average of 135.11394 mg per person,<sup>206</sup> and an average of 58.11 mg per person globally.<sup>207</sup> The discrepancy is huge. The Ukrainian total ME is almost 15 times lower than the European index and over six times lower than the worldwide index. It is important that the most significant part of the Ukrainian ME index is methadone, which is unavailable for pain treatment in Ukraine. This medicine is being distributed exclusively as substitution therapy in addiction treatment and thus is not available for analgesia.<sup>208</sup> These circumstances offer grounds to estimate a significantly lower ME index for Ukrainian pain management than officially estimated. Even with such roughly estimated ME data, by comparison, the Canadian ME at 753.4017 mg per capita annually is almost 83 times higher than the Ukrainian indicator.

The amount of morphine and other narcotic analgesics consumption in Ukraine per capita has declined since 2009. Morphine consumption decreased slightly, from 0.6673 mg per person in 2009 to 0.6418 mg per person in 2010, while the total ME also decreased from 10.7508 mg per person to 9.0964 mg per person in 2010.<sup>209</sup> The reduction is not considered large, although this tendency contradicts the global trend, as the average use of narcotic analgesics worldwide is rising steadily<sup>210</sup> each year.

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<sup>204</sup> See more Opioid Consumption Data, online: Pain and Policy Studies Group <<http://www.painpolicy.wisc.edu/opioid-consumption-data#Morphine%20Equivalence>> (Morphine Equivalence Metric includes the cumulative use of opioid analgesics: Fentanyl, Hydromorphone, Methadone, Morphine, Oxycodone and Pethidine).

<sup>205</sup> Opioid Consumption Data for Ukraine, online: Pain and Policy Studies Group <<http://www.painpolicy.wisc.edu/country/profile/ukraine>>.

<sup>206</sup> Euro Regional Opioid Consumption in Morphine Equivalent, online: Pain and Policy Studies Group <<http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/euroME.pdf>>.

<sup>207</sup> Pain and Policy Studies Group, Global Opioid Consumption in Morphine Equivalent, online: Pain and Policy Studies Group <<http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/GlobalME.pdf>>.

<sup>208</sup> This information was confirmed to the author by Ukrainian doctors during the scientific conferences on the issues of pain treatment.

<sup>209</sup> The data of 2009 was collected and used in Datsyuk, Volokh & Sholoyko, *supra* note 197.

<sup>210</sup> See Morphine Equivalence Trend, online: Pain and Policy Studies Group <<http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/GlobalME.pdf>>.

### 2.1.2. The Correlation between the Level of Drug Addiction and the Strictness of the Regulations for Opioids Use in Medical Practice

Essentially, the regulatory procedures are necessary to ensure access to opioid medicines for legal medical purposes and to limit illegal access and use. Properly implemented, these procedures should equally ensure both sides of the equation: equitable legal access for medical purposes and the limitation of illegal access. It is unacceptable that either issue should be compromised in favour of the other. Moreover, the substantial research conducted by the United Nations (UN)<sup>211</sup> proved the absence of positive correlation between strictness of the regulations governing the use of opioids in healthcare and an actual decrease in illegal use of narcotics. According to this research, “*the largest numbers of drug injectors live in China, USA and Russia. [...] the three nations [...] have among the world’s most punitive drug laws.*”<sup>212</sup> This means that the time and effort-consuming procedures of prescription and actual use of controlled substances in healthcare settings, sometimes almost unfeasible, not only limit access to adequate analgesia, but also often fail to protect from illegal use of narcotics. If so, none of the two goals of the regulation of opioid medicines is achieved by strict laws.

Indeed, there is no evidence of a decrease in the number of people addicted to drugs in Ukraine. Official sources are very careful about the public disclosure of the decrease or increase in the number of drug addicts in Ukrainian society, but official statistics does indicate the amount of illicit drugs seized by the Ukrainian authorities is rising.<sup>213</sup> The average age of those who are dependent on drugs in the Ukraine is dropping. According to the official data released by the Ukrainian Medical and Monitoring Center for Alcohol and Drugs Addiction in 2012, one in four senior students aged 15–17 has illegally used narcotics for non-medical purposes at least once.<sup>214</sup> Overall, out of the Ukrainian population of 45 million people, 170,000 people are officially registered as drug addicts.

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<sup>211</sup> B.M. Mathers et al, “Global epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review” (2008) 732 *The Lancet* 1733.

<sup>212</sup> Evan Wood et al, “The War on Drugs: a Devastating Public-Policy Disaster” (March 2009) 373:9668 *The Lancet* 989.

<sup>213</sup> See “Narcotic Situation in Ukraine Cut-off 2012 (data of 2011)” (“Зріз наркотичної ситуації в Україні 2012 (дані 2011 року)”), online: Ukrainian medical and monitoring center for alcohol and narcotics within Ministry of Healthcare of Ukraine <[http://www.damonitoring.net.ua/file/EMCDDA%20Drug%20Country%20Profile%20Ukraine%202012%20\(data%202011\)%20ukrainian.pdf](http://www.damonitoring.net.ua/file/EMCDDA%20Drug%20Country%20Profile%20Ukraine%202012%20(data%202011)%20ukrainian.pdf)>.

<sup>214</sup> *Ibid* at para 5.

However, as a Ukrainian drug therapist recognized in an interview for the EpochTimes,<sup>215</sup> “[...] in fact the number [of drug addicted people] is 7–10 times higher. It reaches approximately 1.5–2 million people [...]”. Some drug-addicted people say that they are not interested in medicines used to treat pain because the concentration of narcotic active substance in these medicines is usually insufficient to provide the result they want. In an interview, a Ukrainian oncologist said that one of his patients, a drug-addicted person with 15 years’ experience, had once “sensitized” him to the point that “*the concentration in homemade narcotics is about 8%, and 1% Morphine Hydrochloride has no effect on him*”.<sup>216</sup> Hypothetically, a higher dose of a weaker opioid may potentially bring the desired effect to a drug-addicted person. However, obtaining large doses from healthcare settings is a rather difficult task for them.

Moreover, considering the issue of excessive drug prohibitions globally, there are international studies<sup>217</sup> that reveal the fact that imposed prohibitions related to drug circulation add considerable value to the profits from the illicit drug markets and even provide a financial base for terrorist groups.<sup>218</sup>

It appears that Ukraine’s use of opioids for medical purposes is considerably less than the average global use and even much less than the average use in developed countries. There is no evidence that the number of drug addicts is reduced by the tightened rules for medical use of controlled substances in Ukraine. In other words, there is no evidence to show that the stricter rules for medical use of opioids result in a general decrease in drug addiction levels in the general population. On the contrary, strict regulation may bring serious adverse effects.

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<sup>215</sup> Anton Lunin, “Drugs addiction – invisible enemy of Ukrainian nation” (“Наркоманія — невидимий ворог української нації”), (8 October 2012) online: EpochTimes <<http://www.epochtimes.com.ua/opinion/ukraine/narkomaniya-nevidimiy-vorog-ukrayinskoyi-natsiyi-105847.html>>.

<sup>216</sup> Andrew Rokhansky et al, *supra* note 8 at 96.

<sup>217</sup> Jeffrey A. Miron & Jeffrey Zwiebel, “The Economic Case Against Drug Prohibition” (1995) 9: 4 Journal of Economic Perspectives 175; see also Gaurav Mehra, “The Economic Consequences of Drug Prohibition” (21 August 2012), posted in Civil Liberties, Economics, Law, Politics, Regulation, War on Drugs, online: <<http://mises.ca/posts/blog/the-economic-consequences-of-drug-prohibition/>>.

<sup>218</sup> See Eugene O’Scapella, “How Drug Prohibition Finances and Otherwise Enables Terrorism” Submission to the Senate of Canada Special Committee on Illegal Drugs (29 October 2001) online: Parliament of Canada <<http://www.parl.gc.ca/Content/SEN/Committee/371/ille/presentation/oscapella1-e.htm>>; see also Ted Galen Carpenter “Drug Prohibition is a Terrorist’s Best Friend” (Washington, 2005), online: Cato Institute <<http://www.cato.org/about>>.

### 2.1.3. The Use of Opioids for Analgesia as a Financial Matter

The relation of countries' gross national income to their per capita consumption of opioid analgesics has been clearly demonstrated in a study by Jason Nickerson and Amir Attaran, "The Inadequate Treatment of Pain: Collateral Damage from the War on Drugs",<sup>219</sup> which shows that the residents of more economically developed countries have at best five thousand times better access to opioid analgesics than those who live in low income economies. At the same time the factors that influence the access to adequate analgesia are not exclusively of a financial nature.

Ukraine is neither the richest country in the world, nor the poorest. According to the World Bank data<sup>220</sup> Ukraine's GDP per capita in 2011 was approximately \$3,576.00. For comparison, the richest identified country had GDP per capita of approximately \$163,126.00 (Monaco), and the lowest GDP per capita was \$246.00 (Congo). Analgesics are certainly not the most expensive category of medicines, particularly morphine,<sup>221</sup> which is recommended by the WHO as the "gold standard" for pain control and is also becoming more available for patients even in poorer countries like Uganda, with an approximately GDP per capita of \$472.00 in 2010.<sup>222</sup> According to the data provided by the Pain and Policy Studies Group of the Wisconsin University, 2010 mg/per capita consumption data of Ukraine (0.6418 mg/per capita)<sup>223</sup> is only about 20% higher than the consumption data of Uganda (0.4260 mg/per capita),<sup>224</sup> while the Ukrainian per/capita GDP is over six times higher than same indicator of Uganda in 2010.<sup>225</sup> Year 2010 is used for comparison because no consumption data for Uganda is available for consecutive years. Republic of Moldova, a neighbour of Ukraine with a significantly

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<sup>219</sup> Jason W. Nickerson & Amir Attaran, "The Inadequate Treatment of Pain: Collateral Damage from the War on Drugs", online: (January 2012) 9:1 PLoS Medicine 1 <<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001153>>.

<sup>220</sup> See Countries Comparison, GDP per capita, online: WorldBank <[http://data.worldbank.org/indicator/NY.GDP.PCAP.CD/countries/1W?order=wbapi\\_data\\_value\\_2012%20wbapi\\_data\\_value%20wbapi\\_data\\_value-last&sort=desc&display=default](http://data.worldbank.org/indicator/NY.GDP.PCAP.CD/countries/1W?order=wbapi_data_value_2012%20wbapi_data_value%20wbapi_data_value-last&sort=desc&display=default)>.

<sup>221</sup> See *supra* note 201.

<sup>222</sup> See *supra* note 220.

<sup>223</sup> Pain and Policy Studies Group, Opioid Consumption Data: Ukraine, online: <<http://www.painpolicy.wisc.edu/country/profile/ukraine>>.

<sup>224</sup> Pain and Policy Studies Group, Opioid Consumption Data: Uganda, online: <<http://www.painpolicy.wisc.edu/country/profile/uganda>>.

<sup>225</sup> See *supra* note 220.

lower per capita GDP of 2011(\$ 1,971.00),<sup>226</sup> the per capita morphine consumption for the same year (mg/per capita 1.1931)<sup>227</sup> is almost twice as high as in Ukraine.

This means that the availability or accessibility of opioids for analgesia should hardly depend on merely financial issues in Ukraine, or specifically on budgetary allocations. To a greater extent this is a matter of adequate regulations. The above data shows that even countries much poorer than Ukraine are able to provide significant access to morphine.

## **2.2. How Ukrainian People Act Under Strict Prohibitions Regarding Opioids**

### 2.2.1. Breaking the Regulations on Circulation of Narcotics for Medical Purposes

Following the above statement, putting too many restrictions on the use of opioids in healthcare may in fact bring contrary results.<sup>228</sup> Instead of preventing drug abuse and related crimes, excessive restrictions and procedures which limit access to adequate analgesics in reality push people into breaking the law in order to obtain necessary medication. People who are denied adequate amounts of painkillers seek relief from pain and obtain medication illegally at so-called “black” (illegal) markets.

Example 1. The story of Lyudmila,<sup>229</sup> a patient with stage four cancer from Cherkassy (a city in Central Ukraine), is striking. Lyudmila was prescribed 6 ampoules of morphine (1 ampoule 6 times daily), but the dose was not enough to provide pain relief, and the prescription could not be adequately administered, because a nurse, could not visit Lyudmila 6 times a day, as she had many other patients in need of help. When her suffering became unbearable, she sent her husband to seek narcotics from drug dealers. “*Go fast and look for drug dealers near bars, near restaurants [...]*” Lyudmila told her husband, as she could no longer bear her severe cancer pain.<sup>230</sup>

Example 2. In one family in the countryside a young man, being a former drug addict at that time, had to prepare a “home-made drug” for his grandmother who was suffering from cancer, as she did not receive adequate analgesics. Because nurses do not make house calls at night, the older woman screamed in pain all night long. There was a newborn in their family at that time, so the situation became unmanageable and unbearable for all the family members. “*I had already started to get mad,*” the patient’s grandson said. Then he decided to use his “skills” from his former life as a drug addict to prepare at home a certain substance of sedative and analgesic effect using ingredients with opioid effects for his grandmother. That brought great relief for the whole family. But the grandson returned to his drug habits after being free from them for months. Being a former drug addict he did not manage to refrain from the temptation of drugs when preparing

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<sup>226</sup> *Ibid.*

<sup>227</sup> Pain and Policy Studies Group, Opioid Consumption Data: Republic of Moldova, online: <<http://www.painpolicy.wisc.edu/country/profile/republic-moldova>>.

<sup>228</sup> See Wood et al, *supra* note 212; see also Jason Silverstain, “How the War on Drugs Punishes Those Who Suffer”, online: (6 September 2013) PLOS <<http://blogs.plos.org/publichealth/2013/09/06/how-the-war-on-drugs-punishes-those-who-suffer/>>.

<sup>229</sup> TSN-News on Ukrainian National Channel “1+1” (16 March 2013), online: TSN <<http://tsn.ua/groshi/hvori-na-rak-ukrayinci-shukayut-znebolyuvalne-v-narkomaniv.html>>.

<sup>230</sup> *Ibid.*

them for his grandmother and after six months of freedom from the drug habit the young man went back to taking drugs.<sup>231</sup>

### Example 3.

According to the judgement of conviction<sup>232</sup> dated 30 April 2010 a cancer patient in Ukraine was accused of illegal purchase of narcotic drugs with punishment determined by the law of three years sentence. The punishment, however, was not assigned due to the health condition of the person.

According to the data from the Ukrainian courts decisions database in the period from 2007 to the present date, 10 judgements of conviction<sup>233</sup> were made against people with health conditions requiring pain control, mostly in rural areas, who planted cannabis or poppy in small quantities exclusively for relief of their pain and/or kept these substances at their homes for use as painkillers. All these people recognized their “guilt”. As it was ascertained by courts, they did not have intention to sell the narcotic substances, nor did they cause any danger for the society. They were even released from the penalty meant for the “crime” of illegal planting and keeping of drugs.

Presumably, the strict regulations of narcotics use in healthcare are designed to prevent drug addiction and crime committed as a result of it, rather than continuing to deprive the Ukrainian people of adequate pain management. However, it has become obvious that the measures taken do not work properly. Instead, in many cases the strict rules push patients and their families to commit acts prohibited by the law.

### 2.2.2. Attempting and Committing Suicides

There is another possible regretful consequence of the denial of adequate pain control. Suicidal thoughts, attempted suicides and committed suicides are not uncommon among pain sufferers. According to William Breitbart,<sup>234</sup> “*Uncontrolled pain is a major risk*

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<sup>231</sup> Andrey Rochansky et al, *supra* note 8 at 36.

<sup>232</sup> Judgement of conviction 1-227/10 [30 April 2010] Brovarsky city-district court of Kyivska oblast (Броварський міськрайонний суд Київської області)

<sup>233</sup> Judgement of conviction 1/1017/149/11 [15 August 2011] Myronivsky district court of Kyivska oblast (Миронівський районний суд Київської області); Judgement of conviction 1-153/2010 [23 April 2010] Voznyesensky city-district court of Mykolayivska oblast (Вознесенський міськрайонний суд Миколаївської області); Judgement of conviction 1-485\08 [24 October 2008] Bohunivsky district court of the city of Zhytomyr (Богунський районний суд м. Житомира); Judgement of conviction 1-186/11 (or 5-186/11) [22 September 2011] Sokyransky district court of Chernyvetska oblast (Сокирянський районний суд Чернівецької області); Judgement of conviction 1-232/07 [24 December 2007] Mykolayivsky district court of Lvivska oblast (Миколаївський районний суд Львівської області); Judgement of conviction 1-101-09 [06 July 2009] Izyaslavsky district court of Khmelnytska oblast (Із’яславський районний суд Хмельницької області); Judgement of conviction 0911/2615/2012 [13 March 2013] Nadvirnyansky district court of Ivano-Frankivska oblast (Надвірнянський районний суд Івано-Франківської області); Judgement of conviction 1-100/2010 [27 October 2010] Semenivsky district court of Chernihivska oblast (Семенівський районний суд Чернігівської області); Judgement of conviction 1011/1121/12 [19 December 2012] Zguryvskyj district court of Kyivska oblast (Згурівський районний суд Київської області); Judgement of conviction 1-125/11 [25 July 2011] Halytsky district court of Ivano-Frankivska oblast (Галицький районний суд Івано-Франківської області).

<sup>234</sup> William Breitbart, “Suicide Risk and Pain in Cancer and AIDS Patients” Psychiatry Service and Pain Service, Department of Neurology, Memorial Sloan-Kettering Cancer Center (New York), online:

*factor for suicide and suicidal thoughts in cancer patients.*” Pain is also an accompanying symptom of AIDS, which contributes significantly to the suicide risk in patients with this diagnosis.<sup>235</sup> A recent study<sup>236</sup> has proven the connection between non-cancer pain conditions like migraines and back pain and an increased risk of suicide. All these appear to be true for Ukraine, as the following examples demonstrate.

Example 1. A cancer patient, a former KGB agent from Ukraine, revealed that he had a handgun under his pillow to shoot himself “*when the pain gets too strong*”. He died of natural causes three months after being interviewed.<sup>237</sup>

Example 2: From the Story of Vlad Zhukovsky, told in the HRW Report “Uncontrolled Pain”.<sup>238</sup> “One day, in June 2008, Vlad’s pain became so severe that he could no longer bear it and decided to jump from his hospital window. While his mother was pleading with nurses to give him more pain medications, Vlad climbed into the open window. Most of his body was already outside his fall imminent when his roommate, a retired police officer, noticed what was happening, grabbed him by the leg, and forced him back in. He later told his mother that he had wanted to fall “head down and be dead right away so it wouldn’t hurt anymore.” Vlad, who was very religious, was deeply troubled by his suicide attempt. He repeatedly told his mother afterwards that he worried that the pain might make him do something sinful that would prevent him from seeing her again in heaven.” In October 2010 Vlad Zhukovsky died.

Example 3. In an interview with Nikolay Ivanovych, a 62-year-old cancer patient in Ukraine, he said: “*I do not know whether I can ask to increase the dose [of opioid analgesic]. Maybe the big dose will kill me? And the doctor does not want to have it on his conscience? But when pain is very severe, at night I ask for death. I would want a disaster to happen (an earthquake or an explosion), but that nobody but me would be harmed.*”<sup>239</sup>

Example 4. Just recently, on June 12th, 2013 in one palliative care room within a Ukrainian hospital # 2 in Cherkassy (a city in the Central Ukraine) terminal cancer patient attempted suicide by arson. The reason was unbearable pain that persisted after 50mg of morphine daily and that the patient could no longer tolerate. According to the doctor Kateryna Pohorila, “*We could not prescribe him more according to the law. We combined different medications, but the therapy was ineffective.*”

The man barricaded himself in his room and set it on fire. After high flames were up he pulled down the barricades and ran out crying, “*I am not guilty.*”<sup>240</sup>

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University of UTAH <<http://healthsciences.utah.edu/pain-research-center/>>; see also W. Breitbart “Cancer pain and suicide” in Foley K, Bonica JJ, Ventafridda V, eds. *Advances in pain research and therapy*, vol 16. (New York: Raven Press”, 1990) 399; see also N.L. Farberow, et al, “An eight year survey of hospital suicides” (1971) 1:3 *Life Threatening Behaviour* 198.

235 See Breitbart, *supra* note 234.

236 Mark A. Ilgen et al, “Noncancer Pain Conditions and Risk of Suicide” (July 2013) 70:7 *JAMA Psychiatry* 692.

237 “Freedom from Pain”, video, online: Al Jazeera <<http://www.internationalreporting.org/pain/al-jazeera/>>; see also Amon & Lohman, *supra* note 96.

238 HRW *Uncontrolled Pain*, *supra* note 2.

239 Andrew Rokhansky et al, *supra* note 8 at 32.

240 Natalya Tavanets, “If you don’t make the doctors give me a death injection, you will see what I do” (“Якщо ти не змушиш лікарів зробити мені смертельний укол, побачиш, що я зроблю”) (19 June 2013) 25 *Vechirni Cherkassy* (“Вечірні Черкаси”), online: *Vechirni Cherkassy*

This incident showed practical absence of a standard of palliative care in Ukraine. First, ambiguity in law regarding prescription of doses of medicines and doctors' fear of criminal responsibility for “overuse” of opioids make the introduction of adequate doses of opioid analgesics close to impossible. This is what happened to the patient who as a result attempted suicide in despair. Second, this patient had been placed in a ward together with a comatose patient, which certainly contradicts the principles of palliative care, because it depresses, admitted Ksenia Shapoval, Coordinator of the International Initiative “Palliative Care” of International Renaissance Foundation. Third, it is indescribably sad and beyond any logic, that after this incident the patient was not reassessed and given adequate pain relief. Instead he was sent to a psychiatric facility.

Example 5. Even more recently, in August, 2013, a cancer patient from Odesa (a city in Southern Ukraine) committed suicide<sup>241</sup> by jumping off his balcony. He had a written message in his hands, saying that “[he] can no longer suffer pain”. According to the news report, the healthcare providers consider that this suicide could have been prevented by narcotic medicines for pain control.

These findings lead to the conclusion that failure to provide necessary medicine to relieve pain and thus leaving people in suffering may cause attempted or even committed suicides.

### 2.2.3. Trying to Preserve One's Human Dignity

Pain destroys a person's physical and emotional/mental health, becoming the first and primary care and concern in many cases in which it could even impair one's ability to make independent decisions about one's life, and making one dependent on the others for one's well-being. In other words, pain changes the patients' mental abilities and their personalities and subsequent actions. People in pain become different from who they are without pain. It often prevents them from living, acting and communicating with others in a dignified manner. Human dignity is an issue without limits, particularly if related to pain. The denial of adequate analgesia in Ukraine provides evidence of how such denial affects the dignity of the patients with under-treated pain. Patients would prefer to be remembered after their death as active and full of life human beings at the prime of their lives, rather than to be recalled by their family and friends as helpless and screaming creatures. Unfortunately, this is what a lot of incurable Ukrainian patients still have to fight for. According to Nikolay Ivanovych, a 62-year-old cancer patient from Ukraine:

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<<http://vechirka.netzhittya/yakshho-ti-ne-zmusish-likariv-zrobiti-meni-smertelnij-ukol-pobachish-shho-ya-zroblyu/>>.

<sup>241</sup> “Seriously ill man from Odessa committed suicide because of inaccessibility of medicines” (“Тяжелобольной одессит совершил самоубийство из-за недоступности медпрепаратов”) (8 August 2013) the events, online: GazetaUA <<http://news.mail.ru/inworld/ukraina/incident/14245142/>>.

I have a very good grandson. But I try to appear less at his eyes, particularly when I feel completely bad. I would want that he remembers his grandfather as a man who taught him how to fish, rather than the sick and screaming stack of bones I became now.<sup>242</sup>

Vlad Zhukovsky, another Ukrainian cancer patient, told the HRW, “*A few months before his death*” that he wanted to be remembered as “*an ordinary, happy person, as normal, sociable Vlad.*”<sup>243</sup>

#### 2.2.4. Changing the Patients’ Roles in the Families and Separating Them from Families

Pain not only dramatically worsens the quality of patients’ lives, but inevitably affects their roles as family members and their ability to live within the family. As has been observed by Diederik Lohman and Joseph Amon in their article “Denial of Pain Treatment and the Prohibition of Torture, Cruel, Inhuman or Degrading Treatment or Punishment”:<sup>244</sup>

Frequently, [people in pain] become completely dependent on their relatives while at the same time being unable to interact with them in a meaningful way.

According to the evidence collected by the Human Rights Watch, some patients suffering from pain reported that “*they could no longer tolerate having their children around them or became abusive to their spouses as a result of the pain*”.<sup>245</sup>

As a result of inadequate responses of the Ukrainian healthcare system to patients’ pain, people are driven to taking decisions contrary to their actual desires. There are also examples of how pain may separate families. One former Ukrainian KGB agent with cancer told to the Human Rights Watch that he decided to isolate himself from his family because of his severe pain that was not properly managed.<sup>246</sup> He didn’t want his family to hear him screaming in pain, so he chose to spend his last months alone instead of surrounded by his family. This example places uncontrolled pain as a profound obstacle to enjoying family life.

Because of the Ukrainian requirement that healthcare facilities introduce opioid pain management for terminal patients, the hospices become much better places than patients’ homes. This circumstance forced many people to leave their homes and families and to

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<sup>242</sup> Andrew Rokhansky et al, *supra* note 8 at 30.

<sup>243</sup> HRW Uncontrolled Pain, *supra* note 2 at 4.

<sup>244</sup> Amon & Lohman, *supra* note 96 at 173.

<sup>245</sup> *Ibid* at 172.

<sup>246</sup> *Ibid.*

spend the last months of their lives in hospices seeking pain relief. Nikolay Nikolayevych, a 62-year-old cancer patient in Ukraine, revealed in his interview to the human rights defendants<sup>247</sup> that “[he] would not want to die in the hospital”. He said, “I understand that my wife and son have troubles with me. But I would not want to die in the hospital.” Zinaida Maximova, a psychologist with the palliative care unit in Ukraine, told the Ukrainian TSN-news<sup>248</sup> that “part of [their] patients would prefer to go home, but they are withheld by the fear of being left without injections [painkiller] [...]”.

In addition to this evidence and examples, in the study “Impact of home care on hospital days: a meta-analysis”, Hughes et al.<sup>249</sup> found that the quality of care for palliative patients at their homes reduces the percentage of those who die in hospices or hospitals and reduces the number of “hospital days”. As an example, an “Epidemiological study of place of death in Portugal in 2010 and comparison with the preferences of the Portuguese population” by Gomez et al.<sup>250</sup> also resulted in the conclusion that “[t]here is a substantial gap between the reality and population preferences for place of death in Portugal.”

Eventually, the decision making regarding where to live and where to die is a rather complex challenge for an individual, with many objective and subjective factors coming into the equation. No substantial research and data on how the adequacy of pain management directly affects decision-making in palliative care has been found. However, better quality of out-patient palliative care makes people more likely to choose to spend the last days of their lives in their homes rather than in healthcare facilities. It means that the quality of palliative care (having pain management as an important component) affects the choices and decisions of people in terms of places to die. They tend to spend their days with families, but access to adequate care is a mandatory condition for this choice. There are documented cases when inadequate analgesia, particularly in out-patient care, separates people from their families, in contradiction to their actual wishes. It happens that the choices to separate from families are being “dictated” by pain, not by

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<sup>247</sup> Andrew Rokhansky et al, *supra* note 8.

<sup>248</sup> TSN-news of May 16, 2013, online: TSN < <http://ru.tsn.ua/video/video-novini/kabmin-uprostil-dostup-k-lekarstvam-soderzhaschih-narkoticheskie-veschestva.html?type=2>>.

<sup>249</sup> S.L. Hughes et al, “Impact of Home Care on Hospital Days: a Meta-Analysis” (October 1997) 32:4 Health Services Research Journal 415, online: VHL Research Portal <<http://bvshalud.org/portal/resource/en/mdl-9327811>>.

<sup>250</sup> B. Gomez et al, “Epidemiological Study of Place of Death in Portugal in 2010 and Comparison with the Preferences of the Portuguese Population”, abstract, online: VHL Research Portal <<http://bvshalud.org/portal/resource/en/mdl-24016640>>.

people. Not all patients chose to separate themselves from families in search of pain relief, and not all patients chose to die in hospices directly due to more adequate analgesia there. However, if there are even only some who choose to be separated from families for the sake of analgesia, it means that inadequate analgesia available at home practically pushes them to undesirable decisions they probably would not otherwise have made.

#### 2.2.5. Losing Opportunities to Work and Being Driven into Poverty and/or into Dependence on Others

According to Foley et al.,<sup>251</sup> patients with serious pain often appear unable “to work or care for their families”. Even more, the caregivers (naturally mostly relatives) “suffer distress, anxiety and depression. They may have to give up their own employment to care for a dying relative”.<sup>252</sup> This puts on patients an additional burden of shame, which definitely interferes with normal family relationships and undermines a patient’s psychological state and dignity. Pain deprives many of an ability to move and even to think normally, not to mention the ability to work and pay one’s way or support a family. Naturally pain causes sick leaves, absenteeism at work and sub-standard productivity, all having a negative impact on the families’ incomes, as well as a concrete negative economic consequence for society in general. Chronic pain may cause one to leave their job temporarily on medical leave or even permanently give up the employment. For individuals, the loss of the ability to work is a loss of an opportunity of adequate self-expression, a huge and important part of one’s life. For Ukrainians with rather low incomes (average monthly wages equal to CAD374.46),<sup>253</sup> and even lower disability payments (may be as low as only 60% of wages),<sup>254</sup> the ability to work in fact raises more basic concerns than professional self-expression. The cost of medication puts undue pressure on both patients and families to work in order to be able to afford the

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<sup>251</sup> Foley et al, *supra* note at 12; see also Daut, Cleland & Flanery, “Development of the Wisconsin Brief Pain Questionnaire to Assess Pain in Cancer and Other Diseases” (1983) 17:2 Pain 197.

<sup>252</sup> Foley et al, *supra* note at 12.

<sup>253</sup> According to the official information of the Ukrainian Pensions Fund, announced at the official web-site of the Ukrainian Pension Fund, available online:

<[http://www.pfu.gov.ua/pfu/control/uk/publish/article;jsessionid=BFF6299093A42BFC7AA7DA15A32C8C6F.app1:1?art\\_id=210845&cat\\_id=95535](http://www.pfu.gov.ua/pfu/control/uk/publish/article;jsessionid=BFF6299093A42BFC7AA7DA15A32C8C6F.app1:1?art_id=210845&cat_id=95535)>, average wages in Ukraine in April 2013 was UAH 2932.06, what was equal to 374.46 according to the converter with exchange rate of July 11th, 2013, online: <[http://coinmill.com/CAD\\_UAH.html#UAH=2932.06](http://coinmill.com/CAD_UAH.html#UAH=2932.06)> [Accessed on July 11, 2013]

<sup>254</sup> Law of Ukraine “On obligatory state social insurance for temporary loss of working capacity and expenses associated with bury” (“Про загальнообов’язкове державне соціальне страхування у зв’язку з тимчасовою втратою працездатності та витратами, зумовленими похованням”) 2240, 18 January 2001 at article 37.

medication. A family's wellbeing depends also on the ability to provide the means for medical treatment, since the high prices for medicine<sup>255</sup> and the not yet common extended medical insurance (according to most recent estimations in 2011 only 2 per cent of Ukrainians had extended medical benefits)<sup>256</sup> can dramatically affect the lives of patients and their families. Without a doubt, inadequate pain control causes unnecessarily lost careers and incomes of Ukrainian patients and their families.

### **2.3. How the Ukrainian Healthcare Providers Act to Better Treat Pain**

Alongside unnecessary suffering for Ukrainian patients and their families, in Ukraine healthcare providers themselves often become victims of the system of excessive restrictions, inadequate education and unreasonable legal intimidation.

The connection between the Ukrainian healthcare providers and the problem of pain management is stated concisely on the home page of the official website of the StopPain initiative:

***“When I see a patient's sufferings and cannot help, it kills me...”***

Logically, to perform their professional duties adequately, medical doctors in any country need certain conditions.

- 1) They should be sufficiently trained and have opportunity to learn about the latest achievements in medicine and the best medical practices in the country and throughout the world.
- 2) “A standard of care” should be established, so that every provider is aware of the expectations and requirements that should be met in his/her practice.
- 3) Appropriate resources should be available and reasonably accessible so that the established standard of care is realistically achievable.

Under the current conditions of uncertain standard of care, inconsistent training and barely available resources, one can hardly expect compliance to the *“orientation on contemporary standards of health and medical care”* required by Ukrainian law.<sup>257</sup> In the case of pain management in Ukraine, it becomes rather obvious that the above-mentioned

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<sup>255</sup> See e.g. Poltavets & Konovalova, *supra* note 194; see also “Prices for imported medicines are for some reason higher than abroad”, *supra* note 198; see also Datsyuk, Volokh & Sholoyko, *supra* note 197.

<sup>256</sup> “How much is medical insurance in Ukraine” (“Скільки коштує медична страховка в Україні”) (2 August 2013) Ukrainian Observer, online: Ukrainsky Obozrevatel <<http://10.0.1.243:15871/cgi-bin/blockpage.cgi?ws-session=3731236161>>.

<sup>257</sup> Law of Ukraine 2801-XII, *supra* note 19.

preconditions for performing the duty of due care for patients with pain are practically absent.

1) Healthcare providers are not sufficiently trained in the basics of pain management because:

- they don't have the benefit of pain management courses in medical schools;
- there is no actual system of advanced training that would ensure the doctors' awareness of contemporary best practices of safe pain control recommended by the WHO;
- there is no universal system of notification for Ukrainian medical doctors regarding new medicines registered in Ukraine; and
- there is no system for informing the healthcare providers about changes in law that affect their practice.

2) No standard of care.

In Ukraine there are no official guidelines or recommendations for healthcare providers on standards of evaluating pain and how to treat it for different health conditions. Not all Ukrainian doctors are aware of WHO guidelines for the treatment of cancer pain, for instance. However, many doctors recognize the need for universal guidelines on the treatment of pain, as confirmed by the results of the questionnaire offered to Ukrainian medical doctors.<sup>258</sup>

3) Inadequate availability and accessibility of necessary resources.

Because the treatment of pain in many cases requires analgesics, their availability and accessibility is essential for effective pain relief. The high price of non-opioid analgesics and lack of adequate supply in the Ukrainian healthcare units constitute barriers to introducing sufficient pain control. Excessive restrictions and unfeasible requirements for the use of opioid analgesics significantly limit their use on practice.

Thus, in practice, the Ukrainian healthcare providers don't have appropriate conditions to sufficiently perform their professional duties. As a result they are exposed to everyday stress and moral suffering as they have to watch their patients' pain while being unable to provide necessary treatment.

The sensitive and unresolved issue of providing possible relief to patients on one hand makes patients and their families seek alternative ways to deal with the problem,

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<sup>258</sup> Appendix 1, *supra* note 50 at 6.

sometimes seeking analgesics from illegal traders,<sup>259</sup> and on the other hand, healthcare providers often go to extreme lengths, including breaking the law for the sake of relieving their patients' suffering. According to many interviews,<sup>260</sup> of course, mostly anonymous, patients, their relatives and healthcare providers recognized that they sometimes chose to “act on the edge of law”<sup>261</sup> to provide at least some pain relief to the suffering patients. Patients' relatives and nurses often have to make informal arrangements contrary to the rules. Under such arrangements, relatives would come to the hospitals, take ampoules of morphine, do injections on their own, and would bring empty ampoules back to the healthcare setting, so that the documentation would exonerate a nurse from being present directly in the administration of the injection. Or sometimes, a nurse would home visit only once a day and would leave a one-day supply of narcotic painkiller for a patient to avoid further repeated home visits needed during a one-day span for the same injections. For nurses, usually overwhelmed by their duties, the lack of transportation and even fuel, repeated daily home visits for each and every dose of treatment are simply not feasible and would leave a patient in tremendous suffering.<sup>262</sup> The restrictive rules are preventing healthcare providers from performing their professional duties and pushing them to illegal conduct or acts, which may result in administrative or even criminal punishment.<sup>263</sup> Certainly, breaking the rules, while perfectly justified by the reality of their practices, is not a “safe” alternative for the medical doctors and nurses, and creates a stressful climate, the opposite of a “healthy” atmosphere at work. Because of these particular hardships regarding the access to opioid painkillers for in-home patients, the medical staff of all cancer hospitals and clinics are exposed to distress when they have to make decisions regarding discharging incurable patients and sending them home for symptomatic treatment. The Ukrainian rules do not allow terminally ill people to remain hospitalized with curable patients. The healthcare providers clearly realize that by discharging those patients from the healthcare facility, they send them to inevitable suffering from pain before their death. There is practically nothing they can do about this

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<sup>259</sup> See the evidence, provided in subchapter 2.2.1 at 52-53, above.

<sup>260</sup> See Andrew Rokhansky et al, *supra* note 8.

<sup>261</sup> HRW Uncontrolled Pain, *supra* note 2.

<sup>262</sup> Andrew Rokhansky et al, *supra* note 8.

<sup>263</sup> *Criminal Code of Ukraine (Кримінальний кодекс України)*, Law of Ukraine 2341-III, 5 April 2001 at articles 319-320, which establish responsibility for illegal prescription of opioids and for violation of the rules of circulation of opioids.

state of affairs but to bear it.<sup>264</sup> Although not often, it happens that under-treated pain sufferers appeal to lawyers to support their right for adequate medical care. The lawyers naturally do their best to ensure adequate pain control for a separate client through applications to a particular healthcare setting management or to regulatory authorities of a particular district. This sometimes results in concentrating all efforts of certain clinic staff to one patient, leaving other patients even more under-treated.<sup>265</sup>

To sum up, those Ukrainian healthcare providers, as well as family members, who strive to decrease suffering of patients choose different ways to achieve this goal, while exposing themselves to risks of legal sanctions.

## **2.4. Concluding Remarks**

The barriers to pain management make the use of opioid analgesics in Ukraine sub-standard compared to many developed countries in the world. The restrictions and low levels of opioid use in medical practice do not, however, prevent or result in a decrease of the levels of drug addiction and drug abuse. In many cases the regulations cause even more adverse effects, because people in unrelieved pain, together with their relatives, are often being pushed by these strict rules to search for alternative ways to get pain relief. As a result of excessive restrictions and impractical rules for the use of opioids for pain control, the Ukrainian healthcare providers, together with patients and their relatives, are forced to invent semi-legal or sometimes completely illegal strategies to provide the best possible relief of pain and to decrease suffering of the patients. Even with efforts by doctors and relatives of the patients, they are often left with untreated or under-treated pain, which makes them suffer, undermines their human dignity, deprives them of opportunities and forces them to make difficult choices that otherwise they would not have made.

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<sup>264</sup> “Freedom from Pain” video, *supra* note 237 at episode with Iryna Shlyaga (11<sup>th</sup> min of video).

<sup>265</sup> E. Novitsky, Report on the Activity of the Human Rights Organization in Simferopol (Southern Ukraine) in defending the right for pain control, presented during the First National Congress on Palliative Care (Sept. 26-27, 2012, Irpin, Ukraine), online: LigaLife <<http://ligalife.com.ua/p.pdf>>.

### **Chapter 3. The Ukrainian Legislation on Pain Management in View of the International Legislation and Human Rights**

Adequate pain management has exceeded the bounds of a purely medical problem. To a far greater degree, it has become an issue of adequate healthcare and pharmaceutical regulation. The question of the competence of the medical field in pain management has been recognized as a cultural, social, economic and even sometimes religious or political problem, requiring a very complex solution.<sup>266</sup> Pain management has been adequately placed by Brennan et al. at “*the convergence of medicine, law and ethics*”.<sup>267</sup> In this age in which most pain can be successfully relieved by relatively cheap and safe remedies,<sup>268</sup> leaving people with untreated or under-treated pain, thus exposing them to needless and avoidable suffering, raises the issue to the level of human rights.<sup>269</sup> As was emphasized again by Brennan et al., “*the unreasonable failure to treat pain is poor medicine, unethical practice and is an abrogation of a fundamental human right.*”<sup>270</sup> Advocating better healthcare, including pain control, and eliminating the gap between medical achievements in pain relief and the actual introduction of pain treatment have resulted in official declarations,<sup>271</sup> actions and initiatives<sup>272</sup> at both national and international levels throughout the world. Although not all challenges have been addressed so far, these efforts brought a lot of positive results in different

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<sup>266</sup> See Brennan et al, *supra* note 22 at 211.

<sup>267</sup> *Ibid* at 217; See also earlier published R.C. Koshy et al, “Cancer Pain Management in Developing Countries: A Mosaic of Complex Issues Resulting in Inadequate Analgesia” (1998) 6:5 Support Cancer Care 430.

<sup>268</sup> See *supra* notes 6 and 7 with all provided references.

<sup>269</sup> See *supra* note 22 with all provided references; see also Allyn L. Taylor, “Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs” (2007) Health Law, Ethics and Policy 555 at 564 (“Although not technologically binding, the increasing number of intergovernmental resolutions adopted by the General Assembly and other international forums reflects the world community’s growing recognition of the critical link between access to essential medication and human rights. The specific reference to the link between palliative care and human rights may reflect the community’s emerging recognition that allowing millions to suffer preventable excruciating pain is an affront to human dignity.”)

<sup>270</sup> Brennan et al, *supra* note 22 at 211.

<sup>271</sup> See e.g. Joint Declaration and Statement of Commitment on Palliative Care and Pain Treatment as Human Rights, International Association for Hospice and Palliative Care Alliance, online: <[http://hospicecare.com/uploads/2011/8/jdsc\\_en.pdf](http://hospicecare.com/uploads/2011/8/jdsc_en.pdf)>; see also International Pain Summit of the International Association for the Study of Pain, Declaration of Montreal: Declaration That Access to Pain Management Is a Fundamental Human Right, Report (2011) 25 Journal of Pain & Palliative Care Pharmacotherapy 29, online: <<http://informahealthcare.com/doi/pdf/10.3109/15360288.2010.547560>>; but see Jonathan Liberman et al, “Ending Inequities in Access to Effective Pain Relief” (2010) 376 Lancet 856 at 857 (“But while resolutions can be powerful instruments of change, they are not self-implementing.”)

<sup>272</sup> E.g. HRW Uncontrolled Pain, *supra* note 2.

countries.<sup>273</sup> Although the “*right to pain management*” is not directly articulated in international documents or in contemporary national constitutions,<sup>274</sup> several international instruments, discussed in the present chapter, contain entitlements that implicitly include adequate pain relief. These entitlements primarily pertain to the right to *the highest attainable standard of health* and *the prohibition of cruel, inhuman or degrading treatment*.

According to the Constitution of Ukraine, all international treaties in force ratified by the Parliament of Ukraine (called “*Verkhovna Rada*”) shall be an integral part of the Ukrainian national legislation.<sup>275</sup> Moreover, the accepted international provisions prevail over the provisions of Ukrainian domestic legislation.<sup>276</sup> This is why I present the analysis of the norms of international law together with the Ukrainian domestic legislation and where applicable I underline the differences.

The discussion of the challenges of implementation is equally important, particularly because the adoption of laws in Ukraine does not always result in their realization in practice.<sup>277</sup> I also consider Ukrainian case law on the issue of pain management to see how the legislation is being applied for the defence of human rights of Ukrainian patients regarding pain relief.

### **3.1. The Ukrainian Rules of Opioids Use and Their Compliance with the Single Convention on Narcotic Drugs**

Although the Ukrainian Constitution establishes priority of international legislation over domestic norms, arguably the Ukrainian rules for the use of narcotics in healthcare are more restrictive than the requirements of the Single Convention on Narcotic Drugs, 1961 (*Single Convention*),<sup>278</sup> and at certain points contradict this treaty. Note that the goal of the Single Convention is to limit circulation of drugs exclusively for medical and scientific purposes,<sup>279</sup> but not to entirely exclude narcotic medicines from circulation.

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<sup>273</sup> See particularly Uganda Case Study and Vietnam Case Study in Lohman , Shleifer & Amon, *supra* note 22 at 7.

<sup>274</sup> Brennan et al, *supra* note 22 at 211.

<sup>275</sup> *Constitution of Ukraine*, *supra* note 44 at article 9.

<sup>276</sup> *Ibid.*

<sup>277</sup> See discussion of the legal paradox of two contradictory laws in force at the same time in Ukraine at 68-69, below.

<sup>278</sup> *Single Convention*, *supra* note 9.

<sup>279</sup> *Ibid* at article 4, part c) and article 9 part 4.

Furthermore, opioids must be made available for medicine and science.<sup>280</sup> It means that the governments of the member states are obliged to establish all necessary control measures regarding the use of opioids to prevent drug abuse, but not at the expense of necessary medical care, including adequate analgesia. In other words, the Single Convention does not intend to limit the legitimate use of narcotics, but rather seeks to ensure and control the legal circulation of these substances. For these purposes the treaty establishes a mechanism for identifying the limits of drug requirements<sup>281</sup> necessary for medicine and science in the participating countries and calls for effective control over the manufacture of opioids and their trade and distribution within the established limits. According to the provisions of the Single Convention<sup>282</sup> such control is associated at most with the requirement that the manufacture, trade and distribution of narcotic medicines be conducted under proper licences. The purpose of the mentioned mechanism of estimates<sup>283</sup> is to identify necessary legitimate limits,<sup>284</sup> and the purpose of the licences is to control,<sup>285</sup> not to limit. Virtually no particular licence requirements are established by this international document, so that every country can chose the most appropriate licence requirements to effectively control the circulation of narcotic substances in healthcare and science in their territories. Although the member states adherent to the Single Convention are not precluded from adopting stricter measures of control comparative to the Single Convention requirements,<sup>286</sup> it is also said in this treaty that “*narcotic drugs [are...] indispensable for the relief of pain and suffering.*”<sup>287</sup> In performing such control, the Ukrainian government chose to establish a three-fold licensing sequence<sup>288</sup> for the use of opioid medicines in healthcare settings and numerous complex and highly impractical regulations of the use of opioid analgesics, which were discussed in the first chapter and which limit reasonable availability of opioids in healthcare settings of Ukraine for medical purposes. The strict Ukrainian rules for the use of narcotics are not directly prohibited by the Single Convention, but they restrict access to opioids in healthcare,

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<sup>280</sup> *Ibid* at Preamble.

<sup>281</sup> *Ibid* at article 12.

<sup>282</sup> *Ibid* at articles 29-30.

<sup>283</sup> *Ibid* at article 12.

<sup>284</sup> *Ibid* at articles 21-24.

<sup>285</sup> *Ibid*.

<sup>286</sup> *Ibid* at article 39.

<sup>287</sup> *Ibid* at Preamble.

<sup>288</sup> See information about the licensing conditions for medical use of opioids in subchapter 1.5.2. at 28-32, above.

failing to respect the requirement of the treaty to make opioids available for legitimate medical care.

This state of affairs may be compared with the issues considered in at least two notable cases decided by the *Supreme Court of Canada*. First, *Canada (Attorney General) v PHS Community Services Society*<sup>289</sup> in 2011 considered the legality of refusal by the federal Minister of Health to extend the exemption for Insite from the application of the provisions of Canadian provincial drug law, the Controlled Drugs and Substances Act.<sup>290</sup> Insite provided a legal environment for safer injections of controlled substances, thus saving lives by preventing deaths by overdoses, HIV/AIDS and hepatitis C “without increasing the incidence of drug use and crime in the surrounding area”.<sup>291</sup> According to the Court’s decision, the closing down of the Insite would pose a threat to the lives and health of the people who inject drugs there; without the Insite these people would still do the injections, but without necessary sanitation and supervision by the health professionals. This would limit their constitutional rights to life and the security of the person and would not accord with the principles of fundamental justice. The Minister’s refusal to grant an exception was recognized as violating the Charter, and the Minister was ordered to grant an exemption, thus providing legality for the work of this institution. This decision did not overturn the federal drug laws and did not legalize the use of illegal drugs in general, but required the Minister to provide necessary exemption to the life-saving institution, the activity of which proved to protect the human rights of the citizens. Second is the recent Supreme Court of Canada case of *AGs v Bedford, Lebovich and Scott*.<sup>292</sup> While prostitution in Canada is not criminalized, the provisions of the Criminal Code of Canada prohibited bawdy-houses,<sup>293</sup> living on the avails of prostitution<sup>294</sup> and communicating in public for the purpose of prostitution.<sup>295</sup> These legislative restrictions were challenged on their constitutionality in terms of observance of the rights of the prostitutes. As recognized fact in this Court case’s reasoning, these criminal provisions,

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<sup>289</sup> *Canada (Attorney General) v PHS Community Services Society* [2011] 3 SCR 134, online: <<http://scc-csc.lexum.com/scc-csc/scc-csc/en/item/7960/index.do>>.

<sup>290</sup> *Controlled Drugs and Substances Act*, S.C. 1996, c. 19.

<sup>291</sup> *Canada (Attorney General) v PHS Community Services Society*, *supra* note 289.

<sup>292</sup> *Canada (Attorney General) v Bedford*, 2013 SCC 72, online: <<https://www.documentcloud.org/documents/979787-ags-v-bedford-lebovitch-and-scott.html>> [*AGs v Bedford*].

<sup>293</sup> *Criminal Code of Canada*, R.S.C. 1985, c. C-46, S 210.

<sup>294</sup> *Ibid* at Section 212 (l) (j).

<sup>295</sup> *Ibid* at Section 213 (l) (c).

although “*primarily concerned with preventing the public nuisance*”,<sup>296</sup> were however recognized by the Court as “*inconsistent with the Charter*”,<sup>297</sup> as they infringed on “*the rights of the prostitutes by depriving them of security of person in a manner that is not in accordance with the principles of fundamental justice.*”<sup>298</sup>

In both court cases the issues were considered from the perspectives of *the fundamental justice principles*, testing their *arbitrariness, gross disproportionality and overbreadth*,<sup>299</sup> and giving *priority to the actual purposes and objectives of the laws*, as well as their relationship with the interests of the state.

Arguably, the matter of the use of opioids in Ukrainian healthcare may be viewed by analogy to the issues of prostitution in Canada as well as to the Insite exemption regarding the drug legislation. The use of narcotic analgesics in Ukraine is legal, as is prostitution in Canada. However, the Ukrainian regulatory provisions on the use of narcotic painkillers are such that make their use overwhelmingly difficult, just as the challenged criminal provisions in Canada made prostitution rather unsafe. Therefore, the Canadian legislation allowed prostitution on one hand, but practically made it unsafe on the other hand; the Ukrainian legislation requires adequate use of opioids in healthcare on one hand, but makes it barely feasible in practice on the other hand. Very closely to this, the constitutional rights of the Canadians (*inter alia*, those who inject narcotic drugs) include the right to life and security of the person, exactly what was ensured by the Insite exemption and what would be threatened if such exemption was revoked. Similarly, in Ukraine, recognizing unacceptability of drug abuse, the constitutional rights of the Ukrainian people in pain are threatened and limited by the disproportional strictness of the rules on the use of opioid substances.

The third article of the Ukrainian Constitution proclaims “[*a*]n individual, his life and health” as “*the highest social value*”.<sup>300</sup> This constitutional provision puts the quality of life of an individual higher than other tasks and social priorities. Applying this constitutional provision, if analgesics are vital for improving of the lives of Ukrainian patients, their availability and accessibility must be a highest priority according to the Constitution. The prevention of drug abuse is also an important social task, but not to be

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<sup>296</sup> *AGs v Bedford*, *supra* note 292 at 7.

<sup>297</sup> *AGs v Bedford*, *supra* note 292 at 6.

<sup>298</sup> *AGs v Bedford*, *supra* note 292; see also *Canada (Attorney General) v PHS Community Services Society*, *supra* note 289 at para 128-135.

<sup>299</sup> *AGs v Bedford*, *supra* note 292 at 7.

<sup>300</sup> *Constitution of Ukraine*, *supra* note 44 at article 3.

achieved at the expense of such “social value” as one’s health and well-being. As admitted in the above-mentioned (*Canada*) *AGs v Bedford*, “The Parliament has the power to regulate against nuisances, but not at the cost of the health, safety and lives of prostitutes.”<sup>301</sup> According to similar logic, the Government of Ukraine has the power to regulate against non-medical drug use, but not at the expense of the well-being of patients in pain and their personal and social security.

Canadian case-law, however, lies beyond the Ukrainian legal boundaries. The considered Courts’ decisions cannot be applied directly to the matter of Ukrainian right for pain management. At the same time, this discussion illustrates the logic of the compliance (or noncompliance) of certain regulations with human rights and values, declared in the legislations on both national and international levels. Such logic is not bounded by Canadian or any other jurisdiction, and therefore, may be extrapolated to the matter of Ukrainian opioids regulations versus human rights and social values.

The Ukrainian legislative restrictions and complicated procedures on the use of opioids in healthcare are formally not directly prohibited by the Ukrainian Constitution and international law. However, as they limit access to adequate analgesia and thus undermine the quality of lives of the Ukrainian patients and threaten their health security, they violate the Ukrainian Constitution and the Single Convention on Narcotic Drugs, as well as other domestic and international norms, establishing the right for personal and social security that will be discussed in greater detail later in the present thesis.<sup>302</sup>

## **3.2. Novel Ukrainian Legislation Regarding Pain Management and Challenges in their Implementation**

### **3.2.1. Newly Adopted Regulations of Narcotic Substances in Ukrainian Healthcare: An Unaccomplished Step towards Better Pain Control**

Ukraine has taken several progressive steps towards better access to adequate pain relief, including the adoption of regulations<sup>303</sup> that ease access to analgesia.<sup>304</sup> However, the mechanism for realization of these provisions has not yet shown to be effective. The efficacy of the new Decree is only as viable as the new rules are implemented in actual

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<sup>301</sup> *AGs v Bedford*, *supra* note 292 at para 136.

<sup>302</sup> See paragraph 3.4.6., at 98-99, below.

<sup>303</sup> Decree 333, *supra* note 21.

<sup>304</sup> See Appendix 2, Table 4.

practice. This is currently a matter of great concern, as the new rules are not being implemented in practice.

Even on the stage of becoming a Draft Decree, the future - at that time - Decree 333<sup>305</sup> on the rules of narcotic medicines use in Ukrainian healthcare settings had been formulated by the Ukrainian Ministry of Healthcare and developed by the State Department of Drug Control many months before its actual adoption in May 2013. By October 15, 2012, the Project had already been completed and sent to the Ukrainian Government.<sup>306</sup> Then it took many months for the Government to consider the regulations and to adopt them in May 2013, while thousands of patients were dying in tremendous suffering without receiving adequate pain relief.

Currently, after the adoption of this significant document with such crucial changes for the patients,<sup>307</sup> again for many months no mechanism to implement these rules has been introduced.<sup>308</sup> Surprisingly, while the new regulations are already legally in force, the “old” rules<sup>309</sup> remain valid as well. The two laws contain directly contradictory provisions, and there are no official explanations of any kind regarding rules for the transition period and /or when healthcare providers should start referring to the new rules exclusively.

Factually, the new law has been adopted and was left on the table of the state officials. No steps towards its implementation have been observed at present. Instead the “old” rules remain in force without being adapted to the new legislative provisions. These “old” rules are being applied. In practice, the new regulations make no real changes in the Ukrainian pain management thus far.

### 3.2.2. Creating Constructive Legislative Framework vs. Implementing the Law Properly

According to the Law of Ukraine “On narcotic medicines, psychotropic substances and precursors”<sup>310</sup> (*Law on Narcotics*) the Ministry of Healthcare of Ukraine is authorised only to “*elaborate the projects of the acts of legislation, which regulate the rules of conducting of the activity in the sphere of the circulation of the narcotic medicines,*

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<sup>305</sup> Order 11, *supra* note 47.

<sup>306</sup> Official answer of the Ministry of Healthcare to the request of the Project “StopPain” in Ukraine launched by International Renaissance Fund re the Project of the Decree 333. The answer was shared by the “StopPain” Campaign in Ukraine.

<sup>307</sup> See Appendix 2, Table 4.

<sup>308</sup> See subchapter 1.5.1. at 27-28, above.

<sup>309</sup> Order 11, *supra* note 47.

<sup>310</sup> Law On Narcotic Medicines, *supra* note 43.

[...]”.<sup>311</sup> Nowhere does it authorize this central body of the Ukrainian executive power to “adopt” such acts of legislation. Instead, this law says that the activity with regards to narcotic substances in Ukraine shall be conducted according to “this law” of Ukraine and the acts of the Cabinet of Ministries of Ukraine (the Government of Ukraine) or central bodies of power “in cases formalized in [this law]”.<sup>312</sup> Therefore, the Ministry of Healthcare’s Order 11,<sup>313</sup> which regulates the rules of conducting of the activity regarding the circulation of the narcotics, appears contrary to the above-mentioned Law on Narcotics, and is therefore illegitimate. It is surprising that this Order 11, after being adopted by the Ministry of Healthcare, successfully passed review by the legal experts of the Ukrainian Ministry of Justice.

In Ukraine the Decrees are issued by the Government (The Cabinet of Ministers of Ukraine, being the highest body of the executive branch of power in Ukraine) and the President of Ukraine (the Head of the State). The Orders are usually issued by the Ministries (the central bodies of the executive power in Ukraine) within their authorities as per the Laws (acts of the Ukrainian Parliament, the Verkhovna Rada of Ukraine) and the Governmental Decrees. Accordingly, the Decrees of the Cabinet of Ministers of Ukraine stand higher in the hierarchy of Ukrainian legislative acts than the Orders of the Ministries of Ukraine (See footnote 290).

This procedure is mandatory when all Ministries of Ukraine adopt orders or other acts of same level.<sup>314</sup> In other words, this Order 11 should have never existed in the Ukrainian legislation; instead, the issues of narcotics circulation activity should

have always been regulated by an act of the Ukrainian Government. The Decree 333, which was adopted exactly by the Government of Ukraine, complies with the law. Apart from the issues of legal authorities, theoretically speaking, the “new” Decree 333 is legally more valid than the “old” Order 11,<sup>315</sup> which is currently being followed in practice. The matter is that the Decree 333 was adopted by the Government of Ukraine (the Cabinet of Ministers of Ukraine), which stands higher in the hierarchy of state power of Ukraine than the Ministry of Healthcare, which issued the Order 11. Although the

<sup>311</sup> See *ibid* at article 5; see also Law of Ukraine “On measures of struggle illegal circulation of narcotic medicines, psychotropic substances and precursors and their abuse” (“Про заходи протидії незаконному обігу наркотичних засобів, психотропних речовин і прекурсорів та зловживанню ними”) 62/95-ВР, 15 February 1995 at Preamble, online: Rada < <http://zakon3.rada.gov.ua/laws/show/62/95-%D0%B2%D1%80>>.

<sup>312</sup> See *ibid* at article 7.

<sup>313</sup> Order 11, *supra* note 47.

<sup>314</sup> Decree of the Cabinet of Ministers of Ukraine “On adoption of the Regulation of the state registration of legislative acts of ministries and other bodies of executive power” (“Про затвердження Положення про державну реєстрацію нормативно-правових актів міністерств та інших органів виконавчої влади”) 731, 28 December 1992, online: <<http://zakon2.rada.gov.ua/laws/show/731-92-%D0%BF>>.

<sup>315</sup> Order 11, *supra* note 47.

theory of law in Ukraine<sup>316</sup> recognizes the *factual repeal of law* in case of adoption of another act with contradictory provisions by a higher authority, in practice this can hardly be the case, at least unless everyone is instructed to act accordingly. An *active repeal of law*<sup>317</sup> (may also be referred to as *explicit repeal*) by the act of the state body which had adopted the act would be more common for Ukraine, although none of these ways of repealing the old regulations have happened so far in relation to Order 11 in Ukraine. This act has not been explicitly repealed, and although the factual repeal (may also be referred to as passive repeal) took place, this has not become a common practice in the country. It means that imagining a case is brought to the Ukrainian court regarding application of the provisions on opioid medicines circulation in medical practice, the court would definitely have to make a decision on basis of Decree 333 rather than Order 11. But this would become only a particular case decision and would not provide changes to medical practices all over the state.<sup>318</sup> The legality of the provisions of Order 11, where they contradict Decree 333, however, could be challenged in the Administrative Court of the Ukrainian capital.<sup>319</sup> Such Court Decision would become an effective remedy for repeal of the contradicting provisions of the Order 11. However, no application has been brought.

The adoption of the new act was not followed by step-by-step changing of the existing order of circulation of narcotic substances to the new rules. Strangely, adoption of an act with provisions directly contradictory to another existing act did not change the legislative act in force. There had not been any measures taken to adapt the legislative framework to the new rules. And the new rules agreed and issued on the level of government and being higher in legal force than the old ones, are not being applied. This is a kind of a legislative paradox of Ukraine, which violates the rights of the Ukrainian patients. This also brings a confirmation that the implementation of law is vital and equally important as the law itself.

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<sup>316</sup> See *Constitution of Ukraine*, *supra* note 44 at articles 8 and 9; See also Skakun, *supra* note 41; see also Law Project 7409, *supra* note 41 (Active (or explicit) repeal of an act is made by means of adoption of another act by the state body with a clear provision that a certain act is being repealed).

<sup>317</sup> *Ibid* at article 65.

<sup>318</sup> Ukraine is a civil law country, where the court decisions are considered as individual acts of power, which do not extrapolate to general public and legal relations. Therefore, an individual Court decision in the sphere of medical care does not necessarily change medical practice in general.

<sup>319</sup> See Code of Administrative Court Procedure of Ukraine (Кодекс адміністративного судочинства України) 2747-15, 2005, online: Rada <<http://zakon4.rada.gov.ua/laws/show/2747-15/page>>.

### **3.3. Human Rights Commonly Associated with Access to Healthcare, Including Pain Control**

#### 3.3.1. The Right to Highest Attainable Standard of Health

##### 3.3.1. a) The Right to Health in International and National Legislation

The concept of *the right to health* in its rather intangible nature has for decades been under evolution of jurisprudential thinking.<sup>320</sup> From prohibition of stigmatization and discrimination in healthcare issues,<sup>321</sup> the right to health has developed to a progressive entitlement to the highest attainable standard of health, provided in the Article 12 of the International Covenant on Economic, Social and Cultural Rights (*ICESCR*):<sup>322</sup>

The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

In addition to this legislative provision there are several other international treaties, ratified by Ukraine, that formalize the right to health by different specific entitlements. Primarily, the Universal Declaration of Human Rights<sup>323</sup> (*UDHR*) includes “*the right to a standard of living adequate for the health and well-being of himself and of his family, including [...] medical care [...]*”.<sup>324</sup> The UDHR entitles everyone to “*a social and international order in which the rights and freedoms [...] can be fully realized*”, thus obliging governments to ensure this adequate “*social order*” is implemented, protected and in force, allowing everyone the enjoyment of the rights proclaimed in the Declaration. Then the European Social Charter<sup>325</sup> declares “*the right to protection of health*” and requires that the governments “*take appropriate measures with a view to ensuring the effective exercise*” of the right declared.

However, arguably, none of these instruments has yet provided a definite mechanism of realization of the right to health.<sup>326</sup> Moreover, this goal can hardly be fully achieved

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<sup>320</sup> Michael Kirby “The Right to Health Fifty Years On: Still Skeptical?” (1999) 4:1 Health and Human Rights 6 at 7-11.

<sup>321</sup> See L.O. Gostin & Z. Lazzarini, *Human Rights and Public Health in the AIDS Pandemic* (New York: Oxford University Press, 1997).

<sup>322</sup> ICESCR, *supra* note 193.

<sup>323</sup> UDHR, *supra* note 193.

<sup>324</sup> *Ibid* at article 25.

<sup>325</sup> European Social Charter, *supra* note 193.

<sup>326</sup> See e.g. S.D. Jama, “The International Human Right to Health” (1994) 22:68 Southern University Law Review 22; see also V.A. Leary, “The Right to Health in International Human Rights Law”, (1994) 1:24 Health and Human Rights 56; see also Lawrence O. Gostin, “The Human Right to Health: A Right to the “Highest Attainable Standard of Health” (March-April 2001) 31:2 Hastings Center Report 29; see also Kisha Braithwaite, “Health Is a Human Right, Right?” (2008) 98 (Suppl 1) American Journal of Public Health S5.

under the conditions of drastic economic inequity between the countries.<sup>327</sup> In the present chapter I will discuss the provisions related to the right to health which are incorporated into the international documents accepted by Ukraine. I will particularly focus on the mechanisms and measurements of the realization of the right to health in association with the idea of the right to adequate pain relief.

Alongside the international entitlements and in compliance with them, Ukrainian internal legislation contains rather supportive provisions. The principle of using the most advanced standards in health care is reflected in the Law of Ukraine “The Basics of Legislation of Ukraine for Health Care”,<sup>328</sup> which articulates the “*commitment to contemporary standards of health and medical practice*” as one of the basic principles of the Ukrainian healthcare.<sup>329</sup> The Constitution of Ukraine, being the law of highest force in the country, entitles everyone to “*the right to health protection, medical care [...]*”<sup>330</sup> and obliges the Government to provide “*conditions for effective and accessible medical services to all Ukrainian citizens*”<sup>331</sup> and “*free of charge*”.<sup>332</sup> Above all, as mentioned above, the Constitution declares that “*one’s life and health, [...] are considered in Ukraine the highest social value*”,<sup>333</sup> thus determining the priority of the healthcare issues in relation to addressing all other social needs and concerns.

### 3.3.1. b) Highest Attainable Standard of Health and the Treatment of Pain

Alongside rather general entitlements to health, health protection and medical services, a more specific principle of “*commitment to contemporary standards of health and medical practice*” especially corresponds to the international entitlement of “*the highest attainable standard of physical and mental health*”. The wording “the highest attainable standard of health” logically calls for application of the most contemporary “best practices” achieved in healthcare to date in order to bring a patient to the highest possible level of well-being in one’s “*biological and socio-economic preconditions*”.<sup>334</sup> For the issue of pain management, logically, the highest attainable standard means decrease of pain to the level

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<sup>327</sup> Amir Attaran “Human Rights and Biomedical Research Funding for the Developing World: Discovering State Obligations under the Right to Health” (1999) 4:1 Health and Human Rights 26.

<sup>328</sup> Law 2801-XII, *supra* note 19 at article 4.

<sup>329</sup> *Ibid.*

<sup>330</sup> *Constitution of Ukraine*, *supra* note 44 at article 49 part 1.

<sup>331</sup> *Ibid.*

<sup>332</sup> *Ibid* at article 49 part 3.

<sup>333</sup> *Ibid* at article 3.

<sup>334</sup> Committee on Economic, Social and Cultural Rights, General Comment # 14, The right to the highest attainable standard of health (Article 12 of the ICESCR), (Geneva, 2000) at para 9 [General Comment # 14 to ICESCR].

of mild or non-existent so far as the side effects of pain management are tolerated by the patient. Of all other international entitlements related to the right to health, the ICESCR, entitling “everyone to the enjoyment of the highest attainable standard of [...] health”, has been fairly called by Michael Kirby<sup>335</sup> “the primary treaty provision in the relation to the right to health”. This idea had been accepted before as basic in the WHO Constitution, which proclaimed, “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”<sup>336</sup>

The outstanding importance of the ICESCR provisions is that they not only bring a rather developed “general statement” of the entitlement to the “highest attainable standard”, but also provide a positive obligation of the Governments in the form of “specific steps to which the States commit themselves” in realization of the right to health.<sup>337</sup> However, this positive obligation is also defined rather broadly with much room for interpretation, which makes the defence of the entitlement to health a rather complicated matter, as I will further discuss. According to the Article 2.1 of the ICESCR:

Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.<sup>338</sup>

### 3.3.1. c) Limitation to “Available Resources”

If the “general statement” regarding the right to health of article 12 of the ICESCR provides a universal entitlement to “everyone”, article 2.1 of the Covenant imposes concrete corresponding duties of the governments to apply “maximum of its available resources” and “with a view” to achieving this health entitlement “progressively.”

The wording of article 2.1 has been called by Amir Attaran in his article “Human Rights and Biomedical Research Funding for the Developing World: Discovering State Obligations under the Right to Health”<sup>339</sup> a “*resource phrase*”, which in practice narrows the entitlement to the highest attainable standard of health to the frame of

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<sup>335</sup> Kirby. *supra* note 320 at 11.

<sup>336</sup> Constitution of WHO, 22 July 1946, Forty-fifth ed, Suppl. (October 2006), online: WHO <<http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf>>.

<sup>337</sup> ICESCR, *supra* note 193 at article 11.

<sup>338</sup> *Ibid* at article 2.

<sup>339</sup> Attaran, *supra* note 327 at 37.

“*maximum available resources*” in a given country. The complexity of the issue has been brought up by Amir Attaran also by citing R. Robertson:<sup>340</sup>

It is a difficult phrase – two warranting adjectives describing an undefined noun. “Maximum: stands for idealism; “available” stands for reality. “Maximum” is a sword of human rights rhetoric; “available” is the wiggle room for the state.

Furthermore, as argued by Robertson<sup>341</sup> in his article “Measuring state compliance with the obligation to devote the “maximum available resources” to realizing economic, social and cultural rights”, “*availability of resources is subject to broad interpretation*”. Indeed, the wording of article 2.1 gives rise to numerous clarifying questions, some of which have been partially answered by Robertson in his paper. What types of resources shall be used by the state to comply with the article 2.1 requirements? How can the compliance of the use of the resources be measured? And lastly, how should these resources be allocated between the state’s obligations? While Robertson offers to conditionally determine five categories of resources (human, technological, informational, natural and financial) and suggests that “*Governments are obliged to take measures beyond merely opening up the public treasury in their attempts to combat human misery and promote human development*”,<sup>342</sup> logically there is a need for a simple and clear criteria to measure a state’s compliance with the requirement to use the “*maximum of its available resources*”. A more comprehensive and measurable approach became basic in the Analytical Report of 2011, by Radhika Balakrishnan et al., “Maximum Available Resources and Human Rights”,<sup>343</sup> which analyses this issue from the perspective of mainly *financial* resources that can be available from different sources. Again Amir Attaran, in the above-mentioned article, offered to “*read down*” and to simplify the measurement of “compliance” specifically for the purpose of the realistic implementation of this provision in real life and without “*endless and paralyzing debate about which resources are germane to compliance measurement and which are extraneous*”.<sup>344</sup> In a more recent article, “The

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<sup>340</sup> *Ibid*, citing R. Robertson, “Measuring State Compliance with the Obligation to Devote the “Maximum Available Resources” to Realisation of Economic, Social and Cultural Rights” (1994) 16:4 Human Rights Quarterly 693.

<sup>341</sup> R. Robertson, “Measuring State Compliance with the Obligation to Devote the “Maximum Available Resources” to Realisation Economic, Social and Cultural Rights” (1994) 16:4 Human Rights Quarterly 693.

<sup>342</sup> *Ibid*.

<sup>343</sup> Radhika Balakrishnan et al, “Maximum Available Resources & Human Rights: Analytical Report” (Center for Women’s Global Leadership, Princetonian Graphics, Inc., the USA, 2011), online: <<http://www.escri-net.org/sites/default/files/Maximumavailable%20resources.pdf>>.

<sup>344</sup> Attaran, *supra* note 327 at 37.

Requirement of Using the ‘Maximum of Available Resources’ for Human Rights Realisation: A Question of Quality as Well as Quantity”, Sigrun Skogly<sup>345</sup> agrees to the essentialness of a finance (budgetary) approach to measurement of the states’ compliance with the requirement to use maximum available resources, but also calls for “qualitative evaluation”<sup>346</sup> of the use of these resources primarily for the purpose of evaluating the effectiveness of the spending. Indeed, while agreeing that the provision of the ICESCR requires application of all available resources to whatever groups they are related, it appears equally reasonable to recognize that accepting a feasible approach to determination of the compliance of governments with the resource phrase is essential, because it would provide criteria for the determination of states’ compliance with the provision of the international law.

#### 3.3.1. d) Application of Maximum Resources

Another important question regarding measurement of the realization of the right to health is the determination of whether “*maximum available resources*” are being applied and how they are being allocated among all of a state’s obligations. It is unclear from the provisions of the ICESCR which portion of a state’s available resources shall be “ideally” allocated specifically for healthcare. The World Bank statistics<sup>347</sup> show that countries have their own approaches to this matter. According to their data, in 2011 countries spent from as little as 1.6 per cent of their GDP (South Sudan) to as much as 19.5 (Liberia) per cent on healthcare. Ukraine allocated 7.2 per cent of its GDP.

The General Comment #14, which was adopted by the Committee on Economic Social and Cultural Rights to interpret and clarify the right to the highest attainable standard of health according to the article 12 of the ICESCR, does not provide much clarification on this matter, because there is no suggestion as to what percentage of GDP or amount of finance resources per capita must go to healthcare, nor is other measurement offered to define adequacy or acceptability of resources for healthcare. Moreover, it is uncertain how the resources allocated for healthcare must be distributed within healthcare needs. For example, what share of financial resources should be allocated to effective pain management as opposed to the treatment of arthritis? Even within pain management,

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<sup>345</sup> Sigrun Skogly, “The Requirement of Using the ‘Maximum of Available Resources’ for Human Rights Realisation: A Question of Quality as Well as Quantity?” (2012) 12:3 Human Rights Law Review 393.

<sup>346</sup> *Ibid* at 402.

<sup>347</sup> World Bank official data, Health expenditures total (% of GDP), online: World Bank <[http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS?order=wbapi\\_data\\_value\\_2011+wbapi\\_data\\_value+wbapi\\_data\\_value-last&sort=asc](http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS?order=wbapi_data_value_2011+wbapi_data_value+wbapi_data_value-last&sort=asc)>.

which portion of the allocations should go to the funding of research for better pain management instead of towards affordability of available medicines for pain control? For example, in the Soobramoney Case<sup>348</sup> (South Africa) the inevitability of “*difficult decisions*” with regards to health priorities under conditions of limited resources was recognized. It was held that the “*court will be slow to interfere with rational decisions taken in good faith by the political organs and medical authorities whose responsibility it is to deal with such matters.*” In other words, the court called for common sense and most importantly for “good faith” in making really “*difficult decisions*” for the reason of being limited in available resources.

Generally speaking, case law of South Africa provides particularly illustrative evidence of how estimative and relative the measurement of the realization of the obligation to use maximum available resources can be. In addition to Soobramoney Case, other cases like, for example, the Case of Irene Grootboom<sup>349</sup> and the South Africa’s Treatment Action Campaign (The Mother-to-Child Transmission Prevention Court Case)<sup>350</sup> show how

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<sup>348</sup> The appellant (a 41-year-old diabetic suffering from ischaemic heart disease, cerebrovascular disease and irreversible chronic renal failure) was denied regular renal dialysis, which could prolong his life. The denial was grounded on the hospital’s guidelines, according to which the patient was not eligible for the treatment. The eligibility criteria were established, because of severe shortage of the hospital’s resources, what made it impossible to treat all patients. The lack of resources provided rationale for the court’s decision to dismiss the patient’s application. No breach of law was found. See *Soobramoney v Minister of Health*, 27 November 1997 KwaZulu-Natal Constitutional Court, online:

<<http://www.saflii.org/za/cases/ZACC/1997/17.pdf>> or  
<[http://www.healthlink.org.za/uploads/files/chap3\\_98.pdf](http://www.healthlink.org.za/uploads/files/chap3_98.pdf)>.

<sup>349</sup> The judgement of the case called for a devise and implementation by the state “within its available resources a comprehensive and coordinated programme progressively to realise the right of access to adequate housing.” The program required “reasonable measures” “to provide relief for people who have no access to land, no roof over their heads, and who are living in intolerable conditions or crisis situations.” The court recognized the Government’s failure to follow the law in terms of using available resources, by not providing adequate living conditions for the responders, who were living in shacks without any sanitary conditions, no electricity and no other conditions of living. See *Government of the Republic of South Africa and Others v Grootboom and Others* (CCT11/00) [2000] ZACC 19; 2001 (1) SA 46; 2000 (11) BCLR 1169 (4 October 2000), online: <<http://www.saflii.org/za/cases/ZACC/2000/19.html>>.

<sup>350</sup> As a result of a skillful litigation the Mother-to-Child Transmission Prevention Court Case provided a court’s judgement, which obliged the Government of South Africa to “without delay” “remove the restrictions that prevent nevirapine from being made available for the purpose of reducing the risk of mother-to-child transmission of HIV at public hospitals and clinics that are not research and training sites”. The court’s decision resulted in a nation-wide program to prevent the mother-to-baby transmission of HIV, which initially the Government of South Africa was reluctant to implement. See *Minister of Health and Others v Treatment Action Campaign and Others* (No 2) (CCT8/02) [2002] ZACC 15; 2002 (5) SA 721; 2002 (10) BCLR 1033 (5 July 2002) online: <[http://www.saflii.org/cgi-bin/disp.pl?file=za/cases/ZACC/2002/15.html&query=Mother-to-Child Transmission Prevention](http://www.saflii.org/cgi-bin/disp.pl?file=za/cases/ZACC/2002/15.html&query=Mother-to-Child%20Transmission%20Prevention)>; also Melanie Elizabeth Campbell, *Women’s Access to Nevirapine to Prevent Mother-to-Child Transmission of HIV: a Case Study of Policy Development in South Africa*, Master’s Thesis (Graduate Department of Phar-

different the scope and extent of one's rights can be under the ICESCR in terms of the "available resources" and regarding the progressiveness of the realization of one's rights, depending on the current level of economic development of the state, the "available resources" for realization of human rights and most importantly, the government's willingness and prioritization of human rights issues. Eventually, the matter of prioritization in the use of resources remains a rather complicated challenge without a mandatory unified approach to solving the matter.

#### 3.3.1. e) Progressiveness in Application of the Maximum Available Resources

Measuring "available resources" application and their allocations go closely with the issue of measuring the progressiveness of the realization of the right to health, which is also not absolutely clear from article 2.1. It is uncertain from the ICESCR at what pace each state should "take steps" toward the realization of the right to health in order to comply with requirements of article 2.1 of the covenant. Here General Comment #14 appears very important and helpful, as this document at least clearly prohibits "*retrogressive measures*" regarding healthcare and obliges states "*to move as expeditiously and effectively as possible*" toward the realization of the right to health.

#### 3.3.1. f) What the Patients are Entitled to in Terms of Pain Control

Ideally, referring merely to article 12 of the ICESCR, the "highest attainable standard of health" with reference to pain management can be reached by applying the best known appropriate contemporary medical and/or pharmaceutical findings. The application of the "resource phrase" narrows these pharmaceutical and medical findings to the measure of their availability within the state under the condition of maximum application of available resources to this purpose at some reasonable pace. So to say, as definitely as possible from the considered above legislative provisions, the international right to health currently entitles the patients to the best pain relief remedies affordable by the state and so far made available there.

At the same time the entitlements with regards to health, which are provided by international treaties, whatever they mean precisely, do not always prove to affect significantly the public health indicators.<sup>351</sup> The research by Palmer et al., "Does ratification of human-rights treaties have effects on population health", has shown no

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maceutical Sciences, University of Toronto, 2003), online:

<[http://individual.utoronto.ca/melaniecampbell/MEC\\_Thesis\\_Final\\_04.PDF](http://individual.utoronto.ca/melaniecampbell/MEC_Thesis_Final_04.PDF)>.

<sup>351</sup> See Alexis Palmer et al, "Does Ratification of Human-Rights Treaties Have Effects on Population Health" (June 6, 2009) 373 *The Lancet* 1987.

significant relation of the changes in health status with ratification of human-rights treaties.<sup>352</sup> The authors of this research conclude that a better link is provided rather by “*economic status*” and the “*central role of financing*” in improving health indicators.<sup>353</sup> These findings however, should barely apply to the issues of pain control by opioids. According to my research regarding the prices of morphine and the economic abilities of Ukraine<sup>354</sup> in previous chapters, cost hardly plays a crucial role in realization of the right for the highest attainable standard of health in terms of pain control with opioids. That is why failure in realization of this right cannot be justified or linked to lack of “*available resources*”. Settling of this matter depends rather on the government’s willingness to take the problem of pain control seriously and to apply a constructive approach to its decision.

### 3.3.2. Essential Medicines for Pain Control as a “Minimum” Obligation of the State

So far the entitlement to health appears “enforceable” in the light of *minimum or “at least” core obligations*, defined by the Committee on Economic Social and Cultural Rights in their General Comments #3<sup>355</sup> and #14.<sup>356</sup> Among these minimum obligations there is an obligation “*to provide essential Drugs, as [...] defined under the WHO Action Programme on Essential Drugs*”.<sup>357</sup> The Committee on Economic, Social and Cultural Rights explained and confirmed that “*availability*” of “*essential drugs*” is one of the “*interrelated and essential elements*” of “*the right to health*”.<sup>358</sup> The access to essential drugs is also required by the provisions of the Declaration of Alma-Ata,<sup>359</sup> to which *inter alia* Comment # 14 refers. Most importantly, core obligations, identified in the General Comment #14 cannot “*under any circumstances*” be suspended.<sup>360</sup> It means that the “*resource phrase*” does not apply to these core obligations, and that governments cannot refer to any justification that “*every effort has nevertheless been made to use all available resources at its disposal to satisfy*”<sup>361</sup> these obligations.

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<sup>352</sup> *Ibid* at 1989.

<sup>353</sup> *Ibid* at 1992.

<sup>354</sup> See subchapter 1.6.2. at 42-45, above; further discussion of this matter with considerations on the improvements will be found in subchapter 4.4.2. at 131-133, below.

<sup>355</sup> Committee on Economic, Social and Cultural Rights, General Comment # 3, The Nature of States Parties' Obligations (Article 2, Para. 1 of the ICESCR) (Geneva, 1990) [General Comment # 3 to ICESCR].

<sup>356</sup> See General Comment # 14 to ICESCR, *supra* note 334 at para 43 at 13.

<sup>357</sup> *Ibid*.

<sup>358</sup> *Ibid* at para 12.

<sup>359</sup> Declaration of Alma Ata. International conference on primary health care (Alma-Ata, USSR, 6-12 September 1978) at para VII, online: WHO <[www.who.int/hpr/NPH/docs/declaration\\_almaata.pdf](http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf)>.

<sup>360</sup> See General Comment # 14 to ICESCR, *supra* note 334 at para 47.

<sup>361</sup> *Ibid*.

Considering that analgesics like morphine, codeine, acetylsalicylic acid, ibuprofen and paracetamol are listed in the WHO Essential Medicines List,<sup>362</sup> their availability and arguably also accessibility<sup>363</sup> are the core content of the right to health, formalized in international legislation. Contrary to this, as one may observe from Table 6 below (column 1) in Ukraine not all essential medicines, as defined by the WHO, are included in the *Ukrainian internal essential medicines list*<sup>364</sup> (see Table 6, column 2). Besides, far fewer of them are included in the list of “*minimum pharmacy assortment*”<sup>365</sup> (see Table 6, column 5) in Ukraine. This matter is important, because the every medicine from this minimum pharmacy assortment must be available in every pharmacy in Ukraine; otherwise the pharmacy as a legal entity may be a subject to financial sanctions. Absence of essential medicines in this list makes the issue of their actual availability at least geographically rather questionable, because it is not always economically beneficial for pharmacies (particularly in remote areas) to keep the stock of certain infrequently sought medicines of low prices, which therefore do not generate much profit. At the same time, as Table 6 shows, this medicine is registered in Ukraine (see Table 6, column 3), which makes it possible to be available in circulation on the territory of the state, and is included in the *list of medicines which may be purchased for healthcare settings from the state funds*<sup>366</sup> (see Table 6, column 4). However, it cannot be sold to individuals without a special doctor’s prescription<sup>367</sup> (see Table 6, column 6).

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<sup>362</sup> WHO Model List of Essential Medicines, *supra* note 188.

<sup>363</sup> Lohman , Shleifer & Amon, *supra* note 22 at 7.

<sup>364</sup> Ukrainian National list of Essential Medicines, *supra* note 189.

<sup>365</sup> Order of the Ministry of Healthcare of Ukraine “On adoption of the Mandatory minimum assortment of the (social oriented) medicines of national production and medicinal products for the pharmaceutical institutions” (“Про затвердження обов’язкового мінімального асортименту (“соціально орієнтованих”) лікарських засобів вітчизняного виробництва і виробів медичного призначення для аптечних закладів”) 1000 , 29 November 2011, online: Rada <<http://zakon2.rada.gov.ua/laws/show/z0524-12>>.

<sup>366</sup> Decree of the Cabinet of Ministers of Ukraine “On regulation of purchase of medicines by healthcare settings and institutions financed from the state budget” (“Про порядок закупівлі лікарських засобів закладами та установами охорони здоров'я, що фінансуються з бюджету”) 1071, 5 September 1996, online: Rada <<http://zakon2.rada.gov.ua/laws/show/1071-96-%D0%BF>>.

<sup>367</sup> Order of the Ministry of Healthcare of Ukraine “On adoption of the List of medicines, permitted to use in Ukraine, which may be dispensed without prescriptions from pharmacies and their affiliations” (“Про затвердження Переліку лікарських засобів, дозволених до застосування в Україні, які відпускаються без рецептів з аптек та їх структурних підрозділів”) 78 , 03 February 2012, online: Rada <<http://zakon2.rada.gov.ua/laws/show/z0277-12>>.

**Table 6. WHO Essential Medicines List vs. Ukrainian Mandatory Internal Lists**

1	2	3	4	5	6
<b>WHO Essential Medicines List</b>	<b>Ukrainian Essential Medicines List</b>	<b>Registration in Ukraine</b>	<b>Medicine that may be purchased for state funds</b>	<b>Minimum Pharmacy Assortment</b>	<b>Medicines that may be sold to individuals without prescription</b>
<b>Non-opioids and non-steroidal anti-inflammatory medicines (NSAIDs)/Antimigren Medicines (for treatment of acute attack)</b>					
acetylsalicylic acid	Yes	Yes	Yes	Yes	Yes
ibuprofen	Yes	Yes	Yes	Yes	Yes
paracetamol	Yes	Yes	Yes	Yes	Yes
<b>Opioid analgesics</b>					
codeine	No	Yes	Yes	No	No
morphine	Yes	Yes	Yes	No	No
<b>Local anesthetics</b>					
bupivacaine	Yes	Yes	Yes	No	No
lidocaine	Yes	Yes	Yes	Yes	No

Moreover, the WHO Essential Medicines List provides not only international names of active substances considered essential, but also forms of these medicines. It means that states' "minimum" obligation is to ensure availability of not only types of medicines included in the list, but also in all their recommended forms. However, Ukraine fails to fulfill this requirement even with regards to the most essential "gold standard" medicine for treatment of moderate to severe pain – morphine. Although the WHO Essential Medicines List clearly refers to morphine in injections, tablets and oral liquid form, in Ukraine this medicine was available exclusively in the form of injections until just several months ago, when tablet morphine production began. Import of oral morphine has also been impossible, because this medicine in oral form was not registered in Ukraine, and therefore could not be imported to Ukraine according to Ukrainian law.<sup>368</sup>

The important matter is how the core obligation of Ukraine regarding the access to essential medicines can be ensured in courts. The study by Hogerzeil et al., "Is access to essential medicines as part of the fulfilment of the right to health enforceable through the

<sup>368</sup> Law on Medicines, *supra* note 42.

courts”,<sup>369</sup> contains analysis of 712 cases from 12 countries. The study has shown that “[s]killful litigation can help to ensure that governments fulfill their constitutional and treaty obligations [regarding access to essential medicines].”<sup>370</sup> Unfortunately, the Ukrainian case law database does not provide many examples of successful litigation and actual defence of human rights of the Ukrainians for essential medicines, and none regarding access to pain medication in particular. One relatively successful case will be discussed further in the present chapter.<sup>371</sup>

All these findings mean that the Ukrainian State has so far failed to provide adequate access to the most basic, economically reasonable and safe medicines for the treatment of pain, which are defined as essential by the WHO. Subsequently, such failure constitutes a breach of international law, because it violates the “*core obligation*” of the right to health.

### 3.3.3. The Right to Protection from Cruel, Inhuman and/or Degrading Treatment

Failing to provide conditions for adequate pain control and leaving thousands of people in suffering that could otherwise be cured through known safe and even relevantly inexpensive remedies hardly complies with the right to the highest attainable standard of health, nor with the right to be free from *cruel, inhuman and/or degrading treatment*.

#### 3.3.3. a) Legislative Basis

The human right to be protected from cruel inhuman or degrading treatment is provided by numerous international documents signed and ratified by Ukraine:

- The UDHR<sup>372</sup>, declaring that “[n]o one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.”
- European Convention for the Protection of Human Rights and Fundamental Freedoms<sup>373</sup> (*ECPHRFF*), provides a similar prohibition<sup>374</sup> and establishes *the European Court of Human Rights*, where rights may be defended;<sup>375</sup>

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<sup>369</sup> Hans V. Hogerzeil et al, “Is access to essential medicines as part of the fulfillment of the right to health enforceable through the courts?” (July 22, 2006) 368 *The Lancet* 305.

<sup>370</sup> *Ibid* at 305.

<sup>371</sup> See the case-law discussion at 105-106, below.

<sup>372</sup> UDHR, *supra* note 193 at article 5.

<sup>373</sup> European Convention for the Protection of Human Rights and Fundamental Freedoms (*ECPHRFF*), as amended by Protocols Nos. 11 and 14, (4 November 1950) ETS 5, Council of Europe, online: <[http://www.echr.coe.int/Documents/Convention\\_ENG.pdf](http://www.echr.coe.int/Documents/Convention_ENG.pdf)>. The European Convention was ratified by the Ukrainian Parliament by adoption the Law of Ukraine “On ratification of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950, First protocol and protocols # 2,4,7 and 11 to the Convention” (“Про ратифікацію Конвенції про захист прав людини і основоположних

- European Convention on Prevention of Torture and Inhuman or Degrading Treatment or Punishment<sup>376</sup>(*ECAT*);
- International Covenant on Civil and Political Rights<sup>377</sup>(*ICCPR*), declaring that “[n]o one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation”<sup>378</sup>, establishing a *Human Rights Committee*<sup>379</sup> and obliging States to “submit reports on the measures they have adopted which give effect to the rights recognized [in the ICCPR] and on the progress made in the enjoyment of those rights”<sup>380</sup>; and
- the International Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment<sup>381</sup> (*CAT*), which obliges states to “to prevent in any territory under its jurisdiction other [than torture] acts of cruel, inhuman or degrading treatment or punishment [...] when such acts are committed by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity”<sup>382</sup>.

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свобод 1950 року, Першого протоколу та протоколів N 2, 4, 7 та 11 до Конвенції”) 475/97-вр, 17 July 1997, online: Rada <<http://zakon4.rada.gov.ua/laws/show/475/97-%D0%B2%D1%80>> [ECPHRFF].

<sup>374</sup> *Ibid* at article 3.

<sup>375</sup> ECPHRFF, *supra* note 373 at articles 19-51.

<sup>376</sup> European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (ECAT) (26 November 1987) ETS 126, Council of Europe, online: Council of Europe <<http://www.cpt.coe.int/en/documents/ecpt.htm>>, ratified by Ukraine according to the Law of Ukraine “On Ratification of the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment” (“Про ратифікацію Європейської конвенції про запобігання тортурам та нелюдському або такому, що принижує гідність, поводженню чи покаранню”) 33/97-ВР, 24 January 1997, online: Rada <<http://zakon4.rada.gov.ua/laws/show/33/97-%D0%B2%D1%80>> [ECAT].

<sup>377</sup> International Covenant on Civil and Political Rights (ICCPR) (16 December 1966) 999 UNTS 171 and 1057 UNTS 407/[1980] ATS 23/6 ILM 368 (1967), online:

<<http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx>>, ratified by Ukraine according to the

Decree of Presidium of Verkhovna Rada of the Ukrainian Soviet Republic “On ratification of the International Covenant on Civil and Political Rights” (“Про ратифікацію Міжнародного пакту про економічні, соціальні і культурні права та Міжнародного пакту про громадянські і політичні права”) 2148, 19 October 1973, online: Rada <<http://zakon4.rada.gov.ua/laws/show/2148-08>> [ICCPR].

<sup>378</sup> *Ibid* at article 7.

<sup>379</sup> ICCPR, *supra* note 377 at art 28.

<sup>380</sup> *Ibid* at article 40.

<sup>381</sup> Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT), 10 December 1984, online: <<http://www.ohchr.org/EN/ProfessionalInterest/Pages/CAT.aspx>>, ratified by Ukraine according to the Decree of Presidium of Verkhovna Rada of the Ukrainian Soviet Republic “On Ratification of the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment” (“Про ратифікацію Конвенції проти катувань та інших жорстоких, нелюдських або таких, що принижують гідність, видів поводження і покарання”) 3484-XI, 26 January 1987, online: Rada <<http://zakon4.rada.gov.ua/laws/show/3484-11>> [CAT].

<sup>382</sup> *Ibid* at article 16.

An identical provision on *prohibition of cruel inhuman or degrading treatment* is formalized directly in the Ukrainian Constitution.<sup>383</sup>

### 3.3.3. b) Denial of Pain Control: Torture or Ill-treatment

Although the right to be free from ill-treatment goes closely with the prohibition of torture, the definitions are in fact quite different. A failure to ensure access to pain medication can hardly be called torture. This omission is more likely to be qualified as cruel, inhuman and/or degrading treatment. The CAT definition of torture<sup>384</sup> requires intent to inflict suffering for a specific purpose or reason and involvement of someone in public capacity. Failure to ensure adequate pain control in Ukraine in most cases is not intentionally caused by a certain state official in relation to a given person and for that particular purpose. It is rather a negligent failure of the government to respond to the needs of people in their jurisdiction and does not involve an intention to achieve any specific outcome. Although intentionally depriving someone in pain of possible pain relief for a specific purpose would constitute torture,<sup>385</sup> such cases are beyond the area of the present research. Simultaneously, negligent failure to address the issues of pain control, making people suffer, although not amounting to torture under the CAT definition, may constitute cruel, inhuman and/or degrading treatment or punishment, equally prohibited by the international legislation. This view was supported by Professor Manfred Novak (the former United Nations Special Rapporteur on Torture), who underlined in his Report to Human Rights Council in 2009<sup>386</sup> that:

“De facto, denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment.”

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<sup>383</sup> *Constitution of Ukraine, supra* note 44 at article 28.

<sup>384</sup> See CAT, *supra* note 381 (“Torture” means any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him or a third person information or a confession, punishing him for an act he or a third person has committed or is suspected of having committed, or intimidating or coercing him or a third person, or for any reason based on discrimination of any kind, when such pain or suffering is inflicted by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity. It does not include pain or suffering arising only from, inherent in or incidental to lawful sanctions.”)

<sup>385</sup> Amon & Lohman, *supra* note 96.

<sup>386</sup> Statement by Manfred Nowak, Special Rapporteur on Torture at the 10th session of the Human Rights Council (Geneva, 10 March 2009), online: United Nations <<http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=9376&LangID=E>>.

Besides, according to the recent Report<sup>387</sup> of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment J. Mendez, “*Acts falling short of this definition [of torture] may constitute cruel, inhuman or degrading treatment or punishment [...]*.” The point that failure to provide possible pain relief and leaving people in needless and preventable suffering can be referred to as so-called “ill-treatment” was also thoroughly considered by Joseph Amon and Diederik Lohman in their article “Denial of Pain Treatment and the Prohibition of Torture, Cruel, Inhuman or Degrading Treatment or Punishment.”<sup>388</sup> In justification of this approach the authors refer to a number of cases decided by the European Court of Human Rights where “*courts have found a great variety of different types of suffering of different origins to potentially constitute torture or ill-treatment*”.<sup>389</sup> The authors logically extrapolate by analogy this jurisprudence to the issue of pain relief.

### 3.3.3. c) How Prohibition of Ill-treatment is Applied in European Court of Human Rights

Indeed, the case-law of the European Court of Human Rights provides numerous examples where inappropriate treatment (although not torture) was recognized as ill-treatment in violation of the article 3 of the European Convention and required both pecuniary and non-pecuniary damages. There are several recent cases involving healthcare issues. In the case of *R.R. v. Poland* (2011),<sup>390</sup> the applicant was recognised as having been ill-treated by doctors, as they delayed without sufficient reason her genetic testing when she was pregnant, and did not react appropriately to her pleas for timely testing. The delay resulted in late testing (which showed abnormality of the fetus) and subsequently deprived the applicant of her autonomous choice regarding parenthood (it was too late for an abortion). The plaintiff gave birth to a baby girl with Turner syndrome. In the case of *Sakhvadze v. Russia* (2012)<sup>391</sup> the applicant was awarded damages for having been treated contrary to article 3 of the European Convention, prohibiting ill-treatment. The recognition of ill-treatment was based on the evidence that the applicant, being a detainee, was not provided with needed and requested medical assistance, causing

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<sup>387</sup> Mendez J., Report of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment. Human Rights Council Twenty-second session (1 February 2013), Agenda item 3, A/HRC/22/53, online: <<http://hospicecare.com/uploads/2013/6/Mendez%20Rapporteur%20HRC.pdf>>.

<sup>388</sup> Amon & Lohman, *supra* note 96.

<sup>389</sup> *Ibid* at 172-173.

<sup>390</sup> *R.R. v Poland*, 26 May 2011, available online: HUDOC <<http://hudoc.echr.coe.int/>>.

<sup>391</sup> *Sakhvadze v Russia*, 10 January 2012, available online: HUDOC <<http://hudoc.echr.coe.int/>>.

his suffering. In the case of *Okhrimenko v. Ukraine*<sup>392</sup> the applicant (also a detainee) claimed he had been ill-treated due to insufficient medical treatment of his condition, including inadequate analgesia with narcotic medicines. The applicant was diagnosed and treated by the doctors of the detention center, and also by the doctors from civil hospitals. The European Court of Human Rights did not find it appropriate “to decide on the necessity and appropriateness of the medical treatment prescribed for the applicant by the civil doctors”.<sup>393</sup> So the correctness of treatment by civilian doctors was not challenged.

It is important that in the cases where the legislative provisions prohibiting ill-treatment were applied, the court referred to a “*minimum severity test*” to decide on the appropriateness of article 3 application. The minimum level of severity is to be defined and decided by judges on a case-to-case basis on the grounds of intensity of physical and/or mental suffering caused.<sup>394</sup>

Based on these findings, ill-treatment, even not amounting to torture under the CAT definition, is equally unacceptable and contrary to the law. Denial of adequate pain control that results in suffering meeting the minimum severity test is considered as ill-treatment, contrary to the norms of international legislation.

#### 3.3.3. d) States’ Obligations regarding Prohibition of Ill-treatment

International human rights are commonly understood in association with the states’ obligations to respect, protect and fulfill them.<sup>395</sup> While the requirement “to respect” is understood as a passive obligation to refrain from interfering in the realization of the rights, the other two undertakings call for active measures by the state. The duty “to protect” requires protection from the abuse of rights, and the duty “to fulfill” calls for active actions of the states to ensure the enjoyment of the rights. With regards to the right to be free from cruel, inhuman or degrading treatment, these obligations mean that the governments not only have a negative duty to refrain from such ill-treatment, but also a positive obligation to take concrete actions to not allow the ill-treatment happen. The CAT contains a direct requirement that the states “prevent” cruel, inhuman or degrading treatment in territories within their jurisdictions and specifically by taking “effective

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<sup>392</sup> *Okhrimenko v Ukraine*, 2009, available online: HUDOC <<http://hudoc.echr.coe.int/>>.

<sup>393</sup> *Ibid* at para 88.

<sup>394</sup> See *Pretty v the United Kingdom*, 2346/02, ECHR 2002-III at para 52 and further references.

<sup>395</sup> International Human Rights Law, United Nations Office of the High Commissioner of Human Rights, online: United Nations <<http://www.ohchr.org/EN/ProfessionalInterest/Pages/InternationalLaw.aspx>>.

*legislative, administrative, judicial or other measures*”.<sup>396</sup> The positive obligation is also formalized in article 7 of the ICCPR in the form of governments’ duty “*to protect people in their jurisdiction*” from such prohibited acts by taking concrete steps for this purpose.<sup>397</sup> The active measures of protection according to the provisions of CAT shall include “*effective legislative, administrative, judicial or other measures.*”<sup>398</sup> This means that the Government of Ukraine must elaborate and implement effective measures including, but not limited to, those of a legislative, administrative or judicial nature to prevent cruel, inhuman or degrading treatment and to immediately suppress violation of this human right if it happens.

However, according to the available evidence and analyzed case law, Ukrainian “legislative measures” can hardly protect someone denied pain relief and thus left suffering from such ill-treatment. Although the Ukrainian Constitution declares prohibition of cruel, inhuman or degrading treatment and adherence to the international legislation, the Criminal Law of Ukraine formalizes only the prohibition of torture without mentioning other forms of ill-treatment which, as discussed above, cannot apply to failure to ensure adequate pain control. In other words, Ukraine as a state is thus far failing to fulfill the obligation to provide active measures of protection from ill-treatment in terms of ensuring adequate legislative environment. Other types of crimes may potentially apply to the case of denial of pain control under certain circumstances like, for example, “*failure of a member of medical profession to provide help to a patient.*”<sup>399</sup> However, the available Ukrainian internal case law does not provide cases of application of this criminal norm to the failure to treat pain. The absence of concrete provisions prohibiting cruel, inhuman or degrading treatment in the Criminal Code of Ukraine means that such treatment practically cannot impose responsibility unless it falls under application of another specific provision of this code. In other words, the cruel, inhuman and degrading treatment is definitely unlawful according to Ukrainian legislation, given that the abovementioned international provisions constitute parts of Ukrainian legislation. However, these provisions do not offer remedies for such wrongdoings (or omissions); therefore, their practical application for the defence of patients’ rights cannot bring

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<sup>396</sup> CAT, *supra* note 381 at article 2.

<sup>397</sup> Human Rights Committee, General Comment 20 to the article 7 of the ICCPR (1992), online: <<http://www1.umn.edu/humanrts/gencomm/hrcom20.htm>>.

<sup>398</sup> CAT, *supra* note 381 article 2.

<sup>399</sup> Criminal Code of Ukraine, *supra* note 263 at article 139.

positive results, which supports the point that Ukraine is currently failing to fulfil international law regarding protection from cruel, inhuman or degrading treatment of the people.

The point that the protection from denial of treatment of pain and prevention of avoidable suffering of pain constitute positive obligations of the Governments has been explicitly supported in a letter to the Commission on Narcotic Drugs from the United Nations Special Rapporteurs Manfred Novak and Anand Grover. The letter reads:

“Governments also have an obligation to take measures to protect people under their jurisdiction from inhuman and degrading treatment. Failure of governments to take reasonable measures to ensure accessibility to pain treatment, which leaves millions of people to suffer needlessly from severe and often prolonged pain, raises questions on whether they have adequately discharged this obligation.”<sup>400</sup>

Besides, on the grounds of analysis of the international law provisions, Amon and Lohman have fairly concluded that the states’ *“positive obligation requires reasonable steps to ensure that patients with severe pain can gain access to adequate treatment.”*<sup>401</sup> Ukraine, being a member of the considered international treaties, has to fulfil this duty. Failure to do so constitutes breach of international law. The jurisprudence of the European Court of Human Rights confirms this, because the considered above cases required states to pay damages to the applicants for failure to fulfil their obligation and protect people in their jurisdiction from ill-treatment.

### **3.4. Other Human Rights that May be Abrogated by the Failure to Provide Adequate Pain Relief**

The view that denial of pain control may constitute violation of many other human rights apart from the right to health and prohibition of torture was expressed by Professor Michael Cousins, a pain specialist from Australia, who when asked in an interview by Global Access to Pain Relief Initiative,<sup>402</sup> “Is the management of pain a human right?”, replied:

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<sup>400</sup> Letter to the Commission on Narcotic Drugs from UN Special Rapporteurs Manfred Novak and Anand Grover, online: Human Rights Watch <[http://www.hrw.org/sites/default/files/related\\_material/12.10.2008%20Letter%20to%20CND%20fromSpecial%20Rapporteurs.pdf](http://www.hrw.org/sites/default/files/related_material/12.10.2008%20Letter%20to%20CND%20fromSpecial%20Rapporteurs.pdf)> , may be accessed through: <http://www.hrw.org/news/2008/12/10/un-human-rights-experts-call-upon-cnd-support-harm-reduction> [Accessed on June 27th, 2013] , also cited in Amon & Lohman, *supra* note 96.

<sup>401</sup> Amon & Lohman, *supra* note 96.

<sup>402</sup> Global Access to Pain Relief Initiative (GAPRI) online: GAPRI <<http://www.uicc.org/programmes/gapri/>>.

Most definitely. For example if you look at the UN Declaration of Human Rights it espouses some very important human rights for people, such as access to clean water and air supply, freedom from hunger, the right to associate politically and other rights. But I put it to you that if you have unrelenting pain, day after day, night after night, you can't enjoy any of those human rights at all.<sup>403</sup>

In support of this, there is a clear acknowledgement expressed by Liliana De Lima, Executive Director of the International Association for Hospice and Palliative Care:<sup>404</sup>

“The fact is that when somebody is in pain, the ability to sleep, eat, work, play and relate to others is affected and all this can be managed with appropriate care. Appropriate pain management can bring back these possibilities.”

Most basically, as stated in General Comment 14 to the ICESCR, “*Health is a fundamental human right indispensable for the exercise of other human rights.*”<sup>405</sup>

Arguably, the right to respect for one’s dignity, respect for one’s family life, as well as the right to work and rest, and by extension, other human rights may be violated or at least limited by inadequate access to known and available pain relief.

### 3.4.1. The Right for Respect to One’s Dignity

The right to dignity as a separate entitlement, independent of other human rights appreciation has been recognized by numerous international instruments. The UDHR recognises everyone’s “*inherent dignity*”<sup>406</sup> and applies this human value with reference to the issues of equality<sup>407</sup> and personal development.<sup>408</sup> The ICCPR,<sup>409</sup> the ICESCR<sup>410</sup> and the ECPHRFF,<sup>411</sup> all ratified by Ukraine, apply to the concept of human dignity and promote this issue as an important value. Considerations of jurisprudence scholars have broadened the concept of dignity as human right to an enormous scale. According to the “Positive Rights Approach” provided by Rex D. Glancy<sup>412</sup> in “The Right to Dignity”,

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<sup>403</sup> GAPRI, “Life Before Death. Pain Control: Fight for the Right”, video, online: GAPRI <<http://www.gapri.org/life-death-pain-control-fight-right>> [GAPRI, Fight for the Right].

<sup>404</sup> More information about Liliana De Lima, online: In the Face of Pain <<http://www.inthefaceofpain.com/voices-of-hope/liliana-de-lima-mha/>>.

<sup>405</sup> General Comment # 14 to ICESCR, *supra* note 334.

<sup>406</sup> UDHR, *supra* note 193 at Preamble.

<sup>407</sup> *Ibid* at article 1.

<sup>408</sup> *Ibid* at article 22.

<sup>409</sup> ICCPR, *supra* note 377 at preamble and article 10.

<sup>410</sup> ICESCR, *supra* note 193 at Preamble.

<sup>411</sup> ECPHRFF, *supra* note 373 at protocol 13.

<sup>412</sup> E.g. Rex D. Glancy, “The Right to Dignity” (2011) *Columbian Human Rights Law Review* 66.

[...] positive jurisprudence based on a fundamental right to dignity not only operates to prevent infraction upon this right but also fosters its appreciation and respect .

The author broadens this concept to the appreciation of the value of human beings as an objective element of the right to dignity. If so, he argues, then the human beings “*must be given the opportunity to be able to exercise their free choice, and anything that prevents this would be a violation of one’s dignity.*” As emphasised by Glansy: “[...] *how can people exercise their free choice if they have no food on the table, or if they are unable to treat their sicknesses?*”<sup>413</sup>

Certainly, pain as well as many other health problems drastically limit one’s choices and preclude their realization.<sup>414</sup> Moreover, it may sometimes push people to decisions and choices they would not otherwise make,<sup>415</sup> thus diminishing their will and dignity. That is why legislative interdictions to “*leave a person in a desperate position [regarding state of health]*” are fairly considered by Aart Hendriks<sup>416</sup> in close association with the right to human dignity in his article “Personal Autonomy, Good Care, Informed Consent and Human Dignity: Some Reflections From a European Perspective”. As it emphasized by Dr. Liz Gwyther, a palliative care doctor from South Africa, “*The fact that pain can be relieved but is not being relieved is really an insult to humanity and human dignity.*”<sup>417</sup>

The publications that consider the intersections of pain and dignity recognize that *pain is “an unpleasant and un-dignifying experience”*<sup>418</sup> and that it “*blocks or seriously impedes the realization of almost all other human values.*”<sup>419</sup> Daryl Pullman in the “Human Dignity and the Ethics and Aesthetics of Pain and Suffering” states, “[...] *unmitigated pain and suffering are often thought to rob human beings of their dignity.*”<sup>420</sup> Finally,

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<sup>413</sup> *Ibid*; see also Oscar Schachter, “Human Dignity as a Normative Concept” (1983) 77 American Journal of International Law 848 at 851.

<sup>414</sup> E.g. career decisions regarding what work one can realistically do v what work the one would wish to do.

<sup>415</sup> E.g. consider the choice of a man with cancer to leave his family, as described in Amon & Lohman, *supra* note 96.

<sup>416</sup> Aart Hendriks, “Personal Autonomy, Good Care, Informed Consent and Human Dignity. - Some Reflections From a European Perspective”, (2009) 28 Medicine & Law 469 at 473 and 477.

<sup>417</sup> GAPRI, Fight for the Right, *supra* note 403.

<sup>418</sup> “Dignity on the Ward: Pain and Older People” A guide for hospital staff, online: <[http://www.ageuk.org.uk/documents/en-gb/professionals/research/dignity%20on%20the%20ward%20pain%20\(2008\)\\_pro.pdf?dtrk=true](http://www.ageuk.org.uk/documents/en-gb/professionals/research/dignity%20on%20the%20ward%20pain%20(2008)_pro.pdf?dtrk=true)> [Dignity on the Ward].

<sup>419</sup> Sandra H. Johnson, “Relieving Unnecessary, Treatable Pain for the Sake of Human Dignity” (2011) 29 Journal of Law, Medicine & Ethics at 11.

<sup>420</sup> Daryl Pullman, “Human Dignity and the Ethics and Aesthetics of Pain and Suffering”, online: <<http://link.springer.com/content/pdf/10.1023%2FA%3A1019521923979.pdf>>.

according to Dr. Rajagopal (India), “Pain of that sort, when somebody is forced to roll into a ball and scream and lose interest in one’s own family and surroundings and practically going mad -- that’s not life with dignity.”<sup>421</sup>

Along with provisions of international treaties, the Ukrainian Constitution entitles everyone “to have one’s dignity respected”<sup>422</sup> and recognizes “an individual, his [...] honour and dignity [...] as the highest social value”.<sup>423</sup> Human dignity, viewed from different angles, is without a doubt extremely undermined by the denial of adequate pain control at all stages of people’s lives. Therefore the right to respect one’s dignity can never be fully realized unless adequate, equal and universal pain management is ensured. Because the right to dignity is an international right as well as a constitutional entitlement of the Ukrainian people, it imposes the state’s corresponding obligations to respect, protect and fulfill this right. The two latter duties require active measures to create conditions for enjoyment of this right and to prevent violations. Accepting the view that dignity is associated with “free choices” of the person, the states’ obligations require, *inter alia*, elimination of obstacles to realization of these “free choices”. Because of solid links between the right to dignity and the matter of pain control, I conclude that ensuring adequate access to pain management is a state’s obligation under the human right to dignity.

#### 3.4.2. The Prohibition of Discrimination

The fact that different ailments receive different levels of care from the Ukrainian Government forces one to consider this problem from the perspective of prohibition of discrimination. I argue that this is an issue in Ukrainian pain management because of the following circumstances. First, the pain (as a symptom) is being underestimated comparative to the disease or health condition itself. In Ukraine, and sadly, also internationally, the problem of how to deliver “care beyond cure”<sup>424</sup> is not new. The lack of attention to the problem of pain control as opposed to the issue of curing the disease was considered thoroughly by Scott Fishman,<sup>425</sup> who raised the problems of absence of enough initiatives, research grants, funding and even adequately trained health

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<sup>421</sup> “GAPRI, Fight for the Right, *supra* note 403.

<sup>422</sup> *Constitution of Ukraine*, *supra* note 44 at article 28.

<sup>423</sup> *Ibid* at article 3.

<sup>424</sup> See Andrea O. Bauman et al, “Who Cares? Who Cures? The ongoing debate in the provision of health care” (1998) 28:5 *Journal of Advanced Nursing* 1040.

<sup>425</sup> Fishman, *supra* note 12.

professionals in the matters of pain control. Most basically, the Ukrainian law introduced a list of health conditions<sup>426</sup> recognized as disabilities in Ukraine but did not say a word about such a common ailment as pain, which undoubtedly limits the well-being of patients. By contrast to such an approach, in a Canadian court case, *Martin v. Whiteford*,<sup>427</sup> the damages to an injured person (a plaintiff) were granted “*not on the basis of permanent injury but rather [as] compensation for the pain and suffering*”. In Ukraine disability lists are based on diseases and conditions (the diagnosis), rather than on symptoms. I challenge the correctness of such approach and would advocate for the approach in the aforementioned *Martin v. Whiteford*, because disregarding symptom and focusing on diagnosis may practically discriminate against those with pain but without a “necessary” diagnosis. In other words, contrary to the logic that pain limits physical and also emotional abilities of people,<sup>428</sup> in Ukraine pain, if not “supported” by the “necessary” diagnoses listed in the abovementioned disabilities list, cannot be officially considered a disability. This is, arguably, a discriminatory approach, because the Ukrainian list of legally-recognized disabilities is under-inclusive, thus the list itself seems unconstitutional. Second, there are several known cases, when even as a symptom pain received differential attitude depending on what diagnosis is associated with it.<sup>429</sup> According to the evidence about the under-treated pain in patients with diseases other than cancer or HIV, which I provided in the first chapter,<sup>430</sup> absence of this so-called “necessary” diagnosis caused denial of or at least certain limits to pain control, and subsequently constituted discrimination of a group of patients. It is if they are being punished for having fortune to be free from cancer or HIV and were less likely to receive adequate treatment of pain in Ukraine. Although there is no legislative provision limiting pain management of patients other than those with HIV or cancer, as the available evidence<sup>431</sup> shows, in practice it sometimes happens that in Ukraine they in fact are less likely to receive adequate treatment of pain.

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<sup>426</sup> Decree of the Cabinet of Ministers of Ukraine “On adoption of the Regulation of the order, conditions and criteria of disability diagnosis” (“Положення про порядок, умови та критерії встановлення інвалідності”) 1317, 3 December 2009, online: Rada <<http://zakon2.rada.gov.ua/laws/show/1317-2009-%D0%BF/page>> [Decree 1317].

<sup>427</sup> *Martin v Whiteford*, [1974] 1 SCR 423.

<sup>428</sup> Martha Butler, “Chronic Pain and Disability”, online: Pain Resource Center <[http://prc.canadianpaincoalition.ca/fr/chronic\\_pain\\_and\\_disability.html](http://prc.canadianpaincoalition.ca/fr/chronic_pain_and_disability.html)>.

<sup>429</sup> See the evidence, provided at 24-25, above.

<sup>430</sup> *Ibid.*

<sup>431</sup> See *Ibid*; see also Andrew Rokhansky et al, *supra* note 8 at 58, 63-65, 82-83 and 69-100; see also Schneider, *supra* note 75.

The prohibition of discrimination is practically synonymous with the right to equality in exercising human rights. This right against discrimination has been formalized in several international treaties.<sup>432</sup> Besides, the Ukrainian Constitution proclaims equality of the Ukrainian citizens in their rights and before the law.<sup>433</sup> As I discussed above,<sup>434</sup> access to healthcare and to essential medicines is a human right recognized in Ukraine in the provisions of internal and international legislation. If so, the conditions for the enjoyment of this right must be equally available to patients with all diagnoses, conditions and/or symptoms without discrimination. Arguably, the differential attitude to treatment of different symptoms may be viewed as discriminatory in relation to patients on the grounds of their diagnosis (or absence of diagnosis) and symptoms. More specifically, the treatment of pain must receive same attitude as the treatment of, for example, nausea or any other physical inconvenience. Therefore the excessive regulations of the use of opioid analgesics imposed by the Ukrainian Government, which constitute a direct limitation in providing adequate pain control, are discriminatory in relation to patients with pain symptoms as opposed to the patients without it. Furthermore, the denial of the treatment of pain to non-cancer, HIV negative and non-palliative patients is also discriminatory on the grounds of absence of the diagnosis. In other words, being more willing to treat cancer pain than to treat pain of unknown origin is synonymous with accepting that the one with cancer is more entitled to receive adequate healthcare than the one without such a diagnosis.

Overall, according to the law the state must provide equal treatment of the Ukrainian patients, whatever health problems they face. Putting complications to the access to the treatment of pain is first of all a violation of the corresponding duty of the State to respect equality in access to healthcare. Second, failure to take positive actions in ensuring access to all essential medicines, including opioids for the treatment of pain, is a violation of the duty to protect and fulfill the right for equality of all Ukrainian patients.

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<sup>432</sup> See ICESCR, *supra* note 193 at article 2 part 2 (“The States Parties to the present Covenant undertake to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.”); see also UDHR, *supra* note 193 at article 7 (“All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination”); see also ECPHRFF, *supra* note 373 at article 14.

<sup>433</sup> *Constitution of Ukraine*, *supra* note 44 at articles 21 and 24.

<sup>434</sup> The discussion of the Ukrainian legislative basis of the right for essential medicines may be found in subchapter 3.3.2. at 79-82, above.

### 3.4.3. The Right to Family Life

Another international and also constitutional right of Ukrainian people, arguably violated by the denial of adequate pain management, is the right to a family. According to the Constitution of Ukraine, “*The family, childhood, motherhood, and fatherhood shall be under the protection of the State.*”<sup>435</sup> The right of a person to a family is also formalized in the Family Code of Ukraine, saying that “[e]veryone has the right to live in the family”<sup>436</sup> and “*the right to respect for his/her family life.*”<sup>437</sup> From an international law perspective the right to family is recognised in several international instruments by providing important entitlements, related mainly to the right to marry and found a family,<sup>438</sup> the freedom of consent in marriage,<sup>439</sup> the principle of non-discrimination and equality of men and women in family,<sup>440</sup> as well as the rights of children and parental care,<sup>441</sup> prohibition of interference with privacy<sup>442</sup> and, importantly, the entitlement to protection of family by the society and the State.<sup>443</sup> This latter entitlement directly imposes a positive obligation of the state to take effective measures to protect families and family lives, including creation of the favourable conditions for life in family and clearly first of all refraining from any measures that could undermine the value of families.

At the same time, the essentially important but not mentioned in international legislation entitlement, which naturally flows from the idea of family, is the right to realise an intention of family members to live together and to interact with each other in a meaningful way. Essentially, the standard marriage vow includes the promise “*to live together*” and to keep each other “*in sickness and in health*”.<sup>444</sup> The fundamentalism of the intention to cohabit and meaningfully interact with each other in a family is recognized in Austrian family legislation.<sup>445</sup> Besides, this issue is given high

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<sup>435</sup> *Constitution of Ukraine*, *supra* note 44 at article 51 part 3.

<sup>436</sup> Family Code of Ukraine (Сімейний кодекс України), Law of Ukraine, 2947-III, 10 January 2002, at article 4 part 3, online: Rada <<http://zakon2.rada.gov.ua/laws/show/2947-14>>.

<sup>437</sup> *Ibid.*

<sup>438</sup> ICCPR, *supra* note 377 at article 23.

<sup>439</sup> ICESCR, *supra* note 193 at article 10; and also ICCPR, *supra* note 377 at article 23.

<sup>440</sup> *Ibid* at article 10.

<sup>441</sup> ICESCR, *supra* note 193 at article 10.

<sup>442</sup> ICCPR, *supra* note 377 at article 17.

<sup>443</sup> *Ibid* at article 23 part 1.

<sup>444</sup> The Standard Marriage Vow, online: International Commitment Ceremonies Registrar <<http://www.unionoflove.com/vows/stdvow.html>>.

<sup>445</sup> See Civil Code of Austria at article 44 (“The marriage contract shall form the basis for family relationships. Under the marriage contract two persons of opposite sex declare their lawful intention to live together in indissoluble matrimony, to beget and raise children and to support each other.”)

consideration and appreciation in immigrant policies of countries, which provide rules and mechanisms for families' reunification. The concepts of these immigration rules may potentially provide same approach to the discussed issue. At the same time, while the concept of family so naturally encompasses the idea of living together as probably the most essential basis for founding a family, this entitlement has been found neither in international law nor in the Ukrainian domestic legislation. Arguably, this situation complicates the realization and defence of the human right to family under certain circumstances.

As a matter of fact, the issues of pain control are very closely linked to the right to family life.<sup>446</sup> Untreated pain causes people's difficult choices to separate from families, which they would not choose otherwise.<sup>447</sup> Certainly, the law does not provide a direct entitlement to keep a family together and to maintain their meaningful communication. Naturally, the decisions with these regards may be deeply personal, and cannot and should not be of any interest for anyone beyond the family members. However, the entitlement of the family to be protected by the society and the state, provided by the ICCPR, as well as by the Ukrainian Constitution, arguably includes protection of family cohabitation unless contrary personal decisions are taken by family members in situations beyond the control of the society or the state. In other words, it is logical to distinguish between the decisions of people to be separated from families, whether they are being made according to their personal choices or if they are caused by lack of adequate protection or conditions created by the society and the state, not by their actual intention. Of course, only the latter case refers to the government's failure to protect families. Therefore, if a patient's decision to be separated from the family is caused by government's failure to provide adequate healthcare, including out-patient care, *inter alia* specifically adequate pain control, this is arguably also a failure to protect the family as well, and therefore it constitutes violation of the right to family as per international and Ukrainian domestic legislation.

#### 3.4.4. The Right to Work and Earn One's Living

What very closely corresponds with the rights to dignity (in terms of making free choices), equality and family in the sense of making choices is that people in pain often

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<sup>446</sup> The evidence and the discussion of patients' decision-making when suffering not properly managed pain are provided in the previous chapter at 56-58, above.

<sup>447</sup> *Ibid.*

have to give up their careers.<sup>448</sup> The *right to work as an expression of a free choice of a type of labour to earn one's living* is recognized by the Ukrainian Constitution<sup>449</sup> and the international treaties.<sup>450</sup>

Arguably, the denial of possible pain relief is a deprivation of the opportunity to work and to gain one's living by work of one's choice. The human right to work, along with other human rights, must be not only respected by the governments, but also protected and fulfilled. This involves a positive obligation of governments to create certain conditions so that all categories of people enjoy this right, including people disabled by pain. At the same time, if pain can be treated and would thus no longer constitute a barrier to one's right to work, the government's obligation regarding the right to work logically shifts to the obligation to ensure adequate treatment of pain.

Simultaneously, it needs to be recognised that as well as the right to family, the human right to work needs to be protected by the state only under the condition of one's free personal choice to work. A choice of a patient with inadequately treated pain to give up work may be viewed as violation of the right to work only under the condition that such choice was caused by inadequate treatment of pain, not by certain personal circumstances beyond the control of a state. According to these considerations ensuring pain control should be viewed, *inter alia*, as removing a serious barrier to the realization of one's right to work, or in other words, as creation of a necessary condition for realization of this human right. Besides, arguably, the violation of the right to work subsequently causes a violation of other constitutional rights of Ukrainian people, including the right to a "*standard of living sufficient for [people] and their families*"<sup>451</sup> and "*to free development of [one's] personality.*"<sup>452</sup>

#### 3.4.5. The Prohibition of Driving into Suicide

In light of the fact that uncontrolled pain has been proven to increase the risk of suicide,<sup>453</sup> while there are known remedies to alleviate the majority of the pain, denying adequate pain relief raises a question about driving patients into suicide.

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<sup>448</sup> The discussion of the patients' career issues is provided in subchapter 2.2.5. at 58-59, above.

<sup>449</sup> *Constitution of Ukraine*, *supra* note 44 at article 43.

<sup>450</sup> UDHR, *supra* note 193 at article 23; and also ICESCR, *supra* note 193 at article 6.

<sup>451</sup> *Constitution of Ukraine*, *supra* note 44 at article 48.

<sup>452</sup> *Ibid* at article 23.

<sup>453</sup> The evidence and the discussion of the suicidal risks caused by denial of pain control are provided in subchapter 2.2.2 at 53-55, above.

The Criminal Code of Ukraine contains a special norm, formalizing *driving someone to suicide by unlawful deeds as a separate type of crime*. According to article 120 of the Criminal Code of Ukraine,

causing somebody to commit suicide or attempt suicide as result of cruel treatment, intimidation, forcing to unlawful deeds or systematic humiliation of one's human dignity – will be punished by custodial restraint up to three years or deprivation of liberty for the same period.<sup>454</sup>

The Supreme Court of Ukraine suggests, for the purpose of causing suicide, the term “cruel treatment” means acts (both deeds and omissions to act) that “[...] *cause [...] physical or mental sufferings ([such as] [...] deprivation of food, water, clothes, sleep, etc.)*”<sup>455</sup> According to this Court's Ruling, article 120 of the Criminal Code of Ukraine is applicable if the attempted or committed suicide is “a consequence of cruel treatment”.<sup>456</sup>

The court emphasised the causal relationship between the cruel treatment and the suicide rather than the nature of such cruel treatment. That is why logically one of reputable scientific commentaries offers to consider also under this important “*etc*” in the interpretation of the “*cruel treatment*”, as suggested by the Supreme Court of Ukraine, “*the deprivation of medicines*.”<sup>457</sup> Another important characteristic is that all official scientific commentaries<sup>458</sup> on article 120 of the Criminal Code of Ukraine explain that measuring intentionality is not required for qualification of driving into suicide.

Intentionality is also not required by the above-mentioned Supreme Court's Ruling or any other norm. This means that if an attempted or committed suicide happened as a result of cruel treatment, article 120 must apply regardless of whether such ill-treatment was given with or without an intention to make the victim commit suicide or develop suicidal behaviour.

These findings lead to the conclusion that failure to provide necessary medicine to relieve one's pain and thus leaving someone in suffering, if it caused an attempted or committed suicide, would constitute a crime under the Ukrainian Criminal Legislation. However, the

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<sup>454</sup> Criminal Code of Ukraine, *supra* note 263 at article 120 part 1.

<sup>455</sup> Ruling of the Supreme Court of Ukraine “On court practice in cases on crimes against human life and health” (“Про судову практику в справах про злочини проти життя і здоров'я особи”) 2, 7 February 2003, online: Rada <<http://zakon4.rada.gov.ua/laws/show/v0002700-03>>.

<sup>456</sup> *Ibid* at para 28.

<sup>457</sup> On-line Commentary to the Article 120 of the Criminal Code of Ukraine, available online: Legal Services Online <<http://yurist-online.com/ukr/uslugi/yuristam/kodeks/024/118.php>>.

<sup>458</sup> Scientific-Practical Commentary to the Criminal Code of Ukraine, by V.V. Stashys & V. Y. Tatsiy (Kyiv, Publishing House “Kyiv”, 2003).

central question is who is to be blamed. From this perspective the practical application of this legislative provision remains a dramatic challenge, arguably hardly feasible. Without going deeply into the theory of the elements of crime, most of the examples of committed or attempted suicides provided in the previous chapter<sup>459</sup> contain all components of the elements: 1) the Object – one’s life; 2) Objective side – “cruel treatment”, attempted suicide and causal relationship and 3) Subjective side – in the form of negligence. The fourth element – 4) the Subject – which is generally a human being of over 18 years – remains questionable, because it appears rather difficult to define whose act (action or omission) caused the suicide or an attempt. If the doctors act according to the rules established by the state officials, then logically the state officials should be liable for the suicides due to denial of pain control. However, as in many other countries, Ukrainian state officials have immunity from criminal charges. Apart from that, it appears very uncertain exactly which state officials could be considered liable for inadequacy of pain management in Ukraine. That is why denial of pain control causing someone’s attempted or committed suicide constitutes a crime of “driving into suicide”, directly formalized in Ukrainian criminal legislation, but realistically there is practically no way to apply this provision, because the subject of the crime, who could potentially be accused, can hardly be defined as immune from prosecution.

#### *3.4.6. Undermining the Right to Personal and Social Security*

The evidence about the people seeking analgesic substances through illegal markets,<sup>460</sup> due to their overwhelmingly hard or even impossible legal access through hospitals, forces us to consider the issues of the personal safety of these people as well as the matter of public security in general. Arguably, pushing people to deal with criminals, who trade narcotics to the drug addicts, potentially puts the safety of these people at risk. This situation is very similar to the matter of prostitution in Canada, discussed in the present chapter, as the legislative bans of certain activities in Canada put at risk the safety of prostitutes, while prostitution itself was not criminalised.

Going to criminals with money in one’s hands (because of the intention to purchase narcotics) naturally creates the risk of robbery, possibly with violence, the possibility of

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<sup>459</sup> See the evidence and the discussion of the suicidal risks caused by denial of pain control are provided in subchapter 2.2.2 at 53-55, above.

<sup>460</sup> The evidence about patients’ and their relatives’ seeking painkillers at illegal markets is provided in subchapter 2.2.1. at 52-53, above.

being assaulted or even murdered. Besides, “adding clients” to the narcotic dealers strengthens their financial position, creating an even greater threat to the overall public social security in the state. Apart from that, the cases when people poison themselves with some home-made substances of unknown quality also expose them to a great risk of serious health damage that may become even lethal. It is the same thing with narcotics purchased from illegal sources. Nobody ensures their quality, so taking them may lead to harm.

The right to personal security<sup>461</sup> has been analysed by the scholars from different perspectives and from various legal entitlements. The meaning and the legal content of this human right are being extended or limited as the right is viewed from different angles in different jurisdictions. All the same, the protections of one’s health, as well as the protection from violence or from any other uncontested application of physical force, are considered among the basic entitlements under the right to security. The international legislative provisions, accepted by Ukraine, recognize the rights to the “security of person”,<sup>462</sup> and the priority of “national security and public safety”.<sup>463</sup> The language of the Constitution of Ukraine is also supportive, as the fundamental law of the state proclaims, “*An individual, his life and health, honour and dignity, inviolability and security shall be recognised in Ukraine as the highest social value*”<sup>464</sup> and “*Affirming and ensuring human rights and freedoms shall be the main duty of the State.*”<sup>465</sup>

According to these provisions the state, by adopting them, agrees to take all appropriate measures to protect people’s safety and prevent violations of this human right. As with the right of protection from ill-treatment, the protection of people’s security is an immediate requirement and an absolute duty of the state with no regards to the available resources or any other circumstances. Therefore, if the current state of legislation, order and policies in practice with regards to the medical use of the controlled substances push people into situations that threaten their safety, denial of adequate pain management must also be viewed as violation of their constitutional and international right to personal and public security.

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<sup>461</sup> See e.g. Liora Lazarus, “The Right to Security - Securing Rights or Securitising Rights” Legal Research Paper Series, Paper No 39/2013 (University of Oxford, January 2013).

<sup>462</sup> UDHR, *supra* note 193 at article 3.

<sup>463</sup> ECPHRFF, *supra* note 373.

<sup>464</sup> *Constitution of Ukraine*, *supra* note 44 at article 3 part 1.

<sup>465</sup> *Ibid* at article 3 part 2.

### 3.4.7. Violation of the Rights of Healthcare Providers

As it was considered in the previous chapter,<sup>466</sup> not only patients and their families become victims of insufficient pain management policy. Tough rules limiting access to adequate analgesics negatively affect healthcare providers and their work conditions. The Constitution of Ukraine entitles everyone, certainly including doctors, to “*proper, safe and healthy labor conditions*”.<sup>467</sup> However, inadequate conditions to treat patients make the appropriateness of the working conditions of healthcare providers questionable. Acting under the excessive regulations and constant control of the narcotic controlling authorities, they often appear unable to provide adequate pain relief for their patients. Arguably, “proper” conditions for the qualified work of healthcare providers would imply availability and accessibility of necessary resources to perform their professional duties adequately. Looking at a patient in pain and being unable to provide possible relief hardly goes in line with “proper” conditions for a doctor’s work. The evidence provided in the previous chapter<sup>468</sup> makes it clear that Ukrainian doctors perform their duties under stress associated with inadequate conditions of pain treatment for their patients. In addition to the excessive restrictions on the use of opioids, many Ukrainian doctors refer to inadequacy in their education about pain management.<sup>469</sup> Requiring doctors to give adequate analgesia without ensuring their proper education and access to necessary information can hardly comply with their human rights. This applies not only to pure medical attainments in the field of pain control, but also to the issues of doctors’ awareness about the rules for using controlled substances and about the new remedies for pain relief in the country.

All necessary things for the proper education of healthcare professionals in Ukraine are not only reasonable in terms of ensuring proper conditions for their work, but are also directly required from the Ukrainian State by the provisions of international law. The right to health encompasses several “*core obligations*” of all states before their people, as defined in General Comment #14 to the right to the highest attainable standards of physical and mental health. Properly trained healthcare personnel are a minimum core

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<sup>466</sup> The evidence and discussion on the conditions of the work of health professionals with regards to their abilities to treat their patients’ pain may be found in subchapter 2.3 at 59-62, above.

<sup>467</sup> *Constitution of Ukraine*, *supra* note 44 at article 43 part 4.

<sup>468</sup> See discussion at 59-62, above.

<sup>469</sup> Appendix 1, *supra* note 50 at 7.

obligation of the governments of all states.<sup>470</sup> Because this is a minimum obligation, no justifications may be accepted for non-fulfillment.

In addition to the international obligations of the Ukrainian State, the Ukrainian internal legislation in fact also contains necessary provisions requiring the Government's proper actions to adequately educate professionals in general and particularly those in medical sphere. According to the Ukrainian Constitution, "*The State shall [...] implement programmes for vocational education, training, and retraining of personnel according to the needs of society.*"<sup>471</sup> Specifically, the Ukrainian healthcare providers "*have the right to professional advanced training no less than once in five years.*"<sup>472</sup> As noted in previous chapters<sup>473</sup> the healthcare providers must have access to advanced training according to the law,<sup>474</sup> but it is questionable whether pain management training is fully consistent with the "*needs of society*". Many Ukrainian healthcare providers do not have necessary knowledge to meet the expectations of their patients in terms of treatment of their pain.

This means that in practice the absence of necessary conditions for pain management in Ukraine violates the rights of the healthcare providers, not only the rights of patients. The Ukrainian State, by not taking reasonable active steps to ensure these conditions, fails to fulfil its duties to respect, protect and fulfil the rights of Ukrainian doctors.

#### 3.4.8. Absence of a Standard of Care for Patients in Pain as an Obstacle to Defend the Rights of Both the Ukrainian Patients and Doctors

According to Ukrainian Law,<sup>475</sup> the system of standards in healthcare must be set by normative and branch standards. The standard of medical care is a complex mix of norms and rules, as well as indicators of quality of the delivery of a certain type of medical care, enunciated in terms of the modern-day level of development of medical knowledge and practice. However, when it comes to pain management, the official Ukrainian "MedStandard" provides these standards only for two cases: "pain in urology" and

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<sup>470</sup> General Comment # 14 to ICESCR, *supra* note 334 at para 43 (e).

<sup>471</sup> *Constitution of Ukraine*, *supra* note 44 at article 43.

<sup>472</sup> Law 2801-XII, *supra* note 19 at article 77 part "b".

<sup>473</sup> The discussion of these findings is provided in subchapter 1.4.1. at 16-18, above.

<sup>474</sup> Law 2801-XII, *supra* note 19.

<sup>475</sup> *Ibid* at article 14 part 1.

“stomach-ache”<sup>476</sup> that provide specific methods of analgesia, suggested medicines and dosages to be used in certain cases. In some other standards for other diagnoses and symptoms, anaesthesia is mentioned as a recommendation within “maintenance therapy”; however, no specific methods or medicines are specified. Some official recommendations are also available for palliative care of cancer and HIV-positive patients; however, there are no detailed instructions for the treatment of pain syndrome that would comply with all relevant WHO recommendations.

The Law of Ukraine “On state social standards and state social guarantees”<sup>477</sup> provides the clarification that the state *social normative in healthcare includes, among others, “the amount of diagnostic, treatment and prophylactic procedures” as well as “indicators of quality of care delivery”*. However, there is no articulation of a process for pain management.

#### 3.4.9. Ambiguity in Regulations re: Off-label Prescriptions

One issue lying on the border between the rights of patients and the rights of healthcare providers is the matter of off-label prescriptions.<sup>478</sup> This issue, however, is groundbreaking, particularly when it comes to prescription of opioid analgesics like morphine, described in the first chapter of the present thesis.<sup>479</sup>

In fact, Ukrainian law does not include any provisions giving a doctor the liberty to overlook or to go beyond the instructions ascribed for the medicine and prescribe it according to his or her professional knowledge. At the same time, from a juridical point, an instruction about the use of a medicine is not considered a source of law in Ukraine. These “documents” are not issued by either of the authorised bodies of the Ukrainian state power, but only by a manufacturer of medicines. Therefore, there are no legal grounds to consider the recommendations for use of medicines binding for healthcare

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<sup>476</sup> Standards of medical care in Ukraine, online: Medstandard <<http://medstandart.net/byopatology/letter-2>>.

<sup>477</sup> Law of Ukraine “On state social standards and state social guarantees” (“Про державні соціальні стандарти та державні соціальні гарантії”) 2017-III, 5 October 2000, available online: Rada <<http://zakon4.rada.gov.ua/laws/show/2017-14>>.

<sup>478</sup> Off-label prescribing is a common definition of a practice that is believed to originate from the United States of America, where the regulations of the Food and Drug Administration (FDA) permit physicians to prescribe approved medications for other than their intended indications. For more information see “Off-Label” and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices”, Information Sheet, online: U.S. Food and Drugs Administration <<http://www.fda.gov/regulatoryinformation/guidances/ucm126486.htm>>.

<sup>479</sup> See discussion of how the Ukrainian doctors decide the issue of off-label prescription of morphine at 33-34, above.

providers. A Ukrainian lawyer would comment on this ambiguity using a version of the democratic principle “*if it ain't forbidden, do it*”. But the healthcare providers do not (and should not) have necessary legal competence to make such comments or decisions. That is why absence of a comprehensive legislative basis regulating off-label drugs use in Ukraine causes different approaches to the prescription of drugs, particularly of controlled substances, which in turn leads to otherwise avoidable suffering of the Ukrainian patients and to unnecessary distress of Ukrainian healthcare providers.

### **3.5. The Ukrainian Case Law on the Issues of Pain Control**

Ukraine is a civil law country, where the civil system does not provide same level of differentiation and flexibility in considering issues of adequate pain relief through court hearings as the common law system. Basically, laws and regulations make the general system of Ukrainian legislation, while cases (legal precedent) are not binding, but may be only persuasive for the courts in deciding similar matters. Judges in Ukraine are supposed to be guided exclusively by the laws and regulations in force. According to the Ukrainian Constitution, “[...] *judicial bodies shall exercise their authority within the limits determined by this Constitution and in accordance with the laws of Ukraine.*”<sup>480</sup>

Logically, considering these peculiarities of the civil system, court cases on adequate pain management may appear no earlier than laws and regulations providing certain normative and standards of medical care on the issue. It is not surprising that there are no cases so far on the issue of adequacy of pain relief in Ukraine where a patient’s application would appear successful.

The search for Ukrainian case law on the issue of pain management has provided a recent Court Decision of one of the Court of General Jurisprudence of Svyatoshynsky Region of Kyiv, dated June 13, 2013.<sup>481</sup> This was the only Court case related to pain control found in an extensive search in the Ukrainian official case law database. The plaintiff – a hepatitis C positive patient – applied to the court with a claim for material and moral damages caused to him by inadequate treatment of his pain. The pain syndrome was associated with several diagnoses. During several months since September 2008 the patient accepted prescribed injectible morphine, which was afterwards changed to a weaker analgesic due to improvement of his condition. The patient was satisfied with that

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<sup>480</sup> *Constitution of Ukraine*, *supra* note 44 at article 5.

<sup>481</sup> Court judgement 2608/8784/12, 13 June 2013, Svyatoshynsky District Court of Kyiv, online: Revestr <<http://www.reyestr.court.gov.ua/Review/32615983>>.

until September 2009, when his health deteriorated, accompanied by severe pains. However, as he argues, his complaints of pain were responded to by numerous and very time-consuming additional investigations instead of prescriptions of any effective pain medication. The court accepted the documents from the defendant (a healthcare institution) stating that the patient had a “dependence syndrome” (a conclusion from an addictionologist) and that the further prescription of opioids was “*not warranted*” (according to the conclusion of a “Sociotherapy” committee). The decision was made exclusively on the basis of these two circumstances, which were accepted by the court as sufficient evidence in support of the position of the defendant. As a result, the patient’s application was dismissed.

This case appears rather illustrative in terms of absence of adequate regulations of the issue of adequate pain control in Ukraine and lack of the practice of skilful litigation on these issues. The court decision (the publicly available full text of the decision, but without any other procedural documents in court’s possession) does not show evidence of consideration by the court any of the human rights that might be abrogated by the denial of adequate pain treatment. According to the analytical part of the decision, they concentrated primarily on the legitimacy of the actions of the healthcare institution staff members. Therefore, obviously there was no reasonable instrument available to the judge on this issue to appraise the circumstances and the available documents. The court could base the decision exclusively on the grounds of available proof, which appeared to be provided exclusively by the medical documents delivered to the court. There was just a bunch of diagnoses, conclusions and recommendations of the healthcare providers, which was accepted by the court “as is”, without any appraisal. The decision does not say a word about an external medical expert conclusion, or any other independent medical opinion regarding the medical correctness of the denial to treat pain by opioid analgesics. The court did not find any violations of the legislative provisions by the healthcare providers. That is why, and most importantly, the evidence about suffering from pain, brought by the plaintiff, was not associated with any breach of law. Thus, naturally any responsibility for the suffering was excluded. Therefore the judge did not find a rationale for damages from the healthcare institution, because no breach of law was found. In other words, in this case the moral values of the doctors of the healthcare institution may be questioned, but hardly their breaking the law. Then why was denial of pain control and leaving a patient in tremendous suffering, so obviously violating his human

rights, not recognized as contrary to the law in this case? Did imperfect regulations or unskilful litigation cause a failure to defend the patient's rights? I argue that both could be. In considering a strategy of litigation, it is essential to correctly identify the respondent. It needs to be someone who failed to follow the law and therefore caused a violation of the rights of a plaintiff. However, the healthcare institution staff could hardly break the law by their failure to provide adequate analgesia simply because there are no legislative provisions or a standard of care for patients with pain in Ukraine. Under such circumstances the judge (obviously being a jurist, rather than a doctor) fairly could not give adequate estimation to the evidence provided in court. Logically, the decision relied heavily on the "Sociotherapy" committee conclusion (stating opioids were not warranted), which appears questionable. Any reliable evidence to the contrary was not provided to the court. There was no opposite medical conclusion, and no medical guidelines or recommendations commonly used in Ukrainian healthcare were available to convince the court that replacement of pain control by additional investigations is contrary to every law formalizing human rights of patients.

This forces me to consider whether another respondent could have been chosen in the litigation and possibly a different strategy as well. The Ministry of Healthcare of Ukraine is an agent of the Ukrainian Government,<sup>482</sup> responsible for the elaboration and implementation of state policy in healthcare, and therefore could be viewed as the institution responsible for the unnecessary suffering of the patient. The application to court against the Ukrainian Healthcare Ministry could be supported by the provisions of international legislation, considered in the present chapter in their associations with the government's obligation to ensure conditions for adequate pain control. Moreover, there is a Ukrainian court case with very close strategy. In December 2009 the Judgment of the County Administrative Court of Kyiv<sup>483</sup> in the case of several Ukrainian citizens v Ministry of Healthcare of Ukraine recognized as contrary to the law the passivity of the Ministry of Healthcare of Ukraine regarding ensuring the *access to essential medicines* for patients with chronic renal insufficiency that were not registered in Ukraine at that time (meaning that their circulation on the Territory of Ukraine was not allowed). The

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<sup>482</sup> Decree of the President of Ukraine "On adoption of the Regulation of the Ministry of Healthcare of Ukraine" ("Положення про Міністерство охорони здоров'я України") 467/2011, 13 April 2011, at para 3, online: Rada <<http://zakon4.rada.gov.ua/laws/show/467/2011>> [Decree 467/2011].

<sup>483</sup> Court Judgment 2a-179/09/2670, 2 December 2009, County Administrative Court of Kyiv, online: Reyestr <<http://www.reyestr.court.gov.ua/Review/3098622>>.

court's ruling recognized the obligation of the Ministry of Healthcare of Ukraine “to take steps” towards ensuring vital medicines for the Ukrainians with renal disease. The decision was built mainly on the provisions of the Law of Ukraine “On Medicines”<sup>484</sup> and of the Regulation of the Ministry of Healthcare of Ukraine in force at that time; however, article 12 of the ICESCR was also mentioned in the rationale. This court case has shown that in fact the international right to necessary medicines can be enforceable in Ukraine through the court in terms of receiving the positive judgment. However, this case can hardly be presented as totally successful, because in fact the court's decision to oblige the Ministry of Healthcare to “take steps” to ensure access to medicines provides no further specification of what steps should be taken and when the results should be seen. This is quite logical. Arguably, a more specific decision could not be issued unless the claim itself was formulated more precisely.

However, despite lacking necessary details, such a ruling, although it can be formally considered positive, in practice raises the same challenges of enforcement as the provisions of the ICESCR in general. Considering such ambiguity, it is not surprising that while the Ukrainian case law contains referrals to the ICESCR and specifically to article 12, the provisions of this article have not yet been directly applied by the Ukrainian courts with regards to health and medical care for patients in pain. Instead, the Ukrainian courts, while mentioning the norms of the ICESCR in the statements of reasons for decisions, base them on more specific provisions of the domestic legislation. So to say the provisions of the ICESCR appear to simply provide a supplement basis that adds value to the arguments, based on specific provisions of Ukrainian internal legislation. No evidence of direct application of international norms in the Ukrainian rights defence has been found by the author with respect to pain control matters.

Overall, the good sign is that the Ukrainian advocates have started to challenge the courts with applications regarding defence of patients' rights, including adequate pain management. However, an extensive search of Ukrainian case law did not provide cases where the patients' rights for relief of avoidable suffering from pain would be successfully recognized and defended through Ukrainian courts. At the same time, the considered cases provide good lessons for health rights advocates in terms of how the available legislative instruments can be developed and improved for the sake of better realization and defence of the rights of the Ukrainian patients. Besides, it reveals

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<sup>484</sup> Law on Medicines, *supra* note 42.

imperfections in the Ukrainian legislation in medical-legal issues, which limits ways to protect and defend human rights of the Ukrainian patients.

### **3.6. Concluding Remarks**

The provisions of Ukrainian internal and international legislation generally recognize the human right to adequate pain relief, approaching this issue from different angles and with reference to different entitlements deriving from the human rights. The law also respects the imperative of governments to ensure the right of every patient to possible and adequate pain relief. However, so far the Ukrainian Government failed to meet its law-based obligations to ensure human rights of the people of Ukraine with regards to pain control. The available case law of Ukraine does not demonstrate the effective use of the legal instruments in the defence of the rights of patients to adequate pain relief.

## **Chapter 4. Recommendations on How to Overcome Barriers to Adequate Pain Management in Ukraine through Law**

It appears that in Ukraine barriers to adequate pain control relate to all three vital spheres (*education, health system policy and availability of medication*) and cause abrogation of a range of human rights of patients and their doctors. Such multidimensional obstacles, causing violation of various human rights, obviously require a complex and all-encompassing strategy to overcome them.

I suggest that the strategy of improvement of the Ukrainian pain management system should provide concrete, realistic mechanisms to effectively overcome all three groups of barriers to the realization of the human right to adequate pain management in Ukraine: educationally, related to the healthcare system policy and to the availability of medicines. Most importantly, I argue that the actions must be directed by the principles of human rights of the Ukrainian patients, their relatives and the healthcare providers. Note that Ukraine is not at the very beginning of the way to adequate pain control. As explained in the previous chapters, certain steps for better availability of opioids in Ukraine have already been taken. That is why I will start the discussion about the possible ways to change the state of pain control in Ukraine by considering the matter of adequate implementation of the new norms of Ukrainian legislation with regards to the use of narcotics in healthcare.

### **4.1. Implementing the Adopted Legislative Changes**

Proper implementation of the legislative changes that have already been made can immediately improve the lives of thousands of Ukrainian palliative patients. This should definitely be the biggest priority. According to Diederik Lohman, a HRW professional, who conducted extensive research on the problems of pain control in Ukraine:

If there are basic and inexpensive steps that you can take, that will have an immediate effect on the lives of tens of thousands of people, you have no excuse for not taking them.<sup>485</sup>

Decree 333 is already in force, so the provisions are not being questioned by the Government of Ukraine. There is a need to appropriately implement it in practice, more precisely, to implement transition from the old rules to the new. It is a general practice in

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<sup>485</sup> GAPRI, Fight for the Right, *supra* note 403.

Ukraine that when the changes are being introduced to the legislation, the amending legislative act usually contains a section called “Transitional Provisions”. This section provides the mechanism of transition to the new rules by establishing specific tasks of the state agencies as well as the deadlines for these tasks’ fulfilment. Besides, it usually establishes the duration of the transition period and the feasible rules to be respected during this time.<sup>486</sup> The transition provisions also usually contain the assignment to a concrete state agency to adopt the current legislative environment to the adopted changes.<sup>487</sup> So adoption of a legislative act with obviously contradictory provisions with another act in force appears quite an unusual way of changing the rules in Ukraine. That is why the method of implementation of the new regulations would be also specific, because the Decree 333 does not contain any transition provisions.

Just recently, on December 30, 2013 an interagency working group was created<sup>488</sup> within the Ministry of Healthcare of Ukraine in order to consider ways to adapt legislative norms on healthcare issues to the changes introduced in the new Decree. Now the following actions are required from the Government of Ukraine that logically could be implemented through the Ministry of Healthcare of Ukraine pursuant to the results of the working group activity:

- To adopt necessary changes to the laws, so that they do not contradict the new Decree 333;
- To adequately inform all medical practitioners about the new rules and to supply them with relevant clarifications and guidelines regarding the new rules, possibly regarding the rules in the transition period;

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<sup>486</sup> See e.g. recent Law of Ukraine “On introduction of amendments to the Law of Ukraine On judicial administration and the status of the judges” and the procedural laws regarding additional means of protection of the security of citizens” 721-18, 16 January 2014, online: Rada <<http://zakon4.rada.gov.ua/laws/show/721-18/page>>.

<sup>487</sup> See e.g. *ibid*; see also e.g. recent Decree of the Cabinet of Ministers of Ukraine “On introduction of amendments to the paragraph 16 of the Regulation of the use of impact munition in the protection of civil order ” (“Про внесення змін до пункту 16 Правил застосування спеціальних засобів при охороні громадського порядку”) 14, 22 January 2014, online: Rada < <http://zakon4.rada.gov.ua/laws/show/14-2014-%D0%BF>>.

<sup>488</sup> Order of the Ministry of Healthcare of Ukraine “On the formation of interagency working group on the matters of the development of the normative acts on the matters of purchase, transportation, storage, dispensation, and utilisation of narcotic drugs, psychotropic substances and precursors in the healthcare system” (“Про утворення міжвідомчої робочої групи з питань удосконалення нормативно-правових актів з питань придбання, перевезення, зберігання, відпуску, використання та знищення наркотичних засобів, психотропних речовин і прекурсорів у закладах охорони здоров’я”) 1164333, 30 December 2013, online: Rada < <http://www.apteka.ua/article/268731>>.

- To set up a date when the old rules are repealed and the new Decree exclusively comes into force on practice;
- To adequately inform the public and particularly the health professionals about this date.

At the same time, along with the implementation of the new regulations, there is a need to consider the following possible outcomes and to adequately maintain the changes during the transition period. If the new easier rules for opioid use are implemented, this may significantly increase opioid consumption. If this might be the case, there would obviously be a need for larger amounts of narcotic drugs for medical purposes required in Ukraine in general. Because the import of narcotic substances is an internationally regulated matter,<sup>489</sup> *the increase in the demand of opioids in Ukrainian healthcare would require an appropriate notification to the International Narcotics Control Board*, estimating the supplementary quantities of opioids required for medical purposes, in order to enable adequate amounts of opioids within the country.<sup>490</sup> However, there is no information about any relevant notification sent to the International Narcotics Control Board (the INCB) by the Ukrainian State Agency for Narcotics Control.<sup>491</sup> Presumably, if nothing relevant is done on the matter, the barriers to adequate pain control in Ukraine may potentially shift in the future from problems connected with accessibility to opioids to problems with their availability within the state.

Apart from that, with better access to opioid analgesics, the role of healthcare providers' qualification and awareness of the issue becomes even more significant. The importance of adequately informing healthcare providers has been recognized and emphasized by specialists from the Wisconsin Pain and Policy studies group:

When policy changes are made to improve the regulatory environment for medical use of controlled medicines, it is important that health professionals, law enforcement, and regulatory personnel be educated about modern pain management as well as the policy changes.<sup>492</sup>

This calls for additional training, guidance or any other information that needs to be provided to the Ukrainian healthcare providers, particularly to the oncologists and others

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<sup>489</sup> Single Convention, *supra* note 9 at articles 19 and 21.

<sup>490</sup> But obtaining the INCB's approval for the supplementary quantities of opioids may appear a complicated task in itself. This issue was thoroughly considered in Nickerson & Attaran, *supra* note 219.

<sup>491</sup> Decree of the President of Ukraine "Matters of the State Agency of Drugs Control" ("Питання Державної служби України з контролю за наркотиками") 457/2011, 13 April 2011, online: Rada <<http://zakon1.rada.gov.ua/laws/show/457/2011>>.

<sup>492</sup> See Pain & Policy Studies Group, *supra* note 75 at 5.

who commonly deal with the treatment of pain.

With all these challenges connected with the enactment of the new Decree on narcotics in medical care, the matter of ensuring adequate pain control for all Ukrainians is an issue that requires a far broader approach that I will further discuss. Further removing multiple challenges of the Ukrainian pain management, I will consider overcoming complex barriers, related to government policy, education and availability of drugs.

#### **4.2. Encouraging the Elaboration of the Statutory Strategy on Pain Management**

As discussed earlier, the legislation of Ukraine related to the pain control matters is on the whole<sup>493</sup> rather favourable. However, many provisions sound rather general and barely address the issue of pain relief. That is why I consider the need for formalization of adequate pain management as a distinct human right with a corresponding duty to deliver sufficient medical care and with legal accountability for non-fulfillment. This calls for adequate amendments to Ukrainian legislation, which, I argue, may be introduced through adoption of a legislative act at the level no lower than a Decree of the Cabinet of Ministers of Ukraine. The government decrees, by their legal force, stand right after the Laws of Ukraine adopted by the Parliament. This means that all other Decrees, Orders and other acts of legislation, as well as by-laws within the state, may not contain provisions contrary to or limiting the rights provided by such Decrees. Because the matter of pain control in Ukraine is rather complex, it requires a strategy of its repair.

The appropriateness of a statutory strategy as a way to settle the problem has been “recognized” by the Ukrainian government, which has just recently approved the statutory *Strategy on Narcotics*.<sup>494</sup> As I have discussed in the previous chapters, most of the barriers to pain management refer to the issue of drug abuse and all the negative consequences ensuing for individuals and for society. However, not undermining the importance of protection from drug abuse and addiction, there is an equal need to acknowledge that ensuring necessary pain control is no less important. While the Strategy on Narcotics has been worked out and accepted as mandatory by the Ukrainian government, there is currently no initiative for a Strategy to ensure adequate pain control. It should be acknowledged that the Strategy on Narcotics mentions “ensuring

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<sup>493</sup> See legal analysis provided in Chapter 3, above.

<sup>494</sup> Order 735-p, *supra* note 11; see also Evan Wood et al, “Vienna Declaration: a Call for Evidence-Based Drug Policies” (20 July 2010) 376:9738 *The Lancet* 310.

*accessibility of narcotic medicines” and “fostering development of palliative care”.*<sup>495</sup>

Such a mention demonstrates acknowledgement of these challenges, but goes without any assignments to the state authorities.

I suggest that the Ukrainian Strategy on Pain Management, adopted by the Ukrainian government in the form of a Decree, should include the following legislative provisions, as I will explain in more detail further in this chapter:

- The definition of *adequate pain management*<sup>496</sup> considered as a human right,<sup>497</sup>
- Specific obligation of health practitioners in Ukraine to perform their duties in full compliance with a standard of medical care for patients with pain or to refer them to another practitioner able to apply the standard,<sup>498</sup>
- Legislative safeguards for healthcare providers to protect them from unfair legal persecution or prosecution for the use of controlled substances in good faith for the purpose of relief of pain and suffering<sup>499</sup> and
- Recognizing pain as disability,<sup>500</sup>

and assignments to the Ministry of Healthcare of Ukraine:

- To work out and adopt (by issuing specific Orders) a standard of qualification and a system of adequate training in pain management for healthcare providers of different specializations on undergraduate and graduate levels,<sup>501</sup>
- To issue an Order establishing standards of medical care for patients with pain with reference to concrete medical guidelines,<sup>502</sup>
- To issue an Order introducing a mechanism of processing applications from patients with pain syndrome regarding adequacy of care for them<sup>503</sup> and
- To put necessary amendments to an Order formalising list of criteria for introducing pain as disability.<sup>504</sup>

As an instrument to implement and guarantee the idea of adequate pain control, this statute will provide a proper, realistic and effective instrument of addressing important challenges of pain control.

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<sup>495</sup> Order 735-p, *supra* note 11 at article 9.

<sup>496</sup> See legislative novels offered at 121, below.

<sup>497</sup> See legislative novels offered at 120-122, below.

<sup>498</sup> See legislative novels offered at 122-123, below.

<sup>499</sup> See legislative novels offered at 125-126, below.

<sup>500</sup> See legislative novels offered at 124-125, below.

<sup>501</sup> See 113-114, below.

<sup>502</sup> See 114-119, below.

<sup>503</sup> See 123-124, below.

<sup>504</sup> See 124-125, below.

#### 4.2.1. Adequate Training for Healthcare Providers in the Strategy for Better Pain Control

There is an opinion, expressed by Allyn Taylor in “Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs”,<sup>505</sup> that

Perhaps the most important barrier to the access to opioid analgesics is the absence of government commitment, including the commitment to encourage or facilitate availability and appropriate education of health care professionals.

This opinion is consistent with the evidence reviewed in the previous chapters of this thesis.<sup>506</sup> Because “pain management” as a human right requires special qualification of people with corresponding duty to ensure this right, these people – medical practitioners – definitely need a realistic opportunity to obtain necessary qualification and education to properly fulfil their professional duties. Demanding from healthcare providers adequate professional response to patients’ pain without providing appropriate professional knowledge would contradict the rights of healthcare providers.

##### 4.2.1. a) What is Suggested

Considering Ukrainian realities about the system of healthcare providers’ education, highlighted in the first chapter, removal of the barriers related to practitioners’ training would require several steps:

- 1) Develop the existing system of continuing education for healthcare providers, providing more attention to the issue of pain management on the basis of accepted programs of studies oriented on most advanced and contemporary standards of care. The standard of care, however, should simultaneously be matched with the realities of Ukrainian healthcare, so that the information for the health practitioners is realistically applicable in their practices for the best achievable comfort of their patients. The doctors’ education should also enlighten and clarify the legislative requirements, rules and procedures of the use of opioid analgesics in Ukraine.
- 2) Introduce pain management training at undergraduate programs in Ukrainian medical schools as well as appropriate residency programs in pain control for the graduates, who would most likely deal with pain syndrome issues in their practice.
- 3) Work out and implement a system of notification of healthcare providers about new medicines introduced in circulation in Ukraine.

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<sup>505</sup> Taylor, *supra* note 269.

<sup>506</sup> See the evidence from the doctors at 16-18, above.

Undergraduate and continuing education on pain management would help to ensure adequate levels of professional knowledge of the Ukrainian physicians in dealing with pain syndromes and their willingness to relieve patients' sufferings from pain on the basis of contemporary medical practice and without misperceptions on medical reasonability or legality of their prescriptions.

#### 4.2.1. b) Who Must Commit the Offered Actions

Although the suggested improvements in doctors' education do not require legislative changes, it is necessary that the programs of studies must be accepted by the Ministry of Healthcare of Ukraine, being a central body of executive power, responsible for requirements to professional training of health practitioners in the state,<sup>507</sup> as well as for determination of priority directions in the development of healthcare in Ukraine.<sup>508</sup>

Acceptance of programs of study on the state level would ensure a consistent approach to the issue throughout the state, what is essential in terms of equal realization of the right to health and the right to effective medical care.

#### 4.2.1. c) Potential Outcome

There is a need for a considered "system" and accepted programmes of continuing education for healthcare providers, which would help ensure the best approach to pain control. Because adequate pain management often requires opioid analgesics, clarifying the legal aspect of prescription and use is particularly important. This would make practitioners confident about what they can at best offer to their patients with regards to opioid analgesia and would reduce unreasonable fears of persecution or prosecution.

#### 4.2.2. Developing a "Standard of Care" as a Strategic Step towards Better Pain Control

Any regulation usually requires clear criteria for defining what is acceptable and what is not. Only on the basis of these defined criteria can regulations practically be enforced and adequately controlled. In regulated professions such criteria can be established in professional standards, which if violated become the basis of negative consequences for the professional.

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<sup>507</sup> Decree of the President of Ukraine 467/2011, *supra* note 482 at para 6.12-6.13.

<sup>508</sup> *Ibid* at para 4 (1).

Logically, doctor-patient relationships regarding treatment of pain require a certain criterion. This criterion is commonly understood as a “*standard of care*”, which involves physicians’ adequate level of qualification in a certain field of medicine, as well as their moral and ethical obligations before patients. Although, according to Peter Moffett and Gregory Moore, “*The concept of “the standard of care” is often discussed among physicians, and yet the legal definition of this term is frequently not understood*”,<sup>509</sup>

this appears to be a necessary reference point in the fulfilment of the “*duty of care*.”<sup>510</sup> In other words, the standard of care provides an orientation, or a reference point to figure out if the treatment and care

According to the most recent definition, **Standard of Care** means what a minimally competent physician in the same field would do under similar circumstances.

provided to a concrete patient was appropriate. At the same time, the legal concept of the standard of care is rather complicated and has been developing and changing for decades,<sup>511</sup> particularly influenced by case law. There are numerous research papers on this matter. According to the most recent case law, the standard of care may be defined from a legal perspective as “*that which a minimally competent physician in the same field would do under similar circumstances*”.<sup>512</sup>

The lack of a standard approach in pain control means in practice that there are no clear requirements and expectations from doctors. Subsequently, a lack of definition of duty of care and uncertain criteria for the “*breach of duty*”

**Duty of Care** is an obligation of a health professional to provide qualified medical care of reasonably expected standard to a patient, once doctor-patient relationship is established.

regarding pain control matters make it almost unfeasible to defend the rights of patients. The duty of care is also a complex category from a legal perspective, which is, however, very important in practice for effective human rights exercising and defence. On the basis of extensive review of

<sup>509</sup> Peter Moffett & Gregory Moore, *supra* note 88 at page 109.

<sup>510</sup> Jocelyn Downie, Timothy Caulfield & Coleen Flood, *Canadian Health Law and Policy*, 4th ed, (LexisNexis Canada Inc., 2011) at 122-123.

<sup>511</sup> Peter Moffett & Gregory Moore, *supra* note 88.

<sup>512</sup> Peter Moffett & Gregory Moore, *supra* note 88 at page 111; see also *Hall v Hilburn* [1985] 466 So. 2<sup>nd</sup> 856 (Sup Ct of Mississippi); *McCourt v Abernathy* [1995] 457 S.E 2<sup>nd</sup> 603 (Sup Ct); *Johnston v St. Francis Medical Center* [2001] No 3-5, 236-CA.

literature<sup>513</sup> and case law,<sup>514</sup> the legal duty of care, owed by a physician to a patient, may be referred to as an obligation of a health professional to provide qualified medical care of a reasonably expected standard to a patient, once doctor-patient relationship is established.

When it comes to rights defence through courts, naturally, there emerges a need for evidence to find either fulfillment or failure to fulfil the duty of care, which is linked with a question of whether the standard of care was met. The case law shows that clinical guidelines play an important role in creating legal arguments related to the standard of care. It would be incorrect to refer the guidelines as complete documentary forms of the standard of care in particular fields of medicine for many reasons. However, as expressed by D. Clay Kelly and Gina Manguno-Mire, “[*Clinical practice guidelines*] provide a standard of care based on an evidence-based consensus in a particular area of medicine.”<sup>515</sup> In other words, clinical guidelines may be referred to as instructions aiming to guide clinicians in their professional decision-making regarding diagnosis, treatment and care in different areas of medicine.

**Clinical Guidelines** provide instructions aiming to guide clinicians in their professional decision-making regarding diagnosis, treatment and care in different areas of medicine.

At the same time, it should be appreciated that medicine is not a precise science. It is natural that even most qualified healthcare professionals may have different opinions on which “best practice” they should orient on when treating a concrete patient at given time in order to meet a standard of care. The need for individual approach in treatment of pain has been accepted and justified in medical literature<sup>516</sup> and recognized by Ukrainian doctors.<sup>517</sup>

According to David B. Brushwood,<sup>518</sup> the idea of guidelines or recommendations for pain management should be very carefully linked with the idea of a “standard of care,” because “*standard of care is not a unitary concept*” and “*there are often [...] several*

<sup>513</sup> Canadian Health Law and Policy, *supra* note 510.

<sup>514</sup> E.g. *Bateman v Doiron* [1991] N.B.J. No. 714, 8 C.C.L.T. (2<sup>nd</sup>) 284 at 290 (N.B.Q.B.), *affd* [1993] N.B.J. No. 598, 18 C.C.L.T. (2<sup>nd</sup>) 1 (N.B.C.A.).

<sup>515</sup> Clay Kelly & Gina Manguno-Mire, *supra* note 90.

<sup>516</sup> See e.g. Portenoy, *supra* note 77.

<sup>517</sup> Appendix 1, *supra* note 50.

<sup>518</sup> David B. Brushwood “Debunking Myths of Negligence in Pain Management Practice” (2007) 21:1 *Journal of Pain and Palliative Care Pharmacotherapy* 47.

*possible “right ways” of things for the patient.*” Therefore, it should be also appreciated that a departure from the guidelines does not necessarily constitute care below standard, certainly if such deviation is reasonably professionally justified. This means that professionalism in developing guidelines and their flexibility are of great importance to make these guidelines most beneficial for patients.

Different countries have different approaches to this matter, but remarkably, Ukraine has none. The current legislation of Washington State,<sup>519</sup> for example, defines the standard of care as actions consistent with *“the degree of skills, care and learning possessed by other persons in the same profession.”* Canadian case law also provides a rather similar approach. The Supreme Court of Canada establishes a doctor’s duty as an obligation *“to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing [...]”*<sup>520</sup> The Ukrainian legislation does not contain any definition of a standard of care or an approach to defining such a standard. Moreover, as discussed in previous chapters,<sup>521</sup> the Ukrainian healthcare providers are in general not adequately trained in pain management issues. Because of this, introducing either of the North American definitions of the standard of care to Ukrainian pain management would result in creation of a standard of care far inferior to the considered best practices globally. Many Ukrainian doctors are not aware of best practices in dealing with pain syndrome. This calls for elaboration of universal medical professional guidelines, instructions or recommendations on the issues of the treatment of pain for the Ukrainian healthcare providers. Where a standard of care for patients with pain does not exist, the guidelines in pain management can provide this necessary “standard” to be met. Note that there are numerous Ukrainian guidelines<sup>522</sup> on the treatment of diseases and conditions, approved by the Ministry of Healthcare of Ukraine. Formally, such guidelines are not legally binding, but rather serve as recommendations for health professionals. At the same time, deviating from the official recommendations would need to be justified.<sup>523</sup> This demonstrates the appropriateness of such an approach

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<sup>519</sup> Revised Code of Washington (RCW) S 4.24.290 “Action for damages based on professional negligence of hospitals or members of healing arts”, online: Washington State Legislation <<http://apps.leg.wa.gov/rcw/default.aspx?cite=4.24.290>>.

<sup>520</sup> *Crits and Crits v Sylvester et al.*, [1956] O.R. 132, (Ont. C.A.), (affirmed [1956] S.C.R. 991).

<sup>521</sup> The evidence is provided at 14, above; and the discussion may be found at 16-18, above.

<sup>522</sup> The Ukrainian medical standards in various fields of medicine are available through official web-site: Medstandard <<http://medstandart.net/>>.

<sup>523</sup> “Ukrainian Treatment: not for the protocol?” (“Лікування по-українськи: не для протоколу?”):

Interview with Olena Lishchyshyna: “Standards protect both the doctor and the patient” (8 March, 2013)

in Ukrainian healthcare. Besides, the advantage of accepted guidelines in treatment of pain was proved almost two decades ago by substantial research initiatives<sup>524</sup> assessing the practical outcomes of the pain control guidelines for post-operative pain, accepted by the Agency for Health Care Policy and Research (the USA). According to these research findings, the implementation of the guidelines for pain control resulted in “*decreased pain intensity score*” and “*increase in patient satisfaction*”.<sup>525</sup>

In addition a *standard of care* is also an appropriate instrument to protect healthcare providers from possible mistakes and/or unfair accusations of professional negligence.

As argued by David B. Brushwood:

Healthcare providers are not required to guarantee good results from their efforts. [...] If they practice at or above the standard of care, then they will not be held liable even if the consequence of the care is a regrettable tragedy.<sup>526</sup>

Today pain management standards and guidelines for pain control, although with different levels of flexibility, are common in the developed world.<sup>527</sup> This approach needs to be considered in Ukraine as well.

While the need for a standard of medical care for patients in pain, with the human right to optimum pain relief, is justified by law, there are concerns of a mostly medical nature about appropriateness and effectiveness of the guidelines for pain control. There are at least two, as considered by Chris Stern Hyman:<sup>528</sup> 1) “*how to give practitioners sufficient specificity so that the guideline is useful*” and 2) how to make the guideline “*sufficiently flexible to allow altering the specifics as additional information is made available by experts*”. While recognizing importance of these concerns, it should also be accepted that addressing them lies within the authority of qualified healthcare professionals, and that these challenges should not become a reason for questioning the need for such pain

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Ukrainian medical newspaper “Your Health” (“Ваше Здоров’я”), online: VZ  
<<http://www.vz.kiev.ua/likuvannya-po-ukra%D1%97nski-ne-dlya-protokolu/>>.

<sup>524</sup> See D.M. Bach, “Implementation of the Agency for Health Care Policy and Research Postoperative Pain Management Guideline” (1995) 30 Nurs Clin North Am 515; see also C. Campense “Development and Implementation of Pain Management Program” (1996) 64 AORN J 931; see also Marilyn Bookbinder et al, “Implementing national Standards for Cancer Pain Management: Program model and Evaluation” (1996) 12:6 Journal of Pain Symptoms Management 334.

<sup>525</sup> Bach, *supra* note 524 at 515.

<sup>526</sup> *Ibid* at 48.

<sup>527</sup> See e.g. “Assessment and Management of Pain” Ontario Nursing Best Practice Guideline (2002), online: <<http://rnao.ca/bpg/guidelines/assessment-and-management-pain>>; see also “Pain Assessment and Management” Winnipeg Regional Health Authority Guideline (2008), online:

<[http://www.wrha.mb.ca/prog/palliative/files/CPG\\_Pain.pdf](http://www.wrha.mb.ca/prog/palliative/files/CPG_Pain.pdf)> ; see also Stern, *supra* note 77 at 341.

<sup>528</sup> Stern, *supra* note 77 at 338.

control guidelines in principle. Ukrainian healthcare providers tend to agree on the need for pain control guidelines,<sup>529</sup> but only if they are reliably worked out by sufficiently qualified pain management professionals, so that the instructions provided are sustainable to follow.

In addition, as concluded by specialists from the Agency for Healthcare Research and Policy (USA),<sup>530</sup> “assessment of pain is a critical step to providing good pain management”. They identified “lack of pain assessment” as “one of the most problematic barriers to achieving good pain control”.<sup>531</sup> As also supported by the specialists from the UK in a Guide for Hospital Staff, “Dignity of the Ward: Pain and Older People”, “If pain is to be managed properly, it must first be thoroughly assessed”.<sup>532</sup> This is to say that elaboration of the professional guidelines on pain control must cover pain assessment along with issues of remedies.

It is important that medical guidelines on pain management are 1) worked out by the most advanced Ukrainian healthcare professionals in this issue; 2) based on global best practices; 3) with reference to actual Ukrainian available resources and regulations and 4) with reasonable flexibility to allow health providers to make their professional decisions. This raises the question of who should elaborate these guidelines. According to the law<sup>533</sup> and also to the general practice<sup>534</sup> in Ukraine, the elaboration of the medical guidelines is coordinated by the Ministry of Healthcare of Ukraine, which forms the interdisciplinary expert groups of professionals<sup>535</sup> to elaborate the standards of medical care. The State Expert Center of Ukraine, being a structural element of the Ministry of Healthcare of Ukraine, coordinates the activities of the working groups and elaborates the standard

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<sup>529</sup> See the evidence and analysis at 14 and subchapter 1.4.3. at 21-23, above; see also Appendix 1, *supra* note 50.

<sup>530</sup> N. Wells, C. Pasero & M. McCaffery, “Improving the Quality of Care through Pain Assessment and Management” in: Hughes RG, editor. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Rockville (MD): Agency for Healthcare Research and Quality (USA, 2008), online: NCBI <<http://www.ncbi.nlm.nih.gov/books/NBK2658/>>.

<sup>531</sup> *Ibid.*

<sup>532</sup> See Dignity on the Ward, *supra* a note 418.

<sup>533</sup> Decree of the President of Ukraine 467/2011, *supra* note 482.

<sup>534</sup> Interview with Olena Lishchyshyna. *supra* note 523.

<sup>535</sup> E.g. Order of the Ministry of Healthcare of Ukraine #810 “On formation of the multidisciplinary working groups on the elaboration of the medical standards (unified clinical protocols) of medical care on the basis of evidence-based medicine in 2013” (“Про створення мультидисциплінарних робочих груп з розробки медичних стандартів (уніфікованих клінічних протоколів) медичної допомоги на засадах доказової медицини в 2013 році”) (18 September 2013), online: Ministry of Healthcare of Ukraine <[http://www.moz.gov.ua/ua/portal/dn\\_20130918\\_0810.html](http://www.moz.gov.ua/ua/portal/dn_20130918_0810.html)>.

protocols,<sup>536</sup> usually based on the international guidelines and adapted to Ukrainian conditions.<sup>537</sup> The protocols are affirmed and put into force by the Ministry of Healthcare of Ukraine by issuing special orders. WHO guidelines on pain control<sup>538</sup> could provide the basis for the Ukrainian standards.

It is important that the control over the determination of the topics of medical documentation and the formation of the multidisciplinary working groups is put on the three departments<sup>539</sup> of the Ministry of Healthcare of Ukraine: the Department of the Reforms and Development of the Medical Care, the Medical Services Quality Control Board and the above-mentioned State Expert Center. Therefore, I suggest that one of these three departments initiates the elaboration of the Ukrainian protocols on the treatment of pain, that a working group is created of the appropriate health professionals, and that the protocols for the treatment of pain are adopted by the orders of the Ministry of Healthcare of Ukraine and made available for all Ukrainian healthcare providers.

#### 4.2.3. Definitive Changes for Better Pain Control

Daniel B. Carr argues that *national recommendations for pain control need to be “coupled to positive incentives for compliance and negative ones for non-compliance”*.<sup>540</sup> Arguably, these “approaches” (or “attitudes”) and “incentives” (or “motives”) can be reasonably introduced through legal obligations according to the law and on the basis of legal formalization of *the human right to adequate pain control*. If adequate pain control is viewed from the perspective of a fundamental human right, then it appears reasonable to directly formalise it in the current legislation. With this, there is a need to not only declare the “*right to pain control*” but most importantly, to precisely identify the meaning of *adequacy* in pain management and to encompass a necessary level of

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<sup>536</sup> E.g. Order of the Ministry of Healthcare of Ukraine “On formation and implementation of the medical-technological documents on standardisation of the medical care in the system of the Ministry of Healthcare of Ukraine” (“Про створення та впровадження медико-технологічних документів зі стандартизації медичної допомоги в системі Міністерства охорони здоров’я України”) 751, 28 September 2013, online: Ministry of Healthcare of Ukraine < [http://www.moz.gov.ua/ua/portal/dn\\_20120928\\_751.html](http://www.moz.gov.ua/ua/portal/dn_20120928_751.html) > [Order 751].

<sup>537</sup> Ukrainian Treatment: not for the protocol? Interview with Olena Lishchyshyna, *supra* note 486.

<sup>538</sup> WHO Guidelines on the Pharmacological Treatment of Persisting Pain in Adults with Medical Illnesses; also the WHO Guidelines on the Pharmacological Treatment of Acute Pain; and also the WHO Guidelines on the Pharmacological Treatment of Persisting Pain in Children with Medical Illness. These documents may be download from the official WHO web-site, online: WHO <[http://www.who.int/medicines/areas/quality\\_safety/guide\\_on\\_pain/en/](http://www.who.int/medicines/areas/quality_safety/guide_on_pain/en/)>.

<sup>539</sup> See Order 751, *supra* note 536.

<sup>540</sup> Carr, *supra* note 22.

flexibility to refer accordingly to the expertise of the healthcare provider in addressing this issue.

Australian legislation provides an example of the relevant legislative provision, as the Medical Treatment Act of 1994<sup>541</sup> formalizes that “[...] *a patient under the care of a health professional has a right to receive relief from pain and suffering to the maximum extent that is reasonable in the circumstances [...]*”. This entitlement considers the maximum possible relief from pain, but fairly refers to the expertise of the healthcare professional in determining what is reasonable in specific circumstances of the patient.<sup>542</sup>

Ukrainian legislators should accept same ideas in Ukrainian medical legislation. Because the issues of healthcare are allied with the matters of equality and prohibition of discrimination, as considered earlier, I suggest the following provisions be incorporated into Ukrainian legislation. First, ***“All Ukrainian patients have equal right to adequate pain control.”***

Then, if using the expression “adequate pain control” or “adequate pain relief” there is a need for unequivocal understanding of this expression by formalising it as a term in legislation as well. Without defining what kind of pain control is considered “adequate”, the right for pain relief would appear vague and practically impossible to be ensured or defended. The Pain and Policy Study Group of Wisconsin University offered a definition of adequate pain control: “[it] means pain management that reduces a patient's moderate or severe pain to a level of mild pain or no pain at all, as reported by the patient”. Taking this offered definition as a basis and with reference to a rather progressive provision in the Australian legislation, I suggest that ***“adequate pain relief means maximum possible under given circumstances and reasonably safe relief from pain and suffering according to the patient’s diagnosis and condition and with all possible safety precautions that would reduce pain to the level of mild or no pain according to the patient.”***

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<sup>541</sup> Australian Capital Territory Medical Treatment Act 72, 1994, online: <<http://www.legislation.act.gov.au/a/1994-72/19941101-4406/pdf/1994-72.pdf>> [Australian Capital Territory Medical Treatment Act].

<sup>542</sup> See e.g. *Medical Board of Australia v Woollard* [2013] WASAT 101, particularly at para 44, online: <<http://www.austlii.edu.au/cgi-bin/sinodisp/au/cases/wa/WASAT/2013/101.html?stem=0&synonyms=0&query=adequate%20pain%20relief>> (The responder (health practitioner) was reprimanded in the relation to his professional conduct with the plaintiff (his patient), including the failure to provide adequate pain control. The respondent was also charged with a fine in favour of the plaintiff. The right for pain control was approached through the standard of care).

Incorporation of these definitions into Ukrainian legislation would provide the essential basis for an approach to the challenge of adequate pain management for the Ukrainian people. Such legislative provisions, if coupled with the medical standards of pain management,<sup>543</sup> would make the right to adequate pain control realistically enforceable through the Ukrainian courts, apart from existing Constitutional means.

#### 4.2.4. Establishing a Duty of Care to Patients with Pain

After direct formalisation of the right to adequate pain control, logically, there emerges a need to establish a mechanism of its realization. The mechanism should consider concrete corresponding duties of concrete participants of the legal relations; therefore, it is essential to directly ***establish a duty of healthcare providers to adequately respond to patients' complaints about pain***. I argue that such duty should be based on the standard of care, which was considered above in the present chapter<sup>544</sup> and which would encompass not only acceptable approaches *to treat pain*, but also – *to assess pain properly*.

The question about a doctor's attitude to a patient's report on pain refers directly to the issue of correct assessment of pain, and therefore is overwhelmingly important. The Australian Medical Treatment Act<sup>545</sup> provides a directive to the health practitioners to respond adequately to patients' complaints on pain: *"In providing relief from pain and suffering to a patient, a health professional shall pay due regard to the patient's account of his or her level of pain and suffering"*.<sup>546</sup> I argue that there is a need for a similar legislative provision in Ukrainian regulations of medical issues.

Together with establishing certain obligations, there is a need for measures of responsibility, discouraging doctors from leaving patients in unnecessary and avoidable suffering. For example, a New York State law<sup>547</sup> considers *"a failure to adequately order, prescribe, administer or dispense pain-relieving medication, for the relief of pain in accordance with a reasonable standard, as "professional misconduct" and a reason for*

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<sup>543</sup> See the discussion of the standard of care for patients with pain at 114-119, above.

<sup>544</sup> The discussion of the relation of the standard of care and the duty of care is provided at 115, above.

<sup>545</sup> Australian Capital Territory Medical Treatment Act, *supra* note 541.

<sup>546</sup> *Ibid* at para 23 (1).

<sup>547</sup> State of New York Act to amend the public health law and the education law, in relation to pain management #10407 (30 March 1994), online: <http://assembly.state.ny.us/leg/?sh=printbill&bn=A10407&term=2003>; see also New York State Education §6530 Definitions of Professional Misconduct, available online: New York State Department of Health <[http://www.health.ny.gov/professionals/office-based\\_surgery/law/6530.htm](http://www.health.ny.gov/professionals/office-based_surgery/law/6530.htm)>.

*possible “penalties”*. In support of this idea an opinion was expressed by Margaret Somerville, Professor of Law and Medicine at McGill University, that “*unreasonable failure to provide adequate pain relief is negligence*”.<sup>548</sup> Generally speaking, if a doctor’s care falls below a given standard; he or she may be liable for all negative consequences caused to a patient. This perfectly aligns with the Ukrainian negligence law<sup>549</sup> that, although being rather broadly formulated, establishes responsibility for not providing due care. According to the Ukrainian legislation<sup>550</sup> doctors have *a duty to provide timely and qualified medical care*. Failure to provide care to a sick person<sup>551</sup> or *inadequate performance of professional obligations*,<sup>552</sup> if causing *drastic consequences to a patient*, constitutes a criminal offence. However, realistically these provisions can hardly apply to the issues of adequacy in pain control in Ukraine, because they are formalized in a rather general manner without specifications of either what should be considered under *inadequate performance of professional obligations* or under *drastic consequences to a patient* in terms of inadequate analgesia. For this reason I suggest that more specifically, inadequate pain relief which causes a patient’s suffering should result in a doctor’s liability (civil or criminal, depending on the severity of the negative consequences). Such legal provisions will also provide instruments for adequate defence of patients’ rights in the Ukrainian courts.

#### 4.2.5. Control of Adequacy of Care for Patient with Pain

Establishing responsibility of healthcare practitioners for breach of the duty of care logically requires authorised bodies to professionally consider patients’ complaints and to assess whether a doctor met a standard of care.

The Rules of Control of Quality of Medical Care<sup>553</sup> in Ukraine were adopted by the Ministry of Healthcare of Ukraine in November 2012. This act formalizes<sup>554</sup> that cases of patients’ or their relatives’ complaints about the quality of medical care shall be performed in the form of clinic-expert assessment of the quality and the scope of the

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<sup>548</sup> Brennan et al, *supra* note 22.

<sup>549</sup> See Criminal Code of Ukraine, *supra* note 263 at article 25.

<sup>550</sup> Law 2801-XII, *supra* note 19.

<sup>551</sup> Criminal Code of Ukraine, *supra* note 263 at article 139 part 1.

<sup>552</sup> *Ibid* at article 140 part 1.

<sup>553</sup> Order of the Ministry of Healthcare of Ukraine “On medical care quality control procedure” (“Про порядок контролю якості медичної допомоги”) 752, 28 September 2012, online: Rada <<http://zakon4.rada.gov.ua/laws/show/z1996-12>> [Order 752].

<sup>554</sup> *Ibid* at para8.

medical care. Such assessment shall be conducted either by medical boards of the healthcare settings (internal control), or by expert boards within the Ministry of Healthcare of Ukraine or within regional health administrations (external control). According to these current rules<sup>555</sup> the medical expert boards are established to control the quality of medical services in Ukraine. There is a system of the assessment and control of the quality of medical care in Ukraine.<sup>556</sup> This professional assessment of the quality of medical care is an important tool to find breach of the duty of care, which may be provided to the Ukrainian courts in litigation for damages.

However, I argue that there is a need to develop this system of medical care quality control to respond adequately to the needs of patients with pain. The quality of control arguably depends on fundamental criteria and methods of assessment. This refers again to the issue of the standard of care in pain management in Ukraine. The above-mentioned Rules of Control of Quality of Medical Care formalize the rule<sup>557</sup> that assessment of the quality of medical care shall be determined on the basis of compliance with the “*established standard*”. However, it remains unclear which Ukrainian “*established standard*” the legislators meant, when it comes to the issue of pain control. Therefore, I believe that the work of Ukrainian medical expert boards in assessment and control of the quality of pain management will become effective mainly when certain criteria in assessment of pain relief are defined and introduced in Ukrainian legislation.

#### 4.2.6. Recognizing Pain as Disability

In order to respect the principle of equity and ensure social justice in Ukrainian healthcare, the legislative Government Decree<sup>558</sup> that contains a list of recognised disabilities must include not only diagnoses and conditions, but also the ailment of pain itself. Arguably, the pain should not require support by a specific diagnosis to be considered as a limitation of one’s working activity, because if it does, it would discriminate against the patients without specific diagnoses. Including the pain in a

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<sup>555</sup> *Ibid.*

<sup>556</sup> Order of the Ministry of Healthcare of Ukraine “On the organization of clinic and expert assessment of the quality of medical care” (“Про організацію клініко-експертної оцінки якості медичної допомоги”) 693, 6 August 2013, online: Rada <<http://zakon1.rada.gov.ua/laws/show/z1717-13>>.

<sup>557</sup> Order 752, *supra* note 553 at para 3.

<sup>558</sup> Decree 1317, *supra* note 426.

Ukrainian list of disabilities would better respect the requirement of equity and non-discrimination, per the Ukrainian legislation.<sup>559</sup>

#### 4.2.7. Informing Patients

The public should be properly informed about patients' right to pain control and about possible avenues to require adequate treatment of pain. According to Dr. Henry Ddungu,<sup>560</sup> a Palliative Care Doctor from Uganda, “*If people knew their rights, I think there would be an outcry for their needs*”. Information on one's rights is essential for the realization of these rights. However, it would be not enough just to be aware of the right to pain management. It is important to be informed about how this right can be realized and protected. Dr. Dinat, a Palliative care Doctor from South Africa, expressed this idea.<sup>561</sup>

Without explaining to people or showing them the consequences of demanding your rights and showing them strategies of how to actually exercise their rights, you're not going to get anywhere.

Indeed, whatever human rights may be formalized in legislation, they cannot benefit people unless they know how to exercise them. Therefore I argue that Ukrainian people should be informed 1) that they have the right to not suffer from preventable pain and to demand adequate analgesia by essential medicines; and also 2) what they can do and where to apply to have this right protected. Although this is not required by the legislation, logically the Ministry of Healthcare of Ukraine should also ensure proper informing of the patients. Patient can receive the information through the Medical Newspaper “Your Health”,<sup>562</sup> an official publication of the Ministry of Healthcare; also, educational pamphlets could be provided to the patients in the waiting areas of hospitals and clinics.

#### 4.2.8. Legislative Protection for the Ukrainian Healthcare Professionals

All the duties related to introducing reasonable pain management, discussed above, require protection of doctors from unfair criminal prosecution for inaccuracies related to

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<sup>559</sup> See especially *Constitution of Ukraine*, *supra* note 44 at article 24; see also Law 2801-XII, *supra* note 19 at article 4.

<sup>560</sup> GAPRI, Fight for the Right, *supra* note 403.

<sup>561</sup> *Ibid.*

<sup>562</sup> All-Ukrainian Medical Newspaper “Your Health” (“Ваше Здоровье”), online: VZ <<http://www.vz.kiev.ua/>>.

the use of controlled substances. Healthcare providers can hardly offer best optimal pain relief under conditions of excessive and intimidating control related to the use of opioid substances, while at the same time providers remain inadequately informed about pain control remedies and their legality.

Presumably, similar consideration led to legislation in New York (USA). The legislation recognizes inadequate pain relief as a breach of the duty of care and simultaneously establishes mandatory *medical education in pain control* and provides *proper protection of physicians when they introduce adequate pain management, consistent with their clinical guidelines*.<sup>563</sup>

The Ukrainian doctors' fears of prosecution related to the use of opioids should also be removed. For this purpose effective defence should be provided for all healthcare professionals dealing with pain and suffering. Australian legislation provides an example of how to create such legislative defence for the healthcare providers, so that they can use opioid analgesics adequately according to their qualifications without unreasonable fears of unfair legal prosecution connected with the use of controlled substances. According to the Consent to Medical Treatment and Palliative Care Act of 1995,<sup>564</sup> "*medical practitioners*" are *protected from any civil or criminal responsibility for any act or omission (including anything related to the use of narcotic medicines) if it was done or made:*

- 1) *with a patient's consent,*
- 2) *"in good faith and without negligence",*
- 3) *following "proper professional standards of medical practice" and*
- 4) *for the sake of preserving or improving patient's "quality of life".*

I suggest that this legislation provides an excellent model for Ukraine. The approach taken in this legislation would remove a significant barrier to adequate pain control, doctors' fears of prosecution for the use of the controlled substances in their practice.

#### 4.2.8.1. Removing Ambiguity Regarding "Off-Label" Prescriptions

A separate challenge, being very close to the matter of protection of the health professionals, relates to the ambiguity in regulating off-label prescriptions. To be more accurate, the challenge is rather in the absence of such regulation. This makes a lot of

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<sup>563</sup> State of New York Act, *supra* note 547; see also New York State Education, *supra* note 547.

<sup>564</sup> Consent to Medical Treatment and Palliative Care Act of South Australia 1.7.2010 (1995) at para 16.

Ukrainian doctors fairly confused regarding the limitation of the maximum dose of morphine imposed by the product use instructions issued by the manufacturer. As a result, doctors prefer to follow the instruction rather than apply their qualifications in order to avoid possible conflicts with controlling authorities.

Such ambiguity and absence of regulation is a definite barrier to adequate pain relief in Ukraine. The Ukrainian Government should consider appropriate regulation clarifying this issue, particularly considering that off-label prescription is a common practice in the developed countries.<sup>565</sup> Moreover, there is a view that in certain cases, off-label use of medicines “*often represents the standard of care*”.<sup>566</sup> Ukraine needs clear legislative provisions allowing health professionals to bypass the recommendations of the drug’s manufacturer and to act in each particular case according to the circumstances. Doctors should be allowed to use their professional judgement rather than rely on instructions of drug manufacturers.

### **4.3. Overcoming Practical Hardships and Ambiguities**

Together with the determination of the statutory strategy and the development of Ukrainian national legislation to create basic conditions for better pain management in Ukraine, there is a need to overcome practical barriers to introducing pain management.

These practical barriers are:

- 1) excessively demanding licence requirements and
- 2) overwhelming documentation and procedures.

Although the present research is focused on and limited to overcoming the barriers to the legal use of opioid substances, it does not aim to undermine the dangers associated with illegal use of narcotics and the consequences of over-prescription.<sup>567</sup> That said, the

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<sup>565</sup> See Standing Senate Committee on Social Affairs, Science and Technology (Canada), “Prescription Pharmaceuticals in Canada – Off-Label Use” (January 2014), online: <<http://www.parl.gc.ca/Content/SEN/Committee/412/soci/rep/rep05jan14-e.pdf>> ; see also Food and Drugs Administration of the USA, “Off-Label “and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators, online: FDA <<http://www.fda.gov/regulatoryinformation/guidances/ucm126486.htm>>; see also “Off-Label Drug Use: What You Need to Know”, online: WebMD <<http://www.webmd.com/a-to-z-guides/features/off-label-drug-use-what-you-need-to-know>> .

<sup>566</sup> *Ibid.*

<sup>567</sup> According to the data, provided by the USA National Institute of Drugs Abuse, the number of unintentional overdose deaths involving opioid analgesics from 1999 till 2007 is considerably higher than the number of deaths due to overuse of cocaine or heroine. See Nore D. Volkow, “Prescription Drug Abuse”, online: National Institute of Drugs Abuse <<http://www.drugabuse.gov/publications/research-reports/prescription-drugs/director>>; see also Lutin, *supra* note 215, see also “Prescription Drug Abuse”, online: Office of National Drugs Control Policy, The Whitehouse (USA)

propositions to ease medical access to opioids in the present chapter are made keeping in mind the dangers of illegal and/or incorrect use of strong medicines; besides, these suggestions should not be viewed as precluding reasonable and legitimate measures to control legal use of substances and overuse as long, as these measures do not limit access to adequate pain relief.<sup>568</sup>

#### 4.3.1. Licensing of the Use of Opioids in Medical Practice

Too-burdensome licence conditions make preserving and using opioids impossible for a lot of healthcare settings in Ukraine, as was admitted by HRW in its Report “*The associated cost and lack of spare rooms are the main reasons that few health clinics and small hospitals obtain narcotics licences.*”<sup>569</sup> Although different health clinics and hospitals require different amounts of opioids, licensing requirements are equal for all healthcare settings irrespective of their size, location and the amount of opioids required. Although recognizing the high importance of the protection of controlled substances from illegal possession and use, I argue that a *differential approach in licensing may* appear reasonable to ensure adequate access in rural areas, particularly remote areas from administrative centres. I am making these suggestions because it seems rather irrational to protect just several ampoules of morphine by building separate premises, equipped with alarms, with thick walls, with firm metal grating and with windows also with metal grates fixed into the walls, in metal cabinets fixed firmly to the walls or to the floor.<sup>570</sup> These demands, although perhaps necessary for central hospitals, where large amounts of opioids are stored, are probably not equally needed for small rural Feldshers’ Stations with just several ampoules or blisters of opioid analgesics in stock. The same distinction should apply with pharmacies. While some may store considerable amounts of narcotic medicines, other may require only small amount due to the much lower amounts of medicine sold there. At the same time, keeping in mind that thefts and robberies of

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<<http://www.whitehouse.gov/ondcp/prescription-drug-abuse>>; but see “Cough and Cold Medicine Abuse”, Drug Facts, online: National Institute of Drugs Abuse

<<http://www.drugabuse.gov/publications/drugfacts/cough-cold-medicine-abuse>> (raising problems of non-opioid medicines abuse).

<sup>568</sup> E.g. measures, discussed in Hallam M. Gugelmann & Jeanmarie Perrone, “Can Prescription Drugs Monitoring Programs Help Limit Opioids Abuse” (2011) 306:20 JAMA 2258; see also Jeanmarie Perrone & Lewis S. Nelson “Prescribing Practices, Knowledge, and Use of Prescription Drugs Monitoring Programs (PDMP) by a National Sample of Medical Toxicologists, 2012” online: (2012) 8 Journal of Medical Toxicology 341; see also Davis S. Craig, “The pharmacists' role in patient-provider pain management treatment agreements” (2012) 25 Journal of Pharmacy Practice 510.

<sup>569</sup> HRW Uncontrolled Pain, *supra* note 2 at 8.

<sup>570</sup> See discussion of the licence conditions in subchapter 1.5.2. at 28-32, above.

opioids from health settings take place all over the world,<sup>571</sup> it is necessary to take measures of precaution. The key point is that such measures must be reasonable and proportional. Certainly, the differential approach would require research and discussions between policy-makers to define the reasonability of requirements for the amounts of opioids stored. In addition, supplementary controlling measures may be required to ensure due adherence to quotas of controlled medicines stored together.

Another possible option is to provide targeted financing to small rural clinics to satisfy the requirements to store and use opioids and thus provide adequate access to narcotic analgesics, guaranteed to every Ukrainian patient in every part of Ukraine. These additional efforts and financing are necessary for the sake of ensuring the realization of the right to adequate pain management of every Ukrainian patient, regardless of the place of residence and the distance to a central hospital carrying opioids. Otherwise, inequity in the access to opioid analgesics between administrative centres and rural areas may fairly raise the issue of discrimination toward those Ukrainians who live in the countryside.

#### 4.3.2. Documentation and Procedures to Prescribe and Administer Opioids

Along with complications related to burdensome licensing requirements, there is an overwhelming documentation and procedures are imposed to prescribe and use narcotic analgesics,<sup>572</sup> which in fact do not result in effective prevention of the illegal use of drugs.<sup>573</sup>

That is why the suggested Strategy on Pain Management should become closer to the requirements of the Single Convention on Narcotics, which formalizes lighter requirements for the control of opioids. The first step towards this goal would be the implementation of Decree 333, which is much closer to the Single Convention requirements than Order 11, which is being currently followed in practice. Second, there is a need to reconsider the requirements for prescriptions and use of opioids in healthcare, so that the doctors do not avoid such prescriptions, just because this would be an overwhelming task.

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<sup>571</sup> See e.g. “Robbers Seeking Opioids and Other Drugs Rattle Pharmacists” (11 January 2012), online: <<http://www.drugfree.org/join-together/community-related/robbers-seeking-opioids-and-other-drugs-ratt>>; see also e.g. Alison Langely, “Robbery at Niagara Drug Store” (21 December 2013), online: <<http://www.niagarafallsreview.ca/2013/12/21/robbery-at-niagara-drug-store>>.

<sup>572</sup> See information on the excessive procedures of the use of opioids in Ukrainian healthcare settings in subchapter 1.5.5. at 36-41, above.

<sup>573</sup> See discussion of the outcome of the strict rules of the use of opioids in Ukraine and worldwide at 49-50, above.

#### **4.4. Overcoming the Barriers Related to the Availability of Medicines**

##### 4.4.1. Variety of Types and Forms of Analgesics

The good news of 2013 about Ukrainian pain management is that oral morphine became available.<sup>574</sup> This is a huge step towards adequacy of pain control within the state. Under conditions of serious formulary deficit of narcotic analgesics in Ukraine, the fact that the oral form of morphine appeared and became available for Ukrainian healthcare providers is an overwhelmingly important achievement, which brings a lot of vital advantages. The main thing is that in contrast to the situation when only injectible morphine was available, which could be injected to the patients exclusively by professional healthcare providers, oral morphine can be accepted by patients of both in- and out-patient care on their own, according to the relevant prescription. A patient or one's relative may buy oral opioids in a pharmacy, so that a hospital or a clinic does not even participate in dispensing the controlled substances, thus avoiding overly elaborate procedures related to the audit of opioids in healthcare settings. Thus, the actual availability of the oral form of morphine may overcome barriers to adequate pain management related to overly strict procedures and documentation within healthcare institutions, as well as barriers associated with the unfeasible requirements that injections are performed exclusively by healthcare professionals. This is to say that the available variety of forms of painkillers (oral forms, as well as trans-dermal and rectal systems) can help healthcare professionals make appropriate choices as remedies for pain for a patient. In fact, considering the realities of current Ukrainian legislation, broadening the formulary options for analgesics is an important and necessary condition for improving real access to adequate analgesia in Ukraine.

The formulary management in general<sup>575</sup> and specifically ensuring the range and variety of forms of medicines, particularly for the treatment of pain,<sup>576</sup> is a really important matter. This issue, being “a component of healthcare management”,<sup>577</sup> requires a rather complex approach, which would involve not merely medical or legal, but also economic, administrative and other fields. Therefore, making a very general suggestion that the Government of Ukraine should consider the elaboration of reasonable strategies to

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<sup>574</sup> Oral form of morphine was officially registered in Ukraine by Order 77, *supra* note 20; see also information about oral form of morphine in Ukraine at 23 and 41, above.

<sup>575</sup> Academy of Managed Care Pharmacy, “Formulary Management” (2009), online:

<<http://amcp.org/WorkArea/DownloadAsset.aspx?id=9298>>.

<sup>576</sup> Cherny et al, *supra* note 5.

<sup>577</sup> See *supra* note 575.

encourage formulary variety of types and forms of medicine for pain relief, I primarily stress the need for 1) prioritization of this challenge; 2) creation of an interdisciplinary and interagency working group of professionals to do necessary research and elaborate the Ukrainian Policy of the Formulary Management; and then 3) consider implementation of this policy in practice. Considering that the Ministry of Healthcare of Ukraine is responsible for the sphere of drugs and medicinal products<sup>578</sup> in the state with a specific structural element for this purpose – the State Administration of Ukraine of Medicinal Products<sup>579</sup> -- it is the task of the Ministry of Healthcare to initiate and coordinate necessary research and the process of elaboration of the Formulary Management Policy with a view to ensure an adequate range of drugs and variety of forms of medicines, including for pain control.

#### 4.4.2. Prices for Analgesics and Actual Supplies to Healthcare Settings

Simultaneously, challenges related to the accessibility opioid medicines constitute an important aspect of their availability. Matters of procedural and information accessibility to the medicines, which are available within the state, relate to removal of the barriers related to doctors' education (access to adequate prescriptions) and government policy (timely and reasonable access to opioid analgesics). Another part of the challenge (physical and economic accessibility) is the matter of *cost of medicines* and their *actual supplies* to the healthcare settings. These issues refer to both opioid and non-opioid analgesics.

Although the price for morphine is comparatively low,<sup>580</sup> the surprising differences in pricing of this medicine for different regions, discussed in the first chapter,<sup>581</sup> generate reasonable concerns and calls for a system of more transparent price-making. This challenge appears even more important in terms of affordability of non-opioid analgesics, which may be rather costly and much less affordable for many Ukrainians.

Little research has yet been conducted in Ukraine to provide evidence about prescriptions or doctor's recommendations not being followed because of unaffordability of the prescribed or advised medicines. However, according to the evidence provided by

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<sup>578</sup> Decree 467/2011, *supra* note 482.

<sup>579</sup> State Administration of Ukraine of Medicinal Products official web-site, online: <<http://www.diklz.gov.ua/en>>.

<sup>580</sup> See the discussion about the price of morphine in Ukraine in subchapter 1.6.2. at 42-45, above with further references on the international date on the price of morphine at *supra* note 201.

<sup>581</sup> See subchapter 1.6.2. at 42-45.

Ukrainian healthcare practitioners in their answers to the questionnaire, price appears to be a barrier to adequate pain management, given that almost all responders confirmed that price influenced their choice of medicines prescribed.<sup>582</sup> Therefore, as discussed earlier,<sup>583</sup> this is currently unclear to what extent the price of pain medication precludes adequate pain control and where this barrier stands in the hierarchy of significance of the barriers. However, evidence shows that a price-related barrier exists, which requires further research in this matter and finding alternate avenues to make analgesics more affordable to the public. That is why I suggest that the issue of affordability of effective painkillers should receive adequate consideration from the Ukrainian government, which should encourage such research and optimal decisions.

As an example, the pilot project of so called “referent prices” and reimbursements for the medicines to treat hypertensive disease was launched by the Ukrainian government in early 2013.<sup>584</sup> The efficacy of this pilot project is not clear at this stage. However, this initiative clearly demonstrates the appreciation by the Ukrainian high officials of the importance of affordability of medicines for the Ukrainian patients with high blood pressure; moreover, it shows available options to make medicines more affordable. Arguably, the quality of life of thousands of Ukrainians who suffer from pain is an issue of no less importance. That is why the affordability of painkillers should also be adequately considered in Ukraine. By saying this, I am not advocating for application of the same mechanism of reference pricing to analgesics, but I advocate for government

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<sup>582</sup> See Appendix 1, *supra* note 50 at 2.

<sup>583</sup> See subchapter 1.6.2. at 44-45.

<sup>584</sup> The Pilot Project of the Reference Pricing and Reimbursement was launched by the Ukrainian Government in 2012 in the relation to the particular list of drugs to treat high blood pressure. In most general features the project is about introducing a mandatory mechanism of defining of referent (comparative) prices for the list of drugs (international non-patent names), plus establishing a maximum margin level for these drugs and plus a mechanism of reimbursement of the referent price for the drugs, purchased by the patients. For the patient it means that on the basis of a doctor’s prescription of the medicine (international non-patent name), one may purchase it at the drug store, paying only the difference between the actual price and the established reference price for this medicine. The referent price values of the sold medicines are reimbursed to the pharmacies by the State. The legislative basis for the project is as follows. See Decree of the Cabinet of Ministers of Ukraine “On the realization of the pilot project on the implementation of the state regulation of the prices of medicines for the treatment of patients with hypertonic disease” (“Про реалізацію пілотного проекту щодо запровадження державного регулювання цін на лікарські засоби для лікування осіб з гіпертонічною хворобою”) 340, 25 April 2012, online: Rada <<http://zakon4.rada.gov.ua/laws/show/340-2012-%D0%BF>> ; see also Order of the Ministry of Healthcare of Ukraine “On affirmation of the Order of the calculation of the threshold level of the gross-selling prices of the medicines for the treatment of the patients with hypertonic disease and the comparative (referent) prices for such medicines” (“Про затвердження Порядку розрахунку граничного рівня оптово-відпускних цін на лікарські засоби для лікування осіб з гіпертонічною хворобою та порівняльних (референтних цін) на такі засоби”) 394, 29 April 2012, online: Rada <<http://zakon4.rada.gov.ua/laws/show/z0863-12/paran12#n12>>.

initiative to ensure adequate access to painkillers equally to the treatment of other health problems. Certainly, if the pilot project of reference pricing proves effective, this may be applied to analgesics as well.

Some Ukrainian doctors in their answers to the questionnaire on pain management told about *short supplies of medicine to treat pain* in their units, while others did not identify any lack of necessary analgesics. Such discrepancy in answers indicates imbalance in the supplies of medicines to healthcare settings, possibly in different regions, or inadequate distribution of medicines between the units within hospitals, or both. In any case, the fact that 27 out of 29 responders to the questionnaire said that the actual availability of medicines in hospitals/units or in public pharmacies influences their choices of analgesics when considering prescriptions<sup>585</sup> definitely calls for substantial research and investigation of this issue. As with the issue of affordability, the Ministry of Healthcare of Ukraine should foster research to provide adequate painkiller supply and elaborate a more effective system of their distribution to healthcare institutions. This challenge appears exceptionally important, considering the fact that in Ukrainian healthcare, as opposed to that of the developed countries, most care is concentrated on in-patient and specialized sectors (where the patients are referred by general physicians), rather than on the primary level,<sup>586</sup> so that the need for adequate supplies of medicines is particularly important for the healthcare institutions, which accept most patients to receive treatment within these institutions, rather than at their homes.

#### **4.5. Skilful Litigation as an Avenue to Defend the Rights to Adequate Analgesia**

As discussed in the previous chapter, there is currently no evidence about successful litigation protecting the rights of Ukrainian patients in matters of adequate pain relief. According to the available case law, the courts of Ukraine did not consider violations of human rights as a result of the denial of pain control, mainly because of the failure to establish the causal relationship between someone's illegal actions (or omissions) and the negative consequences (suffering of patients). At the same time, relatively successful litigation resulted from the application of the right for essential medicines.<sup>587</sup>

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<sup>585</sup> Appendix 1, *supra* note 50 at 2.

<sup>586</sup> Oleksandra Betliy, Oksana Kuziakiv and Kateryna Onishchenko, "The evaluation of health care system in Ukraine in the context of structural and quality-enhancing reforms" Economics Education and Research Consortium Working Paper Series # 07/07, Project # 04-009.

<sup>587</sup> See discussion of the case at 105-106, above.

Generally speaking, the court system is an essential way to defend rights if they are being violated. It is important to use this resource to its fullest extent to protect the rights of Ukrainian patients. Therefore I suggest that the following actions and/or strategies be considered and applied by Ukrainian advocates to better defend the rights of patients with pain.

*First*, one of the functions of the Constitutional court of Ukraine is to provide official clarification of the legislative provisions to Ukrainian citizens.<sup>588</sup> As I considered in the previous chapter, the right to adequate pain control has not been formalized directly in legislation, but logically derives from other human rights, particularly the right to freedom from cruel, inhuman or degrading treatment. The absence of a direct legal provision with an obligation to provide pain relief to the patients complicates the protection of their rights in the courts of Ukraine. If so, there is a need for an official clarification of whether inadequate pain control, which causes suffering, does constitute ill-treatment. The Constitutional Court of Ukraine may issue clarifications of such kind, which would help the Ukrainian advocates to defend the rights of the patients. Moreover, on the basis of such official conclusion, one can further challenge the legality of the Ukrainian acts of legislation which limit access to adequate analgesia.

*Second*, if Ukrainian and foreign case law provides examples of successful defence of the right to essential medicines, then similar arguments may be applied to the issue of access to painkillers in Ukraine. At the same time, as Ukrainian case law shows, it is important to consider thoroughly to whom the application should be addressed. In other words, it is important to define who must be obliged to act to achieve the realization of the right to pain control. Besides, the claims under the lawsuit need to be formulated in a most precise language, so that the court's decision provides an effective remedy. I suggest that in the case of Ukrainian patients suffering from pain, the claims should include not only damages of a pecuniary and/or non-pecuniary nature, but most essentially a requirement to oblige the defendant to act to provide due pain control.

*Third*, it is notable that in Ukraine, the new Decree 333, being of higher legal force than Order 11, provides an excellent instrument to defend the rights of the patients. The courts of Ukraine have to rely on the provisions of Decree 333, rather than on the stricter rules

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<sup>588</sup> Law of Ukraine “On Constitutional Court of Ukraine” (“Про Конституційний Суд України”) 422/96-вр, 16 October 1996, online: Rada <<http://zakon2.rada.gov.ua/laws/show/422/96-%D0%B2%D1%80>>.

in the old Order 11. This may become the basis of successful lawsuits in the advancement of the rights of the Ukrainian patients.

Alternatively, certain provisions of Order 11, contradicting the new Decree 333, may be repealed by the Ukrainian administrative court. According to the Code of Administrative Justice of Ukraine, the administrative courts consider the disputes that arise in relation to the legislative acts and regarding the actions or omissions of the state officials.<sup>589</sup>

Therefore, the legal force of the provisions of Order 11, as well as the passivity of the Government officials on the implementation of Decree 333, may be challenged in the County Administrative Court of Kyiv, according to the rules of territorial jurisdiction.<sup>590</sup>

*Fourth*, because there is no documented standard of care for patients in pain, and the courts accept medical documents and conclusions without an opportunity to give them due evaluation, it is essential to seek medical expertise in support of litigation regarding poor pain control. Unavailability of relevant medical substantiation causes failure to establish a breach of the law. Subsequently, it becomes a failure to recognize the patient's damages. Such rationale may be provided by a medical expert panel, which would include health professionals most advanced in the matters of analgesia. According to Ukrainian law, the expert conclusion<sup>591</sup> is considered appropriate evidence in court, so it is important to effectively use this option at litigation, calling for a conclusion of a medical expert. According to the Ukrainian legislation<sup>592</sup> the court decides which expert (or expert commission) from the specially registered experts shall be appointed to perform the expertise of materials and/or circumstances and to provide a conclusion. It is important that there is an option<sup>593</sup> of cross-expertise in case of reasonable doubts in the correctness and accuracy of the previous expert's (or expert commission's) conclusion. These options may be used in litigation to provide the court with necessary evidence

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<sup>589</sup> *Code of Administrative Justice of Ukraine (Кодекс адміністративного судочинства України)*, Law of Ukraine 2747-IV, 6 July 2005, at article 17 para 2.1., online: Rada <<http://zakon2.rada.gov.ua/laws/show/2747-15>>.

<sup>590</sup> *Ibid* at article 19, para 3.

<sup>591</sup> *Code of Civil Procedure of Ukraine (Цивільний процесуальний кодекс України)*, Law of Ukraine 1618-IV, 18 March 2004, at articles 53, 57 and 66, online: Rada <<http://zakon4.rada.gov.ua/laws/show/1618-15/page2>>.

<sup>592</sup> Law of Ukraine "On the expert evidence" ("Про судову експертизу") 4038-XII, 25 February 1994, online: Rada <<http://zakon4.rada.gov.ua/laws/show/4038-12>>; see also Ruling of the Plenum of Supreme Commercial Court of Ukraine "On certain matters of the practice of the appointment of expert evidence" ("Про деякі питання практики призначення судової експертизи") 4, 23 March 2012, online: Rada <<http://zakon4.rada.gov.ua/laws/show/v0004600-12>>.

<sup>593</sup> Ruling of the Plenum of Supreme Commercial Court of Ukraine "On the expert evidence in criminal and civil cases" ("Про судову експертизу в кримінальних і цивільних справах") 8, 30 May 1997, at para 11, online: Rada <<http://zakon1.rada.gov.ua/laws/show/v0008700-97>>.

about whether the treatment of the patient met the standard of care and whether a violation of the patient's rights occurred. This would provide the necessary basis for the consideration of the circumstances by the court and for the grounded decision.

Finally, when claiming damages,<sup>594</sup> particularly moral damages, the plaintiff may want to apply all possible and appropriate legal instruments considered in this paper: the right to be free from cruel, inhuman and/or degrading treatment; the rights to dignity, to equal treatment, to family, to work, etc. Although the issue of identification of moral damages needs separate discussion, which I do not provide in this research, presumably the violation of rights, which causes suffering, may potentially add value to the moral damages of patients, who undergo suffering due to inadequate pain control.

These ideas may be used in order to more effectively defend the rights of Ukrainian patients through the courts of Ukraine. Because Ukrainian legislation and the court system provide several instruments to have one's rights protected, it is important to use all the options available to accomplish this task effectively through skilful litigation.

#### 4.5.1. Test Case for the Defence of Patients' Rights to Pain Control in Ukraine

I suggest that the test case for the defence of the human right of a patient to pain control would be brought to the court of the appropriate jurisdiction (depending on the patient's place of residency and/or the healthcare setting location)<sup>595</sup> against a healthcare setting where the patient was inadequately treated. Whether the patient was treated as an in- or out-patient, the patient has a legal relationship with the healthcare institution, which therefore, according to the Ukrainian civil legislation,<sup>596</sup> bears the duty of adequate medical care for the patient. It is essential that the claims under the lawsuit include:

- 1) the claim to obligate the healthcare setting to fulfil the actions (to adequately provide to the patient essential medicines according to the National List of Essential Medicines)<sup>597</sup> to relieve pain – if the treatment of pain is still required; or

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<sup>594</sup> Moral damages may be referred to as mental or physical suffering, caused by someone's wrongful actions or omissions. In Ukrainian legislation this matter is regulated by *Civil Code of Ukraine (Цивільний Кодекс України)*, Law of Ukraine 435-15, 2003 at article 23, online: Rada <<http://zakon4.rada.gov.ua/laws/show/435-15>>.

<sup>595</sup> The court is to be determined according to the Ukrainian rules of civil jurisdiction, see *Code of Civil Procedure of Ukraine*, *supra* note 591 at articles 109-110.

<sup>596</sup> *Ibid.*

<sup>597</sup> Ukrainian National List of Essential Medicines, *supra* note 189.

2) the claim to recognize the actions or omissions of the health professionals or the healthcare setting were wrongful – if the treatment of pain is no longer required; and to claim moral damages (as a result of inadequate treatment of pain).

The primary task in the litigation process would be to provide the court with the necessary evidence in order to enable the judge to adequately appraise the circumstances and to further make a grounded decision. This evidence should contain primarily:

- 1) testimony of the patient about how the pain was managed and the actual outcome of the treatment (or denial of treatment), meaning the physical and emotional suffering as a consequence of the treatment which is argued to be inadequate;
- 2) supportive medical documentation regarding the patient's diagnosis and other important related details about the diagnosis and the condition of the patient and
- 3) medical expert evidence regarding the common practice, including the evidence-based international guidelines, and the standard of care for patients with similar complaints and health conditions, and regarding the extent to which the level of care provided to the patient corresponds to the common practice and the standard of care.

Considering doubts about doctors' education in pain control, the courts should seek expert opinions from highly-trained medical professionals, in the subject of pain relief, in order to draw an informed conclusion in the matter.

The next task of high importance would be to demonstrate to the court that the treatment fell below the standard of care and had a drastic effect on the patient, causing suffering from pain that could be avoided otherwise. There would be a need to highlight the entire body of supporting Ukrainian and international legislative provisions, as well as the Ukrainian, foreign and international case law that refer to and provide the link between suffering from pain and violation of the human rights in the particular circumstances of the particular case. More precisely, I suggest that it would be most important to put an emphasis on the minimum component of the right to health,<sup>598</sup> which relates primarily to adequate access to essential medicines and the advice of an adequately trained health professional. Also, depending on the specific case circumstances, it should be highlighted which human rights were abrogated by the denial of adequate pain control. This would be necessary for the determination of moral damages.

The amount of the damages, although important, is not the primary issue. This may potentially become a subject of a separate research; and besides, the recognition of moral

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<sup>598</sup> See General Comment # 14 to ICESCR, *supra* note 334.

damages in principle would mean the practical application of an approach that suffering from pain constitutes a free-standing cause of action and a sufficient circumstance to establish the violation of the human rights in the specific circumstances of the case. Although Ukraine is a state with a civil law doctrine, which does not recognize court cases as binding for other litigations, a successful court case may become an effective instrument of persuasion for future court decisions. Subsequently, this may have an impact on the medical practice of the treatment of pain and the overall attitude of society and State in regards to this issue.

#### **4.6. Concluding Remarks**

These steps and options are necessary to remove major barriers to adequate pain control in Ukraine and to ensure the realisation of human rights associated with maximum levels of health and with an imperative to relieve suffering. The President of Ukraine, as a guarantor of the observance of human and citizen rights and freedoms,<sup>599</sup> is thus personally responsible before the Ukrainian people for creation of legal conditions to properly realise, ensure and defend the right of all Ukrainian patients to adequate pain relief. The Ukrainian government (The Cabinet of Ministers of Ukraine) is responsible to the President of Ukraine for practical elaboration and implementation of such legal conditions so that the rights of Ukrainian people are properly established, ensured and defended. Failure to overcome barriers to adequate pain management, leaving thousands of Ukrainians in needless and avoidable suffering, would be an obvious failure to properly perform the duties of high state officials and a proof of their incapacity to hold their high offices.

At the same time, the Ukrainian advocates for better pain control may choose to use more extensively the available instruments of the human rights defence through the courts of Ukraine and subsequently potentially in the European Court of Human Rights. The offered ideas on litigations provide the grounds for further considerations on the avenues for effective defence of the rights of patients in pain through the court system of Ukraine.

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<sup>599</sup> *Constitution of Ukraine, supra* note 44 at article 102.

## **Conclusions**

According to the findings of the present research, numerous barriers to pain management exist in Ukraine. Many stem from the concern of the Government to prevent harmful drugs use outside the medical context. Most importantly, these barriers cause people's suffering and are in abrogation of their human rights.

The right to the highest attainable standard of health, adherence to the most contemporary standards of healthcare, the right to be free from cruel, inhuman or degrading treatment, the right to respect for one's dignity as well as the rights to family, to work and rest, together with a range of other human rights declared in the Ukrainian and international legislation, undoubtedly raise obligations from both the Ukrainian Government and the healthcare providers to ensure adequate pain relief to Ukrainian patients. Besides, Ukrainian legislation, particularly the recently adopted Decree 333, provides a basis for adequate regulation of pain control with the use of strong medicines. However, progressive legislative provisions with regards to healthcare in general and specifically to pain control are not being implemented. Some of the current legislative norms are either too broadly formulated to be applied to pain management or they are ambiguous or non-existent. The courts of Ukraine do not consider the denial of pain control to be a breach of law, and subsequently do not consider this a violation of the right of the Ukrainian patient.

In the present paper I have made an attempt to consider what role the law can play in removing the barriers to adequate pain management. I argue that the removal of the barriers to pain relief and ensuring guaranteed access to pain management are possible and necessary, and that the law can be a proper instrument to help accomplish this task. It appears that, although certain steps are being taken by the Ukrainian government to improve the current situation regarding pain management, this issue obviously requires a more complex and general approach with regards to all three mentioned spheres of influence that would imply first of all the development of the Ukrainian legislation as well as preparing a solid platform for real implementation of the legislative provisions. The measures to better pain management should be implemented on the basis of human rights and accordingly, on the grounds of appropriate legislation. For this purpose the Ukrainian legislation needs to be supplemented with several provisions with regards to not only specific rights, but also with certain corresponding obligations, control over their fulfillment and responsibility for their violation. In other words, there should be a feasible

mechanism for the realization of the rights of the Ukrainians for adequate pain relief that requires both conceptual and practical approaches. The conceptual approach would call for the development of the law, and the practical approach would employ a program, means and actions for the realistic implementation of the provisions of law.

In addition to the measures that should be taken by the Ukrainian Government, there are also certain remedies through human rights defence in the Ukrainian court system. Skilful litigation may help the advocates for better analgesia not only to effectively defend the rights of individual patients, but also to create standards of courts practice on the issues of healthcare and particularly pain control. As a more general outcome, the practice of rights defence in courts may bring into question the provisions of the current Ukrainian regulations of the issues of opioid use in medical practices.

Consideration of the strategy to improve realization of the patients' rights for adequate pain control requires solid research based not just on the legal side of the issue. Research in health policy as well as in economics is needed to more concretely identify the needs of Ukrainian pain management policy and to offer avenues to address them to the best possible extent in the face of limited resources. For example, lack of understanding about the issues of non-palliative and non-cancer pain management in Ukraine as well as health conditions that require analgesia with non-opioid medicines obviously calls for a deeper research of these issues in terms of identifying the scope of the problem and the financial challenges. Medical research is also needed to identify which of the world evidence-bases and best methods may realistically be afforded and applied in Ukrainian healthcare with the given budgets and conditions. Apart from that, medical ethics research is needed on the issues of the health professionals' attitude to caring for the patients versus curing their illnesses. Such research would help in the elaboration of a Ukrainian standard of care for patients with pain and in overall identification and effective settling of the problems of access to pain control. In other words, in addition to the present research of a mostly legal nature, there is also a need for research in the matters of economics, medicine, ethics and policy. However, all the findings and conclusions that would support state officials' decisions should respect human rights, be implemented through law, in accordance to the law and with a view to secure the human rights of the people.

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**Appendix 1. Results of the Questionnaire**  
**On Barriers to Adequate Pain Management in Ukraine**

Demographics: 29 participants – practicing medical doctors from Ukraine

1) **Regions:**

Kyiv (Central-North Ukraine) - 4  
Dnipropetrovsk (Central Ukraine) - 7  
Odesa (Southern Ukraine) - 1  
Mariupol (Eastern Ukraine) - 1  
Vinnytsya (Central-West Ukraine) - 2  
Zhytomyr (Central-North Ukraine) – 1  
Luhansk (Central-East Ukraine) – 3  
Autonomous Republic of Crimea (Southern Ukraine) - 2

8 participants did not specify region where they practice

2) **Specialization:**

Neurology - 7  
Anaesthesiology - 2  
Internal Healthcare - 2  
Children Neurology -1  
Children Surgery – 1  
Psychophysiology – 1  
Urology – 3  
Gynecology - 3  
Infectious Diseases - 1

8 participants did not provide information about their specialization

The collected evidence is presented summarily without identification of the responders.  
The answers were provided in Russian or Ukrainian languages. They are presented as translated by the researcher.

**Answers to Test Questions:**

Question	Answer	Number of responds
<b>How would you estimate general organization and conditions of pain management for your patients?</b>	A) Excellent. We have qualified medical staff and adequate supply of painkillers, what enables us to treat any pain adequately for all patients. There are no administrative barriers.	1
	B) Good. In most cases we treat pain effectively, as it is possible with painkillers available in the hospital and allowed to be used.	11
	C) Fair. Improvements are needed.	9
	D) Unsatisfactory. Improvements are badly needed.	3
	*) Did not give an answer	5
	<b>Comments:</b> *) “The scheme of recording and prescription of potent drugs is complicated to the greatest possible extent, <b><u>it is easier to not prescribe than to fulfill recording and to keep a journal</u></b> ”  *) “Main problem is <b><u>doctors’ financial disinterestedness.</u></b> ”	
<b>Do following factors influence your choice of analgesic when you are considering prescription?</b>		
<u>- affordability for the patient considering price</u>	a) yes, always b) yes, sometimes c) no, never	14 13 2
<u>- actual availability in hospital/in the unit/in public pharmacies</u>	a) yes, always b) yes, sometimes c) no, never	15 13 0

- whether this is narcotic analgesic or not	a) yes, always b) yes, sometimes c) no, never	11 17 1
- other factors (please, specify)	a) yes, always - pharmaceutical effectiveness - patient's willingness to go through pain - opportunity to renew the prescription – ability to come back for the new prescription  b) yes, sometimes c) no, never	1  1 1
<b>Do you remember cases in your practice when you didn't prescribe narcotic analgesics and had to replace them with non-narcotic medicines due to fear of being unfairly made responsible for using narcotic painkillers?</b>	A) Yes, it happens frequently	6
	B) Yes, such cases took place earlier, now it wouldn't happen	2
	C) No, it never happened in my practice *) <i>One respondent's comment:</i> “all is about correct documentation maintenance”	17
	*) no answer	4
<b>Do you remember cases in your practice when according to your knowledge and qualification you were sure that stronger analgesic should be prescribed, but you were unable to do so for some objective reasons and had to prescribe weaker medicine?</b>	A) Yes, it always happens  “when there is no strong medicine [in the unit]”	5
	B) Yes, it happened earlier  <i>Comments:</i>  “Due to complicated procedure of making prescription of strong medicines.”  “It is necessary to call anesthesiologist who is in charge of analgesics, but he	6

	does not always share the opinion about necessity [to prescribe narcotics], or just “does not want to.”  “Because of absence of necessary medicines.”	
	C) No, it never happened in my practice	14
	*) no answer	4
<b>Do you believe that the barriers to preventing access to narcotics cause your patients to suffer?</b>	YES	20
	Partially	1
	No	4
	No answer	4
<b>Could the standard of medical care for patients in Ukraine be improved if narcotics were more available to them?</b>		
<b>- with cancer?</b>	YES	23
	NO	1
	No answer	5
<b>- with chronic pain?</b>	YES	12
	NO	4
	No answer	13
<b>- with arthritis?</b>	YES	5

	NO	6
	No answer	18
<b>- post-surgery period?</b>	YES	13
	NO	1
	No answer	15
<b>- at childbirth?</b>	YES	8
	NO	6
	No answer	15
<b>- in other cases?</b>	YES	4
	NO	
	No answer	25
	<p><u>Comments:</u></p> <p>“Doctors' qualification is required in addition to availability of medicines.”</p> <p>“The risk of addiction.”</p> <p>“Tablet forms [are needed].”</p> <p>“Individual approach is required.”</p>	

<b>Have you ever heard patients' complaints on high prices for painkillers?</b>	A) Yes, often	12
	B) Yes, sometimes	15
	C) No, never	1
	No answer	1
<b>Are there any instructions/recommendations that you follow when prescribing painkillers? If yes, what are the instructions/recommendations?</b>	Yes  <i>Comments:</i> *) "international recommendations" *) "EENS recommendations" *) "WHO recommendations regarding acute post-operation pain, chronic pain syndrome, chronic cancer pain. Euro-guideline on treatment of acute post-operations pain. Recommendations of PROSPECT group. " *) "instructions from abroad" *) "hospital's internal instructions, orders; Ministry of Healthcare of Ukraine protocols, Ukrainian standards of treatment."	13
	No	3
	No answer	13
<b>Do you believe instructions/recommendations on pain management by medicines, if worked out and implemented on the state level, would be helpful and beneficial for doctors?</b>	A) Yes, certainly	12
	B) Maybe <i>Comments:</i> *) "But they [instructions/recommendations] should be worked out by qualified specialists in these areas" *) "The national recommendations go behind contemporary knowledge, the prescriptions are not adequately worked out in certain cases" *) "individual approach is important"	10
	C) I don't think this would be a good idea	2

	D) No, by no means	
	No answer	5

**Answers to Open Questions:**

Question	Answers and Quotes
<p><b>What problems in organization of pain management in Ukraine would you identify?</b></p>	<p><i>Related to doctor's education and awareness</i></p> <ul style="list-style-type: none"> <li>- <b>We do not have educational programs and relevant specialists on treatment of pain.</b></li> <li>- <b>Often the doctors are afraid of side effects of narcotic medicines (lack of certain knowledge).</b></li> <li>- <b>Not satisfactory awareness of medical doctors.</b></li> <li>- <b>Limited range of specialists who prescribe narrow list of medicines.</b></li> <li>- Lack of understanding and merely symptomatic approach (disregarding the reason of pain)</li> </ul>
	<p><i>Related to the absence of standards</i></p> <ul style="list-style-type: none"> <li>- <b>Absence of standards and protocols</b></li> <li>- <b>Absence of responsibility for patient's pain</b></li> <li>- <b>Uncertainty of the necessity to treat pain in every particular case</b></li> <li>- <b>Treatment of chronic pain is undermined</b></li> <li>- <b>Absence of mandatory protocols in pain management</b></li> </ul>
	<p><i>Related to procedures of prescription of opioids</i></p> <ul style="list-style-type: none"> <li>- <b>Flawed legislation on narcotic medicines circulation that prevents patients' access to narcotic analgesics (mentioned by 2 responders)</b></li> <li>- <b>The doctors are sometimes afraid of prescribing narcotics due to possible conflict situations with controlling bodies.</b></li> <li>- <b>Low accessibility of opioids</b></li> <li>- <b>Maximum daily dose of morphine in the amount of 50mg in oncology</b></li> </ul>

	<ul style="list-style-type: none"> <li>- <b>Maximally complicated recording of medicines</b></li> <li>- <b>Complexity in prescription of satisfactory doses of narcotic medicines for patients with oncology</b></li> <li>- <b>Complexity in prescription of controlled medicines to patients with unconfirmed cancer pathology</b></li> </ul> <p><b>Complications in doing prescriptions of narcotic medicines (bureaucracy)</b> (mentioned by 2 responders)</p>
	<p><u>Related to prices of painkillers</u></p> <ul style="list-style-type: none"> <li>- <b>Absence of support from government</b></li> <li>- <b>Effective medicines are expensive</b></li> </ul> <p><u>Related to availability of forms and types of medicines</u></p> <ul style="list-style-type: none"> <li>- <b>Absence of oral opioids</b> (mentioned by 2 responders)</li> <li>- <b>Absence of certain forms of narcotic medicines like transdermal therapeutic systems of fentanyl , sublingual fentanyl and the like</b></li> <li>- <b>Not sufficient range of medicines in circulation</b></li> <li>- <b>Limited assortment of medicines</b></li> <li>- <b>Absence of wide range of medicines</b></li> </ul> <p><u>Other:</u></p> <ul style="list-style-type: none"> <li>- Pharmaceutical methods are not always effective</li> <li>- Abuse of painkillers</li> <li>- High percentage of side-affects and complications</li> <li>- No differential approach to pain management worked out</li> <li>- Have never faced this problem in practice</li> </ul>
<b>Do you face shortages of painkillers</b>	Shortages of concrete narcotic analgesics like, omnopone, tramadol, fentanyl, ketamine

<p><b>in your hospital/unit? If yes, which painkillers are in short supplies?</b></p>	<p>Tramadol, akuman, morphine Nalbufen These medicines are available, but due to complexity of their recording they are not being prescribed, their prescription is “not desirable”, “should avoid”</p> <p>Shortages of non-narcotic analgesics (mentioned by 4 respondents)</p> <p>“All non-narcotic painkillers are financed by patients themselves and/or their relatives”</p> <p>Yes, we face shortages Yes, all medicines are in short supply Yes, sometimes</p> <p>No shortages (mentioned by 10 responders)</p>
<p><b>Could you, please, describe the process of prescribing narcotic and non-narcotic painkillers and procedure of their writing off?</b></p>	
<p><b>A. When the patient receives treatment in hospital</b></p>	<p>Quotes of the answers:</p> <p><u>For narcotics:</u></p> <p>*) “In the history [of disease] the narcotic is prescribed for three days, for prolonged prescription the commission conclusion is required, signed by three doctors (2 doctors of the level of the unit manager and the deputy chief). The medicines are being prescribed for certain hours (for example 10am., 5pm, 10pm.) The nurse and the doctor put their signatures in narcotics document as well as in the patient's history of disease. Medicines shall be withdrawn and introduced in presence of the doctor. Besides, there is a special exercise-book in every unit, where full and empty ampoules are being counted. In the morning empty ampoules are given to the nurse, who is in her turn</p>

	<p>gives those ampoules to the principal chief nurse.”</p> <ul style="list-style-type: none"><li>*) “[Relevant records shall be made in] patient's history of disease and in “narcotics document.”</li><li>*) “Special strict reporting forms for prescriptions are needed.”</li><li>*) “[Narcotics] may be prescribed exclusively by an expert in resuscitation”</li><li>*) “Plenty of hassle and paperwork.”</li><li>*) “According to the doctor’s prescription, conclusion of the commission of reasonability of the prescription.”</li><li>*) “Prescription according to the need, writing off according to the journal”</li><li>*) “For up to three days according to the doctor’s prescription, for over three days – by the commission of three doctors, notes in journals form.”</li><li>*) “According to the therapeutic indications.”</li><li>*) “On the basis of the doctor’s prescription with affirmation by the head of the unit (in military hospitals.”</li></ul> <p><u>For non-narcotics:</u></p> <ul style="list-style-type: none"><li>*) “Record in drug chart.”</li></ul> <p><u>Both narcotic and non-narcotic medicines</u></p> <ul style="list-style-type: none"><li>*) “The medicines are purchased by the patients according to the prescriptions.”</li></ul>
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**B. When the patient receives treatment at home**

For narcotics:

\*) “A special prescription shall be done ("form #3"), where again three signatures [of doctors] are required (same level [(2 doctors of the level of the unit manager and the deputy chief)]. The prescription is valid for three days. Such prescription is for oral tramadol (30 capsules maximum), tablet codeine (30 tablets for 30 mg each), although in pharmacies they sell no more than 10 tablets (although daily dose is up to 240mg) and Bupren IC (buprenorphine).

With regards to injectable medicines (tramadol, promedol, omnopone, morphine), the scheme is different (I am not aware precisely). But the nurse from polyclinic usually visits patients at homes between 9-00am and 4-00pm to do injections. In the evenings and at night the patients are being left without injective narcotics. Before ambulance teams introduces narcotics at night. Now ambulance is reorganized in emergence first aid, and this is no longer in their duties.”

\*) “Prescriptions are made using special strict reporting forms.”

\*) “Prescriptions are made for non-narcotic analgesics.”

\*) “[Narcotic analgesics] shall not be prescribed.”

\*) “Practically impossible to prescribe.”

\*) “Through the medical consultation commission” (mentioned by two respondents)

\*) “after hospitalisation and releasing home – posting to the accounts of the outpatient clinic according to the place of patient’s residency and [prescription of medicines] according to the instructions of the doctor in the outpatient clinic (neurologist, oncologist).”

\*) “Only non-narcotics.”

For non-narcotics:

	<p>*) “Notes in health record and actual prescription.”</p> <p><u>Both narcotic and non-narcotic medicines</u></p> <p>*) “the medicines are purchased by the patients according to the prescriptions”</p>
<b>Do you face inexpedient difficulties when prescribing analgesics? If yes, what difficulties do you face?</b>	
<b>A. When the patient receives treatment in hospital</b>	<p>Yes, “hassle” and overmuch documentation (mentioned by 3 respondents)</p> <p>“- daily journaling + when prescribing – note”</p> <ul style="list-style-type: none"> <li>- “critique of reasonability” [of the prescription] under everyday control of the manager</li> <li>- If any prescriptions are made – [external] inspections by the auditing control and the public prosecution.”</li> </ul>
	<p>Yes, absence in hand in the unit</p>
	<p>Yes, lack of choice (mentioned by 4 respondents)</p>
	<p>No (mentioned by 2 respondents)</p>
<b>B. When the patient receives treatment at home</b>	<p>Yes, overmuch documentation (mentioned by 2 respondents)</p> <p>Yes, overmuch documentation, even more then in inpatient care</p>
	<p>Yes, lack of choice</p>
	<p>“Practically impossible to prescribe.”</p>
	<p>No</p>
<b>How do you usually learn about new medicines for pain relief?</b>	<p>From medical representatives</p>

	Professional literature Internet Lectures/conferences Self-education At daily briefings [in hospitals, units] From colleagues
<b>What do you know about the new cabinet of Ministers of Ukraine Decree # 333 on the rules of purchase, transportation, storage, dispense, use and utilization of narcotic medicines, psychotropic substances and precursors in healthcare settings?</b>	Out of 10 participants, who provided answers to this question, 7 told they know about the new Decree and 5 of them demonstrated general knowledge on what the Decree is about (simplification of the use of narcotic medicines). 3 out of 10 respondents answered they knew nothing about the Decree.
<b>What changes in your practice happened since May 2013 and to the present day in terms of prescription of opioid analgesics in in- and out-patient care?</b>	All 13 respondents answered that no changes occurred in their practices re the use of narcotic medicines within the given timeframe
<b>Could you, please, list main barriers that the doctors face when treating pain in Ukraine?</b>	
<b>A. When the patient receives treatment in hospital</b>	*) “Absence of satisfactory amount of effective medicines with proved effectiveness.” *) “Absence of strong medicines in the units of general specialization.”

	<ul style="list-style-type: none"> <li>*) “Budgetary, financial incapacity.”</li> <li>*) <b>“- “avalanche” of writings on doctors</b>  <b>- inspections of the management - if you ever prescribe [narcotics]</b>  <b>- it is easier to not prescribe that to “let yourself in for trouble”</b></li> <li>*) “no support from the government”</li> <li>*) <b>“absence of doctors’ motivation, therefore inadequate qualification”</b></li> <li>*) “no barriers”</li> </ul>
<p><b>B. When the patient receives treatment at home</b></p>	<ul style="list-style-type: none"> <li>*) “no support from the government”</li> <li>*) <b>“Prices [for analgesics]”</b></li> <li>*) <b>“Financial incapacity”</b></li> <li>*) <b>“It is impossible to prescribe narcotic medicines”</b></li> <li>*) “Self-treatment”</li> <li>*) “Abuse of medicines”</li> <li>*) <b>“Opioids: difficult prescription”</b></li> <li>*) “inadequacy, complicatedness of prescriptions, necessity of complete documenting of everything”</li> <li>*) “absence of doctors’ motivation, therefore their imperceptions of the new”</li> </ul>
<p><b>Refers to both in-patient and out-</b></p>	<p><b>“- Not sufficient legislative environment regarding circulation of narcotics</b></p>

<p>patient care</p>	<ul style="list-style-type: none"> <li>- <b>Unavailability of tablet forms of narcotic medicines</b></li> <li>- <b>Absence of educational programs for doctors.”</b></li> </ul> <p>“- <b>Not enough range of medicines in circulation</b></p> <ul style="list-style-type: none"> <li>- <b>Legislative contrariety to prescription of opioids and some other groups</b></li> <li>- <b>Absence of responsibility for patient's pain</b></li> <li>- <b>Not satisfactory qualification of doctors</b></li> <li>- <b>Absence of mandatory protocols.”</b></li> </ul>
<p><b>Please, kindly provide your professional comments regarding the fact that the Instruction to medicine Morphine hydrochloride, solution for injection 1% ampouled #5x20, contains recommendations on maximum daily dose of 50mg. In your comments, please, indicate if you think this dose is always enough for full pain relief.</b></p>	<p>This dose is not always enough (admitted by 4 respondents)</p> <p><i>Other comments:</i></p> <p>“Disagree, the dose should be adequate.”</p> <p>“It would be interesting to learn about the WHO recommendations on this issue and about opportunities of their appliance in Ukraine.”</p>
<p><b>If you could, what would you change to improve your patients’ access to adequate pain management?</b></p>	<p>Simplification of prescriptions (5 respondents suggested)</p> <p><i>Other comments:</i></p> <p>“Licensed access of doctors to prescriptions of strong medicines”</p> <p>“Doctors' education”</p> <p>“Education on adequate pain management”</p> <p>Improving of obtaining medicines by patients at homes (5 respondents suggested).</p>

## Appendix 2.

*Table 4. Comparative chart of most critical aspects of the “Old” and the “New” Rules of Ukraine regarding the use of opioids in health care and potential outcome of changes if adequately implemented*

<p><b>Order of the Ministry of Healthcare of Ukraine #11 “On adoption of Regulations of circulation of narcotic drugs, psychotropic substances and precursors in healthcare settings of Ukraine”<sup>600</sup></b></p> <p><i>(old regulations – still in force)</i></p>	<p><b>Decree of the Cabinet of Ministers of Ukraine # 333 “On adoption of Regulations of purchase, transportation, storage, delivery, use and utilization of narcotic drugs, psychotropic substances and precursors in healthcare settings of Ukraine”<sup>601</sup></b></p> <p><i>(new regulations in force)</i></p>	<p><b>Potential outcome of the New Rules if applied on practice</b></p>
<p>In healthcare settings storage of narcotic drugs is allowed in the amounts not exceeding <b>two-weeks</b> need reserve.</p> <p>In units of healthcare settings the reserve of narcotic medicines shall not exceed <b>three-days</b> need. In medical stations (rooms) within</p>	<p>In healthcare settings, their affiliated subsidiaries and other structural subdivisions storage of narcotic drugs is allowed in the amounts not exceeding <b>one-month</b> need reserve. (Para 22)</p> <p>In units and medical stations (rooms) within healthcare settings the narcotic drugs reserve shall be ensured in the amount not exceeding</p>	<p>The opportunity to keep larger supply of opioids in hospitals, units and departments would decrease healthcare providers’ working hours on ordering and acceptance of supplies of opioids. It would also provide better insurance of the adequate supply of necessary analgesics in case of unpredicted situations.</p>

<sup>600</sup> Order of Ministry of Healthcare of Ukraine “On affirming the Rules of circulation of narcotic medicines, psychotropic substances and precursors in healthcare settings of Ukraine” (“Про затвердження Порядку обігу наркотичних засобів, психотропних речовин та прекурсорів у закладах охорони здоров’я України”) 11, 21 January 2010, online: Rada <<http://zakon4.rada.gov.ua/laws/show/z0347-10>>.

<sup>601</sup> Decree of the Cabinet of Ministers of Ukraine “On the adoption of the Regulation on purchase, transportation, storage, dispensation, and utilisation of narcotic drugs, psychotropic substances and precursors in the healthcare system” (“Про затвердження Порядку придбання, перевезення, зберігання, відпуску, використання та знищення наркотичних засобів, психотропних речовин і прекурсорів у закладах охорони здоров’я”) 333, 13 May 2013, online: Rada <<http://zakon2.rada.gov.ua/laws/show/333-2013-п>>.

<p>healthcare settings the narcotic drugs reserve shall not be higher than for one day need (three days need on weekends and holidays).</p> <p>A <b>five-days</b> need reserve of narcotic medicines may be organised in emergency and admission rooms in order to provide due care at nights in case of urgency. (Para 3.5.)</p>	<p><b>seven-days</b> need. (Para 23)</p> <p>A <b>seven-days</b> need reserve of narcotic medicines may be organised in emergency and admission rooms in order to provide due care at nights in case of urgency. (Para 24.)</p>	
<p>A decision to prescribe narcotic medicines for longer than three days period shall be made by <b>a commission on reasonability of prescription of narcotic medicines and validated by a Chief Physician or his or her Deputy.</b> (Para 3.8)</p>	<p>Prescription of narcotic medicines for no longer than ten days shall be made by <b>an attending physician</b> with mandatory substantiation of the necessity of further use of the medicines, what shall be written in the patient's medical records. (Para 26.)</p>	<p>No longer need for the conclusion of the Commission on reasonability of prescription of narcotic medicines to prescribe opioid analgesics for longer than three-days period.</p> <p>It would decrease the amount of healthcare providers' work and will speed up access of patients to pain relief.</p>
<p>In out-patient care narcotic medicines <b>injections shall be introduced exclusively by a healthcare professional</b> from healthcare settings or from feldsher-midwifery stations according to the place of residence with mandatory relevant note in patient's medical record.</p> <p>Other forms of medicines shall be used by patients on their own according to the doctor's prescriptions. (Para 3.11.)</p>	<p>Patients in out-patient care shall be supplied with narcotic medicines by healthcare settings or by pharmacies according to the prescriptions in the amounts not exceeding 10-days need, in cases of palliative care - 15-days need.(Para 27.)</p> <p><b>No need for a healthcare provider participation to provide injections.</b></p>	<p>The permission to supply patients with injectable opioids to be used at home without a healthcare provider would make possible fulfilment of previously almost not feasible task to provide pain relief for patients living long distances from healthcare settings with opioids available.</p>