

Inadequate access to opioid-based pain relief is a human rights issue for cancer patients

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Many cancer patients in Europe are being denied access to adequate pain relief because of over-zealous regulations restricting the availability and accessibility of opioid-based drugs such as morphine.

Authors of the Europe-wide study say that restricting access to pain-killing drugs in this way is a breach of patients' human rights, and they conclude that "there is an ethical and public health imperative to address these issues vigorously and urgently".

The study, which is published online in the cancer journal, *Annals of Oncology* [1] today (Monday 22 February), is a joint report on the availability and accessibility of [opioids](#) for the relief of cancer pain by the European Society for Medical Oncology and the European Association for Palliative Care. The authors collected data from 21 Eastern European countries and 20 Western European countries.

They evaluated the lists of allowed opioid drugs for the management of strong pain (opioid analgesics) for each country, the cost of opioid medication to patients and the regulatory barriers that can make it more difficult, if not impossible, for cancer patients and their doctors to get access to these medications in a timely manner.

They found that in some countries, particularly in Western Europe, access and availability was good (the UK was an example of a country that performed well in this respect), but in other countries, particularly in Eastern Europe, it was much more restricted. In countries, such as

Lithuania, Tajikistan, Belarus, Albania, Georgia and Ukraine, some essential opioid medicines were completely unavailable.

The authors say that in many countries the balance between enabling cancer patients to receive the [pain relief](#) that they need, while, at the same time, preventing [prescription drugs](#) being diverted for substance abuse in illicit drug markets, is weighted too much in favour of the latter.

They write: "Preventing [drug abuse](#) is important, but it should not hinder patients' ability to receive the care they need and deserve. This is the approach of the WHO [World Health Organization] and the INCB [International Narcotics Control Board] . . . Both recommend that opioids should be available for cancer patients at hospital and community levels and that physicians should be able to prescribe opioids according to the individual needs of each patient.

"While most governments allow physicians to prescribe opioids for patients, regulations vary among nations and in many countries, regulations to reduce substance abuse and to restrict the diversion of medicinal opioids into illicit markets unduly interfere with medical availability for the relief of pain."

Regulations that restrict opioid prescribing and which contravene WHO and INCB recommendations include: requiring special patient permits, limiting the authority of physicians to prescribe opioids even for cancer patients with strong pain, imposing arbitrary dose limits that limit the ability to adjust the dose to individual patient needs, imposing severe limits on the duration of the prescription (e.g. less than seven days' supply per prescription), restricting opioid dispensing so that it's harder for patients to access the medication, increasing bureaucratic burdens through the use of complex or poorly accessible prescription forms or complex reporting requirements, and intimidating health care providers and pharmacists with intimidatory legal sanctions.

"As problematic as each of these violations are alone, when they are sequential in the process of prescribing and dispensing, their affects are multiplied, and the impact on patient care is profound," write the authors.

In addition, the authors say that few countries have adequate provisions for efficient emergency prescribing and dispensing of opioids in out-of-hours situations.

One of the authors, Dr Nathan Cherny, of the Cancer Pain and Palliative Medicine Service at the Shaare Zedek Medical Center, Jerusalem, Israel, said: "In most of Western Europe, the issues of availability and accessibility appear to be fairly good. In some Eastern European countries, the situation is catastrophic. Many countries are in flagrant disregard of the regulatory guidelines of the International Narcotics Control Board, and we have highlighted the specific regulations and issues that need to be addressed to bring countries into compliance with the WHO and INCB guidelines.

"This is an issue of cancer patients' human rights, and it's not only a legal imperative, but a moral imperative for the WHO and individual European countries to address the findings of our report. At present, [cancer patients](#) in a number of countries are suffering unnecessarily as a result of the under-treatment of their pain."

The authors make a number of recommendations to improve the availability and accessibility of opioids: the WHO essential medicines list should be the minimum standard for lists of allowed opioid drugs, with the more extensive list of the International Association for Hospice and Palliative Care being a long-term aim for all countries; governments should ensure access to immediate release [morphine](#) as soon as possible; governments should review and repeal over-vigilant and excessive restrictions that impede good clinical care of cancer pain; and regulatory

provisions should be made for emergency prescribing and for allowing pharmacists to correct technical errors in prescriptions in discussion with the prescribing pharmacist.

To coincide with the paper's publication in *Annals of Oncology*, an editorial is published today in the journal *Palliative Medicine* [2]. The authors, led by James Cleary, associate professor of medicine at the Pain and Policy Study Group, WHO Collaborating Center for Policy and Communication in Cancer Care, University of Wisconsin Carbone Cancer Center, USA, write that the study is an important contribution to the discussion of opioid use in Europe. However, they point out that reform of national policies should be preceded by review of the actual laws and regulations, and that, following any reforms, implementation of the reforms was vital.

"Implementation may be the hardest step as it would be false to state that the inadequate treatment of cancer pain is due entirely to regulatory restrictions. We know from experience that policy change alone does not bring about increased access. We need to address the low priority of pain with health care, inadequate education, exaggerated fear of opioids and addiction, and problems in the supply chain for medications," they write. To do this, appropriate resources as well as leadership is required, they conclude.

More information: Notes:

[1] "Formulary availability and regulatory barriers to accessibility of opioids for cancer pain in Europe: a report from the ESMO/EAPC Opioid Policy Initiative." *Annals of Oncology*, Vol. 21: pp 615-626, 2010. [doi:10.1093/annonc/mdp581](https://doi.org/10.1093/annonc/mdp581)

[2] "Access to therapeutic opioid medications in Europe by 2011? Fifty years on from the Single Conventi" *Palliative Medicine* Vol. 24: pp109-110. [doi: 10.1177/0269216309360103](https://doi.org/10.1177/0269216309360103)

[3] The research paper contains tables and graphs showing results by

countries.

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