Briefing 5

Human Rights and Drug Policy

Controlled Essential Medicines

"Numerous studies have identified common problems that impede availability and accessibility of controlled medicines for the treatment of pain. Many countries do not recognize palliative care and pain treatment as priorities in health care, have no relevant policies, have never assessed the need for pain treatment or examined whether that need is met, and have not examined the obstacles to such treatment...The failure to ensure access to controlled medicines for the relief of pain and suffering threatens fundamental rights to health and to protection against cruel, inhuman and degrading treatment."

–Anand Grover and Manfred Nowak, UN Special Rapporteurs on health and torture[1]

"Although the World Health Organization (WHO) considers access to controlled medicines, including morphine and codeine, to be a human right, it is virtually non-existent in over 150 countries."

–Professor Sevil Atasoy, President of the International Narcotics Control Board[2]

Access to controlled essential medicines: the treatment gap

Several drugs on the WHO's Model List of Essential Medicines, including morphine, methadone and buprenorphine, are also controlled substances under the international drug control conventions.[3] These medications are essential in the treatment of moderate to severe pain and opioid drug dependence. Lack of medical access to these essential medicines is a global problem. The WHO estimates that:

- Each year, tens of millions of people suffer untreated moderate to severe pain, including 1 million HIV/AIDS patients and 5.5 million terminal cancer patients.
- If opioid substitution therapy was made readily available globally, it could prevent up to 130,000 new HIV infections annually, reduce the spread of hepatitis C and other blood-borne diseases, and decrease deaths from opioid overdose by 90 percent.[4]

Barriers to access

Medicines controlled under the international drug conventions are subject to stricter regulation than other medicines: government authorization is necessary to import, manufacture or distribute controlled medicines, they may only be dispensed upon prescription, and doctors and pharmacies often require special licenses or permission to prescribe and dispense them.[5] These regulations aim to prevent the diversion of controlled medicines for illicit use.

While these regulations pursue a legitimate goal, governments must make sure they do not unnecessarily impede medical access. The aim of preventing misuse must be balanced against the obligation to ensure access to essential medications.[6] In many countries throughout the world, that balance has not been reached. Unnecessarily strict and complex regulation is recognized as a major barrier to access to controlled medications.[7]

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Several other barriers to access to controlled essential medicines add to, and are often related to, the problem of unnecessarily strict or complex regulation. Many doctors have unfounded fears that prescribing controlled essential medicines will lead to addiction, because they have not received education regarding the WHO's recommendations on prescribing opioids for pain management and substitution therapy.[8] Doctors who are insufficiently educated regarding pain management and their country's regulation of controlled drugs are often deterred from prescribing because they fear losing their medical license, or even prosecution, if they make an error handling these medicines.[9] Many governments have no policies to promote access to pain management, palliative care, or opioid substitution therapy, and have poor supply and distribution systems for controlled medicines.[10] Although morphine and methadone are available very cheaply on the international market, complex regulation and poor distribution systems can increase their price dramatically, making cost a barrier for many patients.[11] For example, in some countries more expensive opioid formulations, such as prolonged-release morphine tablets and transdermal fentanyl patches are available, but the cheaper formulations, including basic oral morphine in tablet or powder form, are not. In some cases pharmaceutical companies withdraw basic oral morphine from the market to promote the sale of more expensive formulations. In other countries, the cheapest oral morphine formulations do not have regulatory approval.[12]

In many low- and middle-income countries with injection-driven epidemics, government policies mandate criteria for access to, or maintenance of, treatment for drug users which can become barriers to treatment. Human Rights Watch, the International Harm Reduction Association, the Open Society Institute and others have documented instances where criteria regulating access to drug treatment, effectively operate as barriers in the countries where they are enforced. For example, this has occurred with laws that require drug users to undergo multiple physiological tests or to be reviewed by panels of physicians prior to admission into drug treatment. This condition can mean that drug users must choose between continued use of illicit drugs or face unmedicated withdrawal, yet the tests and reviews could also be conducted after admission when users have access to treatment while undergoing the tests. Similarly, requirements that prospective patients show multiple documented experiences of drug-free treatment before they can be admitted into maintenance treatment programs, even where drug-free treatment is unaffordable or unavailable; that impose regulatory restrictions on adjustments of the dose of opioid medications patients receive, rather than leave that decision to medical doctors; and that impose automatic expulsion from treatment programs for the use of illicit drugs while in treatment, when drug dependency – recognized as a chronic relapsing medical condition - is the health condition being treated, can all create unnecessary barriers. Countries should regularly review entry criteria to ensure they do not unnecessarily impede access to drug dependence treatment.[13]

Access to controlled essential medicines and the right to the highest attainable standard of health

In 2009, Human Rights Watch documented the poor availability of pain treatment and palliative care in India.[14] Its report, "Unbearable Pain: India's Obligation to Ensure Palliative Care," found that hundreds of thousands of patients with advanced cancer suffer from severe pain without access to morphine or other strong pain relievers. People who had suffered from pain without treatment routinely told Human Rights Watch that their suffering was so severe that they preferred to die rather than live with the pain. The organization attributed this situation to inadequate policy-making by the government, a lack of instruction on palliative care for health care workers, and unnecessarily restrictive drug regulations in more than half of India's states.

Many other countries around the world face problems to those of India because governments have not taken adequate steps to ensure that palliative care is integrated into national cancer and HIV strategies, that doctors and nurses are trained, and that drug regulations do not unnecessarily impede the availability of pain medications like morphine. As a result, millions worldwide suffer unnecessarily from excruciating pain.

At its 12th session in 2009, the **Human Rights Council** adopted a resolution that recognized "access to medicine is a fundamental element in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard

of physical and mental health."[15] The same resolution stressed "the responsibility of States to ensure access to all, without discrimination, of medicines, in particular essential medicines, that are affordable and of good quality."

The protection from discrimination includes people living with HIV/AIDS[16] and people who use drugs.[17]

In 2005, the **Economic and Social Council (ECOSOC)** passed a resolution on "treatment of pain using opioid analgesics" in which it "recognizes the importance of improving the treatment of pain, including by the use of opioid analgesics…and calls upon Member States to remove barriers to the medical use of such analgesics."[18]

In its General Comment on the right to the highest attainable standard of health, the **Committee on Economic, Social and Cultural Rights** emphasized that the provision of essential drugs, as defined by the WHO, is a core obligation of the right to health. The Committee also emphasized that need for "attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with dignity."[19]

In its Concluding Observations on Ukraine's report under the Covenant, in 2008, the Committee stated that is was "gravely concerned at the high prevalence of HIV/AIDS...and the limited access by users to substitution therapy."[20] Injecting drug users who give birth in Russia and Ukraine report that maternity wards frequently offer no substitution treatment, requiring mothers who are receiving methadone or buprenorphine, or those who are active drug users, to leave the hospital prematurely to avoid painful withdrawal symptoms.[21]

In a letter to the Chairperson of the 52nd Commission on Narcotic Drugs, Anand Grover, **Special Rapporteur on the right to the highest attainable standard of health**, and Manfred Nowak, **Special Rapporteur on torture and other cruel, inhuman and degrading treatment or punishment**, wrote that "*human rights law requires that governments must provide essential medicines – which include, among others, opioid analgesics – as part of their minimum core obligations under the right to health.*"[22]

Freedom from cruel, inhuman or degrading treatment

In a January 2009 report to the Human Rights Council, Manfred Nowak, **Special Rapporteur on torture and other cruel, inhuman and degrading treatment or punishment**, stated:

"from a human rights perspective, drug dependence should be treated like any other health-care condition...denial of medical treatment and/or absence of access to medical care in custodial situations may constitute cruel, inhuman or degrading treatment or punishment and is therefore prohibited under international human rights law...States have a positive obligation to ensure the same access to prevention and treatment in places of detention as outside."

The Special Rapporteur also said:

"Given that lack of access to pain treatment and opioid analgesics for patients in need might amount to cruel, inhuman and degrading treatment, all measures should be taken to ensure full access and to overcome current regulatory, educational and attitudinal obstacles to ensure full access to palliative care."[23]

Right to seek, receive and impart information

The right to seek receive and impart information is an important underlying determinant of health. Ensuring accurate information is available can mean many things in different contexts. In some instances it could simply mean making sure some medicines are accurately reflected in official literature while in the case of India, it would likely mean improving palliative care education in medical schools.

States should work to remove barriers related to information about available medicine in order to comply with civil and political rights obligations[24] as well as those related to economic, social and cultural rights. Information should be available and accessible to people in order for them to make informed choices regarding their care. The Committee on Economic, Social and Cultural Rights has made clear that "states should refrain from … censoring, withholding or intentionally misrepresenting health-related information."[25]

1 Letter from Manfred Nowak, Special Rapporteur on Torture, and Anand Grover, Special Rapporteur on the right to the highest attainable standard of health, to Her Excellency Ms Selma Ashipala-Musavyi, Chairperson of the 52nd Session of the Commission on Narcotic Drugs, December 10, 2008, http://www.hrw.org/sites/default/files/related_material/12.10.2008%20Letter%20to%20CND%20fromSpecial%20Rapporteurs.pdf (accessed November 6, 2009), p. 4.
2 Statement by Professor Sevil Atasoy, President of the International Narcotics Control Board, to the Economic and Social Council, 30 July 2009, http://www.incb.org/documents/President_statements_09/2009_ECOSOC_Substantive_Session_published.pdf (accessed November 6, 2009).
3 WHO, *Model List of Essential Medicines*, 15th List, March 2007, http://www.who.int/medicines/publications/essentialmedicines/en/index.html (accessed August 5, 2009); Single Convention on Narcotic Drugs, 1961, adopted March 30, 1961, 520 U.N.T.S. 151, entered into force December 13, 1964; Convention on Psychotropic Substances, 1971 adopted February 21, 1971, 1019 U.N.T.S. 175, entered into force August 16, 1976.
4 WHO, "WHO Briefing Note: Access to Controlled Medications Programme," February, 2009, https://intranet.hrw.org/Program%20Central%20Style%20Guide%20Documents/citationstyle.pdf (accessed August 24, 2009), p.1.
5 Single Convention on Narcotic Drugs, 1961; Convention on Psychotropic Substances, 1971; Human Rights Watch, *"Please, Do Not Make Us Suffer Any More…": Access to pain treatment as a human right*, March, 2009, http://www.hrw.org/en/reports/2009/03/02/please-do-not-make-us-suffer-any-more, pp. 26-35.
6 See WHO, "Achieving Balance in National Opioids Control Policy: Guidelines for Assessment," (Geneva: WHO, 2000) WHO/EDM/QSM/2000.4, http://www.painpolicy.wisc.edu/publicat/00whoabi/00whoabi.pdf (accessed November 9, 2009); The international drug conventions recognize the need for balance between ensuring medical access to controlled narcotic and preventing diversion to illicit use. The Single Convention on Narcotic Drugs, 1961 states that "the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes," preamble, and the Convention on Psychotropic Substances, 1971 similarly states that "that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted," preamble.
7 International Narcotics Review Board, Report of the International Narcotics Control Board for 2008, (New York: United Nations, 2009), http://www.hrw.org/sites/default/files/reports/health1009web.pdf (accessed November 6, 2009), p. iii; Human Rights Watch, *"Please, Do Not Make Us Suffer Any More…"*: Access to pain treatment as a human right, March, 2009, http://www.hrw.org/en/reports/2009/03/02/please-do-not-make-us-suffer-any-more, 26-35.
8 Human Rights Watch, *"Please, Do Not Make Us Suffer Any More…"*, 25-26.
9 Ibid, pp. 33-35.
10 Ibid, pp. 18-25. Palliative care seeks to improve the quality of life of patients with life-limiting illness, by assessing and treating pain and other physical symptoms and providing psychosocial and spiritual care to the patient and their family: see WHO, "WHO Definition of Palliative Care," http://www.who.int/cancer/palliative/definition/en/, (accessed October 23, 2009).
11 Human Rights Watch, *"Please, Do Not Make Us Suffer Any More…"*, 35-37.
12 Ibid, p. 36; E. D. Bruera and L. De Lima, "Opioid cost: a global problem," *Palliative Medicine,* vol. 19 no. 6, 2005, p. 504; Email from Liliana De Lima, September 10, 2009.
13 International Harm Reduction Development Program. Barriers to Access: Medication-Assisted Treatment and Injection-Driven HIV Epidemics. New York: Open Society Institute; 2008; Human Rights Watch, "Rehabilitation Required: Russia's Human Rights Obligation to Provide Evidence-based Drug Dependence Treatment," vol. 19, no. 7(D) (2007); See also International Harm Reduction Association, The Global State of Harm Reduction, 2008
14 Human Rights Watch, *Unbearable Pain: India's Obligation to Ensure Palliative Care*, 28 October 2009, 1-56432-555-5
15 Human Rights Council, Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/RES/12/24, 12 October 2009
16 UN Office of the High Commissioner for Human Rights, *Fact Sheet No. 31, The Right to Health*, June 2008, No. 31, page 21.
17 Ban Ki-Moon (2008) Message on the International Day against Drug Abuse and Illicit Trafficking, 26 June 2008.
18 UN Economic and Social Council, "Treatment of pain using opioid analgesics," ECOSOC 2005/25, E/2005/INF/2/Add.1, p. 70.
19 UN Committee on Economic, Social and Cultural Rights, "Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights," General Comment No. 14, The right to the highest attainable standard of health, E/C.12/2000/4 (2000), para. 12(a), 17, 34, 25 and 43(d).
20 UN Committee on Economic, Social and Cultural Rights, "Consideration of Reports Submitted by States Parties Under Article 16 and 17 of the Covenant, Ukraine, Concluding Observations of the Committee on Economic, Social and Cultural Rights," E/C.12/UKR/CO/5, January 4, 2008, *www2.ohchr.org/english/bodies/cescr/docs/.../E.C.12.UKR.CO.5.doc* (accessed 9 November, 2009), para. 28, 51.
21 International Harm Reduction Development Program. Women, Harm Reduction, and HIV: Key Findings from Azerbaijan, Georgia, Kyrgyzstan, Russia, and Ukraine. New York: Open Society Institute; 2009.
22 Letter from Manfred Nowak and Anand Grover to Special Rapporteur to Her Excellency Ms Selma Ashipala-Musavyi, p. 4.
23 Human Rights Council, Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Manfred Nowak, A/HRC.10/44, January 14, 2009, http://www2.ohchr.org/english/bodies/hrcouncil/docs/10session/A.HRC.10.44AEV.pdf, (accessed November 10, 2009), para. 74(e).
24 ICCPR, Art. 19(2)
25 CESCR, General Comment 14, para 34.